Study on the establishment of a European Audit Capacity to ensure compliance and effective national control and enforcement of the REACH Regulation, on standards for national official control and enforcement systems for the REACH Regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC Regulations

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TABLE OF CONTENTS

ABBREVIATIONS

ADCO	Administrative Cooperation groups
BPC	Border Control Posts
BTSF	Better Training for Safer Food
BSE	Bovine spongiform encephalopathy
CA	Competent Authority
CFP	Common Fisheries Policy
CLP	Classification, Labelling and Packaging (Regulation (EC) No 1272/2008)
DG	Directorate General
DG AGRI	Directorate-General for Agriculture and Rural Development
DG CLIMA	Directorate-General for Climate Action
DG EMPL	Directorate-General for Employment, Social Affairs and Inclusion
DG ENV	Directorate-General for Environment
DG MARE	Directorate-General for Maritime Affairs and Fisheries
DG MOVE	Directorate-General for Mobility and Transport
DG REGIO	Directorate-General for Regional and Urban Policy
DG SANTE	Directorate-General for Health and Food Safety
EAC	European Audit Capacity
ECHA	European Chemicals Agency
EEA	European Economic Area ((Iceland, Liechtenstein, Norway)
EFCA	European Fisheries Control Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association (Iceland, Liechtenstein, Norway and Switzerland)
EMSA	European Maritime Safety Agency
FTE	Full Time Equivalent
HoU	Head of Unit
IMPEL	European Union Network for the Implementation and Enforcement of Environmental Law
MS	EU Member States
MSR	Market Surveillance Regulation
NEA	National Enforcement Authority
OECD	Organisation for Economic Co-operation and Development
OLAF	European Anti-Fraud Office
PIC	Prior Informed Consent (Regulation (EU) No 649/2012)
POPs	Persistent Organic Pollutants (Regulation (EU) No 2019/1021)
RAC	Regional Advisory Council
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RFMO	Regional fisheries management organisation
STCW	Standards of Training, Certification and Watchkeeping
TFEU	Treaty on the Functioning of the European Union

1. INTRODUCTION

This report is the final report for the '*study on the establishment of a European Audit Capacity to ensure compliance and effective national control and enforcement of the REACH Regulation, on standards for national official control and enforcement systems for the REACH Regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC Regulations'* carried out by Milieu under contract number 09029901/2021/854090 for DG Environment of the European Commission.

The report contains:

- A comparative overview and analysis of EU control systems **(Task 1)**.
- An assessment of the different options for all the main aspects/features of a potential European Audit Capacity (EAC) taking into account the result of Task 1, and the feedback received from EU and Member State representatives consulted (i.e., filled matrices and focus groups) leading to the development of three proposed options and an assessment of their feasibility **(Task 2).**
- A revised list of criteria/standards for Member States' control systems taking into account, inter alia, feedback received from EU and Member State representatives consulted (survey questionnaire for experts from Member States' authorities and focus groups) **(Task 3).**
- A legal description of the possibilities of including criteria/standards for Member States' control systems in REACH **(Task 4).**

Context and objectives of the study

The second REACH Refit evaluation published in 2018[1] highlights the necessity of improving the effectiveness of control and enforcement systems across the EU in relation to the REACH[2], CLP[3], POPs[4], and PIC[5] Regulations to ensure proper compliance by dutyholders. Some areas present higher levels of non-compliance (e.g., imported products) or specific difficulties for enforcement (e.g., online sales) and differences in the effectiveness of Member States' controls throughout the EU lead to a non-level playing field. To step up the effectiveness of national control and enforcement systems throughout the EU, the Sustainable Chemicals Strategy adopted in 2020[6], maps out several measures under the section "zero tolerance for non-compliance". One of these measures is '*to propose to entrust the Commission with the duty to carry out audits in Member States, where relevant, to ensure compliance and enforcement of chemicals legislation, in particular REACH, and use infringement procedures as necessary*'.

Within this policy context, the objective of this study is to assist DG ENV in:

[1] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements. Conclusions and Actions, COM/2018/0116 final, Brussels, 5.3.2018.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–849.

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1–1355.

[4] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77.

[5] Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, OJ L 201, 27.7.2012, p. 60–106.

[6] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability. Towards a Toxic-Free Environment, COM(2020) 667 final, Brussels, 14.10.2020.

- identifying how to best establish a EAC to ensure compliance with and effective national control and enforcement systems for the REACH Regulation throughout the EU;
- developing criteria/standards applicable to Member States' control and enforcement systems for that Regulation; and
- assessing the possible extension of the above actions for the purpose of the CLP, POPs and PIC Regulations.

2. OVERVIEW OF EU CONTROL SYSTEMS

2.1 INTRODUCTION

2.1.1 Task objectives

Task 1 aims to map existing EU control systems, including but not limited to auditing systems, to ensure compliance with and enforcement of the legislation by Member States, and to provide a comparative overview of identified systems, in particular with regard to the rationale for establishing the systems, the legal instruments that were necessary to establish the systems, the criteria/standards controlled by the systems, and the organisation and operation of the systems. Task 1 also aims to assess the effectiveness, benefits, efficiency and added value of these systems.

2.1.2 Methodology

Identification of EU control systems

A first list of EU control systems was established in the technical proposal based on the tender specifications. To complement this list, additional desk research was carried out by the project team and several Commission services were contacted, to check whether some of their activities were relevant to the project. Based on this research, the controls carried out by DG REGIO and DG EMPL were added to the list of control systems.

Research on individual EU control systems

Each member of the project team was assigned a control system to research. Based on the data collection template presented in the inception report, each member of the project team carried out preliminary desk research to collect relevant information and documents publicly available online, before contacting the relevant Commission service to ask for additional documentation (not publicly available) and set up an interview. The following interviews were carried out:

Commission service	Date of interview
DG ENV B.2	13.10.2021
DG MOVE	20.10.2021
DG MARE	29.10.2021
DG CLIMA	08.11.2021
DG SANTE	11.11.2021
DG REGIO/DG EMPL (DAC)	17.11.2021

Based on all information gathered, one template was filled in for each system.

Contact points in several control systems were also contacted about the dissemination of a questionnaire to audited Member States, which aimed to collect information on the benefits and added value of audits, as well as the costs and burden incurred by audited Member States. With the support of some DG MARE, the questionnaire was sent to five Member States, but no feedback was received before the submission of this report.

Comparative analysis

All information contained in the templates has been collated in the section below. The structure of the section mirrors, to the extent possible, the headings of the data collection template. As the control systems researched are quite different in their organisation and functioning, comparative tables have been included in the report to provide detailed information on each control system, allowing the

understanding of how each system works. Similarities and differences have been highlighted for each aspect.

The following control systems were identified and included in Task 1. Research was carried out across other DGs, but no other control systems were identified.

2.2 IDENTIFICATION OF EU CONTROL SYSTEMS

Different types of systems have been identified and are assessed in the comparative analysis, as summarised in the table below.

Table 1: Overview of identified EU control systems

Control system	Types of control systems			
	Commission controls of Member States' (MSs) official control systems	Commission controls of MSs spending of EU funds	Assistance to/cooperation with MSs in relation to official controls	Commission controls of operators
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	✓			
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	✓			
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	✓			
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	✓			
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	✓			
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion)	✓	✓	[7].	[8].
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).			✓	
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).				✓

[7] The study focuses on DG REGIO's controls of MSs' official control systems and MSs' spending of EU funds, hence only those two aspects have been mentioned in Table 1. However, assistance to/cooperation with MSs and controls of operators are also aspects covered by DG REGIO.

[8] Ibid footnote 7.

The column 'Commission controls of MSs' official control systems' include systems where Commission services verify how official controls and enforcement (meant to check whether operators comply with EU legislation) are implemented by Member States' competent authorities. These controls commonly include a mission in the Member State.

Regarding Directive 2010/63/EU on the protection of animals used for scientific purposes[9], the provisions of Article 35, requiring the Commission to 'undertake controls of the infrastructure and operation of national inspections in Member States […] when there is due reason for concern' have not yet been applied and no specific control activities by the Commission in application of that article have taken place. No criteria have been designed for assessing concerns that would trigger Commission controls beyond those provided by the Directive, i.e., 'taking into account, inter alia, the proportion of inspections carried out without prior warning'.

Fact-finding missions related to the implementation and enforcement of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[10] (hereafter the Biocidal Products Regulation), carried out by DG SANTE's Directorate for Health and food audits and analysis (Directorate F) in 2018 were included separately in the study given the relevance of the control activities for the EAC in the area of chemicals. Although they are carried out by the same Commission service (DG SANTE Directorate F), these fact-finding missions should be distinguished from audits carried out as per Regulation 2017/625, which establishes the Commission's mandate to audit Member States' control systems related to food and feed law, rules on animal health and welfare, plant health and plant protection products. Regulation (EU) No 528/2012 does not fall within the scope of Regulation 2017/625 and does not establish a mandate for the Commission to control Member States, therefore only fact-finding missions could be carried out, not audits. DG SANTE Directorate F carries out control activities as regards other pieces of legislation as well (for instance the assessment of notified bodies responsible for checking conformity of medical devices).
Regarding visits to Member States undertake by EMSA on the behalf of DG MOVE, it should be noted that the scope covers both implementation measures by the Member State itself and control and enforcement on third parties. In addition, EMSA conducts visits at the request and on behalf of other DGs than DG MOVE – for instance DG Environment in relation to Directive (EU) 2016/802 relating to a reduction in the sulphur content of certain liquid fuels. This report however focuses on the work of the Agency carried out on behalf of DG MOVE.

Controls carried out by DG REGIO and EMPL focus on the assessment of the controls done by Programme Audit Authorities (which verify expenditures of EU funds of each Operational Programme at national level), Managing Authorities and other bodies involved in the implementation of co-financed programmes at national level. This control system therefore targets activities of authorities responsible for the financial control of Operational Programmes. Compared to the other systems in the first group described above, control methods rely to a larger extent on documentary review.

Activities carried out by DG CLIMA are of a different nature as in this case the Commission does not carry out controls of national competent authorities' official control and enforcement activities[11] but may request Member States' competent authorities to carry out investigations on the compliance

[9] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33–79.
[10] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123.
[11] As per Article 28(1) of Regulation (EC) 1005/2009, Member States must carry out inspections of undertakings, following a risk-based approach, including inspections of imports and exports of controlled substances as well as of products and equipment containing or relying on those substances.

of undertakings[12] when considered necessary (Article 28(1) of Regulation (EC) 1005/2009 on substances that deplete the ozone layer[13], hereafter the Ozone Regulation) and assists officials of the Member States' authorities in the performance of their duties, subject to the agreement of the Commission and of the competent authority of the Member State (Article 28(2)). In addition, the Commission is required to take appropriate action to promote an adequate exchange of information and cooperation with and between national authorities (Article 28(4)). In practice, the Commission assists Member States in their duties, mainly by providing relevant information that allows investigations to take place[14].

The last system identified is OLAF's control activities in relation to waste shipment, in the context of the revision of the Waste Shipment Regulation[15]. Although OLAF has already been involved for several years in the monitoring of suspicious shipments, the proposal for the new Waste Shipment Regulation[16] will provide OLAF with new powers including the possibility of carrying out inspections of shipments 'on its own initiative, on the request of one or more Member States, or on a complaint if there is sufficient suspicion that the carriage of the substance or object concerned or the shipment of waste concerned constitutes an illegal shipment' (Articles 64(3) and 65(1) of the Proposal). These provisions may however be subject to amendments during the legislative proposal.

The sections below describe and compare, to the extent possible, the different aspects of these control systems, trying to precisely account for the differences in their types of activities, target of controls and scope. Control systems from the first group (Commission controls of Member States' official control systems) are always compared between each other, while other control systems may be described separately in some sections, to account for the different nature of the activities implemented under them.

2.3 COMPARATIVE OVERVIEW OF EU CONTROL SYSTEMS

2.3.1 Rationale for creating the control system

In DG SANTE, DG MOVE, and DG MARE, the creation of the EU control systems has been the result of a particular event showing the weaknesses in the implementation and enforcement of EU legislation and in some cases in the EU legal framework itself. In two cases, the control systems have been established in response to a food safety or environmental crisis (the outbreak of BSE and the sinking of the Erika). In the case of fisheries' controls, the conclusions from the audit of the European Court of Auditors contributed to the legislative process to improve the control chain (EU and Member States). In the case of DG REGIO, controls done by national Audit Authorities derive from the legal requirement to ensure internal control of budget implementation at all levels of management. The table below summarises, when information was available, the rationales for the creation of all the identified systems.

[12] Natural or legal persons as defined in Article 3 of Regulation (EC) 1005/2009, for instance private companies that import and/or export ozone depleting substances under that Regulation.
[13] Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, OJ L 286, 31.10.2009, p. 1–30.
[14] Reply from the European Commission to the Ombudsman's letter concerning the Commission's and the Member States' implementation of Article 28 (governing inspections) of Regulation 1005/2009 on substances that deplete the ozone layer, Case SI/7/2017/JN, 09 November 2018.
[15] Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, OJ L 190, 12.7.2006, p. 1–98.
[16] Proposal for a Regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056 (2021/0367 (COD)), Brussels, 17.11.2021, COM(2021) 709 final.

Table 2: Rationale for creating the EU control system

Control systems	Rationale	Year of creation of the system
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Creation of the Directorate for Health and Food Audits and Analysis – previously known as the Food and Veterinary Office – was linked to a food safety and health crisis: with the outbreak of bovine spongiform encephalopathy (BSE) in the late 1980s/early 1990s, there was a call for more structured Commission controls on Member States' implementation of controls on operators (as there were at the time only a few auditors spread across several DGs) and more coordination on food and health issues across the EU[17].	1997
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	The rationale for carrying the series of fact-finding missions was to monitor and assess for the first time the implementation and enforcement of Regulation (EU) No 528/2012.	Fact-finding missions on biocides carried out in 2017-2018
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Provisions of Article 35 requiring the Commission to control the infrastructure and operation of national inspections in Member States were introduced in response to the increase in public concerns in relation to animal welfare, in order to improve public confidence in the system of national inspections[18].	2010 (adoption of the legislation)
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Creation of the current control system partly due to the identification by the European Court of auditors in 2007[19] of serious weaknesses in Member States' control systems, including the unreliability of the monitoring and reporting of catches, the lack of general control standards, the lack of systematic follow-up etc. Regulation (EC) 1224/2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy[20] was adopted two years later to improve national control systems and establish the EU control system. In May 2018, the European Commission proposed the revision of the current fisheries control system (Regulation (EC) 1224/2009) aimed at modernising and simplifying the rules for monitoring fisheries activities and ensuring compliance with the Common Fisheries Policy.	2009
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Creation of control system linked to an **environmental disaster**, the sinking of the oil tanker Erika off the French coast in December 1999, which led to the adoption in 2000 of the first Maritime Safety Package ('Erika I') aiming to improve standards and controls of ships transporting dangerous materials[21] and the creation of the European Maritime Safety Agency (EMSA) in 2002[22].	2002
Established by Reg. 2021/1060 – Cohesion funds (DG	The rationale for establishing controls on cohesion expenditures is found in the Treaty (Article 322 TFEU provides the basis for adopting financial rules determining the procedure to be adopted for establishing and implementing the budget and for presenting and auditing accounts, as well as for checks on the	

[17] Interview with DG SANTE.

[18] Bio Intelligence Service and the Institute for European Environmental Policy (IEEP) (2013) Study on possible options for strengthening the EU level role in environmental inspections and strengthening the Commission's capacity to undertake effective investigations of alleged breaches in EU environment law, final report.

[19] ECA (2007) Special Report no 7/2007 on the control, inspection and sanction systems relating to the rules on conservation of Community fisheries resources together with the Commission's replies, (2007/C 317/01).

[20] Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006, OJ L 343, 22.12.2009, p. 1–50.

[21] European Commission (2002) After the Erika disaster, the European Union is at the forefront of maritime safety, MEM0/02/157.

[22] Interview with DG MOVE.

Control systems	Rationale	Year of creation of the system
REGIO / DG EMPL Joint Audit Directorate for Cohesion).	responsibility of financial actors) and in the principle of sound financial management and performance laid out in Article 33 of the Regulation (EU, Euratom) 2018/1046 on the financial rules applicable to the general budget of the Union[23] (hereafter Financial Rules Regulation). Following this principle, internal control of budget implementation must be applied at all levels of management to achieve the prevention, detection, correction and follow-up of fraud and irregularities (Article 36 of the Financial Rules Regulation).	
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Provisions of Article 28 of the Ozone Regulation enabling the Commission to request Member States' competent authorities to carry out investigations, to assist Member States' authorities officials in the performance of their duties, and to promote information exchange and cooperation were already laid down in the previous Ozone Regulation adopted in 2000[24]. These far-reaching provisions may have been set by the legislators based on the strong role of the Commission in the Ozone Regulation[25], the exclusive competence of the EU for the customs union and the strong political consensus for the ozone layer protection policy[26].	2000
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	OLAF has been active in monitoring suspicious shipments for two years, focusing on exports from the EU to third countries, as this is linked to OLAF's competence in fighting customs fraud. Regarding waste shipment controls, OLAF cannot use the full scope of its investigative tools as it does in other sectors. In particular, OLAF cannot carry out the spot checks as there is currently no legal basis for that in the Waste Shipment Regulation. One of the objectives of the ongoing revision of the Waste Shipment Regulation is to provide this legal basis and enable OLAF to use the full range of investigative tools, including spot checks. The second objective is to enable OLAF to monitor not only exports of waste to third countries (as is done currently) but also internal movements of waste within the EU (on which OLAF currently has no legal basis to act), give that an increase in intra-EU movement has been observed in the past years.	Legal act not yet adopted.

2.3.2 Legal basis

Identified EU control systems have all been established by legislative acts, as described in the table below.

Table 3: Legal basis

Control system	Legal basis
Established by Reg (EU) 2017/625) – Food	Control system established by Title VI of Regulation (EU) 2017/625[27]: ■ 'Commission experts shall perform controls, including audits, in each Member State to :

[23] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193, 30.7.2018, p. 1–222.

[24] Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer, OJ L 244, 29.9.2000, p. 1–24.

[25] For instance, the Commission implements both the EU licensing system for import, export and production of ozone depleting substances (Article 18 of the Ozone Regulation) and the registry for laboratories (Article 10(4)).

[26] Final Report "Study on possible options for strengthening the EU level role in environmental inspections and strengthening the Commission's capacity to undertake effective investigations of alleged breaches in EU environment law (europa.eu)", European Commission, DG ENV, 2013, pages 65-66

[27] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142.

Control system	Legal basis
and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ (a) verify the application of the rules referred to in Article 1(2) and those provided for in this Regulation. ■ (b) verify the functioning of national control systems in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation, and of the competent authorities which operate them. ■ (c) investigate and collect information (i) on official controls and enforcement practices in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation; (ii) on official controls and enforcement practices in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation; (iii) in relation to emergency situations, emerging problems or new developments in the Member States in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation' (Article 116(1)). Before December 2019 (date of entry into force of Regulation (EU) 2017/625), the legal basis was Regulation (EC) 882/2004, and before 2004, the mandate for Commission controls was contained in 'sector-specific'/vertical legislation.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Regulation (EU) 528/2012 is not under the scope of Regulation (EU) 2017/625. No legal basis in Regulation 528/2012 to carry out audits (which is why only fact-finding missions have been carried out in relation to biocides). Fact-finding missions on biocides controlled the implementation of a number of legal requirements from Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, as well as the organisation of official controls on biocidal products and treated article (Article 65 of the BPR).
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Control system established by Article 35 of Directive 2010/63/EU : ■ 'The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without warning, undertake controls of the infrastructure and operation of national inspections in Member States' (Article 35(1).
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Control system established by Title X of Regulation (EC) No 1224/2009: ■ 'The Commission shall control and evaluate the application of the rules of the common fisheries policy by the Member States by means of the examination of information and documents and by conducting verifications, autonomous inspections and audits and shall facilitate coordination and cooperation between them. For this purpose, the Commission may, of its own accord and by its own means, initiate and carry out inquiries, verifications, inspections and audits'.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Control system established by: Article 3 of Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency[28] (Member States' visits and inspections): ■ 'The Agency shall carry out visits to Member States in accordance with the methodology established by the Administrative Board' (Article 3(1)). ■ 'The Agency shall carry out inspections on behalf of the Commission as required by binding legal acts of the Union regarding organisations recognised by the Union in accordance with Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations[29], and regarding the training and certification of seafarers in third countries in accordance with Directive 2008/106/EC[30]'.
Established by Reg. 2021/1060 – Cohesion funds	Control system established by: Financial Rules Regulation (2018/1046) – Article 36; and the Common Provisions Regulation (CPR, 1303/2013)[31] – Article 75 – for the programming period 2014-2020 for

[28] Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency, OJ L 208, 5.8.2002, p. 1–9.
[29] Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations, OJ L 131, 28.5.2009, p. 11–23.
[30] Directive 2008/106/EC of the European Parliament and of the Council of 19 November 2008 on the minimum level of training of seafarers, OJ L 323, 3.12.2008, p. 33–61.
[31] Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006, OJ L 347, 20.12.2013, p. 320–469.

Control system	Legal basis
(DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	which accounts will be submitted annually up to 2025; CPR (2021/1060)[32] – Article 70 for the programming period 2021-2027: ■ 'The Commission shall carry out audits up to three calendar years following the acceptance of the accounts in which the expenditure concerned was included. That period shall not apply to operations where there is a suspicion of fraud' (Article 70(2).
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Control system established by Article 28 of the Ozone Regulation: ■ '[…] The competent authorities of the Member States shall carry out the investigations which the Commission considers necessary under this Regulation' (Article 28(1)) ■ 'Subject to the agreement of the Commission and of the competent authority of the Member State within the territory of which the investigations are to be made, the officials of the Commission shall assist the officials of that authority in the performance of their duties' (Article 28(2)) ■ 'In carrying out the tasks assigned to it by this Regulation, the Commission may obtain all necessary information from the governments and competent authorities of the Member States and from undertakings […]' (Article 28(3)) ■ 'The Commission shall take appropriate action to promote an adequate exchange of information and cooperation between national authorities and between national authorities and the Commission […]' (Article 28(4)).
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Section 3 of the Proposal for a Regulation on shipments of waste: ■ 'The Commission[33] may carry out inspections of shipments pursuant to Article 57(2) of this Regulation (Article 65(1) ■ 'The Commission may exercise the powers conferred onto it by this Regulation on its own initiative, on the request of one or more Member States, or on a complaint if there is sufficient suspicion that the carriage of the substance or object concerned or the shipment of waste concerned constitutes an illegal shipment' (Article 64(3)).

2.3.3 Types of EU control activities

EU control systems include a range of different controls, which have different working methods (only desk-based, mix of desk-based assessments and on-site visits) and different potential outcomes (enforcement, collection and dissemination of best practices, recommendations, removal of official EU recognition). The following sections describe the different types of controls carried out by the different control systems.

2.3.3.1 Audit and similar controls

The first type of controls identified are audits and other similar controls. This type of control aims to determine whether Member States' control and enforcement activities and their results comply with mandatory requirements (see section 2.3.4) and whether the systems are effective and suitable for achieving the objectives of the legislation. Although they have different names in different systems (audit, visits), they do use the same working methods and include both desk-based and on-site assessments, and they may lead to enforcement measures in case of non-compliance. Table 4 lists controls targeting Member States' competent authorities.

Table 4: Audits and similar controls of national competent authorities

Control system	Type of activities	Working method	Target	Announced/ Unannounced	Regular/one-off
Established by Reg (EU)	Audits of Member States' official control	■ Desk-based assessment	Selection of (i.e. not all countries	Announced	Regular

[32] Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy, OJ L 231, 30.6.2021, p. 159–706.

[33] According to Recital 49 of the Proposal, 'The Commission may consider, as a matter of its internal organisation, entrusting certain enforcement actions foreseen by this Regulation to the European Anti-Fraud Office (OLAF), which possesses relevant expertise in that regard'. Powers referred to in Article 64-68 will be entrusted to OLAF.

Control system	Type of activities	Working method	Target	Announced/ Unannounced	Regular/one-off
2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	systems in the areas of food and feed safety, animal health, animal welfare, plant health, food quality, and in certain areas of human health protection. As part of those audits, Commission officials can also be present during controls carried out national competent authorities.	■ On-site control[34]	audited in each control programme) ■ Member States' competent authorities ■ Competent authorities of third countries exporting plants, animals and food to the EU		
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Control of the infrastructure and operation of national inspections in Member States	No control yet carried out.	EU Member States' competent authorities	Announced	Irregular: when considered necessary by the Commission.
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Audits of the control systems of Member States (Article 100 of Regulation (EC) 1224/2009)	■ Desk-based assessment ■ On-site control	Selection of (i.e. not all countries audited in each control programme) Member States' competent authorities	Announced	Regular: based on risk assessment
	Verifications: Commission officials may be present during control activities carried out by national control authorities (Article 98 of Regulation (EC) 1224/2009)	■ On-site control	Member States' competent authorities	May be carried out without prior notice, at the discretion of the Commission officials (Article 98(6))	Regular: based on risk assessment
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Visits to Member States[35] to verify the implementation of EU maritime laws and control systems in place[36]	■ Desk-based assessment ■ On-site control[37]	■ EU Member States' competent authorities ■ EFTA Member States' competent authorities ■ All relevant Member	Announced	■ One-off – i.e. when a cycle is launched[39] ■ Every five years for visits relating to standards

[34] Carried out at least partially remotely during the pandemic.

[35] Although they are called 'visits' and not 'audits', to use a more positive term, the process and content are very similar to an audit, according to DG MOVE.

[36] EMSA, Visits to Member States.

[37] Carried out at least partially remotely during the pandemic.

[39] Visits are organised in multi-annual cycles of visits focusing on a specific piece of legislation, during which all member States will be visited. Cycles of visits are usually organised following the revision of a legislation or the adoption of new legislation.

Control system	Type of activities	Working method	Target	Announced/ Unannounced	Regular/one-off
			States are visited in each cycle[38]		for seafarers[40]
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Assessment of the assurance packages i.e. documentation sent by the Member State authorities (Managing Authority, Certifying Authority and Audit Authority of each Operational Programme[41]. Can be complemented by fact finding missions in some Member States before or after receipt of the assurance package[42].	■ Desk-based assessment ■ May be complemented by on-site control	■ Member States' auditing authorities	Assessment of assurance packages is carried out for all programmes. Announced (for control work on-the-spot)	Regular - annual
	Compliance audits to review the work of Audit Authorities (to ensure no serious system deficiency remains undetected and the audit opinions reported are reliable).	■ Desk-based assessment ■ On-site control	Selection of (i.e. not all countries audited in each control programme): EU Member States' auditing authorities	Announced	Regular – based on risk assessment
	Thematic audits to obtain reasonable assurance that the management verifications at the level of Managing Authorities are functioning effectively or to check specific issues in more details (e.g. Simplified Cost Options, public procurement rules, state aid rules).	■ Desk-based assessment ■ On-site control	Selection of (i.e. not all countries audited in each control programme): EU Member States' managing/other authorities	Announced	Regular - based on risk assessment

[38] Some pieces of maritime safety legislation do not apply to all MS. (e.g. the Port State Control Directive does not apply to landlocked Member States); in such cases, those Member States are not visited by EMSA.

[40] Visits to Member States verifying compliance with the minimum requirements of Directive 2008/106/EC on the minimum level of training of seafarers (implementing the International Maritime Organisation's STCW Convention – Standards of Training, Certification and Watchkeeping) are carried out according to a five-year cycle (as per Article 25 Directive 2008/106/EC).

[41] Documents include annual control reports, audit opinions/results) to validate the reported audit opinions and error rates (error rates are calculated based on statistical analysis of a sample of operations). Other relevant documents are also reviewed such as: information received from Commission audits, from OLAF or European Court of Auditors etc.

[42] Fact finding missions carried out before the submission of the assurance package aim at checking the quality and the methods used to collect information before it is submitted to the Commission (preventive tool). The missions carried out after the submission of the assurance package allow clarification of the assessment of results reported by the audit authorities (DG REGIO 2019 Annual Activity Report, p.23).

2.3.3.2 Controls of national authorities, designated bodies in view of EU official recognition

Controls described in the table below differ from audits described in Table 4 as they are carried out in view of the (re)designation of an official body (designated authority, third party conformity assessment body, intermediary body etc.) or in view of the official recognition / listing of non-EU countries' control or certification systems to facilitate access of the country to the EU market.

Table 5: Controls in view of official EU recognition

Control system	Type of activities	Working method	Target	Announced / unannounced	Regular / one-off
Other activities of DG SANTE Dir. F [43]	Joint assessments (with national authorities) of notified bodies responsible for checking conformity of medical devices[44]	■ Desk-based assessment ■ On-site control	■ Notified bodies of Member States, EFTA countries and countries with which the Commission has concluded a Mutual Recognition Agreement (MRA)	Announced	Regular (at least every five years) [45]
	Joint controls with the EFTA Surveillance Authority (ESA): assessment of compliance of border control posts in EFTA States before their designation by said states[46]	■ Desk-based assessment ■ On-site control (when necessary)	■ Border control posts in EFTA States	Announced	Regular
	Technical evaluation of the EU country plans related to the facilities at border control posts (BCPs) before (re-) designation by the Member State.	■ Desk-based assessment	■ Member States' border control posts (customs authorities)	Announced	Regular
	Evaluation of files submitted by non-EU countries to support their requests to export meat and meat products, milk and dairy products, fish and poultry to the EU[47].	■ Desk-based assessment ■ On-site control (if necessary)	■ Competent authorities of third countries exporting animals and food to the EU	Announced	Regular

[43] Activities not based on Regulation (EU) 2017/625

[44] Notified bodies are conformity assessment bodies responsible for checking that medical devices meet the relevant legal requirements, resulting in certification and CE marking (definition from the Health and Food Audits and Analysis webpage). These joint assessments are conducted in view of the designation or the extension / renewal of designation of notified bodies (Articles 3 and 4 of Commission Implementing Regulation (EU) No 920/2013). National authorities responsible for designating notified bodies must take account of the recommendations of the joint assessment when making the final decision on the designation of the notified body.

[45] The validity of the designation is limited up to a maximum of five years (Article 3 of Commission Implementing Regulation (EU) No 920/2013).

[46] Health and food audits and analysis programme 2021.

[47] This evaluation determines whether the country can satisfy the EU import requirements for those commodities. After approval of the country – which may require an audit on the spot after a desk evaluation – and the listing of the country for the commodity in question in the relevant Commission Regulation or Decision, the non-EU country may propose

Control system	Type of activities	Working method	Target	Announced / unannounced	Regular / one-off
	Annual evaluation of monitoring plans submitted by EU Member States and non-EU countries for residues of veterinary medicinal products, pesticides and contaminants in animals and animal products[48].	■ Desk-based assessment	■ Member States' competent authorities ■ Competent authorities of third countries exporting animals and food to the EU	Announced	Regular
	Assessment of non-EU countries' legislation governing good manufacturing practices for pharmacologically active substances[49]	■ Desk-based assessment ■ On-site control	■ Competent authorities of third countries exporting active substances to the EU	Announced	Regular
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Inspections[50] of third countries in relation to the International Maritime Organization's STCW Convention (Standards of Training, Certification and Watchkeeping) [51]	■ Desk-based assessment ■ On-site control[52]	■ Third countries[53]	Announced	One-off: when initially assessed for EU recognition Regular: once within a maximum period of 10 years
	Inspection of recognised organisations[54] [55]	■ Desk-based assessment ■ On-site control[56]	■ Recognised organisations[57]	Announced	One-off inspections when initially assessed for EU recognition Regular – multiple

establishments to be listed in the Commission's TRACES database. Listed establishments must be inspected by the competent authority in the non-EU country to verify that the operators comply with EU hygiene rules.

[48] Following this analysis, non-EU countries are listed in a Commission Decision for the commodities in question – a prerequisite for market access to the EU.

[49] This analysis contributes to the listing of non-EU countries having an equivalent system to that in the EU.

[50] Directive 2008/106/EC establishes an obligation for the Commission, assisted by EMSA, to verify compliance of third countries with the requirements of the STCW Convention for the recognition of their certificates of competency (i.e. documents issued to masters and officers certifying professional competence) and certificates of proficiency of seafarers (documents certifying that the seafarer meets the required standard of competence in a specific duty) by EU Member States. This verification takes place when a Member State has notified the Commission its intention to recognise certificates from a third country. After that, inspections to reassess the recognition of certificates from the third country take place at least once every ten years.

[51] EMSA, Inspections in third countries.

[52] Carried out at least partially remotely during the pandemic.

[53] Third countries that have acceded to the STCW Convention and for which a Member State has notified interest in recognising the country's certificates.

[54] Classification societies are private companies that ensure compliance of ships with statutory instruments (i. e. the technical safety requirements of the International Maritime Organisation) and issue international ship safety certificates, on behalf of the flag state administrations (see Deutsche Flagge, article on classification societies). Flag States within the EU can only delegate responsibilities to classification societies that have been granted recognition at EU level according to Regulation (EC) No 391/2009, which are referred to as 'recognised organisations'. This Regulation also requires the Commission to assess those recognised organisations at least every two years, a task which execution is delegated to EMSA.

[55] EMSA, Inspections of Recognised Organisations

[56] Carried out at least partially remotely during the pandemic.

[57] These include the 12 companies recognised at EU level and may include new companies for which Member States request EU recognition.

Control system	Type of activities	Working method	Target	Announced / unannounced	Regular / one-off
					inspections to each recognised organisation within every two-year assessment cycle plus ad hoc inspections as the Commission may deem necessary

2.3.3.3 Controls of operators

In three of the EU control systems identified, Commission services carry out controls or request Member States' authorities to carry out controls of operators. These controls aim to check compliance of operators with mandatory requirements, they include on-site assessments and may lead to the application of enforcement measures. These controls are not regular – as these are not meant to replace or duplicate a Member State's regular activities related to the control of operators - but are based on suspicion of non-compliance. In the case of DG CLIMA, the control is carried out by the Member State's competent authority (at the request of the Commission or on a risk-based approach); while DG MARE and OLAF carry out the control, together with the Member State's competent authority in the case of OLAF (see section 2.3.7.2).

Table 6: Controls of operators

Control system	Type of activities	Working method	Target	Announced / unannounced	Regular / one-off
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ 'Autonomous inspections' of operators by the Commission (without the presence of national inspectors/officials, according to Article 99 of Regulation (EC) 1224/2009).	■ Monitoring ■ On-site control	■ Operators in the EU	Announced or unannounced	One-off – when irregularities suspected in the application of the rules of the common fisheries policy
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	■ Investigations carried out by national competent authorities at the request of DG CLIMA or on a risk-based approach[58]	■ Monitoring ■ On-site control	■ Undertakings in the EU	No information available	One-off – when there is suspicion of non-compliance or on a risk based approach

[58] The Commission assists Member State authorities in the performance of their duties - either within investigations and/or inspections - by the sharing and exchange of information. The Commission may help the Member State officials by identifying inconsistent data or factual information on misapplications of the Regulation from a number of sources, like: a) the licensing system (Article 18) and registry for laboratories (Article 10(4)); b) reports by Member States (Article 26); c) reports by undertakings (Article 27); d) concerns communicated by stakeholders. The Commission does not carry out its own inspections and so far it has not attended a Member State inspection (see Reply from the European Commission to the Ombudsman's letter concerning the Commission's and the Member States' implementation of Article 28 (governing inspections) of Regulation (EC) 1005/2009 on substances that deplete the ozone layer, Case SI/7/2017/JN, 09 November 2018)

Control system	Type of activities	Working method	Target	Announced / unannounced	Regular / one-off
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	■ Investigations carried out by OLAF in case of suspicion of illegal shipment	■ Monitoring ■ On-site control	■ Shipment of waste between Member States, imported into the EU, exported from the EU or in transit[59]	No information available.	One-off – when there is suspicion of non-compliance.

2.3.3.4 Controls not leading to enforcement or official EU recognition

Finally, some of the controls identified aim to collect information and to advise competent authorities and do not lead to formal enforcement or recognition. Fact-finding missions carried out by DG SANTE cover areas where there is no clear mandate for Commission controls (e.g., biocides). Unlike audits, they do not lead to official recommendations or formal follow-up. They are used to gather information on an area, inform guidance and the dissemination of good practices or inform policy development. Country visits in the area of antimicrobial resistance aim to assist Member States in developing their plan.

Table 7: Examples of controls not leading to enforcement measures or official EU recognition

Control system	Type of activities	Working method	Target	Announced / unnanounced	Regular / one off
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Fact-finding missions: carried out with Member States, often in areas where there is no clear mandate for Commission controls.	■ Desk-based assessment ■ On-site control	■ Member States' competent authorities	Announced	One-off
	Joint country visits (with the European Centre for Disease Prevention and Control) to support Member States in the preparation and implementation of national action plans on preventing the development of antimicrobial resistance	■ Desk-based assessment ■ On-site control	■ Member States' competent authorities ■ EEA countries' competent authorities	At the request of the Member State	One-off

In some of the control systems, audits and similar controls (i.e. those described in Table 4) represent the majority of controls carried out. In DG SANTE, audits and similar controls represent roughly two-thirds of the control activities while analyses represent one third[60] (in 2021, 349 controls were planned in total, including 217 audits and similar controls, and 132 analyses[61]). However, according to DG SANTE, analyses are becoming a more important component of the Directorate's work and feed into audit / control or policy in other directorates[62]. In DG MARE, most controls are 'audits' and 'verifications' (or a combination of 'audits' and 'verifications'). 'Autonomous inspections' are relatively rare[63].

[59] Proposal for a Regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056 (2021/0367 (COD)), Brussels, 17.11.2021, COM(2021) 709 final, Article 64(4).
[60] European Commission, DG Health and Food Safety (2020) Health and food audits and analysis programme 2021, p.6.
[61] European Commission, DG Health and Food Safety (2020) Health and food audits and analysis programme 2021, p.9.
[62] Interview with DG SANTE.
[63] Interview with DG MARE.

2.3.4 Scope of EU controls

The legal acts establishing the EU control systems (see section 2.3.2) define the scope of Commission controls as described in the table below. Criteria upon which Commission controls assess the appropriateness and effectiveness of Member States' control systems are in some cases laid down in the same legislation. The level of details of these criteria varies across legislation: criteria to be met by Member States' control systems are very detailed in Regulation (EU) 2017/625 (DG SANTE) and Regulation (EC) 1224/2009 (DG MARE) and cover the organisation of the control system and the conduct of the controls. In Directive 2010/63 related to animals used for scientific purposes, only a handful of criteria (e.g., frequency of inspections) are laid down in the Directive and recommendations to Member States on the conduct of inspections is included in guidance. Regarding controls carried out by EMSA, provisions to be checked by the Agency are laid down in sectoral maritime safety legislation.

Table 8: Scope of EU controls and criteria verified by EU control systems

Control system	Scope and criteria controlled
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Scope: Based on Article 1(2), controls cover rules related to: (a) food and food safety; (b) deliberate release into the environment of Genetically Modified Organisms (GMOs); (c) feed and feed safety ; (d) animal health requirements ; (e) prevention and minimisation of risks to human and animal health arising from animal by-products and derived products; (f) welfare requirements for animals; (g) protective measures against plant pests; (h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides; (i) organic production and labelling of organic products; (j) use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed Criteria: Regulation (EU) 2017/625 defines ■ General requirements related to competent authorities and general rules for official controls (Articles 4 to 14): o Designate a competent authority and ensure effective coordination between all authorities involved (Article 4) o Have arrangements in place to ensure the effectiveness of official controls; their impartiality, quality and consistency; arrangements in place to ensure that staff performing official controls are free from any conflict of interest (Article 5) o Have or have access to, an adequate laboratory capacity for analysis, testing and diagnosis, a sufficient number of qualified and experienced staff, appropriate and properly maintained facilities and equipment (Article 5) o Have the legal powers to perform official controls and legal procedures in place to ensure that staff have access to the premises of, and documents kept by, operators (Article 5) o Staff performing official controls must receive appropriate training and regular additional training as necessary in their area of competence, and must receive training on control methods, techniques and procedures (Article 5) o Have internal audits carried out and take appropriate measures in the light of the results of those audits (Article 6) o Perform official controls on all operators regularly, on a risk basis and with appropriate frequency; perform official controls in a consistent manner (Article 9) o Perform official controls with a high level of transparency and make available to the public relevant information on official controls (Article 11) o Perform official controls in accordance with documented procedures and have control verification procedures in place (Article 12) o Draw up written records of every official control and inform operators of any non-compliance identified during the control (Article 13) o Official control methods and techniques include as appropriate: inspection of equipment, premises, animals and goods etc.; examination of documents and records; interviews with operators and staff etc. (Article 14)

Control system	Scope and criteria controlled
	■ Requirements specific to the area of legislation controlled, e.g. products of animal origin, food and feed, plant health, animal welfare, plant protection products (Articles 18 to 27) ■ Requirements related to methods used for sampling, analyses, tests and diagnoses (Article 34 to 42) ■ Requirements related to the Multi-annual national control plans (MANCP) (Article 109 to 113) ■ Requirements related to actions of competent authorities and penalties (Article 138 to 140)
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Fact-finding missions are carried out in this area. The scope of fact finding missions is defined based on the legal requirements of the legislation controlled and the objective of the mission (it may focus on selected requirements). The fact-finding missions related to biocides carried out in 2018 focused on the: ■ Obligation for Member States to adopt transposition measures (Article 291 TFEU) ■ Obligation for Member States to designate a competent authority or authorities, with a sufficient number of suitably qualified and experienced staff, which provide advice to applicants and any other interested parties on their respective responsibilities and obligations under the Biocidal Products Regulation (BPR) (Article 81 of BPR) ■ Obligations of Member States related to the submission, validation and evaluation of applications for approval of an active substance (Article 7 and 8 of the BPR) ■ Obligations of Member States related to the authorisation of biocidal product (including simplified authorisation procedure, national authorisations, mutual recognition, Union authorisation, cancellation, review and amendment of authorisations, periods of grace, parallel trade and derogations) ■ Compliance with requirements and official controls (Article 65 of the BPR)
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Scope: Control must address 'the infrastructure and operation of national inspections in Member States' (Article 35 of Directive 2010/63). Criteria included in legislation: ■ Frequency of inspections must be based on a risk analysis for each establishment (taking into account the number and species of animals housed, the record of the breeder, supplier or user in complying with the requirements of this Directive; the number and types of projects carried out by the user; and any information that might indicate non-compliance) (Article 34 of Directive 2010/63) ■ At least one third of users must be inspected each year; (Article 34 of Directive 2010/63) ■ Breeders, suppliers and users of non-human primates must be inspected at least once a year, an appropriate proportion of the inspections must be carried out without prior warning; (Article 34 of Directive 2010/63) ■ Records of inspections kept for at least five years (Article 34 of Directive 2010/63) ■ Member States must lay down rules on penalties and take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive (Article 60 of Directive 2010/63). These criteria are further developed and explained in a guidance document on inspection and enforcement, which provides guidance and principles of good practices in order to fulfil the requirements under Articles 34 and 60 of Directive 2010/63/EU[64].
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Scope: According to Article 100 of Regulation (EC) 1224/2009, the audits may include in particular the evaluation of: ■ the quota and the effort management system ■ data validation systems, including systems of cross-checks of vessel monitoring systems, catch, effort and marketing data and data related to the Community fishing fleet register as well as the verification of licences and fishing authorisations; ■ the administrative organisation, including the adequacy of the available staff and the available means, the training of staff, the delimitation of functions of all authorities involved in control as well as the mechanisms in place to coordinate the work and the joint evaluation of the results of those authorities; ■ the operational systems, including procedures for control of designated ports;

[64] National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes (2014) A working document on Inspections and Enforcement to fulfil the requirements under the Directive.

Control system	Scope and criteria controlled
	■ national control action programmes including the establishment of inspection levels and their implementation; ■ the national system of sanctions, including the adequacy of the sanctions imposed, duration of proceedings, economic benefits forfeited by offenders and the deterrent nature of such system of sanctions. Criteria: Depending on the audit scope, the relevant criteria are all relevant articles in the CFP Regulation (EU) No 1380/2013, Regulation (EC) 1224/2009 and its Implementing Regulation (EC) No 404/2011 as well as other regulations adopted within the framework of the Common Fisheries Policy, notably multiannual plans (MAPs), the IUU Regulation (EC) No 1005/2008, the IUU Implementing Regulation (EC) No 1010/2009, the Mediterranean regulation (EC) No 1967/2006, the Technical measures regulation (EU) 2019/1241, the SMEFF Regulation (EU) 2017/2403, etc. With regard to Regulation (EC) 1224/2009, some of the main assessment criteria are listed below: ■ Member States must adopt appropriate measures, allocate adequate financial, human and technical resources and set up all administrative and technical structures necessary for ensuring control, inspection and enforcement of activities carried out within the scope of the common fisheries policy (Article 5(3)) ■ Member States must ensure that control, inspection and enforcement are carried out on a non-discriminatory basis as regards sectors, vessels or persons, and on the basis of risk management (Article 5(4)) ■ Member States must designate a single authority that coordinates the control activities of all national control authorities (Article 5(5)) ■ Member States must set up a list of officials responsible for carrying out inspections, who must conduct inspections in a non-discriminatory manner at sea, in ports, during transport, on processing premises and during the marketing of the fisheries products (Article 74(1) and (2)) ■ Officials must check in particular: (a) the legality of the catch and the accuracy of the documentations relating to it; (b) the legality of the fishing gear; (c) if appropriate, the stowage plan and the separate stowage of species; (d) the marking of gears; and (e) the information on the engine (Article 74(3) ■ Officials may examine all relevant areas, catches, gear, equipment, containers and packages containing fish or fisheries products and any relevant documents and may question any relevant persons (Article 74(4)) ■ Officials must draw up an inspection report after each inspection and forward it to their competent authorities (Article 76(1)) ■ Officials must communicate their findings from the inspection to the operator, who has the possibility of commenting on the inspection and its findings. The operator's comments must be reflected in the inspection report (Article 76(2)). A copy of the inspection report must be sent to the operator as soon as possible (Article 76(3)) ■ Member States keep an electronic database where they upload all inspection reports (Article 78(1) ■ If an infringement is detected during or after an inspection, the competent authorities of the inspecting Member State must take appropriate measures against the master of the vessel or any other legal or natural person responsible for the infringement (Article 85) ■ Member States must ensure that appropriate measures are systematically taken, including administrative action or criminal proceedings in conformity with their national law, against the natural or legal persons suspected of a breach of any of the rules of the common fisheries policy (Article 89(1)) ■ The overall level of sanctions and accompanying sanctions shall be calculated, in accordance with the relevant provisions of national law, in such way as to make sure that they effectively deprive those responsible of the economic benefit derived from their infringement […] Those sanctions shall also be capable of producing results proportionate to the seriousness of such infringements, thereby effectively discouraging further offences of the same kind (Article 89(2)) ■ Member States may apply a system whereby a fine is proportionate to the turnover of the legal person, or to the financial advantage achieved or envisaged by committing the infringement (Article 89(3))
Established by Reg 1406/2002 – Maritime	Scope: Visits to Member States have concerned the following pieces of legislation:

Control system	Scope and criteria controlled
safety (DG MOVE Dir D /EMSA).	■ Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 establishing the fundamental principles governing the investigation of accidents in the maritime transport sector ■ Directive 97/70/EC setting up a harmonised safety regime for fishing vessels of 24 metres in length and over ■ Directive 98/41/EC on the registration of persons sailing on board passenger ships operating to or from ports of the Member States of the Community ■ Directive 2009/16/EC on port State control ■ Directive 96/98/EC on marine equipment ■ Directive 2000/59/EC on port reception facilities ■ Directive 2002/59/EC establishing a Community vessel traffic monitoring and information system ■ Directive 2001/96/EC on establishing harmonised requirements and procedures for the safe loading and unloading of bulk carriers ■ Directive 2008/106/EC on the minimum level of training of seafarers ■ Directive 2003/25/EC on specific stability requirements for ro-ro passenger ships, as amended ■ Directive 2009/45/EC on safety rules and standards for passenger ships, as amended ■ Directive (EU) 2017/2110 on a system of inspections for the safe operation of ro-ro passenger ships and high-speed passenger craft in regular service Criteria: The criteria checked during the visit depend on the provisions of each piece of legislation concerned (the list of criteria examined during the visit for each one is available on EMSA's website). These criteria generally include the implementation and enforcement system in place and the sanctions imposed in case of non-compliance. While to date, most pieces of legislation were the subject of singular cycles, others have been the subject of multiple cycles. In the latter cases, the first cycle of visits regarding a piece of legislation would generally focus on the implementation of the legislation in general while subsequent cycles may concentrate on specific elements that have been highlighted by the previous cycle[65].
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Scope: ■ Commission audits may be carried out 'up to three calendar years following the acceptance of the accounts in which the expenditure concerned was included'. This period does not apply to operations where there is a suspicion of fraud (Article 70 of Regulation (EU) 2021/1060) ■ Assurance packages submitted to the Commission by Member States every year, which include: o Annual accounts, o The management declaration from the managing authority, confirming the completeness and accuracy of the accounts and that expenditures entered in the accounts comply with applicable rules, o The audit authority's audit opinion, confirming the completeness, accuracy and veracity of the accounts, legality and regularity of the expenditure included in the accounts submitted to the Commission, and the effective functioning of the management and control system; o The annual control report from the audit authority supporting the audit opinion (Article 98 of Regulation (EU) 2021/1060). ■ Compliance audits review the work of national audit authorities – Commission auditors re-perform audits done by national audit authorities to validate their results. National audit authorities are responsible for carrying out system audits, audits on operations and audits of accounts to provide independent assurance to the Commission regarding the effective functioning of the management and control systems and the legality and regularity of the expenditure included in the accounts submitted to the Commission (Article 77 of Regulation (EU) 2021/1060) ■ Thematic audits target specific issues, for example management verifications to prevent and detect public procurement errors. Criteria: ■ Evolution of the error rate ■ Audit work is carried out by national audit authorities in accordance with internationally accepted audit standards (Article 77 of Regulation (EU) 2021/1060).

[65] EMSA (2015) Methodology for visits to Member States, section 2.1.

Control system	Scope and criteria controlled
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable (as DG CLIMA does not carry out controls of Member States' control and enforcement systems).
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable (as OLAF may carry out controls of operators (suspicious shipments) but does not carry out controls of Member States' control and enforcement systems).

2.3.5 Basis for triggering Commission controls

Identified EU control systems can be divided between those systems primarily delivering proactive controls (i.e., carrying out routine / regular controls based on annual or multiannual planning) and reactive controls (i.e., controls following alerts, concerns, or incidents), as shown in the table below, based on desk research and interviews.

Table 9: Proactive and reactive control systems

Control system	Proactive	Reactive
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Controls in Member States are based on annual and multiannual (five-year) control programmes (Article 118 of Regulation (EU) 2017/625)	The annual programme might be changed to respond to urgent issues (Article 118 of Regulation (EU) 2017/625)
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Fact-finding missions are included in the annual and multiannual (five-year) control programmes.	Not applicable.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Not applicable.	Controls of the infrastructure and operation of national inspections in Member States are triggered 'when there is due reason for concern' (Article 35 of Directive 2010/63/EU)
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Two-year risk based rolling audit plan established by DG MARE Unit D4 and approved by DG MARE's management committee	Ad-hoc audits//verifications/inspections can be launched to respond to urgent issues[66] (such as indications of significant and recurrent breaches of CFP rules). Such cases are relatively rare.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Multi-annual (one-off) cycle of visits to Member States planned specific to the relevant legislation ■ Regarding standards for seafarers (STCW Convention) Visits to Member States every five years and inspections of third countries at least once every ten years. Two-year assessment cycle for EU recognised organisations	Ad hoc visits and inspections can be requested by the Commission (for example an investigation following a complaint by a third party)[67]
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ Annual checks of the assurance packages submitted by national Audit Authorities to the Commission as well regular reviews of national system audit reports ■ Two-year audit plan for risk-based audits and fact-finding missions	Additional audits or missions can be identified through the year based on specific concerns.

[66] Interview with DG MARE.

[67] EMSA (2015) Methodology for visits to Member States, section 1.1.

Control system	Proactive	Reactive
	linked to specific spending programmes or Audit Authorities.	
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable.	The commission may request Member States to carry out investigations when considered necessary (Article 28(1) of Ozone Regulation)[68].
Foresee in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable.	OLAF may start an investigation into a shipment when there is suspicion of non-compliance (Commission proposal to revise the Waste Shipment Regulation).

Although they are primarily proactive control systems, based on annual or multiannual planning of controls, the planning of controls carried out by DG SANTE, DG MARE, DG REGIO/EMPL and DG MOVE contain mechanisms to react to ad-hoc and/or urgent issues. DG SANTE's annual control programme can be amended, by means of implementing acts, to take account of developments in the areas controlled and respond to urgent issues (Article 118(2) of Regulation (EU) 2017/625). Similarly in DG MARE or DG REGIO/EMPL, if specific issues or concerns in some Member States are assessed as urgent, ad-hoc controls can be launched. Where necessary, DG MOVE can request EMSA to carry out ad-hoc visits to Member States or inspections of relevant third countries for STCW or inspections of recognised organisations, when there is a need to gather additional elements for proper assessment or to collect evidence for an investigation following a complaint received by DG MOVE from a third party[69].

Criteria for prioritisation of proactive controls

Controls are prioritised based mostly on risk assessment (objective risk criteria, results of previous controls), as shown in the table below. Where there is an obligation for the Commission to control at a certain frequency, it prevails over the risk assessment (e.g., obligations for EMSA to inspect classification societies every two years or do STCW Convention inspections every ten years). In the health and food safety area, there used to be a legal obligation to control border control posts at regular intervals, which has been removed. Those audits are now only based on risks[70].

Another important criterion is reflecting wider policy priorities within a policy area (such as Commission Strategies). In the case of EMSA, controls are also often – but not in every case – prioritised based on the adoption of new EU legal requirements. The table below summarises information collected through desk research and interviews with Commission officials.

Table 10: Criteria for prioritising controls in annual or multiannual planning

Control system	Criteria
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ Legal requirements for control (if there is an obligation for the Commission to carry out controls at a certain frequency; if there is a clear mandate (i.e. if the area is covered by Regulation (EU) 2017/625), audits are carried out, if there is no clear mandate or the legal basis for controls is weak, fact-finding missions can be organised, if appropriate) ■ Food safety and health risks (risk associated with products, their origin, production or trade volumes and flows) ■ Commission political priorities (farm to fork strategy, pharmaceutical strategy etc.)

[68] Member States however conduct their inspections following a proactive risk-based approach (Article 28(1) of Ozone Regulation). They may also carry out investigations and inspections requested by another Member State (Article 28(5)).
[69] EMSA (2015) Methodology for visits to Member States, section 1.1.
[70] Interview with DG SANTE.

Control system	Criteria
	■ Results of previous control activities (based on country profiles – see section 2.3.7.5), past performance of competent authorities and time period since last audit in a country. ■ Balance between EU and non-EU (third) countries ■ Non-EU countries are targeted according to risks associated with their exports to the EU, and take account of the volume of exports, the frequency of non-compliant consignments identified at EU points of entry and risks associated with the type of products. Controls also cover countries with free trade agreements with the EU[71].
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	As above
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Not applicable
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Annual risk assessment based on internal discussions within DG MARE on which risks deserve specific focus. Follow up on key findings of previous audits/inspections (Action Plans, EU Pilots, Infringements) is always included in the plan.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Legal obligation to inspect (for instance EU recognised organisations must be inspected every two years – see 2.3.3.2) ■ New legal requirements (Member States visit cycles are often conducted following the adoption of new legal requirements / after the revision of a Directive) ■ Quantitative criteria (such as number of seafarers in a country for inspections related to training and qualifications of seafarers. ■ Results from previous visits and inspections ■ For Member States visits – equal treatment of all Member States
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	The plans for the audits and fact-finding missions are based on annual risk assessment, where different aspects are assessed (e.g. budget managed, results of previous audits and controls etc.), and internal discussions on how to prioritise the audits.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable

2.3.6 Organisation of the control system

2.3.6.1 Roles and responsibilities

In most of the control systems identified, controls are carried out by Commission staff, as shown in the table below. In some cases, a dedicated Directorate for controls (directorate F in DG SANTE, REGIO.EMPL.DAC in DG REGIO and EMPL) or a dedicated unit (Unit D4 in DG MARE) has been set up within the DG.

Table 11: Responsible services

Control system	Deciding on which controls should be performed	Carrying out the controls	Deciding which follow-up action / enforcement measure to take
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Directorate for Health and food audits and analysis (SANTE.DDG2.F)	Directorate for Health and food audits and analysis (SANTE.DDG2.F)	Directorate for Health and food audits and analysis (SANTE.DDG2.F)

[71] European Commission, DG Health and Food Safety (2020) Health and food audits and analysis programme 2021, p.6.

Control system	Deciding on which controls should be performed	Carrying out the controls	Deciding which follow-up action / enforcement measure to take
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Directorate for Health and food audits and analysis (SANTE.DDG2.F)	Directorate for Health and food audits and analysis (SANTE.DDG2.F)	Not applicable.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No decision taken yet	No decision taken yet	No decision taken yet
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Fisheries Control and Inspection unit (DG MARE D4)	Fisheries Control and Inspection unit (DG MARE D4)	Fisheries Control and Inspection unit (DG MARE D4) after consultation with relevant units in DG MARE and the DG MARE management committee
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Executive Director of EMSA / Administrative Board of EMSA[72], in consultation with the Commission, upon whose request the cycles are conducted.	EMSA – Unit 1.2 Visits & Inspections, Human Element (supported by subject experts from other units of EMSA)	DG MOVE – Maritime Safety (MOVE.DDG2.D.2)
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Joint Audit Directorate for Cohesion (there are 7 units dealing with audits in DAC, including audit coordination unit)	Joint Audit Directorate for Cohesion	Joint Audit Directorate for Cohesion
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Low Carbon Solutions (I): Montreal Protocol, Clean Cooling & Heating, Digital Transition unit (DG CLIMA A.2C.1) (i.e. deciding on whether to ask a Member State to start an investigation)	National competent authority (carries out the investigation) DG CLIMA assesses if the actions of the Member State are appropriate and may request further action	National competent authority which carried out the investigation
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Unit B2 –Illicit trade, Health and Environment – Operations and Investigations (i.e. deciding to open an investigation)	Unit B2 –Illicit trade, Health and Environment – Operations and Investigations	National competent authority in which the control has been carried out

Coordination with EU agencies

Regarding controls in the area of maritime safety, the decision to carry out Member State visits is taken by the Administrative Board of EMSA (in which the Commission is represented), which adopts the multiannual strategy and staff policy plan, as well as the annual work programme and budget of the Agency. As further explained in section 2.3.7.1, the establishment of the control programme is done in coordination with the Commission, which decides which piece of EU maritime legislation should be the subject of a cycle of visits and the scope of visits[73]. The execution of the visits or inspections is delegated to EMSA, as well as the reporting on them. DG MOVE is then responsible for issuing an assessment report to the Member State in question, based on an analysis of the results of the visits and deciding what type of follow-up is needed and whether enforcement measures are required.

[72] According to Article 15(2) of Regulation (EC) No 1406/2002 establishing EMSA, the Executive Director of EMSA prepares the multiannual strategy of the Agency and the annual work programme (which are then adopted by the Administrative Board) and decides to carry out the visits to Member States and inspections provided for in Article 3 of the Regulation, after consultation of the Commission and following the methodology for visits established by the Administrative Board.

[73] EMSA (2015) Methodology for visits to Member States, section 1.1.

The European Fisheries Control Agency (EFCA) is not involved in controls carried out by DG MARE. The Agency supports the coordination of Member States' control activities and facilitates cooperation between them to ensure that legislation is implemented in a systematic and uniform way across the EU. The Agency also develops training materials for fisheries inspectors and supports exchanges of experience and good practice between Member States.

Controls of operators

As described in Table 6, DG CLIMA may request a Member States to carry out an investigation. In this case, DG CLIMA provides information to the Member State about the case concerned and asks for follow-up. The Member State assesses the case, takes action and responds to DG CLIMA, which assesses whether the actions of the Member State are appropriate. If actions taken by the Member States are not sufficient, DG CLIMA may request further action[74]. The Member States' authorities carry out all necessary controls of undertakings as part of the investigation and are responsible for taking enforcement actions if necessary. As mentioned in section 2.3.3.1, DG CLIMA has not carried out any inspection since, on the basis of Article 28 of the Ozone Regulation, it is the Member States that shall conduct the inspections. Until now, DG CLIMA has not attended a Member State's inspection either. DG CLIMA assists Member State authorities in the performance of their duties by the sharing and exchange of information. Similarly, if one of OLAF's investigation leads to the detection of non-compliance, the Member State's competent authority must take enforcement action.

2.3.6.2 Profile and competencies of controllers

Controls are mostly carried out by in-house Commission staff belonging to the responsible DGs, with the exception of controls in the field of maritime safety, the execution of whichis delegated to EMSA.

Commission / EMSA staff carrying out the controls are recruited through competitive examinations with specific requirements in terms of education (i.e., diploma in relevant area) and experience in carrying out audits and/or inspections s. For the Commission, recruitment of controllers is done through EPSO and for EMSA, through procedures specific to the Agency. The table below describes the human resources and qualifications of Commission staff in the different responsible services, as provided by interviews with the different Commission services.

In addition to Commission staff, national experts from Member States may be involved in the audits carried out by DG SANTE (see section 2.3.7.2).

Table 12: Number and qualifications of controllers

Control system	Staff carrying out controls	Staff profile and qualifications
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	90 auditors (out of 157 staff)	■ Diploma in natural sciences (in particular veterinary medicine, food safety, health, environmental health, chemistry/food chemistry, pharmacology/toxicology, pharmacy, medicine, biology, microbiology, biomedical science, agriculture, forestry, horticulture, human and animal nutrition) ■ At least 6 / 7 years professional experience directly related to the tasks to be performed by the auditor[75].
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Same as above.	Same as above.
Established by Directive 2010/63 – Protection of	No control yet carried out	No control yet carried out

[74] Reply from the European Commission to the Ombudsman's letter concerning the Commission's and the Member States' implementation of Article 28 (governing inspections) of Regulation (EC) 1005/2009 on substances that deplete the ozone layer, Case SI/7/2017/JN, 09 November 2018.

[75] See the Notice for open competition EPSO/AD/392/21.

Control system	Staff carrying out controls	Staff profile and qualifications
animals used for scientific purposes (DG ENV Dir. B).		
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	15 staff (out of 27 staff in DG MARE Unit D4) regularly conduct audits and verifications	■ 9 are Temporary Agents (most of whom are national fisheries inspectors), 2 Contractual Agents and 4 Commission Officials (with audit/legal/policy background). ■ In addition, 2 persons (External Contractors) help with the data analysis prior to audits but do not visit the Member States. ■ Most Temporary Agents have the title "Fisheries Inspector" and most Contractual Agents and Officials have the title "Control Expert".
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	210 temporary agents, and in total 252 staff members in EMSA, of which the following number of staff carry out visits and inspections work: ■ Visits to Member States: 6 ■ Seafarer Training (STCW): 7 ■ Classification Societies: 10[76]	■ Mostly maritime professionals – recruited with a minimum of five years of experience as a naval architect, navigating officer or marine engineer on board of seagoing ships, or of relevant work for a ship owner, classification society, administration, shipyard or maritime education and training institution, and if possible, auditing experience[77]
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Around 150 staff in the Joint Audit Directorate	There is no specific profile, but the staff members usually have experience either with audits or with the implementation of Cohesion Policy.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable (Commission not carrying out controls).	Not applicable (Commission not carrying out controls).
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available.	No information available.

Commission and EMSA staff generally do not spend all their working hours doing audits but may also do technical work or carry out other types of controls – for instance in DG SANTE this can involve 'analyses', or evaluations of Member States' control plans (controls described in section 2.3.3.2). In DG SANTE, an auditor does on average seven audits a year, including 3-3.5 as a lead auditor and the rest (3.5-4) as second auditor[78]. In DG MARE, on average, an auditor/inspector probably spends around half the time on audits, including their follow-up, and half the time on other tasks, for example participating in EU or international meetings on fisheries control (e.g. meetings of the European Fisheries Control Agency (EFCA), of Regional fisheries management organisations (RFMOs[79]), or of Regional Advisory Councils (RACs[80])), providing expertise for policy making, replying to questions on fisheries control matters from NGOs and other stakeholders[81], etc. In EMSA, controllers conducting Member State visits are exclusively engaged in inspection work. Staff members from other units of EMSA also support and are part of the visit team (see section 2.3.7.2).An inspector conducts 4-6 inspection per year. In the areas of seafarer training and classification societies, these staff members do not only carry out visits and inspections work but also undertake other technical assistance work related to their respective areas. As per internal EMSA

[76] Figures are averages of annual staff allocations for years 2017-2019 and 2022. The figures referred to in the table do not include staff from the business units, neither staff from human resources engaged in administrative and operational support, editorial reviewing, document management, etc.

[77] See as example call for application (last accessed on 08.11.21).

[78] Interview with DG SANTE.

[79] RFMOs are international organisations regulating regional fishing activities in the high seas.

[80] RACs are regional forums, which aim to involve stakeholders in the fisheries sector more closely in the decision-making process and implementation of the Common fisheries Policy.

[81] Interview with DG MARE.

processes, inspectors involved with seafarer training dedicate around 70% of their time to inspection work. Inspectors dealing with classification societies dedicate about 85% to inspection work.

2.3.6.3 Training of controllers

Based on interviews with Commission services, Commission staff carrying out controls receive training both on core auditing skills (carrying out an audit, collecting evidence, writing reports etc.) and in some cases also receive technical training on the policy area they are controlling.

Table 13: Type of training available to controllers

Control system	Type of training
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Mandatory courses for auditors on core skills (auditing skills, report writing)
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Same as above.
Established by Directive 2010/63 – Protection of animals used for scientific purposes– (DG ENV Dir. B).	No control yet carried out.
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Continuous on-the-job training during audit missions and inspections. ■ General audit training: basic audit principles, planning and executing missions, audit interviews, sampling, audit evidence, documenting and assessing findings, audit report writing, communicating results to stakeholders and ensuring adequate follow up of issues) If possible one audit training per year (as of 2021). Though currently not mandatory, the audit training is highly recommended. The audit training is provided by an external service provider. ■ Technical training related to fisheries (fisheries' data, monitoring systems, etc.) which occur around once or twice a year
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	EMSA staff members conducting visit and inspection work must successfully complete an ISO 9001 Quality Management System Lead Auditor Training Course, unless they would have already received said – or equivalent – training before joining. Refresher training based on ISO 9001 Quality Management System Training Course - Refresher for Lead Auditors is organised periodically by EMSA. Moreover, staff may consider in their annual training maps, other training related to specific areas of interest within their visits and inspection activity, as made available by EMSA. Said training is not compulsory since staff conducting visits to Member States rely for technical expertise on subject experts from the relevant business units in EMSA.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Training sessions are organised regularly for all auditors and specific training sessions are provided for newcomers, including information on the applicable procedures, sampling methodologies and other relevant aspects related to audit work.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable (Commission not carrying out controls)
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available.

2.3.6.4 Budget

When services responsible for the control systems are Commission Directorates or Units (DG SANTE / DG MARE/ DAC within REGIO and EMPL) the human resource costs are covered by the Commission's budget.

The costs of missions (travel and accommodation expenses and daily allowance) are covered by the Commission's administrative budget. DGs have to make yearly claims to cover these expenses. For 2022, DG SANTE has claimed slightly below a million euros for covering these expenses for around

157 on-site audits. This is lower than claims for previous years (around 1,3 million) as many activities will still take place remotely, or partially remotely this year. When national experts (from national authorities) participate in the audits (see section 2.3.7.2), their expenses are paid from the same budget, on the same basis as Commission staff[82].

In DG MARE, costs of missions (travel and accommodation expenses) were estimated at around EUR 100 000 in 2019 (2020-2021 impacted by COVID-19 pandemic). The cost of a typical mission (3 persons, 3-4 days) is around EUR 4000-6000 depending on the location)[83].

Regarding EMSA, staff related costs, mission expenses and overheads are covered by the budget of the Agency (EU subsidy). The annual commitment appropriations for these activities over the period 2017 – 2022 (excluding 2020 and 2021 due to the impact of the pandemic on the field work) average out as follows:

- Visits to Member States: EUR 1,424,814
- Standards for Training and Seafarers: EUR 1,265,567
- Classification Societies: EUR 2,027,811[84]

In total, on average these activities consume 6.5% of the total EU subsidy for EMSA. The annual average number of visits and inspections undertaken within the three areas are 18 (Member State visits), 8 (Seafarer training) and 17 (Classification Societies).

2.3.6.5 IT system

DG SANTE currently uses an IT document and workflow management system called MisDoc, which monitors the audit (or other activity) workflows and stores the information relevant to the audit, including the template (common to the series of audit), the audit reports and supporting documents[85]. The system facilitates the communication between the different units of the Directorate (e.g., notifications are sent to the unit dealing with the follow-up of Commission controls when new audit reports are filed), and avoids any duplication of work (e.g., notifications are sent specifying roles and tasks, and rights are distributed so that only the individuals responsible for a task can complete it). It is also used for planning as it provides an overview of the schedule of all audits, which allows scheduling clashes to be identified. DG SANTE has initiated a replacement of the MisDoc system as the underlying IT system will no longer be supported by the Commission in the long term[86]. DG REGIO and EMPL are using an IT system MAPAR used to monitor the audit workflows and to store information relevant to the audits. EMSA records and processes its visit and inspection findings in its databases. A specific system has not been developed in DG MARE as there is only one unit carrying out audits, which makes their organisation simpler.

2.3.7 Main steps of control process

2.3.7.1 Establishment of the control programme

EU control systems that carry out regular proactive controls (see sections 2.3.3 and 2.3.5) establish

[82] Interview with DG SANTE.
[83] Interview with DG MARE.
[84] These figures are averages of the commitment appropriations between 2017 and 2022, which, apart from direct costs, also takes into account overheads attributable the activity in question. According to EMSA, it would be misleading to extract an average price per mission from these figures since in EMSA, missions can vary significantly from visits to European Member States or class society offices based in Europe, to STCW inspections or class society office inspections worldwide. In addition, it should be noted that, particularly in the Seafarer Training and Classification Societies areas, an element of these appropriations was also in respect of other support activities provided on the respective technical areas (e.g. missions to conferences, IMO meetings, etc.).
[85] European Commission, Register of the European Data Protection Officer.
[86] Interview with DG SANTE.

a control programme, based on the criteria listed in Table 10, laying down the anticipated list of controls (country / legal requirements to be controlled). As shown in Table 9, both multiannual and annual plannings can be established. DG SANTE's health and food safety controls are based on two layers of planning, a five-year multiannual plan, which sets out the main priorities for the controls over the next five years, and an annual control programme. EMSA carries out different types of activities according to different cycle times – this might come from legal requirements to control (obligation to inspect classification societies every two years, third countries every ten years) or legislative cycles (a new visit cycle is initiated when, for example, a new or revised legislation has entered into force or when the Commission deems it otherwise necessary).

The process for establishing the control programme usually involves an initial planning done by the services responsible for carrying out the controls (in the case of EMSA based on a programme agreed with the Commission), an internal consultation with other Commission services (given that prioritisation of controls often takes into account policy needs and priorities), and sometimes with the Member States on the schedule, and an internal approval process. In one case, DG SANTE, the adoption of the control programme requires a formal approval in the form of an implementing act[87].

Table 14: Process for establishing the control programme

Control system	Drafting	Consultation	Approval
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).[88]	■ Each operational unit of the Directorate first does a tentative planning for their own sector of controls. ■ Unit F6 – Internal controls and services is responsible for coordinating the planning process and communicating the result to other SANTE services.	■ Consultation with other Commission services (policy officers in relevant units of DG SANTE or AGRI) to gather their inputs on policy needs / emerging issues and the proposed audits (theme and country selection) ■ Annual work programme communicated around October to Member States, which can comment on the proposed schedule and ask for adjustments before the programme is adopted by the end of the year	■ Approval by Cabinet ■ Annual programme adopted through implementing decision (Article 118(1) of Regulation (EU) 2017/625)
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	As above	As above	As above
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Only reactive controls required by the Directive. No control programme established	Only reactive controls required by the Directive. No control programme established	Only reactive controls required by the Directive. No control programme established
Established by Reg (EC) 1224/2009 – Common Fisheries Policy DG MARE Dir. D).[89]	The annual control programme is established by Unit D4	The annual control programme is established in consultation with other units in DG MARE and approved by the Management Committee	Internal approval process (Management Committee)

[87] The Multi-annual plan 2021-2025 has been established by Commission Implementing Decision (EU) 2020/1550. Since the adoption of Regulation (EU) 2017/625 (this was not required in the previous regulation), the Commission shall establish an annual or multiannual control programme for the controls to be performed by its experts in the Member States and may amend it, by means of implementing acts (Article 118 of Regulation (EU) 2017/625). Article 118 does not make reference to Article 145 on committee procedure in relation to which comitology procedure applies. Based on Article 2(3) of Regulation (EU) No 182/2011, the advisory procedure should apply.

[88] Interview with DG SANTE.

[89] Interview with DG MARE.

Control system	Drafting	Consultation	Approval
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Based on DG MOVE's decision on which legislation should be the subject of a visit cycle, EMSA drafts the multi-annual planning of individual visits in agreement with DG MOVE ■ Similar process for third countries and classification societies	Internal consultations ■ Meeting within EMSA units, to establish an initial annual planning ■ Every May, the Visit and (STCW) Inspection programme for the following year is submitted to the Commission for agreement. In the case of inspections of recognised organisations, an annual co-ordination meeting between EMSA and the Commission is held to formulate the programme for the following year. Regular consultation with Commission is then maintained to ensure agreement on changes in the programmes as necessary. [90]	Work programmes are adopted by the EMSA Administrative Board (on which the Commission is represented).
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Joint Audit Directorate for Cohesion draws up the audit plan on the basis of the audit strategy	Internal consultations Audit plans discussed annually with the national audit authorities in the framework of Annual Coordination Meetings.	Internal approval process
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable (action taken when suspicion of non-compliance arises or on a risk-based approach)	Not applicable (action taken when suspicion of non-compliance arises or on a risk-based approach)	Not applicable (action taken when suspicion of non-compliance arises or on a risk-based approach)
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable (action taken when suspicion of non-compliance arises)	Not applicable (action taken when suspicion of non-compliance arises)	Not applicable (action taken when suspicion of non-compliance arises)

In addition to risk and policy prioritisation, practical reasons are taken into account in establishing the schedule of the controls. As mentioned in the above table, DG SANTE sends the control programme to the Member States concerned before adoption, so that they can request adjustments to the proposed schedule if needed. In doing the planning, the various units also make sure there are no overlaps between the dates of the audits[91]. As visit cycles for different pieces of legislation can be carried out concurrently, EMSA's 'Methodology for visits to Member States' lays down a number of factors which should, to the extent possible, be taken into account when planning the visits. These include provisions such as the one specifying, for example, that a Member State should not receive more than two visits from EMSA per calendar year, regardless of which legislation is checked, and that there should be at least three months between any such two visits[92].

2.3.7.2 Preparation of Commission controls

Setting up the control team

A control team, typically composed of two / three people, is established for each individual control activity. The control team is generally composed of a team leader, who is responsible for carrying out the control procedure, and who can also be responsible for most of the reporting. The team leader

[90] Interview with DG MOVE / consultation with EMSA.
[91] Interview with DG SANTE.
[92] EMSA (2015) Methodology for visits to Member States, section 2.1.

is assisted by one or several team members. Attention is paid to make sure that the control team includes the necessary technical expertise, specific to the area controlled. This is done differently in the three control systems:

- In EMSA, in-house staff from the unit responsible for the area controlled are part of the control team.
- In DG SANTE, when specific technical expertise is not available in-house, an external (national) expert, may be requested to join the audit team. National experts come from a national public authority (which can be the central competent authority, or other national authorities, or regional authorities), and their participation is proposed by DG SANTE and agreed/approved by the competent authority of the national expert's Member State. Their expertise depends on the nature of the audit, they can be laboratory experts, experts on a particular animal disease, customs experts etc. They complement the expertise of the Directorate, which, given the very large number of areas covered by the audits, may not have all the technical expertise necessary for all the audits. In addition to providing technical expertise, national experts may also join the audit team for transparency reasons[93].
- In DG MARE, the audit team leader is often the desk officer for the Member State (main contact person for the Member State in the Unit).

To manage series of audits or individual audits in several Member States, DG SANTE and DG MARE designate a project manager or coordinator, who is tasked with overseeing the procedures in the different Member States. The table below summarises information collected through interviews of Commissions services.

Table 15: Composition of the control team

Control system	Nb of members	Team members
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	2-3 [94]	■ Project leader who supervises the series of audit in several countries on the same topic (which is called a project). ■ Lead auditor, who is tasked with most of the preparatory work and reporting, and second auditor ■ (If necessary) a national expert, who has specific expertise needed for the audit, ■ In some cases, policy officers from DG SANTE or DG AGRI may also participate as observers.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	2-3	■ As above – the composition of the team is similar in fact-finding missions and in audits.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No control yet carried out	No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	2-4	■ Audit team leader designated by the Head of Unit of DG MARE Unit D4 , responsible for the whole audit process (usually a member of the unit, called 'desk officer', who is the main contact person for the Member State concerned and thus has the best knowledge of the country) ■ Audit team members designated by the Head of Unit (usually 2 to 4 persons, depending on the complexity of the audit) ■ Audit coordinator designated in case the audit concerns several Member States
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	2-4	Visits to Member States: ■ One or two members of the Visits and Inspection unit of EMSA

[93] Interview with DG SANTE.

[94] Excluding the project manager and possible policy officers, who are not directly part of the audit team. On average, the Directorate has calculated that in the food area the DG SANTE auditors (excluding national experts) represent two FTEs and in the heath area of 1.75 FTE.

Control system	Nb of members	Team members
		■ One or two members of the unit in EMSA which deals with the specific piece of legislation assessed in the visit, who have the technical knowledge on the subject matter Third country (STCW) inspections ■ Two to four members Inspections of recognised organisations ■ Two to four members The determination of the teams' composition depends on various factors such as the geographical spread of inspection points (i.e. ports, educational institutions, shipyards) or the scope of the inspection that must be covered during the limited duration of a visit.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	2-4	Audit team members designated by the Head of Unit (usually 2 to 4 persons, depending on the complexity of the audit: lead auditor, who is tasked with most of the preparatory work and reporting, and an associated auditor or auditors).
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable	Not applicable
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available	■ OLAF officers ■ Officials of the Member State concerned may participate in the inspections (Article 65(2) of the Proposal for a Regulation on shipments of waste)

Official mandate and announcement letters

In some of the control systems, an official mandate (that auditors carry with them during the control) and formal notifications to Member States authorities, in the form of announcement letters, are necessary for the audit to take place, as specified in the table below.

Table 16: Official mandates and notifications to Member States

Control system	Official documents
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Not applicable.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Not applicable.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No control carried yet out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ 'Written authority' stating the identity and capacity of the auditors (Article 97(4) of Regulation (EC) 1224/2009) and 'written instructions' specifying the control objectives and the authority of the auditors (Article 97(5) Regulation (EC) 1224/2009) issued by the Director General ■ Announcement letters sent to audited Member States generally two months before the mission starts addressed to the director of the competent fisheries authorities with a copy to the permanent representation, the Member State contact person and other representatives of the fisheries administration where relevant. [95]
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ For Member States visits: EMSA sends a formal notification of a visit to the Permanent Representation of the Member State concerned three months

[95] Interview with DG MARE.

Control system	Official documents
	prior to the visit, with a copy to the said Member State's competent authority and to the Commission[96] ■ Formal letters sent by DG MOVE to third countries and the External Action Service; and to classification societies to inform them that they have asked EMSA to inspect them ■ For Member States visits: The Executive Director of EMSA issues decisions indicating the date of the visit and its main objective and purpose (which inspectors should present at the start of the visit and otherwise keep available upon request)[97]
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Formal notification letters are sent to the relevant national authorities with information on the legal basis of the audit and its scope.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	According to the Proposal to revise the Waste Shipment Regulation, the staff carrying out the inspections must carry a 'written authorisation specifying the subject matter and purpose of the inspection' (Article 65(3) of the Proposal for a Regulation on shipments of waste)

Preliminary information gathering and pre-audit questionnaire

The preparatory phase of a control usually includes a preliminary desk-based information gathering, to identify risk areas and potential areas of non-compliance that will have to be investigated further in the control, identify evidence to be gathered on the ground, and prepare a control programme for on-site visits and interviews.

Table 17: Preliminary information gathering

Control system	Sources / tools for preliminary information gathering
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ Analysis of data contained in Country profiles (previous audit reports, recommendations and follow-up, overview of organisation and functioning of the national control system, relevant links to Member States' website) and of multi-annual national control plans (MANCP) and annual reports on controls of the concerned Member State ■ Tailored pre-audit questionnaire sent to the competent authority which takes account of the information already held by the Commission on the Member State's control system for the subject of the audit [98]
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Same as above.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Analysis by audit team of fisheries data (e.g., catch data, effort data, sales data, vessel data, etc.) relevant to the scope of the control ■ Audit questionnaire, often enclosed in the announcement letter, to gather information and data such as relevant national fisheries legislation, organisation charts, system descriptions, monitoring and control procedures, fisheries data, market data, inspection programmes and manuals, etc. within the scope of the specific control. The Member State is requested to reply to the questionnaire within 4-6 weeks of reception.

[96] EMSA (2015) Methodology for visits to Member States, section 2.4.
[97] EMSA (2015) Methodology for visits to Member States, section 2.5.
[98] Interview with DG SANTE.

Control system	Sources / tools for preliminary information gathering
	■ All the information is summarised in an audit planning memorandum.[99]
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Before start of the visit cycle[100]: ■ Ad hoc workshop with EMSA, the Commission and representatives of the relevant competent authorities of the Member States, involving prior analysis of the relevant issues, and the circulation of a questionnaire. Member States can provide relevant information to EMSA during the workshop. ■ EMSA should receive the results from the conformity check of the legal transposition performed by the Commission before the start of the visit cycle, to also be discussed during the workshop Before each visit: ■ Desk-based preparation of the visit ■ Pre-visit questionnaire to the Member State concerning the areas to be focussed on during the visit (related to information that EMSA does not already have through other means)
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Assessment of the assurance packages (i.e. documentation sent annually by the Member State authorities, see section 2.3.4) is done every year by DG REGIO/EMPL. Moreover, the Commission auditors review system audit reports submitted by the national audit authorities. This desk-based assessment informs subsequent compliance and thematic audits (see section 2.3.3.1)
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	No information available.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available.

The preliminary information gathering feeds into the control programme, including site visits and interviews/meetings, which are arranged with the Member State.

Operational procedures / mission checklists

Controls are organised according to standard operating procedures and methodology/instructions, applicable to all control activities carried out by the relevant Commission service/EU agency, explaining the steps and methods to be applied during Commission controls, which are usually complemented by specific templates and checklists for a series of controls or an individual control, defining which verifications or tests should be performed and which evidence should be gathered on the ground. The table below, based on interviews with Commission services, summarises existing official documents in each control system.

Table 18: Standard operating procedures and checklists in the different control systems

Control system	Official documents
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ Standard operating procedures for each area, supported by a number of work instructions and reference documents, applying horizontally to all activities in an area of work ■ Each project (i.e., series of audit on the same topic) has an official template for the audit report (approved by the Head of Unit, and by units F6/F7 and saved in the Directorate's Integrated Audit Management System- "MisDoc") to ensure consistency in approach across the series of audits on a given topic ■ Team leaders and auditors will usually devise their own 'aide memoires' for an audit series also with the aim of ensuring consistency across the series.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Same as above.
Established by Directive 2010/63 – Protection of animals used for	No control carried out yet

[99] Interview with DG MARE.
[100] EMSA (2015) Methodology for visits to Member States, section 2.2. and 2.3.

Control system	Official documents
scientific purposes (DG ENV Dir. B).	
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Unit D4 Standard Operation Procedure, internal audit manual for all control activities ■ Mission checklist developed by the control team setting out the minimum tests/inquiries to be performed per audit area. The checklist is based on applicable legal requirements and risk assessment.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Methodology for visits to Member States – public document ■ Quality processes and procedures under a duly ISO certified QMS – internal use ■ Technical methodologies developed respectively for all Member State visit cycles and for STCW inspections of third countries. These include checklists based on the legal requirements of the different pieces of legislation – internal use
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	The internal procedures include audit checklists for the use of Commission auditors, which are communicated to Member States so that the national audit authorities can use them for their own audit work or as support to prepare their own checklists.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available.

2.3.7.3 Carrying out the controls

Workflow and working methods

Based on interviews with Commission services, it appears that the different control systems have relatively similar workflows, starting with an opening meeting, stating the objectives and scope of the control and reviewing the control programme, and ending with a closing meeting, presenting the preliminary findings of the control to the competent authorities. Common working methods include document review, visits of a sample of facilities, interviews with authority representatives and operators, physical observation of how control / monitoring is done.

Table 19: Working methods used during controls

	Opening meeting	Fieldwork	Assessment of findings	Closing meeting
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ With competent authorit(ies) and other national public authorities as relevant ■ Stating the objectives of the audit, the audit schedule and requesting information (further to that provided in response to the pre-audit questionnaire) required for the successful completion of the audit	■ Completion of the audit, which might typically include visits to the central competent authority, a number of regional and local authorities, laboratories and a number of accompanied site visits (e.g., to farms, processors, feed units, slaughterhouses and retailers)	■ List of findings under each of the specific areas within the scope of the audit. Findings should be based on competent authorities compliance (or not) with legal requirements in respect of the controls they perform on operators. The significance of the findings is expressed in a conclusion (e.g. on the effectiveness of the Member State's control system in the given subject area). Where conclusions are 'negative' recommendations are made to the competent authorities to address the issues and the	■ Presentation of findings to the competent authorities

	Opening meeting	Fieldwork	Assessment of findings	Closing meeting
			recommendations are based on specific legal requirements in the relevant EU legislation.	
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	As above.	As above.	As above – except that recommendations are not issued in fact-finding missions	As above.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No control yet carried out	No control yet carried out	No control yet carried out	No control yet carried out.
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Between Commission auditors and Member States' competent authorities ■ Explaining the audit objective, scope, and approach ■ Planning visits and meetings	■ Filling out the audit checklist ■ Most common methods to assess control systems / procedures include interviews, examination of documents, physical observation of controls / monitoring activities, sample testing	■ List of findings made through the fieldwork kept up-to date throughout the audit ■ Assessment of the significance of all compliance issues/system weaknesses identified ■ Identification of good practices	■ Presentation of preliminary findings to the competent authorities
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Between EMSA team and auditee entity ■ Explain the visit/inspection objective, scope, and approach and confirm pre-agreed programme	■ Document/evidence reviews, verification of facilities, staff interviews and examining files on a sampling basis and observation of operations as necessary. ■ Controls on board of ships to verify the effectiveness of the auditee's work as relevant ■ In the case of Member State visits or third country inspection, a 'Top-down' approach beginning with the central competent authority, and continuing with other authorities or other third party institutions concerned at national, regional and local levels.	■ List of findings per legal requirements controlled	■ Presentation of preliminary findings to the competent authorities
Established by Reg. 2021/1060 – Cohesion funds (DG	■ Between Commission auditors and MS competent authorities	Document review and interviews ■ In the framework of compliance audits, re-performance of audits	■ Identification of deficiencies in management and control systems in place as well as errors in expenditure	Presentation of preliminary findings to the competent authorities

	Opening meeting	Fieldwork	Assessment of findings	Closing meeting
REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ Explain the audit objective, scope, and approach	of operations done by national audit authorities by Commission auditors	declared to the Commission. Specific recommendations to Member States authorities drawn from the results of the audit.	
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable	Not applicable	Not applicable	Not applicable
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable	Not applicable	Not applicable	Not applicable

The pandemic had an important impact on the working methods of all control systems. Where possible, remote auditing methods have been applied, with online opening and closing meetings or other online working sessions, and electronic transmission of documentary evidence to the auditors. However, remote audits could not cover the entire scope otherwise covered by real world verification on the ground.

Investigation powers of controllers

Investigation powers of controllers, such as the power to access documents, request information, and carry out on-site inspections, are specified in most cases in the legislation or in a non-legal document, such as a methodology for carrying out controls, as shown in the table below.

Table 20: Provisions establishing investigation powers of controllers

Control system	Provisions
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ 'Member States shall give the necessary technical assistance and provide the available documentation, including the results of internal audits, upon justified request, and other technical support that Commission experts request to enable them to perform controls efficiently and effectively' (Article 119(b) of Regulation (EU) 2017/625). ■ 'Member States shall give the necessary assistance to ensure that the Commission experts have access to all premises or parts of premises, animals and goods, and to information, including computing systems, relevant for the execution of their duties (Article 119(c))'.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	■ Not applicable. Fact-finding missions are carried out in agreement with the competent authorities of the Member States.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	■ 'The Member State in the territory of which the control […] is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties' (Article 35(2) of Directive 2010//63)
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ 'Commission officials may carry out verifications and inspections on fishing vessels as well as on the premises of businesses and other bodies with activities relating to the common fisheries policy and shall have access to all information and documents needed to exercise their responsibilities, to the same extent and under the same conditions as officials of the Member State in which the verification and inspection take place'. (Article 97(1) of Regulation (EC) 1224/2009).

Control system	Provisions
	■ 'Commission officials shall be entitled to take copies of the relevant files and to take the necessary samples if they have reasonable grounds to believe that the rules of the common fisheries policy are not complied with. They may request the identification of any person found on the inspected premises'. (Article 97(2)). ■ 'Commission officials shall have no powers going beyond those of national inspectors and they shall have no police and enforcement powers' (Article 97(3).
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ 'The Member State shall timely provide EMSA with any amendments to the national legislation or organisation and with any other documents that might be relevant to help EMSA to prepare adequately the visit through desk analysis'. ■ 'Member States shall cooperate with EMSA during the preparatory, control and reporting phases of its visits'. (Methodology for visits to Member States, section 2.3)
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ 'For the purpose of their audits, Commission officials or their authorised representatives shall have access to all necessary records, documents and metadata, irrespective of the medium in which they are stored, relating to operations supported by the Funds or to management and control systems and shall receive copies in the specific format requested' (Article 70 of Regulation (EU) 2021/1060)
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	■ 'In carrying out the tasks assigned to it by this Regulation, the Commission may obtain all necessary information from the governments and competent authorities of the Member States and from undertakings' (Article 28(3) of Regulation (EC) 1005/2009)
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	■ 'The staff of the Commission that conduct an inspection shall be empowered to: (a) have access to any premises, land and means of transport of the person who arranges the shipment, the holder, the carrier, the consignee or the facility that receives the waste; (b) examine any relevant documents related to the subject-matter and purpose of the inspections, irrespective of the medium on which they are stored, and to take or obtain in any form copies of or extracts from such documents; (c) ask the notifier, the person who arranges the shipment, the holder, the carrier, the consignee or the facility that receives the waste for explanations on facts or documents relating to the subject-matter and purpose of the inspections and to record the answers; (d) take and record statements from the notifier, the person who arranges the shipment, the holder, the carrier, the consignee or the facility that receives the waste related to the subject-matter and purpose of the inspections; (e) physically check the waste and take samples of the waste for laboratory tests, where appropriate' (Article 65(4) of the Proposal for a Regulation on shipments of waste)

2.3.7.4 Reporting

Following the control, the team of auditors produces a report summarising the findings and conclusions of the control. In some control systems intermediate reporting steps exist. In DG MARE, immediately following the audit fieldwork in a Member State, a two-page 'Flash report' on preliminary results, conclusion and the reactions of Member states' authorities is issued to stakeholders within DG MARE. This report is not shared with the controlled Member State. Based on this flash report, a debriefing meeting with the Head of Unit of Unit D4 may be organised to determine whether enough evidence has been gathered or if supplementary controls are necessary[101].

Based on interviews with Commission services, reporting is usually done in two steps, a draft report and a final report, to leave the possibility for the Member State to comment on the conclusions and recommendations.

Table 21: Reporting process

Control system	Reporting process
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant	■ Draft audit report sent to Member State for comment (the draft report includes recommendations)

[101] Interview with DG MARE.

Control system	Reporting process
health and PPPs (DG SANTE Dir. F)	■ The audited Member State can provide comments on, and factual corrections to, the draft report (within time limit). The Member State may also elect to produce and action plan in response to the draft report, though they are only obliged to do present their plans upon receipt of the final translated report. ■ The Commission should take those comments into account when preparing the final audit report (Article 117(c) of Regulation (EU) 2017/625) ■ Member State comments published together with final report
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	■ Draft report from fact finding mission sent to the Member State, which can provide comments. ■ Member State comments are published together with final report.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	■ No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Draft audit report sent to Member State for comments ■ The audited Member State has one month to provide comments (Article 101(2) of Regulation (EC) 1224/2009). ■ The Member State's comments are analysed and where justified taken into account in the final text of the audit report. The Member State's comments are enclosed in the final audit report. ■ The final audit report is usually produced one month after reception of the Member States' comments (time limit not specified in the Regulation)
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ Draft visit report sent to Member States within 90 calendar days of the end of the visit ■ A follow-up video/tele-conference with the Member State for clarifications/ questions on the draft visit report may be organised by the Agency ■ The Member State has 30 calendar days to provide comments / factual corrections ■ Final version of the report is sent to the Commission and the Member State visited ■ On request by the Member State and if possible, EMSA produces, together with the draft report, an additional document with suggestions/recommendations for improvement, if possible, based on a SWOT analysis[102]. This document is of an advisory nature [103].
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ Auditors have three months to issue the draft audit report. ■ The report is then shared with the national authorities, who have one month to comment. ■ The final audit report is sent to the MS within three months of the receipt of a complete reply to the draft audit report from the national competent authority[104].
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	■ Not applicable[105].
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	■ According to the Commission proposal to revise the Waste Shipment Regulation, a report should be drafted following inspections (Article 64(6) of the Proposal for a Regulation on shipments of waste)

2.3.7.5 Follow-up actions

Outcome of controls and choice of follow-up actions

Controls lead to conclusions on the performance of Member States in the controlling operators' application of EU legislation and may uncover non-compliances or weaknesses in national control systems. Commission controls have a process in place to ensure that remedial actions are taken by

[102] A SWOT analysis is a tool to understand key internal and external factors - strengths, weaknesses, opportunities, and threats – involved in a process or in an organisation.
[103] EMSA (2015) Methodology for visits to Member States, section 2.6.
[104] Article 75 of Regulation (EU) 1303/2013 (programming period 2014-2020), Article 70 of Regulation (EU) 2021/1060 (programming period 2021-2027).
[105] Reporting is the responsibility of the Member State doing the investigation. In addition, Article 26(1)c of the Ozone Regulation establishes that Member State shall report to the Commission every year on cases of illegal trade, in particular those detected during the inspections carried out pursuant to Article 28.

the Member State, which include a range of actions, from monitoring of corrective actions and follow-up audit to infringement. Follow-up actions are generally progressive, and an infringement procedure will be started only if routine follow up has failed – if after several years, a follow-up audit shows that the Member State has still not taken appropriate remedial actions (DG SANTE). In the case of a very serious breach, the Commission may decide to directly launch EU-pilots or an infringement procedure.

In DG REGIO/EMPL, the Commission can impose immediate measures in the form of interruption of the payment deadline and suspension of payments, which are resumed only when remedial measures have been taken by the Member State.

The follow-up actions in the field of maritime safety are different from the other systems and also differ according to the type of control exercised. With regard to Member State visits, as the related EMSA reports are of an essentially fact-finding nature and contribute to an assessment that is ultimately conducted by the European Commission. Upon request by the Member State, EMSA may support in developing corrective action plans. However, it is the Commission that is solely responsible for deciding on the appropriate follow-up[106]. In the field of Recognised Organisation inspections, when a draft inspection report is submitted, the Organisation may provide additional information and clarification to the Agency – including corrective action – which may lead the Agency to close findings and not include them in the final report if these are adequately addressed. The final report will, together with other inspection reports, contribute to the two-yearly Commission assessment of the Organisation. In all cases, EMSA is also available to assist the Commission in any evaluation of post-assessment follow-up action by the auditee.

Concerning non-EU countries, the EU formal enforcement procedure is not applicable, but a progressive follow-up process is nonetheless started. When dialogue and routine follow-up with the country fail, or when the risk resulting from the non- compliance found for human, animal or plant health is high, the Commission may take measures like adopting trade restrictive decisions (such as additional checks at EU borders) or the removal of the country from the relevant list (thus market access to the EU is blocked for the commodity in question) or, in the case of seafaring States, withdrawal of seafarer certification recognition. The table below, based on interviews with Commission services, sums up the different follow-up measures available in each control system.

In cases where the controls target inspectors (i.e., investigations conducted by Member States upon the request of DG CLIMA and investigations carried out by OLAF), the Member State authorities concerned are responsible for follow-up actions and enforcement measures based on their national legislation.

Table 22: Follow-up process and different follow-up actions possible in the control systems

Control system	Follow-up options
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	For both Member States and non-EU countries, the auditee is invited to present an Action Plan. Member States: ■ First level: Recommendations issued in the audit report ■ Member States are required to take the necessary action on the basis of the audit report (Art. 101(3))+ assessment of action plan by DG SANTE ■ Routine follow-up mainly through General Follow-up Audits ■ Results of follow-up published in country profiles ■ Sectoral follow-up audits may be selected in some cases ■ Second level: if routine follow-up fails (or in rare cases if the situation uncovered by the audit is too serious to be dealt with through standard follow-up): Elevation for enforcement actions. Ultimately, infringement may need to be considered Third countries: ■ First level: Recommendations issued in the audit report + follow-up audits

[106] Interview with DG MOVE.

Control system	Follow-up options
	■ Second level: if dialogue and routine follow-up fails to solve an issue, follow-up by DG SANTE's unit working on bilateral international relations by means of formal letters, and meetings with the country's representatives ■ Third level: the Commission can adopt a formal Commission decision to impose trade-restrictive measures (increased checks at EU borders and, as a last resort, suspension of imports)[107]
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Not applicable – fact-finding missions do not lead to recommendations and follow-up actions.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	Results of the control are communicated to the Member State's competent authorities. The Member State must take measures to take account of the results of the control (Article 28 of Directive 2010/63). No information available on how the Commission will follow up on the measures taken by the Member States.
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Possible follow-up actions/enforcement instruments: ■ Administrative inquiry (Article 102(2) of Regulation (EC) 1224/2009): if irregularities in the implementation of the Common Fisheries Policy or if the control provisions and methods in the Member States are considered not effective. The Commission might participate in the inquiry. This is rarely used. ■ Action Plan (Article 102(4) of Regulation (EC) 1224/2009): If the audit identified shortcomings (system weaknesses and/or recurring compliance issues) in the national control system. The action plan sets out remedial measures and gives a deadline for their implementation. ■ EU Pilot: used as a first step to resolve problems before infringement proceedings ■ Infringement proceedings (Article 258-260 TFEU): considered in the case of serious breaches likely to significantly affect the achievement of Common Fisheries Policy objectives ■ Interruption or suspension of European Maritime, Fisheries and Aquaculture Fund (EMFAF) co-financing (Regulation (EU) 2015/852) in case of infringement proceedings: ■ Quota deduction (Article 105 of Regulation (EC) 1224/2009): if the audit has established that a Member State has exceeded its allocated quotas.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Member States EMSA: ■ Might provide recommendations to the Member State for improvement upon its request (purely advisory document, not a formal action plan) ■ Can support the Member State in developing the corrective action plan. Commission: ■ Upon receipt of the visit report (regardless of corrective action plan), will decide at measures to take, including starting an EU pilot or an infringement procedure Third countries: ■ Voluntarily corrective action plan, where the third country communicates to EMSA how they intend to solve the issues identified in the inspection ■ Following a technical opinion by EMSA on the corrective action plan proposed by the third country ■ The Commission issues an assessment for the third country, which is formally communicated though the External Action Service ■ If the assessment is not satisfactory, the Commission has the discretion to consider various options, including engaging with the third country in efforts to improve the performance as necessary. It may also opt to send a formal notice to the third county, warning about a possible removal of the recognition of the country's certificates of competency by EU Member States if no adequate corrective measures are taken (see section 2.3.3.2) ■ If not satisfactory, the Commission adopts an implementing decision removing the recognition of the country's certificates of competency by EU Member States. Recognised organisations: ■ Upon submission of draft report, the recognised organisation may send additional information to EMSA which, if satisfied that some issues were addressed, could close related findings in the final report to the Commission. ■ At least every two years, the Commission, based on final inspection reports submitted by EMSA, issues a periodic assessment for every recognised

[107] European Commission, DG Health and Food Safety (2020) Health and food audits and analysis programme 2021, p.6.

Control system	Follow-up options
	organisation, asking for explanations regarding pending findings. If, after an additional letter from the Commission, said explanations continue to be insufficient, the Commission adopts a Commission decision requesting the recognised organisation to take specific measures, with specific deadlines. If the deadlines are not met, the classification society may pay monetary penalties. ■ As a last resort, the Commission may remove the EU recognition of the classification society, and therefore its right to act on behalf of Member States to do statutory survey and certification work on ships (see section 2.3.3.2). ■ In all the above instances, EMSA will be available with its technical assistance to support the Commission in evaluating any explanations or follow-up measures that recognised organisation might offer at every step.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	When irregularities are identified the DGs prescribe remedial/corrective actions to improve the functions of the national Management and Control Systems and may interrupt payment deadlines and suspend payment. Payments are resumed after the audit evidence shows the systems were improved and/or appropriate financial corrections were applied. Close follow-up is ensured to check that the recommendations for remedial actions are implemented. Furthermore, both DGs provide targeted support to Managing Authorities and Audit Authorities to improve their administrative and technical capacity.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	The national authority that has carried out the control of the undertaking takes the relevant follow-up actions, based on national legislation.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	According to the Commission proposal to revise the Waste Shipment Regulation, the competent authorities of the Member States concerned by the inspection must ensure the take-back, recovery or disposal of the shipment and may apply penalties. The Commission may also recommend certain follow-up to the relevant authorities, and, where necessary inform the Union institutions, bodies, offices and agencies concerned (Article 64(6) of the Proposal for a Regulation on shipments of waste)

In EU control systems where recommendations and corrective actions are formally requested from Member States, Member States have a legal obligation to implement them, as shown in the table below.

Table 23: Provisions requiring Member States to take remedial actions

Control system	Provisions
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	'Member States shall take appropriate follow-up measures to remedy any specific or systemic shortcomings identified through the controls performed by the Commission experts' (Article 119(a) of Regulation (EU) 2017/625)
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Not applicable (fact-finding missions do not lead to recommendations).
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	'The competent authority of the Member State concerned shall take measures to take account of the results of the control' (Article 28(3) of Directive 2010/63)
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Administrative enquiry (Article 102(2) of Regulation (EC) 1224/2009) 'Member States shall inform the Commission of the results of the inquiry and forward a report to the Commission drawn up not more than three months after the Commission's request. ■ 'If the Commission identifies shortcomings in the control system of a Member State during the verifications or autonomous inspections or in the audit, the Commission shall establish an action plan with that Member State. The Member State shall take all necessary measures to implement that action plan.' (Article 102(4) of Regulation (EC) 1224/2009)
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	EMSA does not require remedial actions, although the findings presented in the report could be indicative of what remedial action might be needed. The prerogative to require remedial action lies with the Commission, which will address this in its assessment issued

Control system	Provisions
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Member States are required to ensure that their management and control systems for programmes (including to ensure the legality and regularity of expenditures) are set up and that they function effectively. If irregularities are detected, the Commission may require a Member State to take the actions necessary to ensure the effective functioning of their management and control systems or the correctness of expenditure in accordance with the Fund-specific rules, and to interrupt or suspend payments until remedial action is taken by the Member State[108].
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable[109].
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	Not applicable[110].

The following section details the process for following up on the uptake of Commission recommendations by Member States, briefly described in Table 22.

Systematic follow-up of remedial actions in DG SANTE

In DG SANTE, follow up on the implementation of remedial actions in the Member States is done centrally by one unit of the Directorate (Unit F7 Country knowledge and enforcement) over three-year cycles[111]. Member States are required to produce an action plan indicating what they have already done post-audit or what they intend to do to address the recommendations made in the report and, subsequently, implement those actions. Follow-up involves an initial assessment on paper of the likelihood of the proposed actions effectively addressing the recommendations made[112] followed by a General Follow-up Audit (GFA) which seeks documentary evidence that actions have been taken. The results of GFAs are then published in the country profiles, which are maintained for each Member State. Progress made in the implementation of the recommendations is monitored according to the following scale:

- "Action taken": Appropriate measures to address the recommendation have been implemented by the competent authority. The recommendation is therefore closed.
- "In progress": Appropriate measures to address the recommendation have been initiated by the competent authority but not all of the measures have been implemented. The recommendation therefore remains open.
- "Closed for other reasons": For administrative, technical or legal reasons, follow-up of the recommendation is no longer appropriate. The recommendation is therefore closed.
- "Action still required": Appropriate measures to address the recommendation have not been initiated by the competent authorities. The recommendation therefore remains open.

Every three years, a GFA is organised in the Member State to follow up on all the recommendations from all the audits carried out in the Member States in the past three years and open recommendations carried over from the previous GFA. DG SANTE seeks both documentary evidence such as training records for staff, revised/new staff instructions and field evidence that measures have been taken and

[108] Articles 74, 75, 83 and 142 of Regulation (EU) 1303/2013 (for programming period 2014-2020); Article 69(3) of Regulation (EU) 2021/1060 (for programming period 2021-2027).
[109] If non-compliances are found during the investigation, Member States will take action to bring them to an end and, if justified, impose sanctions. Pursuant to Article 29 of the Ozone Regulation, Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented.
[110] If non-compliances are found during the investigation, Member States must take action to bring them to an end and, if justified, impose sanctions.
[111] Section based on interview with DG SANTE.
[112] European Commission, DG Health and Food Safety (2020) Overview report - Official controls on feed additives, their ingredients and traceability, p.11.

have been effective in addressing the shortcomings in practice[113]. After the GFA, most recommendations should be closed and only a small number kept open. If some recommendations are still marked as 'action still required' after a second GFA, there is ground for escalation to infringement.

In case there is a disagreement with a Member States on the legal interpretation of a requirement or on a technical issue, the Directorate will generally seek advice in house and if needed from other Commission bodies, in particular the legal service, or an Agency (EFSA's opinion has been requested on technical issues). The meeting closing the GFA allows the discussion of potential disagreements.

2.3.7.6 Timing and resources

The length of a Commission control can vary greatly depending on the type and scope of control. The time of the preparation phase will vary depending on the policy area and legal requirements controlled (if requirements are very prescriptive, there might be a lot of documents to review before the fieldwork), on the familiarity of the auditor with the country, national control system or auditee controlled, and the date of the previous controls (if recent, it is likely that not much will have changed). In DG SANTE, there is also usually a longer desk-based preparation for fact finding missions than for audits as there is no specific legal basis providing for Commission controls[114]. The length of the fieldwork might vary depending on the legal requirements controlled or the complexity of the national control system. It might also vary depending on the types of controls performed; in DG MARE, 'verifications' and 'autonomous inspections' are shorter than audits[115]. Because of these variations, it has proved difficult to collect precise information on the time of each phase of the control. The table below summarises information collected through interviews with Commission services.

Table 24: Time spent by control team in each phase of the control

Control systems	Planning	Fieldwork	Reporting	Follow-up
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	No information available	Between 3 days for border control posts to 2 weeks for audits in non-EU countries. Audits in Member States vary between 1 and 2 weeks (depending on the size of the Member State and the complexity of the control system being audited). A typical input would be 15 days FTEs for 2 auditors and 1 national expert.	Draft report 20 days Comments from auditee 25 days Production of Final report 16 days	Auditees include a timeline for completion of corrective actions in their Action Plans. These are taken into account in assessing the Action Plan. Verification of implementation of corrective actions through GFAs over a three-year cycle
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	As above	As above	As above	Not applicable. No follow-up of fact-finding missions is done
Established by Directive 2010/63 – Protection of animals used for scientific purposes	No control yet carried out	No control yet carried out	No control yet carried out	No control yet carried out

[113] European Commission, DG Health and Food Safety (2020) Overview report - Official controls on feed additives, their ingredients and traceability, p.11.
[114] Interview with DG SANTE.
[115] Interview with DG MARE.

Control systems	Planning	Fieldwork	Reporting	Follow-up
(DG ENV Dir. B).				
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	Typically, around 8-10 weeks from first planning meeting to end of planning phase (analysis of audit questionnaire, data analysis) FTEs: Audit team leader: 5- 15 days; Team members: up to 5 days, supervision by Head of unit: 1 day	Usually, 1 week from opening meeting to closing meeting FTEs: Audit team leader: 5 days; Team members: 5 days	12-16 weeks from closing meeting to final audit report FTEs: Audit team leader: 5- 10 days; Team members: up to 3 days; HoU supervision: 1 day	1-4 weeks for dialogues with Member States on follow up action +formal adoption of action plan, infringements, etc. FTEs: Substantial investment of resources on follow-up, but not quantifiable on average as it depends on follow-up actions triggered (Action Plans, Administrative Inquiry, EU pilot, Infringement)
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Typically around: 4 months from first informal contact with Member State 6 months from notification of STCW inspection 2 months (for recognised organisation inspections; but this may vary significantly) until end of planning phase	3 to 5 days[116] (for inspection of classification societies, around 4 days per office inspected)[117]	Extensive reporting and consolidation phase after each visit or inspection[118] Draft reports are issued within 90 calendar days from Member State visits and 105 days from Recognised Organisation inspections.	Timeline for assistance in evaluating follow-up/corrective measures related to seafarer training or recognised organisations are agreed with the Commission and determined ad hoc according to the development of each follow-up process and the needs of the Commission in this regard.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	Simple cases around 5 days. More complex cases around 20 days.	Simple cases around 10 days (two-person teams). More complex cases around 20 days (two two-person teams).	Regulatory deadline of 3 months to send a draft audit report to the Member State and a final audit report within 3 months of the receipt of a complete Member State reply.	In case a follow-up procedure is needed following submission of the final report, the number of follow-up days depends on the character of the contested issues and whether a financial correction procedure is triggered.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable.	Not applicable.	Not applicable.	Not applicable.
Foreseen in Proposal for Waste Shipment	No information available	No information available	No information available	No information available

[116] Ramboll (2017) Evaluation on the implementation of the Regulation (EC) No 1406/2002 establishing EMSA. Final Report for the European Maritime Safety Agency, p.74.
[117] EMSA, Full list of EMSA visits & inspections.
[118] Ramboll (2017) Evaluation on the implementation of the Regulation (EC) No 1406/2002 establishing EMSA. Final Report for the European Maritime Safety Agency, p.74.

Control systems	Planning	Fieldwork	Reporting	Follow-up
Regulation (OLAF Dir.B).				

2.3.8 Relation with controlled Member State

As indicated in section 2.3.3, national competent authorities are always informed in advance of the schedule and scope of the Commission controls[119]. Based on interviews with Commission services, the ways in which Commission controls are organised share many similarities (opening and closing meetings, representation of competent authorities throughout the control, opportunity to comment on the results of the control etc.)

Table 25: Involvement of controlled national authorities in the control process

Control system	Procedures involving national authorities
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ National authorities are aware in advance of when they are going to be audited and on which topic (the annual control programme and each update of it are communicated to Member States and made publicly available) ■ National authorities audited are involved in the audit process through opening and closing meeting and the pre-audit questionnaire and are represented throughout the audit ■ National authorities have the opportunity to comment on the draft audit report (Article 117(b) of Regulation (EU) 2017/625) and the Commission should take those comments into account when preparing the final audit report (Article 117(c)) ■ There is an ex-post feedback system for auditees in the form of a feedback questionnaire
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	■ As above – the process is similar for fact-finding missions.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	■ No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ National authorities are notified (if possible at least two months in advance) that they are going to be controlled. ■ National authorities controlled are involved in the control process through opening and closing meeting and through the audit questionnaire ■ National authorities should be informed of the preliminary findings of verifications and of autonomous inspections within one day of them having taken place ■ National authorities have the opportunities to comment on the draft audit / inspection report (Art 101(2) of Regulation (EC) 1224/2009) and those comments should be taken into account when drafting the final audit report. A copy of the Member State's comments must be enclosed in the final audit report.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ National authorities are notified three months in advance that they are going to be controlled ■ National authorities controlled are involved in the control process through the opening, mid-cycle (if necessary) and closing workshops organised by EMSA in the course of a visit cycle ■ National authorities have the opportunity to provide factual corrections to draft visit reports before these are finalised and sent to the Commission. ■ Member States can interact directly with the Commission once the assessments related to the EMSA visits are issued.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ For on-the-spot audits, national authorities are notified 12 or 15 working days in advance, with a possibility to shorten the period in urgent cases. ■ Member State authorities can be asked to provide clarifications to the assurance packages submitted or the documentation collected through the audits and fact-finding missions. ■ National authorities are sent the audit reports and they have one month to comment.

[119] The only exception is the 'verifications' as per Article 98 of Regulation (EC) 1224/2009 which may, if considered necessary, be carried out without prior notice; audits are however always announced.

Control system	Procedures involving national authorities
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	■ Exchange of information relevant to national investigations and cooperation between DG CLIMA and Member States' authorities on a daily basis
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	■ Competent authorities are informed of the opening of investigations and involved in inspections carried out by OLAF.

2.3.9 Publication of information / transparency

As shown in the table below, DG SANTE publishes documents resulting from the audits and fact-finding missions[120] and the horizontal analyses of series of audits and fact-finding missions, while other controls systems in DG MARE, REGIO/EMPL and EMSA keep documents only accessible to interested parties, the Commission and the Member States, unless they need to accommodate requests in terms of Regulation (EC) No 1049/2001 regarding public access to documents.

Table 26: Documents made publicly available

Control system	Documents made publicly available (Yes/no)				
	Report on controls/ conclusions and recommendations	Member state comments on report / conclusions from controls	Assessment of follow up actions taken by Member States	Results from follow-up actions / monitoring	Horizontal / overview reports on control activities
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	Yes[121]	Yes	Yes	Yes	Yes
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	Yes[122]	Yes	Not applicable [123]	Not applicable	Yes
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	No control yet carried out	No control yet carried out	No control yet carried out	No control yet carried out	No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	No. (report addressed to the Member State)	No	No	No	No (internal documents) But overall report in implementation of Regulation (EC) 1224/2009 is published[124]

[120] All individual reports from audits are published. Regarding fact finding missions, it may be decided not to publish individual country reports, as was done for the Overview report on preparedness in Member States to respond to African swine fever in wild boars DG(SANTE) 2019-6836. In addition, for fact-finding missions, there is no systematic follow-up of the implementation of recommendations as there is for audits. Therefore, follow-up status of fact-finding missions are not included in country profiles.

[121] For Member States, audit reports are systematically published, for third countries, there are sometimes bilateral agreements stipulating that the permission of the country is necessary for publication.

[122] Fact-finding missions do not lead to recommendations.

[123] For fact-finding mission, there is no systematic follow-up as there is for audits, therefore, follow-up status of fact-finding missions are not included in country profiles.

[124] Report from the European Commission and the Council on the application of Council Regulation (EC) No 1224/2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy as required under Article 118 for the period 2015-2019, 22.06.2021, COM(2021)316 final.

Control system	Documents made publicly available (Yes/no)				
	Report on controls/ conclusions and recommendations	Member state comments on report / conclusions from controls	Assessment of follow up actions taken by Member States	Results from follow-up actions / monitoring	Horizontal / overview reports on control activities
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	No (shared with Commission and Member States)	No	No	No	No (restricted to Commission and Member States)
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	No	No	No	No	Yes, as part of the Annual Activity Report of each DG
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available	No information available	No information available	No information available	No information available

2.3.10 Internal or external evaluation of the control system

Among the control systems, only DG SANTE clearly reported having a feedback mechanism for controlled Member States, which takes the form of a feedback questionnaire to be completed after each audit. Given the very low response rate, the Directorate is however considering switching to an annual feedback questionnaire, where a Member State could comment on all audits performed during a year, still with the possibility of contacting the Directorate if there is a need to discuss a specific audit[125].

In terms of evaluating the procedures and management of the control systems, DG SANTE reported having internal indicators to assess performance internally. This is otherwise ensured by internal audits by the Commission Internal Audit Service (for all Commission departments and executive agencies) and the Court of Auditors, and/or external evaluations by independent contractors (e.g. EMSA, DG CLIMA).

Table 27: Internal or external evaluation and feedback systems in place

Control system	Procedures in place
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ The Directorate has a range of indicators used to assess performance against the plans and the various criteria set out in the internal operating procedures. ■ The Directorate is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors. ■ There is a feedback system for auditees.
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	■ Same as above.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	■ The Directorate is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors.
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ The Unit is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors. ■ There is no formal feedback system for audited Member States.

[125] Interview with DG SANTE.

Control system	Procedures in place
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	■ EMSA is subject to an external evaluation every five years (last one carried out in 2017) and audits by the Court of Auditors. ■ DG MOVE is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors. ■ The EMSA visits and inspections activity is ISO certified and thus subject to annual audits by external contractors. ■ The feedback from visited Member States is reflected in the discussions on and approval of the Agency's Annual report by the Administrative Board which is made up of all Member States and the Commission.
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	■ In line with Article 128 of Regulation (EC) 1303/2006 and Article 77 of Regulation (EU) 2021/1060 the Commission and the audit authorities meet on a regular basis and, unless otherwise agreed, at least once a year to examine the audit strategy, the annual control report and the audit opinion, to coordinate their audit plans and methods, and to exchange views on issues relating to the improvement of management and control systems. ■ Regular peer reviews of Annual Activity Reports (AAR) of DG REGIO and EMPL, presenting the residual total error rate in Cohesion expenditures, by Secretariat General and DG Budget[126] ■ The Directorate is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	■ The Regulation was evaluated by independent contractors in 2018. ■ The Unit is subject to audits by the Internal Audit Service of the Commission and by the Court of Auditors. No other internal procedures in place.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	■ No information available.

2.3.11 Horizontal analysis of controls

All control systems have tools to monitor the results of audits horizontally, with a view to drawing general conclusions, identifying common good practices and common challenges in relation to a specific area/legislation. Those tools are described in the table below, based on information provided through interviews with Commission services.

Table 28: Tools to monitor and disseminate overall results of audits

Control system	Tools
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs (DG SANTE Dir. F).	■ Overview reports provide an overview of a series of audits in different countries on the same topic of national controls (Article 113 of Regulation (EU) 2017/625). ■ Annual reports provide an overview of the overall outcome of national control activities (based on national reports submitted by Member States) and Commission control activities (Article 114 of Regulation (EU) 2017/625).
Reg. 528/2012 – Biocides (DG SANTE Dir. F).	■ Same as above.
Established by Directive 2010/63 – Protection of animals used for scientific purposes (DG ENV Dir. B).	■ No control yet carried out
Established by Reg (EC) 1224/2009 – Common Fisheries Policy (DG MARE Dir. D).	■ Information on the implementation of the annual control program is included in the Annual Activity Reports of the DG. ■ As provided by Article 118 of Regulation (EC) 1224/2009, the Commission shall draw up a report every five years on the implementation of the Regulation to be submitted to the European Parliament and the Council. The report is based on information and data provided by the Member States and the Commission's own observations (notably observations made in audits and inspections). ■ Overall results summarised in internal notes to support decision-making on follow-up actions by the Commission.

[126] European Court of Auditors (2021) Special Report 26/2021: Regularity of spending in EU Cohesion policy: Commission discloses annually a minimum estimated level of error that is not final, doi:10.2865/496206.

Control system	Tools
	■ Information sessions are organised for audited MS for certain audit cycles.
Established by Reg 1406/2002 – Maritime safety (DG MOVE Dir D /EMSA).	Horizontal analyses: reports on cycles of visits linked to a specific EU legislation (mid-term report if considered necessary and report at the end of the cycle) focusing on: ■ the effectiveness of the implementation measures in place, ■ identification and analysis of areas of common concern, ■ best practices identified and lessons learnt, ■ feedback for the evaluation of the legislation and its further development, and ■ the overall cost-effectiveness of the measures in place.[127]
Established by Reg. 2021/1060 – Cohesion funds (DG REGIO / DG EMPL Joint Audit Directorate for Cohesion).	The results of the controls are published as part of the Annual Activity Reports of the DGs, together with estimates of the share the cost of the controls represents compared to the Cohesion Policy funding managed by the respective DG.
Established by Reg. 1005/2009 – Ozone depleting substances (DG CLIMA Dir C).	No information available.
Foreseen in Proposal for Waste Shipment Regulation (OLAF Dir.B).	No information available.

As mentioned in section 2.3.7.1, the tools described above are used for the planning of controls. They are also used as a basis for discussing common issues and disseminating good practices. The publication of these reports is often complemented with workshops gathering Member States competent authorities. EMSA organises closing workshops in visit cycles to discuss the results from end-of-cycle horizontal analyses[128]. DG SANTE often organises two-day workshops following the publication of overview reports, to discuss points that are relevant to all Member States. As not all Member States can be audited on each topic every time, these workshops are a way to draw all Member States' attention to common issues and encourage the improvement of the whole system[129]. Similarly, DG REGIO organises capacity-building events and joint workshops with managing or audit authorities as preventive and corrective actions. DG REGIO is also working closely with all audit authorities throughout the year to address the issues raised in EU audits (bilateral meetings with national audit authorities and meetings with representatives from all audit authorities)[130].

Results from horizontal analysis reports can also feed into guidance or training programmes for Member States. In DG SANTE, the fact-finding missions, which are carried out, mainly, in areas where there is not yet an EU legal basis providing for Commission audits, or where new requirements have been introduced very recently are often taken as a basis for guidance or training. The Better Training for Safer Food (BTSF) programme is often used for dissemination of information / training linked to the fact-finding missions.

Results from controls can also feed into the evidence base of the legislative process of a new piece of legislation or in the evaluation of the performance of a piece of legislation and the design of possible legislative options to revise it.

2.4 ASSESSMENT OF EU CONTROL SYSTEMS

2.4.1 Good practices leading to effective control systems

2.4.1.1 Good practices

According to DG SANTE, the transparency of the control system (e.g., the publication of all audit

[127] EMSA, Horizontal analysis.
[128] EMSA (2015) Methodology for visits to Member States, section 2.7.
[129] Interview with DG SANTE.
[130] European Commission, DG REGIO (2020) 2019 Annual Activity Report.

reports, responses of Member States, monitoring of recommendations) supports its effectiveness. The publication of the audit reports is an incentive for authorities to fully cooperate (for instance if they do not provide certain information or documents, this will appear in the report) and to improve their own system, as issues found in the audit are visible to trade partners. It is then in the interest of national authorities to demonstrate to their trade partners that they have addressed the recommendations rapidly (which is visible in the country profile). According to DG SANTE, the publication of reports has not been a controversial issue with the Member States, given that confidential data is not included in the reports. In other systems however, the protection of professional and commercial data has been pointed out as the main reason put forward for not providing public access to audit reports and could be an obstacle to implementing it[131].

Another good practice mentioned by DG SANTE is the dissemination of the results of the audits to Member States through networks of authorities, overview reports, and workshops. As the Directorate cannot generally audit all Member States in most audit series, the dissemination of the results allows all Member States that have not been audited to take lessons learnt from the audit series. There are two networks of national authorities, meeting between two and four times a year. The first one gathers competent authorities responsible for the multi-annual national control plans and annual reports, and the second gathers national audit systems experts. Both are relevant fora for discussing good practices and common challenges[132].

2.4.1.2 Efficiency gains

The COVID-19 pandemic had a strong impact on the execution of audits and visits in 2020 and 2021, requiring shifting to essentially desk-based controls of documentation sent by authorities, complemented by online interviews and meetings with competent authorities and stakeholders in the Member States. According to interviewed officials in DG SANTE, DG MOVE and DG MARE, there have been some positive outcomes and efficiency gains due to those changes. Both DGs mentioned that they realised part of the work could be done efficiently remotely or online, in particular in the preparatory phase (opening meeting, requests for clarifications, data analysis) and the final phase (closing meeting, request for missing data, etc.). According to interviewees in DG SANTE, opening meetings done by videoconference result into more focused discussions than meetings in the Member States, as less people participate, and discussions online require more prior preparation and exchange of documents. On-site visits must be maintained to gather evidence, but they can be made more efficient if they have been prepared by an online meeting and could then potentially require a smaller team and be shorter. According to DG SANTE, some of these elements might be introduced permanently in the normal operating procedures of the Directorate for Health and Food Audits and Analysis. DG MARE also mentioned during the interview that it could be a good way to conduct more efficient audits in the future. Finally, in EMSA, any verification work that during the pandemic was carried out using remote auditing techniques with equally effective results is increasingly being conducted remotely to minimise the scope of the remaining on-site fieldwork.

The control system of Cohesion Policy relies a lot on the national authorities, for instance compliance audits are carried out only when there are doubts about the reliability of the work of the programme Audit Authorities. Therefore, when the work of the national authorities is good and complete, there is less need for audits or fact-finding missions. However, the capacities of the relevant Audit Authorities for Cohesion Policy funding programmes in the Member States have been developed through the years and strengthened thanks to the experience of past audits.

2.4.2 Weaknesses of existing control systems

Lack of resources and not being able to focus full-time on the audit during the entire audit process

[131] Interview with DG SANTE.
[132] Interview with DG SANTE.

was pointed out as a possible concern in DG MARE. Also, easier access to fisheries data would improve the audit planning in DG MARE. Other Commission services mentioned low or decreasing resources without specifying that it was an issue. [133].

A possible area of improvement mentioned by DG SANTE is the use of results of audits and fact-finding missions in policy making. Fact finding missions can provide valuable evidence for the drafting of new legal requirements or new legislation and audits can provide evidence for revising existing legislation. However, these activities are mostly considered by policy makers as purely control activities and not as an input to policymaking[134].

2.4.3 Benefits / added value of EU control systems

During interviews, Commission control systems generally considered as benefits of the EU control systems the improvements over time in the performance of individual Member States' control systems. Those benefits are observed through the monitoring of the uptake of recommendations and follow-up audits. No other indicators or benefits measurements were mentioned during interviews. Such benefits were reported by interviewees for all control systems.

[133] Interview with DG MARE.
[134] Interview with DG SANTE.

3. DEVELOPMENT OF OPTIONS FOR THE ESTABLISHMENT OF A EUROPEAN AUDIT CAPACITY

There are two distinct sub-tasks under Task 2 on the development of different options for the establishment of an EAC:

- Task 2.1 includes an assessment of the different possibilities/options for all the main aspects/features of a potential EAC leading to the development of three proposed options to be validated by the Commission.
- Task 2.2 entails a detailed assessment of the feasibility of these three selected options linked to their application in the context of the REACH Regulation but also CLP, PIC and POPs Regulations.

3.1 ASSESSMENT OF ASPECTS RELEVANT FOR A EUROPEAN AUDIT CAPACITY

The assessment under this task aims to identify the advantages and disadvantages of each alternative regarding its contribution to ensuring compliance and effectiveness of chemical legislation, improving the effectiveness of Member State (MS) control systems throughout the EU and feasibility to apply it in a EAC. The main aspects of a EAC as listed in the Terms of Reference and complemented through desk research and analysis of the other EU control systems under Task 1 are:

- Basis for triggering the control activity and frequency;
- Scope of audits;
- Working methods used;
- Additional activities;
- Follow-up actions;
- Transparency;
- Actors to be involved (institution in charge of EAC and auditors);
- Internal or external evaluation of the control system.
- Cooperation with other actors and Member States.

Some of the aspects above concern mutually exclusive alternatives, while others concern different options that can be combined.

3.1.1 Methodological approach

For each of the aspects for which different options can be identified, an assessment matrix was developed listing:

- The different options
- Potential advantages and disadvantages proposed by the contractor

It contained additional columns to be filled where experts consulted had to mention:

- Whether they agree with the advantages proposed by the contractor
- Whether they agree with the disadvantages proposed by the contractor
- How and to what extent the options contribute to increasing effectiveness of official control systems throughout the EU and ensuring compliance
- How and to what extent does the options impact on the feasibility of a EAC
- Which option the consulted experts consider the most favourable for each aspect
- Other comments (e.g., complementarity between options, costs, relative importance of certain advantages/ disadvantages over others)

This assessment matrix was developed in Excel which also included guidelines explaining how it had to be filled.

As soon as the matrix was validated by DG ENV, it was sent to the relevant experts consulted with an explanation of how to fill it. The following experts were selected and contacted considering their experience with REACH, CLP, POPs and PIC Regulations and their experience with EU control systems:

- Experts having experience with enforcement of REACH, CLP, POPs, and PIC Regulations from
  - ECHA
  - DG ENV and DG GROW, with experience in REACH or enforcement of legislation.
  - Member States participating in the Enforcement FORUM – as many as possible based on their interest and willingness to provide feedback.
- Experts having experience in implementing EU control systems in Member States:
  - DG SANTE in relation to controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
  - DG MARE in relation to control activities referred to in Title X of Regulation (EC) No 1224/2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy.
  - EMSA in relation to visits to Member States and inspections.
  - DG EMPL/ DG REGIO (DAC) in relation to audit and control systems in relation to Cohesion Policy.
  - DG CLIMA working on ozone depleting substances control system.

Table 29: Overview of consultations on EAC aspects

EU level	Member State level
Four matrices received: ■ DG ENV ■ DG GROW ■ DG MARE ■ ECHA	Matrices received from experts from 17 countries
Participants at the EU-level focus group: ■ DG ENV ■ DG GROW ■ DG EMPL/REGIO DAC ■ DG MOVE ■ DG SANTE ■ ECHA	Participants from 8 MSs

The result of the feedback received on the different options for each aspect was presented at two focus groups held in January 2022 respectively targeting:

- Experts from other EU control systems, ECHA, DG ENV and DG GROW with experience in REACH, and
- Experts from Member States authorities involved in REACH and the majority of whom participate in the FORUM[135].

It is worth noting that some experts from Member States both in the matrices to be filled and during the focus group expressed some concern and even some strong disagreements concerning the set-up

[135] Forum for Exchange of Information on Enforcement established under the REACH Regulation.

of the EAC:

- Some stressed that they should have been first consulted on the need to have such auditing system at all and not only on the potential options of the different aspects.
- Some feared that it would create overlaps with the peer-review mechanism under the Market Surveillance Regulation (MSR) leading to unnecessary administrative burden.
- Some stressed that there are already mechanisms in place to ensure compliance and effective national control and enforcement of the REACH Regulation through the FORUM and Article 117 reporting and are therefore not sure about the added value of the EAC.

Others supported the EAC initiative but stressed that they would need to know more about the overall design of the EAC in the future before providing their opinion on these specific aspects.

Based on the feedback received, but also the result of Task 1, an assessment of the different options for each of the EAC aspects was carried out and is presented in the next section.

3.1.2 Analysis of potential options for main EAC aspects

3.1.2.1 Basis for triggering the audit

This aspect refers to how and under which conditions the control activity/audit is triggered. The following options were proposed:

- Triggered based on specific concern (e.g., alert, whistle-blower, non-compliance in certain REACH obligation) / Ad hoc/ reactive approach.
- Triggered based on general concern (e.g., known aspect with low compliance in the EU or in certain MSs, known aspect with difficulties for enforcement, information on high presence of some dangerous substances in certain MSs or in the EU / reactive approach).
- Triggered based on an audit programme/ plan covering all aspects of the legislation (e.g., based on risk criteria, priorities, representative selection of MSs)/ Regular/ Proactive approach.

Audit triggered based on specific concern

The main advantage of this option is that it focuses mainly on the national enforcement of specific cases of non-compliance allowing limited human and financial resources to be mobilised only where such concerns are identified. However, such trigger mechanism may create an unequal playing field for Member States where some Member States may be more audited than others. Furthermore 'structural' problems of national control systems would be less likely to be detected. Such approach may also limit the development of auditors' expertise and experience as they may intervene less frequently than in more systematic audit systems. It also requires defining criteria to interpret what a specific concern means.

The control system under *Directive 2010/63/EC on the protection of animals used for scientific purposes* has a rather similar trigger mechanism. Controls are triggered only when there is a concern. Such concern is not defined in the Directive and therefore could apply to both general and specific concerns.

Such trigger mechanism is considered to have a rather low contribution to the improvement of effectiveness of official national control systems throughout the EU since it may create disparities between Member States, some potentially being more audited than others. The need to identify a 'specific concern' as a condition to trigger the audit may also significantly limit the number of audits to be carried out and therefore impair the effectiveness of the EAC.

On the feasibility of such trigger, no (e.g., financial, legal, technical) constraints were identified.

Audit triggered based on general concerns

The main advantage of this option is that it can focus on concerns that are common to several Member State control systems, including structural ones (e.g., identified through Article 117 questionnaires, fact finding missions, FORUM discussions, peer-reviews) allowing to target resources where support and changes are really needed

The control system under *Directive 2010/63/EC on the protection of animals used for scientific purposes* has a rather similar trigger mechanism. Under this Directive, controls covering the infrastructure and operation of national inspections in Member States are triggered when there is due reason for concern which can be both specific or general.

Such trigger mechanism is considered to have a rather low contribution to the improvement of effectiveness of official national control systems throughout the EU since the need to define and identify a 'general concern' may also limit the number and frequency of audits to be carried out and therefore impair the effectiveness of the EAC.

On the feasibility of such trigger, no major (e.g., financial, legal, technical) constraints were identified.

Triggered based on an audit programme/ plan covering all aspects of the legislation

Under such trigger mechanism audits are performed on a regular basis allowing regular checks of the Member State control systems. Therefore, weaknesses of Member State control systems and their causes can be identified before alerts or concerns occur. Furthermore, in such trigger mechanism resources can be planned and allocated in advance. However, such trigger mechanism can be resource-intensive[136] and put higher burden on Member State Competent Authorities compared to the two options above in particular for Member States with a federal enforcement structure due to a high number of authorities involved. Such trigger mechanism is considered to have a rather high contribution to the improvement of effectiveness of official national control systems throughout the EU since it will apply to all Member States on a regular basis. Such high contribution may be impaired if audits become a formality due to their regular occurrence.

No EU control system has only this trigger mechanism. Instead, the majority of EU control systems have audit programmes but can also trigger audits on an ad hoc basis based on concern (Regulation (EU) 2017/625, Regulation (EC) 1224/2009 – Common Fisheries Policy –, Regulation (EC) 1406/2002 – Maritime safety –, Regulation (EU). 2021/1060 – Cohesion funds).

Hybrid - regular audits based on programme together with ad hoc audits based on concern

Several consultees proposed a hybrid trigger mechanism, where, by default audits would be based on an audit programme/plan but could also be triggered based on general/specific concerns. This would include all the advantages of the three options and therefore have a high contribution to improve effectiveness of official national control systems throughout the EU and ensure compliance but may end-up being the most resource intensive option both for auditors and audited Member States impacting its feasibility. As mentioned above most EU control systems identified under this report have adopted this combined approach.

Note that consultees did not express strong disagreements on the different options mentioned above.

[136] Although this depends on frequency and duration of audits.

3.1.2.2 Scope of audits

This aspect refers to the scope of the audits, the two main alternatives are:

- General audits on the entire national control system of REACH Regulation.
- Targeted or specific audits (e.g., audits on specific aspects of the implementation of national control of REACH Regulation).

A combination of audits with general and specific scope is also possible.

This aspect has strong links with the aspect on trigger as for example general audits on the entire national control system are unlikely to be triggered based on concern but rather through systematic audit programmes.

General audits assessing the overall functioning of national control systems

Such wide-scope audits could cover multiple issues/ aspects of the control system and provide better understanding of the entire system to properly identify potential issues and develop sound recommendations. However, this would require quite some time, resources, and data collection since it is an audit of an entire enforcement system. Such audits are considered to have a rather high contribution to the improvement of effectiveness of official national control systems throughout the EU since it will provide a thorough analysis of the overall functioning of national control systems, but its feasibility was questioned by some experts from Member States authorities that consider that it would put too much burden on enforcement authorities.

Targeted audits focusing on certain aspects (e.g., important, or recurring problems with the application or enforcement of the rules)

Targeted audits would focus on specific issues of concern and thus be more efficient in addressing pressing concerns in Member State enforcement systems. It would require less time and financial resources from auditors and audited Member States. It would however not allow having a detailed comparative overview and understanding of the whole enforcement systems across Member States like a general audit would. Therefore, such targeted audits may have fewer impacts on the contribution to the improvement of effectiveness of official national control systems throughout the EU compared to more general audits. On the feasibility of this option, no major obstacles were identified. On the contrary several experts from Member States authorities consider that this is the most feasible one as it would be the least resource intensive and the simplest to implement.

Combination of general audits and targeted audits

The combination of general and targeted audits was perceived by some experts from Member States authorities and EU experts as the most effective option to improve official national control systems throughout the EU and ensure compliance, since it will allow assessing entire Member States enforcement systems but also to respond to specific concerns through targeted audits. However, on the feasibility aspects of such option it was stressed that it would require the most financial and human resources. Most EU control systems identified under this report[137] have this hybrid audit system where general audits covering a wide array of aspects are carried out according to an audit plan and can be complemented by targeted audits where for example there is, an urgent issue[138], a complaint by a third party[139] or a specific concern[140].

[137] The EU control system established by *Directive 2010/63 – Protection of animals used for scientific purposes* is a bit different as the Directive provides for controls of the infrastructure and operation of national inspections in Member States triggered when there is due reason for concern.
[138] EU control system established by Regulation (EC) 1224/2009 – Common Fisheries Policy.
[139] EU control system established by Regulation 1406/2002 – Maritime safety – DG MOVE.
[140] EU control system established by Regulation 2021/1060 – Cohesion funds.

Note that there were strong conflicting views among consultees on this aspect, with some advocating for a combination of general and targeted audits whereas others supporting targeted audits as they feared that general audits would be too resource intensive in particular for audited Member States.

3.1.2.3 Working methods used

This aspect refers to the working methods and activities that would be part of the audit (e.g., document/database verification, on the spot/remote verifications). The main alternatives concern whether the verifications take place on the spot or remotely but in practice, different methods can be combined and used to complement each other (this is the case in other EU control systems identified in Task 1).

On-the-spot verification (including both, visits to Competent Authorities and accompanying authorities during site visits)

On-the -spot verifications allow face-to-face communications with the audited entity which can help clarify questions more quickly and identify additional issues to be audited or checked through additional activities. They allow verifying or confirming whether controls are implemented as foreseen or prescribed in the relevant national documentation and national control procedures. They may lead to a more comprehensive verification of the effectiveness of national control systems in practice and guarantee a more effective audit with better communication with the enforcement personnel. Such controls would therefore provide a high contribution to improving effectiveness of official national control systems throughout the EU and ensuring compliance.

This could however be quite costly and difficult to organise for both auditors and audited Member States, in particular in the case of the REACH Regulation where several Member State administrative and inspection authorities are involved, and thus most likely to be less frequent than remote verifications. In some of the existing EU control systems, on-the-spot checks are performed only occasionally. Such cost and organisation issues may limit the feasibility of this option.

Remote verification

Remote verifications are easy to organise, less costly and can be more frequent. They could cover the different national authorities, through videoconference interviews, requests for documentary evidence or data. This working method also covers desk verification of documents and databases. As detailed in Section 2 on EU control systems, there have been some positive outcomes and efficiency gains linked to the shift from on-spot checks to remote verifications during the COVID crisis as in particular for the preparatory phase (opening meeting, requests for clarifications, data analysis), and the final phase (closing meeting, request for missing data)[141]. However, clarifications/communication can require more time and may entail missing relevant practical evidence on Member States control systems problems in detecting non-compliance issues impacting the effectiveness of such audits. It also requires setting beforehand a secured system to exchange confidential data/files. This is the most feasible option but the contribution to improving effectiveness of official national control systems is assessed as medium since it allows higher frequency and practicality of remote checks (e.g., remote verifications could continue even during the lockdowns and limitations caused by the COVID-19 pandemic) throughout the EU but may lead to less detailed/in-depth audits compared to on-the-spot verification

Combination of remote and on-the-spot verification

This option was the most preferred option for experts from several Member States and EU control systems. They stressed that certain parts of an audit can be performed remotely, but that it was also

[141] According to interviewed officials in DG SANTE, DG MOVE and DG MARE

essential to meet face-to-face with the auditees and perform detailed on-the-spot verifications and investigations. They suggested that on-the-spot verification due to their cost and time and human resources needed should be an exception and not be carried out systematically to ensure an adequate balance between the two approaches. All EU control systems identified under this report have in place such combined approach[142]. Such an option would provide a high contribution to improving effectiveness of official national control systems throughout the EU and ensuring compliance. However, the feasibility aspects of on-the-spot verifications should be considered taking into account their frequency and duration and the cost they would entail

3.1.2.4 Additional activities

This aspect refers to the possibility of carrying out other control related activities in combination with or in addition to audits on national official control systems (e.g., through fact finding missions, evaluation questionnaires, documentary evaluation, targeted studies, inspections on targeted operators, peer reviews by other Member States etc.). These activities are not mutually exclusive and can complement each other, while also complementing the main audit activities.

Evaluation questionnaires (MS to answer how they enforce REACH in practice more generally and regularly)

The added value of such questionnaires to improve effectiveness of official national control systems throughout the EU and ensuring compliance was questioned by consultees if audits are carried out. Such questionnaires could however be useful as preparatory information to identify priorities/areas of concern for future audits and can be used as a complement in areas not covered by audits. Furthermore, administrative burden on Member State authorities and on the EAC due to potential overlaps with the reporting obligation based on Article 117 and 127 of REACH is limited since such reporting must only be carried out every five years and questionnaires do not need necessarily to require the same information unless it needs to be updated. No issues of feasibility were identified since such questionnaires are already being implemented with a template and methodology in place and their result can therefore easily be used without additional cost as preparatory information for the audits.

Fact finding missions (e.g., gathering and reviewing specific information and data)

The added value of such missions to improve effectiveness of official national control systems throughout the EU and ensuring compliance was questioned by consultees if audits are carried out. Fact finding missions can however allow focusing on specific issues/ risks. They can be useful to identify priorities/areas of concern for the audits and, to verify how a specific area of the legislation and its enforcement is working in practice and/or whether potential issues need to be addressed by legislation[143]. Note that in the context of Regulation (EU) No 528/2012 on biocidal products fact-finding missions were carried out to monitor and assess its implementation and enforcement.

Inspections of targeted operators

Inspections of targeted operators can be focused on specific issues/ risks and can have direct effects to ensure compliance with REACH by specific operators. However, several drawbacks were identified in particular that it would create a risk of overlaps with MS control activities and double work with potential impacts on national inspection plannings. Some legal feasibility issues were

[142]This is uncertain for the EU control system established by *Directive 2010/63 – Protection of animals used for scientific purposes* since no audits have been carried out so far.

[143] According to an interview with DG SANTE official, fact-finding missions can provide valuable evidence for the drafting of new legal requirements or new legislation and audits can provide evidence for revising existing legislation. However, these activities are mostly considered by policy makers as purely control activities and not as an input to policymaking

raised as enforcement should be ensured mainly by Member States. Such inspections would enhance compliance with REACH regulation but would have limited contribution for the improvement of the effectiveness of official national control systems throughout the EU.

Only the EU control system established by *Regulation (EC) 1224/2009 – Common Fisheries Policy* sets the possibility for 'autonomous' inspections of operators by the Commission. These inspections are relatively rare according to DG MARE[144]. Under the *Proposal for Waste Shipment Regulation*, OLAF is entitled to carry out on-site control in case of suspicion of illegal shipment.

Note that this option was rejected by some Member State experts. This rejection was further reiterated at the Member State focus group where some participants stressed that such option was not within the competence of the Commission.

Peer reviews by Member States

A peer review mechanism between Member State enforcement authorities could be a complementary activity to the EAC. In such peer review mechanism, Member State experts from enforcement authorities could assess certain aspects of the enforcement system of another Member State. It would allow sharing experiences and lessons learned and identifying solutions to similar enforcement issues and challenges across Member States. Peer reviews could result in recommendations to improve enforcement systems and facilitate mutual learning and exchange of good practices. This would lead to improve effectiveness of official national control systems throughout the EU and to ensure compliance. However, such peer review mechanism would need to be designed in such a way to co-exist with the EAC without overlaps of competences (e.g., focus on certain aspects not planned to be covered by EAC in audit programs or not covered in ad hoc controls) and with peer reviews carried out under the Market Surveillance Regulation framework. Such potential overlap could limit their added value and therefore the contribution of the peer review to improve effectiveness of official national control systems throughout the EU and to ensure compliance. The peer review could potentially be coordinated by the Commission or ECHA (e.g., within Forum) and would entail additional resources mainly from Member States that will have to provide reviewers and cover travel expenses in peer-reviewed Member States. Such additional resources and cost may impair the feasibility of this mechanism. However, there may be some possible synergies with the peer review mechanism under the Market Surveillance Regulation where the same Member State enforcement authorities may be involved (e.g., streamlined peer-reviews covering enforcement aspects under REACH not already covered by the Market Surveillance Regulation and those covered by the Market Surveillance Regulation) limiting their cost. At the time of writing the Market Surveillance Regulation's peer review mechanism is still being designed. It is based on voluntary participation of market surveillance authorities and aims to strengthen the consistency of market surveillance activities in relation to the application of the Regulation and in accordance with Article 12 of this Regulation. It covers best practices developed by some market surveillance authorities which may be of benefit for other market surveillance authorities and other relevant aspects related to the effectiveness of market surveillance activities.

3.1.2.5 Follow-up actions

This aspect refers to the follow-up of the audits and relevant procedures. Options differ mainly on whether or not Member States are required to take measures to address weaknesses/shortcomings and recommendations set in the audit reports without prejudice to the obligation of Member States to comply with the legislation and related provisions on enforcement in any case.

Shortcomings and weaknesses identified under the audit report and no Member State obligation to address them without prejudice to the obligation of Member States to comply with the legislation and related provisions on enforcement

[144] See footnote 49.

Based on trust and a cooperative approach such an option would put less burden on Member State authorities that will have more leeway and flexibility to address shortcomings and weaknesses. There is however the risk that such shortcomings and weaknesses will not be properly addressed due to the lack of clear request to do so and subsequent targeted follow up by the Commission. Such risks may therefore lead to a limited contribution on the improvement of effectiveness of official national control systems throughout the EU and ensuring compliance. No concerns on the feasibility of this option were identified, since it does not require additional resources for Member States to take actions or for the monitoring of Member States measures to address audit reports conclusions.

Shortcoming and weaknesses identified under the audit reports and Member State obligations to address them

Such an option would enhance that systematic action is taken by Member States to address the shortcomings and weaknesses identified and will also ensure that a follow up system by the Commission is set out to verify whether they are satisfactorily addressed. This is not considered as an additional cost for Member States since Member States must anyway maintain a system of official controls and other activities as appropriate to the circumstances according to 125 of REACH. On the other hand, this would require additional monitoring and related procedures to be set-up by auditors/the Commission to ensure that these shortcomings/weaknesses and recommendations are addressed and could thus be quite resource intensive. For example, as described in the section on the overview of EU control systems, DG SANTE has set-up one specific unit to follow up on the implementation of remedial actions in the Member States requiring, inter alia, an initial assessment of the likelihood of the proposed actions effectively addressing the recommendations made, a general follow-up audit which seeks documentary evidence that actions have been taken and potential infringement procedures if some recommendations are still not addressed.

This option should provide a high contribution on the improvement of effectiveness of official national control systems throughout the EU and ensuring compliance. Some Member State experts strongly disagree on the option to require Member State to address audit reports' weaknesses/shortcomings and recommendations. This disagreement was further reaffirmed at the Member State focus group. On the contrary, at the EU level focus group most of the participants agreed that to have an effective audit capacity system, there should be such indication on the obligation of the Member States as a conclusion to the audit conducted. Such disagreement may have an impact on the feasibility of this option.

Most EU control systems identified under this report require Member States to take necessary actions to address recommendations set in audit reports (e.g., EU control systems established by Regulation (EU) 2017/625, by Directive 2010/63 – Protection of animals used for scientific purposes, by Regulation (EC) 1224/2009 – Common Fisheries Policy, by Regulation 2021/1060 – Cohesion funds).

3.1.2.6 Transparency

This aspect refers to how transparency is assured through planning of the audits, reporting and publication of the reports (including of the audit plans/programmes if relevant). Three alternative levels of transparency were proposed:

- No publication – the audit reports are not made publicly available and are shared only with the audited entities.
- Sharing results with the FORUM – the audit reports are not made publicly available but are shared and discussed within the FORUM.
- Open publication – the audit reports are made publicly available.

No publication

The non-publication of reports would allow the preparation of less formal audit reports. However, this would impede:

- the scrutiny by independent experts or civil society,
- knowledge exchange/ learning from peers,
- public pressure to improve compliance and implement follow-up measures.

It may also decrease public confidence in enforcement systems and Commission actions.

Based on the above, this option should provide a limited contribution on the improvement of effectiveness of official national control systems throughout the EU and ensuring compliance. Such 'no publication' option will however not impede potential access to document requests that need to be assessed under the ATD Regulation[145] (See Article 4(2) on exceptions to the obligation to disclose documents[146]).
Note that several EU control systems do not publish audit reports (i.e., EU control systems established by Regulation (EC) 1224/2009 – Common Fisheries Policy, Regulation 2021/1060 – Cohesion funds[147], Regulation 1406/2002 – Maritime safety).

Discussion at the FORUM but not available to the public (with removal of any confidential data if necessary)

This option would allow knowledge exchange/ learning from peers[148]. FORUM scrutiny would be an incentive for Member States to implement follow-up measures from audit reports. Such an option would however still impede public scrutiny and decrease public confidence in enforcement systems and Commission actions. As mentioned above the non-publication of the audit reports to the public at large does not prevent potential request for access to documents that need to be assessed under the ATD Regulation.

Publication of all reports (with removal of any confidential data if necessary)

This option will allow better scrutiny by independent experts and civil society and enhance public pressure on Member States to improve compliance and implement follow-up measures.[149] This should have a positive contribution to the improvement of effectiveness of official national control systems throughout the EU and ensuring compliance. However, some consultees stressed that publicly available reports could result in watered done audit reports and may facilitate companies in their decisions to locate to a Member States considered to have weaker enforcement regimes. No feasibility issues were identified under this option.

Note that only the EU control system established by Regulation (EU) 2017/625 implements this 'complete publication' option[150].

There are some conflicting views from consultees on transparency. EU experts were rather in favor of the publication of all the audit reports and Member State experts were rather in favor of the non-publication of audit reports that would remain available only to auditors and audited Member States

[145] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.
[146] The institutions shall refuse access to a document where disclosure would undermine the protection of […] the purpose of inspections, investigations, and audits, unless there is an overriding public interest in disclosure.
[147] Note that an overall implementation report is published.
[148] According to interview with DG SANTE official, the dissemination of the results of the audits to Member States through networks of authorities, overview reports, and workshops was considered as a good practice allowing all Member States that have not been audited to take lessons learnt from the audit series.
[149] This was confirmed in interview with DG SANTE official that considered that the publication of the audit reports is an incentive for authorities to fully cooperate and to improve their own system.
[150] For Member States, audit reports are systematically published, for audited third countries, there are sometimes bilateral agreements stipulating that the permission of the country is necessary for publication.

or available only to FORUM members to be discussed where needed during FORUM meetings. Some experts from Member States and EU control systems considered an alternative option which was the publication of a summary report available for all audited Member States, and a more detailed, Member State -specific version of the audit report sent to Member States only.

3.1.2.7 Actors to be involved

This aspect refers to the main actors to be considered to carry out the audits. It concerns:

- **Entity in charge of the audit** – the EU institution and/or agency that will oversee the EAC (e.g., start and steer the process, approve the final report and follow-up activities etc.), regardless of whether the audits are carried in-house or not, and whether some responsibilities are shared between an EU institution and an agency.
- **Auditors** – the experts that will be carrying out the audits, they can be in-house staff of the entity overseeing EAC, independent experts, external consultants or Member State experts from enforcement authorities. Combinations of those alternatives can be possible in practice.

The main question is linked to the legal limitations in the powers of the actor as regards the full extent of the activities to be performed (legal feasibility). Practical feasibility and potential to improve the effectiveness of MS control systems throughout the EU and compliance can be linked to expertise and/or experience. Considerations related to human and financial resources needed to oversee the EAC are assumed to be similar across alternatives as the EAC would require some investment in terms of human resource and financial costs in any case, even if those are re-directed from existing services. This is valid even if the EAC is established under an existing service and audit experts or other resources from similar services are 're-directed' to the EAC (i.e., this will create a need to fill resource in another area meaning that financial and human resources are required nonetheless as a consequence of the establishment of EAC).

Entities in charge of the audit

- ***The European Commission***

Under this option there would be no need to create *a sui generis* body. The Commission has also proven experience in overseeing and carrying out audits in other policy areas and would be the relevant institution to carry out follow-up actions through mechanisms that require close cooperation with Member States. It can also start infringement proceedings. Furthermore, audits often require interpretation questions on legislation that could be dealt with by the Commission legal services. On the legal feasibility aspects, it is unlikely to entail major legal implications since the Commission is the guardian of the treaties and in charge of the application of EU legal texts. Such a role would however require mobilizing time and resources to develop additional expertise on auditing enforcement of chemicals legislation.

- ***ECHA***

Under this option there would be no need to create a sui generis body. Furthermore, ECHA has experience on enforcement matters since it is the host of the FORUM (which e.g., develops pilot projects on non-compliance issues, is involved in the development of the paper on strategies and minimum criteria for enforcement of Chemical Regulations) and is, through its role at the FORUM, in close contact with Member State competent authorities. However, unlike the Commission, ECHA is not the guardian of the Treaties, and its role cannot thus interfere with the one of the Commission in ensuring the application of EU law. This would limit for instance, its role in follow-up actions that may result from the findings of the audits and thus impact the feasibility of this option.

- ***Another body not part of the Commission or ECHA***

Few advantages were identified for this option (e.g., more impartiality and independence as no link

with Member States and not influenced by political context) whereas several major disadvantages appear to significantly impact the feasibility of this option:

- Creating a new body can have major political, legal and budgetary implications.
- Most likely to take a lot of time to be set-up and start the auditing.
- Lack of previous close contact with Member State competent authorities would decrease the effectiveness of audits.

Based on the feedback received from consultees there seem to be a convergence of views from Member State's and EU's experts that the European Commission (i.e., necessary legal powers, audit experience, REACH expertise, in charge of follow up via infringement procedures, where appropriate) with possible shared responsibilities with ECHA (i.e., REACH expertise, host of the FORUM) should be the institution in charge of the EAC. It is to be noted that a shared responsibility is also an approach used under the EU control system established by Regulation (EC) 1406/2002 – Maritime safety where EMSA is in charge of ad hoc visits to Member States or inspections of relevant third countries.

No Member State or EU experts selected the creation of another body, not part of the Commission or ECHA, as a preferred option. Note that none of the EU control systems have set up another body not part of the Commission or an EU agency.

Auditors

- ***Auditors from the Commission***

Auditors from the Commission would have expertise on REACH but also on CLP, POPs, PIC from the policy side, on enforcement systems through Article 117 reporting under REACH and knowledge on auditing, due to their experience in auditing in other areas of EU legislation. However, they would need to develop additional specialised expertise in auditing within the context of those pieces of legislation (e.g., through training, new human resources etc.). No major feasibility issues were identified apart that the Commission has limited recruitment flexibility.

- ***ECHA officials***

ECHA officials would have expertise on REACH and enforcement through ECHA's involvement in the FORUM with good knowledge of Member State controls and enforcement criteria developed by the Forum[151]. They know Member State enforcement authorities with whom they have strong relationships, and which should increase the acceptability of the audit results by Member States. They could also easily be involved in auditing control systems for other chemicals legislations under ECHA remit such as CLP, POPS, PIC. However, this would mean that ECHA would need to develop auditing expertise and hire additional resources. No major feasibility issues were identified. It was mentioned in the consultation that this option would be feasible if the division of responsibilities is clarified between the Commission and ECHA as well as independence is ensured from other ECHA activities.

- ***Independent experts/ external consultants via public tenders***

Such experts would have the advantage to have specialised expertise (tailored to the audit at hand) and independent views compared to the Commission or ECHA. However, public tender procedures can be long and delay the start of audits. Furthermore, external experts would have limited

[151] The Forum has developed a paper on *Strategies and minimum criteria for enforcement of Chemical Regulations*[151], most recently revised in 2017, which provides principles and guidance to develop a national enforcement strategy and establishes minimum criteria for chemical inspections.

knowledge/experience with EU procedures. Furthermore, Member State authorities may be reluctant to provide access to internal processes and sensitive data to such 'non-official' experts. Such drawbacks would limit the feasibility of this option. No EU control systems identified under this report have systematically implemented this option[152].

On the type of auditors, there was no strong disagreement on the three options proposed. In fact, it was suggested that a mix of auditors from the Commission, ECHA and external experts, where needed, could be an option. At the Member State focus group, it was suggested that national experts from other Member States enforcement authorities could also be involved in the audit based on their strong expertise and experience of control systems.

3.1.2.8 Internal or external evaluation of the European Audit Capacity control system

This aspect refers to the evaluation of the control system itself implemented by the EAC. This could be performed internally or externally and could be a regular process that assesses the effectiveness and efficiency of the control system, identifying areas for improvement. The main alternatives concern whether an evaluation is carried out or not and less whether this process is internal or external (for instance, both types of evaluations can be combined - more frequent internal evaluations can be complemented by occasional external evaluations).

The main questions are linked to the potential of some form of regular evaluation to improve the system's functioning and thus compliance with chemicals legislation in the EU.

No evaluation
This would require no additional resources but may compromise integrity, objectivity, and independence of the EAC and would impede the possibility to take stock of good practices and weaknesses of the system. No feasibility issues were identified but such an approach would potentially limit trust from Member State authorities audited and therefore limit the EAC's contribution to improve official national control systems throughout the EU and ensure compliance.

Note that at the EU focus group it was mentioned that since there is the evaluation of the legislation and the EAC would be within the scope of the internal audit service in the Commission, it is not clear why there should be a separate evaluation scheme for the EAC. It was also pointed out that since there is already an obligation to report on the experience acquired with the operation of REACH[153] every five years, the EAC will most likely be part of this evaluation as well.

Internal evaluation by the body responsible for the audits

This would allow the identification of good practices and weaknesses of the system and could be integrated in the working methods/ practices of the institution. Furthermore, recommendations and lessons learnt could be applied nearly immediately. With such an evaluation, internal assessors may build and retain knowledge of EAC criteria and processes over time to improve next quality assurance audits. It could however create conflicts of interest and challenges to ensure the independence of internal assessors. On the feasibility aspects such internal audit should not be difficult to organise as it is common practice within the Commission. Such evaluations would ensure an improvement of the EAC over time and would thus create a knock-on effect to improve official national control systems throughout the EU and ensure compliance

External evaluation by independent assessors
This would allow the identification of good practices and weaknesses of the system, and this would

[152] Under the control system set up by Regulation 2021/1060 – Cohesion funds – DG REGIO / DG EMPL Commission auditors are sometimes supported by external auditors when their workload is too high. However, this is occasional.
[153] Article 117(4) REACH

safeguard the independence and impartiality of the assessors. However, the procedure to select assessors may be long and would require additional resources (e.g., tendering and contract management). Furthermore, expertise may not always be available outside the EU institutions. Such evaluations would ensure an improvement of the EAC over time and could a knock-on effect to improve official national control systems throughout the EU and ensure compliance. However, on the feasibility aspects external evaluations may be more challenging to put in place than internal ones and would entail additional resources and administrative burden.

3.1.2.9 Possible ways of cooperation with other bodies and Member States

This aspect refers to possible ways of cooperation between the EAC and other bodies such as the FORUM, European Union Product Compliance Network and administrative cooperation groups (ADCOs), OLAF, European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL), European Court of Auditors, but also audited Member States. Cooperation can be sought with any combination of these bodies as well as other relevant bodies. The possible ways of cooperation can be based on meetings, establishment of joint task forces or steering groups, establishment of data repositories or other activities that can be integrated in the working practices of the relevant bodies. All these options are of equal importance to facilitate cooperation and would thus be beneficial for the adequate functioning of the EAC. The table below shows examples of cooperation with other EU bodies. This is very preliminary since such cooperation would depend on how the EAC would look like when in operation.

Table 30: Possible cooperation with other EU bodies and audited MS

Relevant EU body/audited Member States	Potential cooperation with EAC
ECHA	▪ ECHA could provide expertise support and be involved in audits as further described above (i.e., Commission lead of EAC with shared responsibilities with ECHA)
FORUM	▪ Discussion of result of audits with FORUM member ▪ Support to development of audit programs ▪ Consultation of FORUM members before carrying out audits based on concerns in Member States. ▪ Forum members as contact points for the EAC during audits ▪ Discussion of horizontal report on audits carried out during audit program period
The EU Product Compliance Network	▪ Presentation results of audits to the EU Product Compliance Network (e.g., areas for improvements/good practices to be shared) ▪ Result of audits could feed-into the evaluation of national market surveillance strategies to be carried out by the EU Product Compliance Network ▪ Work of the EU Product Compliance Network could feed into audits of EAC
IMPEL	▪ Training for EAC auditors on enforcement of environmental law topics
Audited Member States	▪ Possibility for audited Member States to comment on draft audit reports that must be addressed by auditors

Based on all these aspects as well as the problems observed with REACH's implementation several options for the design of a EAC are defined and analysed in section 3.2.

3.2 ASSESSMENT OF OPTIONS FOR EUROPEAN AUDIT CAPACITY

This section provides an assessment of the options for designing a EAC. It should be emphasised that this assessment be considered within the broader policy context of a revision of the REACH Regulation. Based on available information, the following sections offer an assessment and comparison of the options for designing a EAC.

3.2.1 Context and options

3.2.1.1 Context, problem definition and need for action

The 2019 European Green Deal[154] defines an ambitious goal of zero pollution and a toxic-free environment. The Chemicals Strategy for Sustainability[155] outlines more practical actions for achieving this including improving enforcement of chemicals legislation and adopting a zero-tolerance approach to non-compliance. As one of the cornerstones of EU chemicals legislation, the REACH Regulation is critical in meeting these ambitious goals. The latest evaluation[156] of REACH concluded that the Regulation is effective overall and has contributed to achieving the desired objectives. However, there are areas for improving its implementation, especially with relation to increasing compliance and improving enforcement: '*Member States should ensure a more effective and harmonised enforcement of REACH*'[157]. Various other studies and data point to a need to increase compliance and to strengthen enforcement and ensure its effectiveness and consistency across the EU.

For instance, the Chemicals Strategy for Sustainability notes that the objective of ensuring that '*all chemicals, materials and products produced in the EU or placed on the European market fully comply with EU information, safety and environmental requirements*' has yet to be achieved[158]. This is evidenced by alerts related to non-compliant products in Safety Gate and the non-compliance rates detected by Member States' enforcement activities. Almost 30% of the alerts in Safety Gate on dangerous products on the market involve risks linked to chemicals. General compliance rates reported by Member States have tended to decrease in previous years. Data from the five-year Member States' reporting indicate that REACH compliance between 2007 and 2019 ranged between 76% and 87%[159], with a tendency to slowly decrease in the period 2015-2019 compared to the previous reporting period[160].

Areas with lower levels of compliance include imports of products, registration, and supply chain obligations. Almost 90% of products concerned by Safety Gate alerts relating to chemicals risks come from outside the EU[161]. Data reported by Member States also show that the level of compliance in imported goods has decreased over the years (in the period 2007-2019), bottoming out at 71% in 2018[162]. Among other areas checked by Member States, supply chain obligations are where highest rates of non-compliance are reported by Member States' authorities (they are also the most frequently checked REACH requirement)[163]. Results of the Forum's[164] coordinated enforcement projects in the period 2010-2014 showed that a relatively high level of non-compliance could be found regarding registration obligations and Safety Data Sheets[165]. This was a finding also in more recent studies of the classification of mixtures. The results of this project also point at different interpretations among Member States of requirements in the legislation as a challenge for the harmonisation of

[154] European Green Deal - COM(2019) 640 final.
[155] Chemicals Strategy for Sustainability - COM(2020) 667 final.
[156] Commission General Report on the operation of REACH and review of certain elements, Conclusions and Actions - COM(2018) 116 final and SWD(2018) 58 final, Part 1/7.
[157] COM(2018) 116 final, p. 4.
[158] Chemicals Strategy for Sustainability, p. 17.
[159] Median compliance rates across EU Member States; range between lowest median compliance rate in 2018 and highest median compliance rate in 2007.
[160] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (2021) REACH and CLP enforcement. EU level enforcement indicators. Publications Office, https://data.europa.eu/doi/10.2873/478225, indicator EU1 p. 14.
[161] Chemicals Strategy for Sustainability, p. 17.
[162] REACH and CLP enforcement, EU level enforcement indicators, indicator EU3, p. 16.
[163] Member States Reports on the operation of REACH (Article 117), 2015 and 2020.
[164] Forum for Exchange of Information on Enforcement established under the REACH Regulation.
[165] SWD(2018) 58 final. Part 1/7, p.61.

enforcement[166]. Regarding registration obligations, the level of compliance established by ECHA[167] ranges between 60 % and 70 % over the period 2007-2019[168]. A recent study on the level of enforcement for items sold online found that 78% of the items checked for REACH restrictions did not comply and 5% did not comply with the obligations for providing Safety Data Sheets[169].

Based on these considerations, the Chemicals Strategy for Sustainability highlights the need to increase both enforcement of REACH and market surveillance. The Strategy also emphasises significant differences between Member States depending on available resources for enforcement and various policies and strategies, which may lead to varying effectiveness of enforcement across Member States. Therefore, this leads to a non-level playing field for operators and a sub-optimal level of protection of human health and the environment in all Member States. Varying levels of commitment, time allocated and resources have also been observed in Forum activities, leading ECHA to recommend that national enforcement would benefit from increased resourcing[170].

In this context, the Inception Impact Assessment (IIA)[171] for the REACH revision defines the main objectives as ensuring that the provisions reflect the ambitions for health and environmental protection and support the functioning of the internal market. In line with the actions outlined in the Chemicals Strategy for Sustainability, particularly to '*propose to entrust the Commission with the duty to carry out audits in Member States, where relevant, to ensure compliance and enforcement of chemicals legislation, in particular REACH, and use infringement procedures as necessary*'[172] and the commitment to make a '*proposal to amend REACH to introduce a European Audit Capacity*'[173], one of the options considered in the revision is the introduction of a EAC . The EAC would aim to contribute to increasing and ensuring compliance and effective national enforcement across the EU by auditing Member States' official control systems and their operation against common standard criteria, identifying possible weaknesses and their causes and recommending Member States (MSs) to address them, which would reduce risks for health and the environment from chemicals across the EU.

3.2.1.2 Options

Building upon the different tasks in this study, three options for the design of a EAC have been developed and are summarised in the following table (for full details see Annex 1). While the assessment is performed for the options as outlined below, different elements from the separate options may be combined.

Table 31: Overview of options

Option	Short description/ Main aspects
Option 1: A comprehensive audit capacity system	A combination of: ■ Regular programmed audits of *general* nature, i.e., covering all aspects of enforcement and of REACH legislation, and covering all MSs, (e.g. each MS is audited every five years). ■ Programmed audits of *specific* nature, i.e. covering certain aspects of enforcement

[166] ECHA (2019) Forum REF-6 PROJECT REPORT Classification and labelling of mixtures.
[167] Data relate to two combined aspects of compliance: 1) compliance of registration dossiers (CCh) and dossier evaluation cases (DEV); 2) registration dossiers' compliance with some information requirements (substance identity, SME status, hazardous information).
[168] REACH and CLP enforcement, EU level enforcement indicators, indicator EU4, p. 17.
[169] ECHA (2021) Forum REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online.
[170] ECHA (2021) Report on the Operation of REACH and CLP 2021.
[171] Ref. Ares(2021)2962933 - 04/05/2021, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en
[172] Chemicals Strategy for Sustainability, p. 18.
[173] Chemicals Strategy for Sustainability, Annex, pp.4-5.

Option	Short description/ Main aspects
	and of the REACH legislation, including recurring problems, and a representative number of MS, as relevant (e.g. each MS is audited every five years although not all MS are necessarily audited on the same topic). ■ *Ad hoc* targeted controls based on specific concern(s) can be triggered e.g., by alert, whistle-blower, important or recurring problems with the application or enforcement of the rules. ■ Potential *additional activities such as fact-finding missions* may also be carried out. Audits are based on a combination of remote and on-the-spot verification. Auditors come from the Commission and where appropriate, ECHA, national experts from Member States' enforcement authorities other than the audited Member State or external experts via public procurement tenders. Detailed conclusions and actions for follow-up are provided to the MS identifying the weaknesses to be addressed as regards general and specific aspects of the control system or its implementation. All reports are published (without any sensitive data as necessary). MSs are required to take measures to address the shortcomings identified in the audit report. Follow-up mechanism to check action taken by MSs is set up. Audit criteria are laid down in legislation.
Option 2: An audit capacity system	A combination of: ■ Programmed audits of *specific* nature, i.e. covering certain aspects of enforcement and of the REACH legislation, including recurring problems, and a representative number of MS, as relevant (e.g. each MS is audited every five years although not all MS are necessarily audited on the same topic). ■ *Ad hoc* targeted controls based on specific concern can be triggered e.g., by alert, whistle-blower, important or recurring problems with the application or enforcement of the rules. Audits are based on a combination of remote and on-the-spot verification (with priority given to remote verification to the extent possible), without additional activities. Auditors come from the Commission and where appropriate, ECHA. Detailed conclusions and actions for follow-up are provided to the MS identifying the weaknesses to be addressed as regards specific aspects of the control system or its implementation. A summary report is made public. MSs are required to take measures to address the shortcomings identified in the audit report. Follow-up mechanism to check action taken by MSs is set up. Audit criteria are laid down in legislation.
Option 3: A minimal control capacity system	A combination of: ■ *Ad hoc* targeted controls based on specific concern can be triggered e.g., by alert, whistle-blower, important or recurring problems with the application or enforcement of the rules. Occasional frequency for controls. Controls based only on a combination of remote and on the spot verification (assumption that such controls would also include those triggered in cases of serious concern that would require an on-the-spot check), without additional activities.

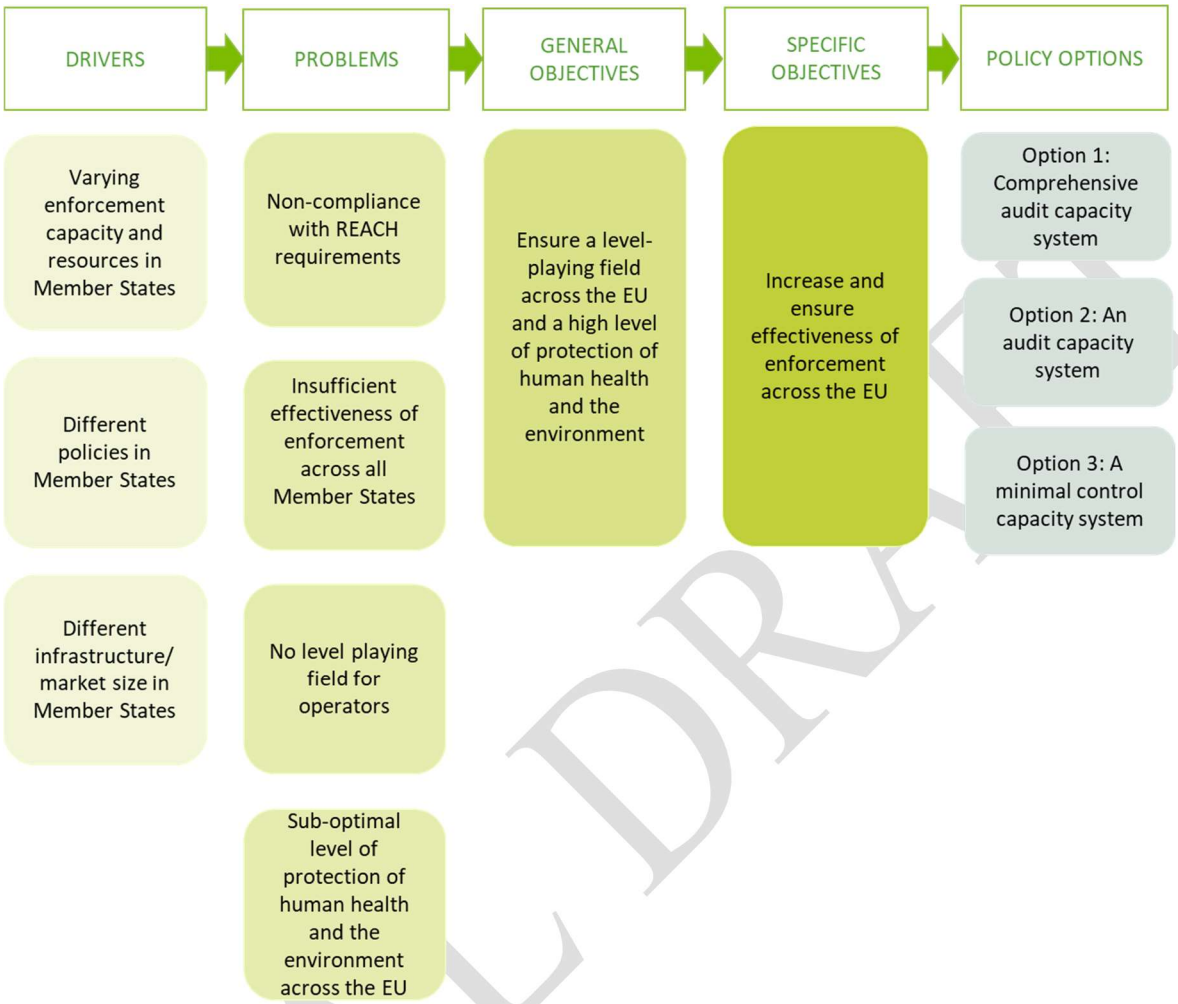
Option	Short description/ Main aspects
	Controllers come from the Commission. Control reports do not specify actions for follow-up, but only identify specific shortcomings to be addressed by the MS. Lack of specific recommendations/ instructions is without prejudice to the obligation of MSs to take action to ensure compliance with legislation. A summary report is made public. Follow-up mechanism to check action taken by MSs is set up. Audit criteria laid down in a guidance. ■ Complementary voluntary action: *Peer review* system (beyond Market Surveillance Regulation, covering all aspects of REACH, arranged voluntarily between MS). Peer reviewers are MS representatives. Control reports are drafted and discussed amongst MSs, ECHA and the Commission (e.g. in FORUM).

Usually, policy options are compared to a baseline option of not changing the current situation or continuing 'business as usual'. In this case that would be not having a EAC and continuing existing practices such as Art. 117 reporting under REACH and the work of the Forum. It should be noted that the baseline also includes the peer review system under the Market Surveillance Regulation. For the sake of comparison, it is assumed that under the baseline scenario similar trends of compliance and non-compliance (i.e., similar level of effectiveness) as observed during the period 2007-2019 would occur.

3.2.1.1 Intervention logic

The underlying drivers, problems, and options for designing a EAC represented visually by the intervention logic in the next figure.

Figure 1: Intervention logic for the EAC options



3.2.2 Identification of impacts and Assessment of the options

As presented in the previous section, there are three options under consideration to address the identified problems with enforcement of REACH requirements The first step in assessing the options is mapping their impacts. For this, three broad categories of impacts are considered: economic (including costs), social and environmental. Based on this mapping of impacts, the options are assessed against the following criteria[174]:

The three options proposed above are assessed and compared to the baseline and between each other for the following key criteria based on the Terms of Reference and the Better Regulation Guidelines and Toolbox (2021 edition[175]):

- **Effectiveness** – effectiveness of the options to ensure compliance with the REACH Regulation and effective and consistent Member State control and enforcement systems of that Regulation throughout the EU and effectiveness of the options to contribute to the desired benefits, expressed as positive economic, environmental and social impacts.
- **Efficiency** – this considers the estimated costs of implementing the options and possible implications in terms of budget for the Commission or another relevant EU body, including resources and additional expertise needed as well as for the Member States in

[174] The assessment criteria have been derived from the study Terms of Reference and those suggestion in the Better Regulation Tool #11, Section 7 'How do the options compare' (p 72).
[175] European Commission, Better regulation: guidelines and toolbox

relation to the expected effectiveness of each option.

- **EU-added value**, including a review of subsidiarity and proportionality concerns.
- **Coherence with other EU legislation** - including synergies and possible efficiency gains.

3.2.2.1 Mapping of impacts

The impacts of the three options can be understood to result either directly from the implementation of the options or indirectly from improved enforcement and thus increased detection of non-compliance with the REACH Regulation (or more broadly EU chemicals legislation) and corrective action taken and deterrent effect of effective enforcement against non-compliance. The impacts of the options include:

- Economic impacts (direct): the options will result in implementation costs to set up the EAC and carry out the audits, primarily for EU institutions and Member State authorities (see section 3.2.2.3 for details on costs).
- Economic impacts (indirect): In the short-term, improved enforcement may result in extra costs for businesses, especially those that are currently non-compliant and potentially not yet detected, to ensure they fulfil the REACH requirements. This may also result in higher prices for consumers for some products that are currently non-compliant. However, these costs should be considered part of the compliance costs for REACH and thus part of the baseline rather than additional indirect costs associated with EAC. Furthermore, in the long-term the economic impacts are likely to be positive. The better detection of non-compliance or fraudulent practices will improve the level-playing field for businesses (including SMEs), especially those already complying with the REACH requirements, and strengthen competition and the overall functioning of the internal market. There may also be positive economic impacts associated with improved health and environment (e.g. fewer sick leaves, lower costs to health systems).
- Social impacts (indirect): The better detection of non-compliance will ensure safer chemicals and products, both EU produced and those from third countries entering the EU market, and reduce the risk of exposure to hazardous chemicals, which will in turn have benefits for human health, including at the workplace (e.g. fewer sick leaves, longer life expectancy). Minor negative social impacts could be expected in cases where additional enforcement has short-term impacts on certain businesses leading to, for instance, job losses and unemployment.
- Environmental impacts (indirect): The better detection of non-compliance will reduce the risk of hazardous chemicals entering the environment and threatening ecosystems, which will contribute to improving the overall state of the environment in the EU and better protection of human health of the EU citizens. This in turn can further enhance the social impacts by improving the overall quality of life of EU citizens.

With the exception of implementation costs, the impacts are overall positive, and relate to the expected benefits of the intervention, as discussed in the assessment of the effectiveness of the options in the following section.

3.2.2.2 Effectiveness

The effectiveness of the options concerns the extent to which each option contributes to achieving the specific objective of improving and ensuring effectiveness of REACH enforcement throughout the EU, reducing non-compliance with the legislation and delivering the wider impacts of the options, particularly their benefits. As evidenced by existing EU control systems (see section 2.4) audits or similar forms of control can be positive for strengthening and ensuring effective enforcement of EU legislation across all Member States. Existing EU control systems carry out a critical assessment of

the operation of national control systems which is independent from that of the national competent authorities of their own system, thus, contributing to an objective identification of possible weaknesses and their potential causes and to the taking of appropriate corrective action. Furthermore, they provide an overview at EU level of different strengths and weaknesses of national systems and their potential reasons. The identification of specific issues, provision of recommendations as well as exchanges between EU auditors and MS authorities are considered helpful for national authorities to develop their capacities and improve the functioning of their control systems, in turn improving the enforcement of EU legislation. During the Member State focus group, experts from national authorities emphasised the importance of exchanging information and sharing lessons as a way to continuously improve national practices. The outcome of the activity contributes to strengthening enforcement systems in the EU as whole, and not only in the Member States individually considered. All three options propose some form of a European Audit/Control Capacity for REACH, which would strengthen the opportunities for problem identification and learning while ensuring appropriate corrective action is taken by the Member States and followed up at the EU level. This in turn would make national practices consistent with the objective of an effective enforcement of REACH across Member States.

Generally speaking, it can be assumed that the broader the coverage of the audit system and the wider representativeness of Member States audited, the more effective it will be in terms of improving enforcement throughout the EU. Therefore, a broader scope of the audits (i.e., covering more issues of REACH implementation under a general audit), consistent coverage of all MS in the audits (i.e., through programmed regular audits) and a higher number of audits overall would help identify and address more potential shortcomings contributing to a greater extent to improving REACH enforcement across the EU and reducing non-compliance. This would be a proactive approach that can identify and prevent potential issues before serious problems with enforcement or non-compliance occur. The provision of recommendations for improvements in the audit reports together with the establishment of a mechanism for following up on the actions taken by Member States to address the shortcomings identified would further enhance effectiveness. At the same time, the publication of the audit reports might produce additional pressure on Member States to take corrective action. The discussion of findings at the Forum can facilitate the exchange of good practices and lessons learned between competent authorities, further strengthening enforcement under all three options.

In this sense, it can be assumed that Option 1, which envisages regular general and specific audits as well as additional control activities, provision of recommendations for corrective action based on binding criteria for official control systems and publication of the audit reports, would be the most effective in contributing to building strong national control systems, improving enforcement and reducing non-compliance with REACH. Option 2 would be potentially less effective than Option 1 because the scope of the audits would be specific, targeting therefore certain issues only, no additional activities are expected and only a summary audit report would be published. However, Option 2 would be more effective than Option 3 because the latter would entail, as regards Commission ad hoc controls, a reactive approach of EU controls to respond to specific concerns that have materialized rather than a proactive approach aiming to prevent them, not necessarily covering all Member States. Its potentially lower number of controls per year compared to the programmed audits may also lead to a less frequent identification of weaknesses/good practices in national control systems which may also be useful to non-controlled Member States. As regards MS peer reviews, as they are based on a voluntary approach, it is difficult to predict their scope and frequency and therefore also their effectiveness. While all three options are expected to contribute to some degree to improving the effectiveness of Member States' control systems (Option 1 is expected to contribute the most based on the reasons above and Option 3 the least), only Options 1 and 2 are expected to result in strengthening the effectiveness of national control systems in all Member States thanks to their proactive controls in all of them.

At the same time, during a focus group several experts from Member States authorities indicated that the proposed EAC might not be necessary. For these experts the need for an EAC is not clear

primarily because its difference from existing control mechanisms (e.g. reporting under Art. 117 of REACH, peer review under the MSR) may not be clearly understood at this point in time; the different between EAC and existing control mechanisms would need to be clearly communicated when a specific option is proposed. They also expressed concern that the need to dedicate resources to participating in audits of their own enforcement systems would detract resources from regular enforcement activities, and risks weakening the overall enforcement. These Member States' experts favour simpler approaches that would not increase their administrative burden; it is therefore likely that they would prefer an option with less frequent audits and/or audits with a more specific scope. Experts from other Member States authorities indicated the importance of having a level playing field where all Member States would be subject to audits and a situation where certain Member States would be audited more frequently than others should be avoided. These Member States' experts favour an option with clearly defined audit programmes that cover all Member States. These considerations are likely to impact the acceptability of the options by the Member States. A potential trade-off would need to be made between the effectiveness and efficiency (in terms of potential administrative burden) of each option to ensure it can contribute to the desired objective while being acceptable to key stakeholders such as the Member State authorities.

3.2.2.3 Efficiency, including cost assessment

The assessment of the costs is done in line with Tools #56, #57 and #58 of the Better Regulation Toolbox. It consists of two main steps: 1) identification of the resource requirements and associated costs as well as who will bear them for each of the three options; and 2) development of cost estimates based on the principle of proportionate analysis by focusing on major costs and simplified assumptions (Tool #57, p. 505).

Identification and typology of costs

Based on the typology of costs described in Tool #56, the costs associated with the options for design of the EAC and the groups of stakeholders that would bear them are mapped in the following table. The types of costs are the same across the three options, potential differences in their magnitude are discussed in the rest of this section.

Table 32: Types of costs by stakeholder group for the three options

Type of costs	Public administration - EU	Public administration - MS	Business	Citizens and consumers
Direct compliance (and enforcement) costs* including:	✓	✓		
One-off costs	✓	(✓)***		
Recurring annual costs (fixed)	✓	(✓)***		
Recurring annual costs (varying)	✓	✓		
Indirect costs**			✓	✓

*Notes: *In this case, the compliance and enforcement costs associated with new provisions on EAC are analysed together. Other direct costs can include hassle costs but as advised in Tool #56 such costs are usually not estimated.*
***This includes any substitution costs, transaction costs or even opportunity costs for consumers and businesses. However, as explained in section 3.2.2.1, these costs may be associated with compliance with the REACH requirements and not be new or additional, they are thus not estimated.*
****There might be recurring annual costs for the performance of peer reviews (e.g. if teams are set up to carry those out), however at this stage it is not clear to what extent these costs might take place or whether they would be additional to what is already incurred in the baseline (as Member States peer reviews are also foreseen in the MSR).*

As presented in the table above, the most significant costs associated with the options, which require more detailed assessment, are the direct compliance costs for public administrations at the EU and MS levels. Each option will entail set-up/one-off costs and recurring costs. Set-up or one-off costs for establishing the EAC will be borne by the EU institution responsible for it, i.e., the Commission with some involvement from ECHA (this is relevant for Options 1, 2 and 3 concerning ad hoc

controls; for peer reviews under Option 3 see a separate paragraph at the end of the section). These costs are associated with key activities such as establishment of working procedures for the EAC and establishment of a team of auditors and other supporting staff for the EAC (while the costs of the team such as salaries or consultant fees will be recurring costs (see below) the costs associated with hiring, internal relocation across services or training can be considered as one-off costs). All these costs are human resource costs that can be expected to be very similar between Option 1 and Option 2 as the differences in some aspects of the options (e.g. size of the team at the EU level, number of expected controls per year) will not really add or remove from the activities necessary to introduce and set up a new mechanism such as the EAC. For instance, a key set-up activity will be to ensure that the EAC is staffed with experts with the necessary expertise (e.g., on auditing, chemicals legislation), which can be done through hiring, internal relocation from existing services, internal or external training of existing staff or even outsourcing. It is expected that this activity would not be necessary under Option 3 or that its cost would be lower (since it might not require an 'establishment' of a 'control capacity' as such but a simpler form of setting up a new mechanism for ad hoc controls) and thus the one-off costs under Options 1 and 2 would be higher than for Option 3.

Recurring annual costs of implementation are associated with the functioning of the EAC and the performance of audits/ controls. Therefore, these costs will include both fixed costs (e.g., salaries for the staff of the EAC, establishment of an audit programme, exchange of information with other bodies, overhead costs) and varying costs that will depend on the number and nature of the audits performed each year. Most of the recurring costs, especially the fixed ones, will be borne by the EU institution responsible for the EAC, while some of the varying costs will also be borne by the Member States (i.e., those associated with audits/controls). Most of the recurring costs are human resource costs. For instance, it is not expected that specific IT tools or solutions, other than what administrations currently use, are necessary and overhead costs (e.g., linked to hardware, software, buildings) can be factored into the human resource costs to capture any such costs. It can also be expected that the fixed annual costs will be similar across the three options (Option 3 might require a smaller team at the EU level with lower fixed costs compared to the other options).

Under Option 3's voluntary action of MS peer reviews, the one-off and fixed recurring costs would be borne by the Member States carrying out the peer reviews. However, at this stage it is unclear whether they would be new and additional to the baseline (i.e., costs for establishing and performing peer reviews under similar mechanism of the MSR) and to what extent they would differ per country.

The most significant differences in terms of costs between the three options are likely to be the varying costs associated with specific audits/controls/peer reviews carried out (number, scope, etc.). These costs would be borne at the EU level (for EU-lead audits and controls under all options) or at the MS level (for peer reviews). In addition, under all options, the Member State, which is being audited, controlled or peer reviewed, will also bear some costs associated with providing information, documentation, participating in meetings etc.

Assumptions and estimation of costs for public authorities

Given the above considerations, the main additional costs, which are also likely to differ significantly between the three options and could be examined in more detail, would be the costs per audit (for Options 1 and 2) and controls/ peer reviews (Option 3). Consequently, rough estimates for the costs per audit/ control activity under each of the three options are developed as a way to distinguish the budgetary implications of the options based on the following assumptions and considerations:

- EU level: At this level the costs concern the European Commission and, if necessary, ECHA. The costs associated with an audit or control activity will be predominantly the human resource costs, which can be expressed in terms of person days without or with associated financial rates per person day based on the Standard Cost Model (Tool #58). There will also be travel costs for any on-the-spot checks. These costs would include daily allowances, hotel and transportation costs.

- MS level: The potential costs for a MS can be divided in two types. On the one hand, there will be costs for the audited MS in the form of human resources costs for staff from the audited/peer reviewed MS cooperating with the audit/control/peer review team (for all options). On the other hand, in some options MS experts may be involved in the audit/ control (Option 1) or will be carrying out the peer review (Option 3). In the following analysis the human resource costs for such MS experts is assessed at the MS level (it is possible that in some cases, some of the costs related to the MS experts carrying out peer reviews may be covered by existing MSR peer reviews, these considerations are analysed qualitatively in the comparison of the options). In both cases, the costs can be estimated using the Standard Cost Model and based on the same assumptions as the EU level costs. Under Option 1, national experts participating in the audit teams will also incur travel expenses based on the same costs as EU officials, although it is possible that in some cases those costs or some of them may be covered by the EU.
- Range: In reality the efforts and associated costs will vary in each individual case of an audit/ control/peer review. For simplicity, in the following analysis a low and a high level of effort and associated cost is used. The range is based on the available information about person days needed for control activities in existing EU control systems (see details below). Using a range allows the analysis to capture the lowest and the highest costs that can be expected based on the available data and assumptions, the costs of individual activities can be expected to lie within this range.
- Frequency: For programmed audits (specific or general), it is assumed that each MS is audited once every five years[176] per specific or general audit, this would imply approximately 5-6 audits per year for Option 2 and 10-12 audits per year for Option 1. Nevertheless, general and specific audits under Option 1 could be combined, avoiding that one MS is audited more frequently than once every five years. This should not prevent however that they could also be carried out separately if considered appropriate. For the purpose of this study, it is assumed that under Option 1 general and specific audits are combined (see the following bullet point). For other controls (ad hoc targeted controls, additional fact-finding missions or peer reviews), it is assumed that 0-2 such activities take place per year throughout the EU. Concerning on-the-spot checks, it is assumed that all EU audits under Options 1 and all ad hoc controls under all options involve such checks, while only around half of the audits in Option 2 include on-the-spot visits (meaning 2-3 per year). Peer reviews may include on-the-spot checks however the related travel costs are not estimated since at this stage it is not clear whether the MS carrying out the peer review would choose to do a visit or perform only remote verification. Moreover, the travel costs may vary among MSs depending on their provisions defining daily allowances and potential ceilings for accommodation as well as depending on transport distance to the MSs peer reviewed.
- Scope: General and specific programmed audits can be combined into one audit of the same MS but it can be assumed that general audits of the whole enforcement system of Member States would be lengthier and more resource-intensive than targeted audits. Thus, they would require the 'high' range of person days per audit (see Table 33). Other audits, control activities and peer reviews can be assumed to be simpler and requiring the 'low' range of person days per activity.

EU person days required per audit/ control

Based on the information collected for other EU control systems (see section 2.3) the following assumptions are made about the range of resources needed to perform one audit/ control at the EU level (i.e., Commission, with or without ECHA experts) expressed in full-time equivalent person days (FTE). The ranges provided in the following table can be used to capture the varying degree of complexity or scope of an audit/ control.

[176] There was consensus in the focus groups that this is a good frequency to ensure all MS are audited at reasonable intervals.

Table 33: Person days needed for audits/ controls under existing EU control systems

Control system	Staff (EU - level)[177]	Fieldwork/ data collection	Reporting	Total
Established by Reg (EU) 2017/625) – Food and feed law, animal health and welfare, plant health and PPPs – DG SANTE Dir. F.	2 people	15 FTE for 2 people (implying 7.5 FTE per person)	20 days for draft report, 16 days for final report (assuming this means FTE, this would be 36 FTE per report)	-
Established by Reg (EC) 1224/2009 – Common Fisheries Policy – DG MARE Dir. D.	2-4 people	5 days for leader and 5 days for other team members (implying 5 FTE per person)	5-10 days for team leader, 3 days for other team members and 1 day for HoU (assuming this means FTE and the team is 2 people in addition to leader, this would be 12-17 FTE per report)	-
Established by Reg 1406/2002 – Maritime safety – DG MOVE Dir D /EMSA.	2-3 people	3-5 days (assuming this means FTE per person, this would be 3-5 FTE per person)	-	-
Established by Reg. 2021/1060 – Cohesion funds – DG REGIO / DG EMPL Joint Audit Directorate for Cohesion.	2-4 people	10 days for 2 people in simple cases (implying 5 FTE per person) or 20 days in more complicated cases (implying 10 FTE per person)	-	-
FTE per audit/ control (low)	**2 people**	3 FTE per person **or 6 FTE per audit/ control** (for the entire team of 2 experts)	**12 FTE per audit report** (for the entire team)	**18 FTE per audit/ control**
FTE per audit/ control (high)	**4 people**	10 FTE per person or **40 FTE per audit/ control** (for the entire team of 4 experts)	**36 FTE per audit report** (for the entire team)	**76 FTE per audit/ control**

MS person days required per audit/ control

As information about the amount of person days required for Member State authorities per audit is not available, the following assumptions are made:

- The amount of person days (FTE) required for a national expert (either from the audited MS to cooperate/provide information to the audit team or from another MS to participate in the audit and/or peer review) is the same as for EU experts (based on Table 33).
- Audited/controlled/peer reviewed MS: Maximum two representatives of the competent authority are involved during any audit/ control/ peer review to provide information and cooperate with the auditing/control/peer review team. Using the assumption of 3-10 FTE per person (based on the table above), this would mean **6-20 FTE per audit/ control/peer review** for the audited/controlled/peer reviewed MS.
- Other MS: In the case of audits, one national expert may participate in the audit team in addition to the EU experts (relevant for Option 1). Using the assumptions from the table above, the person days required would be **3-10 FTE per audit**. In the case of peer reviews, two national experts carry out the review (relevant for Option 3). Using the assumption of 3-10 FTE per person (based on the table above), this would imply **6-20 FTE per peer review**.

[177] This covers only EU-level experts, they could be representatives of Commission services, executive agencies etc. It does not include experts from MSs where, in addition, they may participate in the audit/control team.

Consequently, the person days to be used for estimating the costs of audits under each option are summarised in the following table.

Table 34: Estimated person days per control activity

Person days	FTE Low	FTE High	General audit (High)	Specific audit (Low)	Ad hoc control (Low)	Fact-finding mission (Low)	Peer review (Low)
EU level (incl. fieldwork and reporting)	18	76	76	18	18	18	-
Audited/controlled/peer reviewed MS: Cooperation with audit team or team for peer review	6	20	20	6	6	6	6
Other MS: Participation in audit team	3	10	10	3	-	-	-
Other MS: Carrying out peer review	6	20	-	-	-	-	6

*Explanation: Using the ranges provided in **Table 33** and the bullet points above, the low and high levels of FTE are shown for each level and for the entire team involved in a control activity. Based on the key assumptions (explained in the introduction of this section), the FTE only for general audits is expected to require the high FTE. For other control activities the low FTE is used.*

At the EU level there would also be travel-related costs - primarily EU level officials who would travel to the audited/ controlled MS (with the exception of Option 1 where a national expert from another MS would also participate, however these costs could be covered by the EU and for simplicity it is assumed that this would be the case). A range is proposed for the duration of each on-the-spot check based on the following assumptions:

- High-end: this would be relevant for the general audits in Option 1. Assuming that all fieldwork takes place on site and using the high-end data from Table 33, this implies that **a four-person team** (including a national expert from another MS) travels to the audited MS and stays there for **10 days**.
- Low-end: this would be relevant for the specific audits in Option 2 that include on-the-spot checks and the ad hoc controls in all options. Assuming that all fieldwork takes place on site and using the low-end data from Table 33, this suggests that **a two-person team** travels to the controlled MS for **3 days**.

Given the uncertainties associated with travel and the exact duration of visits, the rather broad range of their duration aims to capture this and offer an indication of the highest possible costs that can be expected at this stage. It is likely that in practice the travel costs may lie within the range and be below the 'high' estimate.

Labour and travel costs

To estimate the costs of the options in monetary terms, the labour and travel costs for each activity need to be estimated first. The human resource or labour costs are estimated using the Standard Cost Model where the amount of person days necessary for one activity is multiplied by a daily labour cost (the approach and labour costs are summarised in the following box). The travel costs include daily allowances, hotel and transport for an on-the-spot check based on the EU Staff Regulations provisions about missions (the approach and costs are explained further in the box).

Box 1: Labour and travel costs

Standard Cost Model and labour costs used for estimations

The Standard Cost Model[178] expresses costs as the 'price per action' (usually expressed as labour costs and an added 25% of overhead costs) multiplied by the 'quantity' of actions carried out (in this case the person days necessary for implementation of one audit).

A proxy for the labour costs can be a daily wage for public administration officials at the EU level or in Member States. In order to obtain daily wages from monthly salary data or hourly wage data, the wages are converted based on the assumption of 215 person days of fulltime equivalent (FTE) in a year[179] or alternatively 1 720 person hours of FTE in a year[180], these assumptions imply a person day of FTE has 8 hours and a person month of FTE has 18 days.

EU labour cost

The daily rate for EU officials is based on the assumption of 18 working days in a month and the average monthly salary for grade AD8 (as a medium grade for officials) as referred to in the Staff Regulations, applicable from 1 July 2020 (specifically Table 1.1 in Annex 1 to COM(2020) 773 final[181]). After adding a 25% overhead cost, this results in an EU **daily labour cost of EUR 534 for 2020**.

Member State labour cost

Data about labour costs in the Member States is obtained from Eurostat's Labour Cost Survey, the latest available being 2016[182]. Therefore, the EU27 'total labour cost' reported for public administration (i.e. category '*public administration and defense, compulsory social security*' per employee FTE) is adjusted for inflation to obtain a daily labour cost for 2020[183], which can be comparable to the EU labour cost. A 25% overhead cost is then added to obtain an average Member State **daily labour cost of EUR 294 for 2020**. It should be kept in mind that this an EU-wide average national wage that can vary in practice in each Member State. However, as the involvement of particular Member States is not known at this stage, it is proposed to use this average national wage for all Member States.

Travel costs used for estimations

The Staff Regulations specify that EU officials are compensated for missions to EU MSs based on daily subsistence allowances and hotel ceilings defined per MS. The latest update of these allowances and ceilings was published in a 2021 Eurostat Report and concern the reference values 2020 (specifically Annex 1 in document Ares (2021) 3465732-26/05/2021[184]). Taking the EU average of these values this results in: **daily allowance of EUR 94 for 2020** and **hotel ceiling of EUR 172 for 2020**.

The Staff Regulations (Annex VII[185]) specify that for missions to close destinations (400 km in one direction) officials are reimbursed for first class train travel and for farther destinations for air travel. Assuming that the starting point for the on-the-spot checks is Brussels, travel to three of the neighbour MSs' capitals would be by train while for all other capitals by air. In order to obtain a rough estimate of the transport costs, desk search was carried out to identify prices for first class train tickets from Brussels to Paris, Amsterdam and Luxembourg and for plane tickets from Brussels to other EU capitals using online search engines and fare comparators. Taking the EU average of these prices results in: **transport cost of EUR 129**.

Although the travel costs will vary in practice depending on the destination and even timing of the journey, it is proposed to use average EU costs at this stage as the involvement of particular Member States is not known at this stage.

EU and MS costs per control activity

Using the estimated person days per control activity in terms of FTE and the daily labour costs as well as the assumptions about travel, the cost for one audit/ control/ peer review is summarised in the following table.

[178] Tool #58 of the Better Regulation Toolbox published in 2021.

[179] Eurostat, 2017, Guidelines Unit Costs for Direct Personnel Costs applicable to all grants awarded by Eurostat

[180] European Commission, 2019, H2020 Programme User's Guide for the Personnel Costs Wizard

[181] 2020 Report on remunerations, COM(2020) 773 final, Annexes

[182] Dataset 'LCS surveys 2008, 2012 and 2016 [lc_ncost_r2]' downloaded on 04.06.21 from Eurostat

[183] Based on the annual inflation rates reported for 2017-2020 by Eurostat: 2020, 2019, 2018, 2017.

[184] Eurostat Report on the 2021 update of mission expenses (daily subsistence allowances and hotel ceilings) for Intra-EU and Extra-EU destinations

[185] Staff Regulations

Table 35: Estimated costs [2020 prices] per control activity

Costs	General audit - labour	Specific audit - labour	Ad hoc control - labour	Fact-finding mission - labour	Peer review - labour	Travel (high)	Travel (low)
EU level (incl. fieldwork and reporting)	40.584 €	9.612 €	9.612 €	9.612 €	-	10.468 €	1.510 €
Audited/controlled/peer reviewed MS: Cooperation with audit team or team for peer review	5.880 €	1.764 €	1.764 €	1.764 €	1.764 €	-	-
Other MS: Participation in audit team	2.940 €	882 €*	-	-	-	-	-
Other MS: Carrying out peer review	-	-	-	-	1.764 €	-	-

*Explanation: The labour cost is estimated using the FTEs per activity presented in the previous table and the daily labour costs provided in the box above (i.e. FTE*daily labour cost). The travel cost is estimated using the assumptions about the composition of the teams, duration of on-the-spot checks/ visits explained above and the daily allowance, hotel ceiling and transport costs provided in the box above (i.e. number of persons*total duration in days*daily allowance + number of persons*(total duration in days -1)*hotel allowance + number of persons*transport cost).*
**Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option*

EU and MS costs for the three options

Based on the assumptions described above, using the estimated labour costs per audit/ control/peer review activity, the travel costs and the expected frequency of the activities, the overall annual costs for each option are summarised in the following tables. These costs would be new and additional to the baseline as the EAC, or control capacity system would be a new legal provision.

Table 36: Estimated annual costs [2020 prices] per option – low*

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	General audit - labour cost	Specific audit - labour cost	Ad hoc control - labour cost	Fact-finding mission - labour cost	Peer review - labour cost	Audits - frequency per year (low)	Other controls - frequency per year (low)	LABOUR COST TOTAL (LOW)	On-the-spot check - programmed audit travel cost	On-the-spot check – ad hoc control travel cost	Audits visits – frequency per year (low)	Ad hoc controls visits – frequency per year (low)	TRAVEL COST (LOW)	TOTAL COSTS (LOW)
Option 1														
Estimation								*B*G+D*H+E*H*					J*L+K*M	I+N
EU	40.584 €		9.612 €	9.612 €		5	0	202.920 €	10.468 €	1.510 €	5	0	52.340 €	255.260 €
Audited MSs	5.880 €		1.764 €	1.764 €		5	0	29.400 €						29.400 €
Other MSs	2.940 €					5		14.700 €						14.700 €
Option 2														
Estimation								*C*G+D*H*					J*L+K*M	I+N
EU		9.612 €	9.612 €			5	0	48.060 €	1.510 €	1510	2	0	3.020 €	51.080 €
Audited MSs		1.764 €	1.764 €			5	0	8.820 €						8.820 €
Other MSs**		882 €				5		4.410 €						4.410 €
Option 3														
Estimation								*D*H+F*H*					K*M	I+N
EU			9.612 €				0	0 €		1.510 €		0	0 €	0 €
Audited MSs			1.764 €		1.764 €		0	0 €						0 €
Other MSs					1.764 €		0	0 €						0 €

Explanation: Column A designated the level at which costs would occur: EU level covers any EU body (Commission and ECHA); Audited/controlled/peer reviewed MS covers all MS that might be audited/controlled/peer reviewed in a given year; Other MS covers all other MS that may be involved by providing experts or carrying out peer reviews during a year. Columns B-F show the labour per control activity based on Table 35*. Since it is assumed that a general audit would include specific audits in its FTE, specific audits are not added in Option 1. Columns G-H show the expected minimum frequency of the control activities based on the key assumptions (explained in the introduction of this section). Column I shows the total labour cost estimated for all activities carried out in a given year. Column J shows the travel cost per programmed audit and column K per ad hoc control based on the assumptions and costs presented in the previous sub-section, it covers travel costs for EU officials (Commission and ECHA) and a national expert from Other MS that participates in audits. Columns L-M show the expected minimum frequency of on-the-spot checks. Column N shows the total travel cost for all activities in a given year. Column O provides the total costs per option. The total cost refers to the cost covering all MS audited/controlled/peer reviewed in a year, not the cost per MS.*

**The total annual costs are estimated as a range (low-high) to capture the possible variations of frequency in the control activities per year.*

*** Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option.*

Table 37: Estimated annual costs [2020 prices] per option – high*

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	General audit - labour cost	Specific audit - labour cost	Ad hoc control - labour cost	Fact-finding mission - labour cost	Peer review - labour cost	Auditts - frequency per year (high)	Other controls - frequency per year (high)	LABOUR COST TOTAL (HIGH)	On-the-spot check - programmed audit travel cost	On-the-spot check - ad hoc control travel cost	Audits visits - frequency per year (high)	Ad hoc controls visits - frequency per year (high)	TRAVEL COST (HIGH)	TOTAL COSTS (HIGH)
Option 1														
Estimation								*B*G+D*H+E*H*					J*L+K*M	I+N
EU	40.584 €		9.612 €	9.612 €		6	2	281.952 €	10.468 €	1.510 €	6	2	65.828 €	347.780 €
Audited MSs	5.880 €		1.764 €	1.764 €		6	2	42.336 €						42.336 €
Other MSs	2.940 €					6		17.640 €						17.640 €
Option 2														
Estimation								*C*G+D*H*					J*L+K*M	I+N
EU		9.612 €	9.612 €			6	2	76.896 €	1.510 €	1.510 €	3	2	7.550 €	84.446 €
Audited MSs		1.764 €	1.764 €			6	2	14.112 €						14.112 €
Other MSs**		882 €				6		5.292 €						5.292 €
Option 3														
Estimation								*D*H+F*H*					K*M	I+N
EU			9.612 €				2	19.224 €		1.510 €		2	3.020 €	22.244 €
Audited MSs			1.764 €		1.764 €		2	7.056 €						
Other MSs					1.764 €		2	3.528 €						

Explanation: Column A designated the level at which costs would occur: EU level covers any EU body (Commission and ECHA); Audited/controlled/peer reviewed MS covers all MS that might be audited/controlled/peer reviewed in a given year; Other MS covers all other MS that may be involved by providing experts or carrying out peer reviews during a year. Columns B-F show the labour per control activity based on Table 35*. Since it is assumed that a general audit would include specific audits in its FTE, specific audits are not added in Option 1. Columns G-H show the expected minimum frequency of the control activities based on the key assumptions (explained in the introduction of this section). Column I shows the total labour cost estimated for all activities carried out in a given year. Column J shows the travel cost per programmed audit and column K per ad hoc control based on the assumptions and costs presented in the previous sub-section, it covers travel costs for EU officials (Commission and ECHA) and a national expert from Other MS that participates in audits. . Columns L-M show the expected maximum frequency of on-the-spot checks. Column N shows the total travel cost for all activities in a given year. Column O provides the total costs per option. The total cost refers to the cost covering all MS audited/controlled/peer reviewed in a year, not the cost per MS.*

**The total annual costs are estimated as a range (low-high) to capture the possible variations of frequency in the control activities per year.*
*** Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option.*

The above-mentioned costs capture recurring varying costs associated with control activities. Further additional costs for the Commission to prepare audit programmes and/or to follow up on the corrective actions taken by MS might occur but such costs are not considered as their magnitude is not clear at this stage. Furthermore, depending on synergies established with the peer review mechanism under the MSR (e.g., joint peer reviews that cover also the enforcement of aspects of REACH not subject to the MSR, common criteria for review)[186] the additional costs associated with peer reviews may be reduced as they could be considered part of the baseline implementation of peer reviews under the MSR. Moreover, some costs (e.g., travel costs) associated with national experts taking part in the audit team might be covered by the EU in some cases, reducing the burden on MS.

Nonetheless, experts from MSs expressed concern that EAC may result in a high administrative burden on MSs. This may be due to the fact that involvement of representatives from the audited MS would likely have to be absorbed by existing human resources and budget, while at the EU level this may involve a dedicated team and budget for the EAC. Nevertheless, the extent of this risk is unclear and may not be significant in all Member States or over the longer term, if the audits in fact lead to better or more efficient MS enforcement activities. The estimated annual costs of audits and the estimated labour costs per control activity (presented in the tables above) aim to capture the different efforts that may be required by Member States for different control activities and their frequency through the use of ranges for the potential number of audits carried out per year.

Indirect costs for other stakeholders and potential benefits

As shown in Table 32, businesses, citizens and consumers may incur some indirect costs as a result of the EAC. The expected improvement of enforcement and better detection of non-compliance fostered by the Capacity might lead non-compliant businesses to fulfil the REACH requirements, incurring some short-term costs (however these costs might not be considered additional to the baseline as they are linked to compliance with REACH). This may also result in some price increases or substitution costs for consumers to replace previously non-compliant products with compliant ones. However, these are likely to be short-term impacts. In the long-term, the EAC is expected to ensure effective MS enforcement of the legislation across the EU providing a level playing field for all businesses and improving competition. This is expected to remove costs associated with unfair competition from non-compliance with REACH and have positive impacts in the longer run. Additional benefits from improvements in the protection of human health and the environment may also be expected.

3.2.2.4 EU-added value

The EU added value of the proposed options considers their capacity to deliver outcomes and benefits that would not be possible through Member State action alone, as well as whether the proposed EU action does not go beyond what is strictly necessary to achieve the objectives.

Legal basis and subsidiarity

The Union can only act in areas where the Treaties confer competence to it. In areas not falling under its exclusive competence, the Union may only act where the principle of subsidiarity is respected. The legal basis of REACH is Article 95 TEC (now 114 TFEU), which refers to the internal market. The establishment of a EAC whose purpose would be to increase and ensure effectiveness of MS enforcement systems throughout the EU of and compliance with REACH would therefore also be covered by Article 114 TFEU.

Furthermore, the subsidiarity principle applies. Subsidiarity means that the Union should only act if

[186] At this stage details about the functioning of the peer review process under the MSR are not available. Synergies with a peer review system specific for REACH can be considered to avoid potential overlaps.

and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States but can be better achieved at Union level[187]. Currently, each Member State has its own enforcement regime of REACH in place. As mentioned above, studies and data indicate that the enforcement of REACH can be improved throughout the EU to avoid the frequent and increasing cases of non-compliance, which is occurring to varying extents across the Member States. Member States currently cooperate within a Forum, but this alone has not led to the desired level of effective enforcement in the whole EU. The proposed policy options, which if adopted would lead to the creation of a European Audit/Control/Peer Review Capacity, would provide for an objective assessment of MSs control systems independent from that of the MSs, both supporting and controlling the extent of enforcement across the Member States, and ensuring that corrective action is taken by MSs to improve potential weaknesses in their systems, contributing to stronger and more harmonised and effective enforcement throughout the EU that would not be possible based on Member States acting alone.

The principle of subsidiarity is therefore fulfilled.

Proportionality

Every action of the Union must be limited in its content and form to what is necessary to achieve the objective of the Treaties that it intends to implement[188]. Establishing a EAC does not appear to be disproportionate to achieve better compliance with REACH. As established above, the initiative is consistent with the principle of subsidiarity in that it is limited to an aspect that the Member States cannot achieve satisfactorily on their own (centrally organised audit/control of MSs' enforcement activities across the EU). There are important differences, however, between the three options proposed to establish the EAC. As discussed under Effectiveness above, some MS have expressed reservations about the audit capacity system more generally, concerned that it would be unnecessary given existing enforcement activities and mechanisms to share information and approaches across the EU (the Forum). However, as valuable as the exchange of information and coordination promoted by Forum is, such a body composed of representatives of MSs cannot, by definition, provide an assessment and follow-up of potential corrective actions that is independent from those MSs. Moreover, it is expected that relying on current measures only would lead to maintaining the situation as it is and therefore the objective of the action would not be achieved. It is noted that the three options will achieve the objective of ensuring effectiveness of national control systems across the EU to different degrees. Taking into account that the burden associated with each option will also amount to different levels, it can be considered that in principle, each option is proportionate to the results it obtains.

3.2.2.5 Coherence with other EU legislation

The EAC is expected to cover the REACH Regulation, however coherence should be ensured with other relevant chemicals legislation such as the CLP, PIC and POPs Regulations. All three Regulations have provisions concerning enforcement, penalties and reporting in place which, as in REACH, merely provide a minimum framework and do not refer to any EU-level auditing of the MS enforcement systems and activities. There is, therefore, no risk that the establishment of a EAC would collide with existing EU legislation or undermine the effectiveness of existing similar functions or bodies. In fact, there may be potential synergies, in particular where the Member States' competent authorities dealing with the relevant chemicals Regulations are the same. For instance, in such cases, audits or other forms of checks envisioned in the options for a EAC for REACH may also involve checks on the enforcement of the CLP, PIC or POPs Regulations.

Under Option 3 the possibility for peer reviews is considered, which may create a risk of overlaps with the peer review mechanism under the MSR. To ensure that overlaps are minimised and

[187] Article 5(3) TEU, former Article 5 EC.
[188] Article 5(4) TEU.

excessive administrative burden is placed on MSs, the two mechanisms should be complementary. For example, they may be based on joint programmes, similar assessment criteria or other possible synergies.

3.2.3 Comparison of the options

Based on the above criteria and analysis, the three options are compared in the following table. As all options are additional to the baseline of no action (i.e., no EAC and similar levels of non-compliance as currently observed), it is expected that all options offer improvements compared to the baseline. To aid in the understanding, the key assessment conclusions are summarised for each criterion into a composite score, based on the legend provided at the bottom of the table and the summary explanations in the table for each criterion.

Table 38: Comparison of the three options and baseline

Option	Effectiveness	Efficiency	EU added value	Coherence with other EU legislation
Option 1: Comprehensive audit capacity system	+++	+	++	++
	The combination of regularly programmed audits of a general and specific nature and other ad hoc controls, as well as recommendations to MSs based on binding criteria for official controls, follow-up mechanism to check the corrective actions taken and the publication of the audit reports have the strongest potential to improve enforcement systems and ensure compliance. Potential participation of ECHA and MS experts in the audit teams can further strengthen effectiveness. Covering all MS through regular programmed audits will ensure potential issues are identified everywhere across the EU. Improving and ensuring effective enforcement systems in the EU which thus, are able to detect non-compliances, ensure that corrective action is taken and also act as a deterrent for non-compliances, will reduce risks of exposure to hazardous chemicals and improve human health as well as the overall state of the environment. The broader scope of the audits and possibility for additional checks is expected to facilitate the detection of potential weaknesses in MSs control systems, including systemic ones, as well as the causes that lead to those shortcomings and therefore action can be targeted to those.	The implementation costs for this option are significantly higher than those for the other options, due primarily to the inclusion of the general audits, which increase the frequency or length of audits to be performed. This impacts both the EU bodies and the MS authorities involved in the audits. Annual labour costs: EU level: € 202 920-281 952 Audited MSs: € 29 400-42 336 Other MSs: €14 700-17 640 Annual travel costs: EU level: €52 340-65 828 The MS labour costs per one MS would vary according to the type of control activity carried out, the costs per activity per MS are estimated to be: Audited MS: €1 764 (other controls) - €5 880 (general audit); Other MS: €882 (specific audit) – €2 940 (general audit). There are possible opportunity costs for MS authorities with limited resources or fixed budgets for enforcement due to the need to support EU audits/ controls. In the long-term improvement of competition and ensuring a level playing field for businesses as well as economic benefits from improved human health and environment are expected.	From a subsidiarity perspective, the EU added value is clear, as a comprehensive audit capacity with general planned audits, independent and objective view of MS systems and a possibility to take corrective action are clearly functions that could best be carried out through EU action. The option is considered proportionate for its bigger contribution to improving the effectiveness of control systems in MSs but also across the EU compared to the other two options.	No clear overlaps with enforcement provisions in other relevant chemicals legislation. Potential for synergies with enforcement activities related to CLP, PIC or POPs Regulations.

Option	Effectiveness	Efficiency	EU added value	Coherence with other EU legislation
Option 2: An audit capacity system	++	++	++	++
	The more specific scope of audits (compared to Option 1) and publication only of a summary audit report are likely to contribute to a lesser extent to improving enforcement systems with the related environmental and human health benefits (compared to Option 1). Nevertheless, the provision of recommendations to MSs based on binding criteria for official controls and the establishment of a follow-up mechanism to check the corrective actions taken will contribute to improving the effectiveness of enforcement systems. Covering a representative number of MS per specific audit series and all MS in a given period will ensure potential issues are corrected across the EU. Improving enforcement will contribute to the broader social and environmental benefits.	The estimated implementation costs for EU and MS authorities would be lower as less lengthy or complex audits and controls are expected than under Option 1. Annual labour costs: EU level: € 48 060-76 896 Audited MSs: € 8 820-14 112; Other MSs: €4 410-5 292. Annual travel costs: EU level: €3 020-7 550 The MS labour costs per one MS would vary according to the type of control activity carried out, the costs per activity per MS are estimated to be: Audited MS: €1 764 (specific audit and other controls); Other MS: €882 (specific audit). If the audit capacity is successful in achieving the objective, short and long-term indirect economic impacts would occur similar to option 1.	From a subsidiarity perspective, the EU added value is clear, as a comprehensive audit capacity with planned audits, independent and objective view of MS systems and a possibility to take corrective action are clearly functions that could best be carried out through EU action. The option is considered sound from a proportionality perspective.	No clear overlaps with enforcement provisions in other relevant chemicals legislation. Potential for synergies with enforcement activities related to CLP, PIC or POPs Regulations.
Option 3: A minimal control capacity system	+	+	++	++
	Ad hoc nature and scope of controls, based on not binding criteria for control systems, voluntary nature of peer reviews and smaller number of controls (compared to Option 1 and Option 2) are likely to contribute less to improving enforcement systems in all the EU. There is risk that not all MS are controlled (if no concerns are raised) and thus that some potential enforcement issues are not identified. No specific recommendations will be	Implementation costs would be lower than under Options 1 and 2, and some effectiveness would still be gained under the minimal control system. However, the lower costs (i.e. efficiency gain) would not offset the lower effectiveness expected from the lower number and more limited scope of audits/ controls. Annual labour costs: EU level: € 0-19 224	From a subsidiarity perspective, some EU added value is expected, as ad hoc Commission controls can provide an independent and objective view of MS systems and a possibility to take corrective action, which are clearly functions that could best be carried out through EU action. The issue of subsidiarity is less relevant for peer reviews, which will be led by MSs. Nevertheless, there would be some added value in having a system for	No clear overlaps with enforcement provisions in other relevant chemicals legislation. Potential for synergies with enforcement activities related to CLP, PIC or POPs Regulations. Risk of potential overlaps between peer reviews under REACH and those under the MSR, such overlaps should be avoided and minimised.

Option	Effectiveness	Efficiency	EU added value	Coherence with other EU legislation
	issued to MSs and only a summary control report would be published, which implies lower contribution to improving national control systems. Nonetheless, the identification of shortcomings in the MS control systems and establishment of a follow-up mechanism to check the corrective actions taken will contribute to improving the control systems of individual MSs and the experience may also be useful to other MSs to some extent. Lower contribution to improving enforcement means also lower contribution to the broader social and environment benefits (compared to Option 1 and Option 2).	Audited MSs: € 0-7 056 Other MSs: €0-3 528 Annual travel costs: EU level: €0-3 020 The MS labour costs per one MS would vary according to the type of control activity carried out, the costs per activity per MS are estimated to be: Controlled/peer reviewed MS: €1 764 (ad hoc control or peer review); Other MS: €1 764 (peer review).	reviews of MS control systems. The option is considered sound from a proportionality perspective.	

Score:

+++	High, positive effect
++	Medium, positive effect
+	Low, positive effect
0	Neutral effect
-	Low, negative effect
--	Medium, negative effect
---	High, negative effect

Note: As all options are additional to the baseline of no action (i.e., no EAC and similar levels of non-compliance as currently observed), it is expected that all options offer improvements compared to the baseline.

3.2.4 Feasibility of extending the options to the CLP, POPs and PIC Regulations

The options considered above could also be applied to audit/control/peer review national control systems implemented for the enforcement of the CLP, POPs and PIC Regulations. As the aspects assessed are mainly related to the infrastructure and procedures needed for the setting of the audit capacity rather than to the scope of the legislation enforced by national controls, that assessment and its conclusions can, overall, be considered, in principle, also applicable to the case that the system in any of the three options would also be covered within its scope these Regulations.

Costs per specific audits, ad hoc controls and peer reviews could be considered the same. A minor difference is that the PIC Regulation is not within the scope of Market Surveillance Regulation and therefore peer reviews under that Regulation do not cover any aspect of the enforcement of the PIC Regulation and it cannot benefit from potential synergies. As the scope of the Member States' enforcement obligations within any of these three regulations is narrower than within REACH, it could be expected that the general audits would require less time and resources and therefore a lower cost than that estimated for REACH.

Moreover, as very often enforcement authorities in MSs for those regulations (in particular for CLP) are the same as those for REACH and there are synergies among those regulations, the possibility of combining the audit/control/peer review of REACH and CLP and/or other regulations could lead to efficiency gains, further contributing to the effectiveness of national controls systems as regards chemical legislation.

In order to estimate the potential costs of the three options if they also cover the CLP Regulation, the costs for the options covering REACH are used, together with the following assumptions:

- Option 1: the general audits can be extended to cover also the CLP Regulation. This implies that the same overall number of audits would take place per year but that the costs for one audit would be higher. It is assumed that the visit to collect data on the spot would be extended by 3 days and the labour costs would increase by around 30% per general audit. The rest of the activities under this option are assumed to remain unchanged,
- Option 2: it is assumed that the efforts to perform audits for the CLP Regulation would require the same effort as for REACH. Hence the additional coverage would result in additional specific audits per year – it is assumed that two additional audits for CLP would take place per year (i.e. a range of 7-8 audits per year, half of those include on-the-spot visits). The rest of the activities under this option are assumed to remain unchanged,
- Option 3: it is assumed that the efforts to perform controls for the CLP Regulation would require the same effort as for REACH. Hence the additional coverage would result in additional ad hoc controls per year – it is assumed that one additional control for CLP would take place per year (i.e. 0-3 controls per year). The rest of the activities under this option are assumed to remain unchanged,

Therefore, including audits/ controls of the CLP Regulation raises the costs per control activity only for general audits. For other activities the cost per activity is expected to be the same as for REACH (see the following table for an overview).

Table 39: Estimated costs [2020 prices] per control activity including REACH and CLP Regulation

Option	Option 1		Option 2		Option 3		
Costs	General audit – labour	Travel	Specific audit – labour	Travel	Ad hoc control – labour	Travel	Peer review – labour
EU level (incl. fieldwork and reporting)	52.759 €	13.660 €	9.612 €	1.510 €	9.612 €	1.510 €	-
Audited/controlled/peer reviewed MS: Cooperation	7.644 €	-	1.764 €	-	1.764 €	-	1.764 €

Option	Option 1		Option 2		Option 3		
Costs	General audit – labour	Travel	Specific audit – labour	Travel	Ad hoc control – labour	Travel	Peer review – labour
with audit team or team for peer review							
Other MS: Participation in audit team	3.822 €	-	882 €*	-	-	-	-
Other MS: Carrying out peer review	-	-	-	-	-	-	1.764 €

Explanation: The costs are estimated using the costs per activity covering only REACH as presented in Table 35 and the above assumptions (i.e. general audits are assumed to cost 30% more and their related visits to last 3 additional days; the rest of the costs per activity are identical).
** Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option*

Using these updated costs per activity, the overall costs of the three options for including audits/ controls of the CLP Regulation in addition to REACH are provided in the next two tables.

Table 40: Estimated annual costs [2020 prices] per option including REACH and CLP Regulation – low*

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	General audit - labour cost	Specific audit - labour cost	Ad hoc control - labour cost	Fact-finding mission - labour cost	Peer review - labour cost	Audits - frequency per year (low)	Other controls - frequency per year (low)	LABOUR COST TOTAL (LOW)	On-the-spot check - programmed audit travel cost	On-the-spot check - ad hoc control travel cost	Audits visits - frequency per year (low)	Ad hoc controls visits - frequency per year (low)	TRAVEL COST (LOW)	TOTAL COSTS (LOW)
Option 1														
Estimation								*B*G+D*H+E*H*					*J*L+K*M*	*I+N*
EU	52.759 €		9.612 €	9.612 €		5	0	263.796 €	13.660 €	1.510 €	5	0	68.300 €	332.096 €
Audited MSs	7.644 €		1.764 €	1.764 €		5	0	38.220 €						38.220 €
Other MSs	3.822 €					5		19.110 €						19.110 €
Option 2														
Estimation								*C*G+D*H*					*J*L+K*M*	*I+N*
EU		9.612 €	9.612 €			7	0	67.284 €	1.510 €	1.510 €	3	0	4.530 €	71.814 €
Audited MSs		1.764 €	1.764 €			7	0	12.348 €						12.348 €
Other MSs**		882 €				7		6.174 €						6.174 €
Option 3														
Estimation								*D*H+F*H*					*K*M*	*I+N*
EU			9.612 €				0	0 €		1.510 €		0	0 €	0 €
Audited MSs			1.764 €		1.764 €		0	0 €						0 €
Other MSs					1.764 €		0	0 €						0 €

Explanation: This estimation is based on the same approach as Table 36*. Under Option 1, the costs per activity include CLP Regulation (i.e. 30% higher labour cost for general audits and higher travel cost). For Option 2, the frequency of specific audits is increased by 2 and of on-the-spot checks is increased by 1. In the low-end scenario, it is assumed that no ad hoc controls take place. Column O provides the total costs per option. The total cost refers to the cost covering all MS audited/controlled/peer reviewed in a year, not the cost per MS.*
**The total annual costs are estimated as a range (low-high) to capture the possible variations of frequency in the control activities per year.*
***Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option.*

Table 41: Estimated annual costs [2020 prices] per option including REACH and CLP Regulation – high*

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	General audit - labour cost	Specific audit - labour cost	Ad hoc control - labour cost	Fact-finding mission - labour cost	Peer review - labour cost	Audits - frequency per year (high)	Other controls - frequency per year (high)	LABOUR COST TOTAL (HIGH)	On-the-spot check - programmed audit travel cost	On-the-spot check - ad hoc control travel cost	Audits visits - frequency per year (high)	Ad hoc controls visits - frequency per year (high)	TRAVEL COST (HIGH)	TOTAL COSTS (HIGH)
Option 1														
Estimation								*B*G+D*H+E*H*					J*L+K*M	I+N
EU	52.759 €		9.612 €	9.612 €		6	2	355.003 €	13.660 €	1.510 €	6	2	84.980 €	439.983 €
Audited MSs	7.644 €		1.764 €	1.764 €		6	2	52.920 €						52.920 €
Other MSs	3.822 €					6		22.932 €						22.932 €
Option 2														
Estimation								*C*G+D*H*					J*L+K*M	I+N
EU		9.612 €	9.612 €			8	2	96.120 €	1.510 €	1.510 €	4	2	9.060 €	105.180 €
Audited MSs		1.764 €	1.764 €			8	2	17.640 €						17.640 €
Other MSs**		882 €				8		7.056 €						7.056 €
Option 3														
Estimation								*D*H+F*H*					K*M	I+N
EU			9.612 €				3	28.836 €		1.510 €		3	4.530 €	33.366 €
Audited MSs			1.764 €		1.764 €		3	10.584 €						
Other MSs					1.764 €		3	5.292 €						

Explanation: This estimation is based on the same approach as Table 37*. Under Option 1, the costs per activity include CLP Regulation (i.e. 30% higher labour cost for general audits and higher travel cost). For Option 2, the frequency of specific audits is increased by 2 and of on-the-spot checks is increased by 1. Under Option 3, the frequency of ad hoc controls and on-the-spot checks is increased by 1. Column O provides the total costs per option. The total cost refers to the cost covering all MS audited/controlled/peer reviewed in a year, not the cost per MS.*
**The total annual costs are estimated as a range (low-high) to capture the possible variations of frequency in the control activities per year.*
***Although option 2 does not foresee that national experts may take part in the audit team, costs are also estimated for the case that this possibility could be considered within that option*

4. DEVELOPMENT OF CRITERIA / STANDARDS FOR MEMBER STATES' CONTROL SYSTEMS

4.1 INTRODUCTION

4.1.1 Task objectives

Task 3 aims to propose a list of criteria/standards relevant for the design, organisation and effectiveness evaluation of Member States official control and enforcement system of the REACH Regulation, and for their implementation and effectiveness evaluation, against which the EAC will perform its control activities. The criteria cover all aspects relevant for the design and implementation of a control and enforcement system.

4.1.2 Methodology

First list of criteria / standards

A first list of proposed criteria was developed by the contractor and submitted as part of the interim report of the study. This list includes criteria related to the main obligations placed on Member States by the REACH Regulation in relation to enforcement:

- Criteria related to competent authorities in charge of enforcement as Title XIII of the REACH Regulation requires Member States to appoint competent authorities for tasks allotted to competent authorities by the Regulation, provide them with adequate resources to fulfil their tasks and to ensure cooperation between competent authorities;
- Criteria related to official control systems as Article 125 of the REACH Regulation requires Member States to 'maintain a system of official controls' to ensure that dutyholders comply with their obligations under the Regulation, including criteria related to sanctions as Article 126 of the REACH Regulation requires Member States lay down provisions on penalties applicable for infringement of the Regulation.

The list also includes criteria related to the evaluation and improvement of the control system.

The list of criteria has been established based on criteria contained in legislation establishing control systems identified in Task 1, in particular Regulation (EU) 2017/625 on official controls to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, which is the most detailed regarding criteria for Member States' control systems, and other relevant pieces of legislation, such as Regulation (EC) 1224/2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, or Regulation (EU) 2019/1020 on market surveillance. Criteria contained in Regulation (EU) 2017/625 and Regulation (EC) 1224/2009 are described in section 2.3.4 of this report.

The list also takes into account guidance documents or other relevant documents laying down criteria for enforcement, including:

- The Forum for Exchange of Information on enforcement's paper on *Strategies and minimum criteria for enforcement of Chemical Regulations*[189], most recently revised in 2017, which provides principles and guidance to develop a national enforcement strategy and established minimum criteria for chemical inspections (Annex I);
- The Commission guidance on the implementation of the provisions for the conduct of audits

[189] ECHA – Forum for Exchange of Information on enforcement (2017) Strategies and minimum criteria for enforcement of Chemical Regulations.

under Article 6 of Regulation (EU) 2017/625[190];

- The guidance document on inspections and enforcement to fulfil the requirements under Articles 34 and 60 of Directive 2010/63/EU on the protection of animals used for scientific purposes[191];
- The OECD Regulatory Enforcement and Inspections Toolkit[192], published in 2018;
- The European Parliament and Council Recommendation providing for minimum criteria for environmental inspections in the Member States[193].

The list of criteria was revised based on Commission comments before it was submitted to consultation to Member States. It was then revised based on the feedback received through the survey, during the focus groups, as well as written comments received before and after the focus group.

Online survey

An online survey was carried out to gather the opinions of experts from CARACAL, Forum, PIC DNAs and POPs competent authorities on the relevance of the preliminary list of criteria established by the contractor (provided to respondents as a background document); the relevance of establishing common EU standards against which the EAC may control Member States' control and enforcement systems, and whether these standards should be laid down in the legislation as binding elements for national control systems; the relevance of extending the EAC to chemicals legislation other than REACH; and costs and benefits for Member States of being subject to Commission controls. The online survey, together with the background document, were made available to national authorities through the contact points of the different committees and expert groups on 14 December 2021, with a deadline for responses on 14 January. The survey questionnaire is available in Annex 3.

The survey gathered 53 responses, including 35 from experts from national enforcement authorities and 18 from experts from other competent authorities from 27 Member States/EEA countries. All respondents indicated that their authority is responsible for the REACH Regulation, 52 that their authority is responsible for the CLP Regulation, 42 for the POPs Regulation, and 39 for the PIC Regulation. About one fourth of the responses (13) come from the same Member State. The feedback on the list of criteria is presented in the section below. The quantitative results from the survey (scoring the relevance of each criterion) have not been included in the section as responses sometimes reflect a judgement the EAC rather than on each individual criterion (several respondents mentioned that they replied 'not relevant' for all criteria because they considered the establishment of an EAC not relevant). Results from the survey are however available in Annex 4 and feedback provided by EU and Member States' experts on criteria as part of the survey, focus group and / or through written comments is available in Annex 5.

Focus group

Focus groups with representatives of four EU control systems, DG Environment and DG GROW, ECHA and with experts from competent authorities from eight Member States, mostly participating in Forum, were held respectively on 20 and 26 January 2022. The list of criteria was discussed in both focus group. With representatives of EU control systems, the objective of the discussion was to gather their views on whether the proposed list of criteria was relevant and comprehensive based on their experience with assessing Member States' control systems. In particular, they were asked to

[190] European Commission, Commission Notice on a guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 of the European Parliament and of the Council, C/2021/1154, OJ C 66, 26.2.2021, p. 22–32.

[191] National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes (2014) A working document on Inspections and Enforcement to fulfil the requirements under the Directive.

[192] OECD (2018) OECD Regulatory Enforcement and Inspections Toolkit, OECD Publishing, Paris. https://doi.org/10.1787/9789264303959-en

[193] European Parliament and Council Recommendation of 4 April 2001 providing for minimum criteria for environmental inspections in the Member States, OJ L 118, 27.4.2001, p. 41–46.

report on which criteria they may had often identified shortcomings linked to systemic deficiencies or important weaknesses affecting the effectiveness of the national control systems. With Member States' authorities, the objective was to discuss the results of the survey and gather more in-depth feedback on the criteria and sub-criteria proposed, their adequacy to ensure the effectiveness of national control systems, the required level of flexibility in those criteria to apply to all Member States' control systems, the level of detail required for those criteria to be verifiable by an EU controller, as well as the advantages and disadvantages of having criteria laid down in the legislation and implications for the EAC.

4.2 LIST OF CRITERIA / STANDARDS

4.2.1 Overview of proposed criteria

The table below summarises the 23 criteria identified to assess the effectiveness of national control and enforcement systems.

Table 42: Overview of proposed criteria

Number	Criterion
Criteria related to the authorities responsible for enforcement	
Criterion 1	Designation of enforcement authorities
Criterion 2	Preventing conflict of interest
Criterion 3	General obligation to ensure effectiveness of controls
Criterion 4	Powers and competences of authorities responsible for controls
Criterion 5	Efficient and effective cooperation, communication and coordination within and between authorities responsible for controls
Criterion 6	Resources
Criterion 7	Training
Criterion 8	Coordinated enforcement
Criterion 9	Internal and external audits
Criteria related to controls	
Planning of controls	
Criterion 10	Enforcement strategy
Criterion 11	Scope of controls
Criterion 12	Risk-based planning
Implementation of controls and reporting	
Criterion 13	Documented processes and procedures
Criterion 14	Control methods
Criterion 15	Reporting on controls
Criterion 16	Follow-up on controls
Criterion 17	Enforcement measures and penalties
Criterion 18	Right of appeal and formal complaints
Criterion 19	Transparency
Criteria related to quality management and evaluation	
Criterion 20	Horizontal analysis
Criterion 21	Quality control and control verification procedures
Criterion 22	Internal evaluation
Criterion 23	Feedback from controlled dutyholders

4.2.2 Criteria related to the authorities responsible for enforcement

Criterion 1: Designation of enforcement authorities

Criterion 1: Member States must designate the authority or authorities responsible to organise and/or perform official controls.

This criterion is a fundamental component of an official control system and a prerequisite for controlling compliance of operators with the requirements of the REACH Regulation. It may be verified by an EAC directly e.g., by reviewing, among other elements, information provided as part of Article 117 reporting exercise, national legislation, statuses and mandates of authorities and indirectly, e.g., in case the EAC may find that the reasons for a shortcoming in the implementation of official controls may be linked to some weaknesses concerning this criterion. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is already a legal requirement in Article 121 of the REACH Regulation, which requires Member States to 'appoint the competent authority or competent authorities responsible for performing the tasks allotted to competent authorities' by the Regulation. Similar legal requirements are laid down in Article 43 of the CLP Regulation ('Member States shall appoint […] the authorities responsible for the enforcement of the obligations set out in this Regulation'), Article 18 of the PIC Regulation ('Each Member State shall designate authorities such as customs authorities that shall have the responsibility of controlling the import and export of chemicals listed in Annex I') and Article 19 of the POPs Regulation ('Each Member State shall designate a competent authority or authorities responsible for the administrative tasks and enforcement required by this Regulation'). The criterion is also a legal requirement in the Market Surveillance Regulation. Article 10 provides that 'each Member State shall designate one or more market surveillance authorities in its territory'.

This criterion is included in the Forum paper[194] (section 3.2 Organisation of enforcement). Criteria applicable in other areas of the legislation also contain provisions in this regard (requirement to designate a competent authority in Article 4 of Regulation (EU) 2017/625 or to 'set up all administrative and technical structures necessary for ensuring control, inspection and enforcement' in Article 5 of Regulation (EC) 1224/2009).

Criterion 2: Preventing conflict of interest

Criterion 2: Member States must ensure that staff performing official controls are free from any conflict of interest.

- Subcriterion 2.1: Authorities responsible for controls have mandates, procedures and funding mechanisms that exclude conflict of interests.
- Subcriterion 2.2: Authorities responsible for controls have procedures in place to ensure that staff performing controls and other official activities are free from any conflict of interest

This criterion aims to guarantee that authorities responsible for enforcement carry out their task independently and without bias, ensuring both the effectiveness of controls and the equal treatment of dutyholders. This criterion may be checked by the EAC e.g. by reviewing statuses and mandates of responsible authorities. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not specified as a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. However, it is a legal requirement in Article 11 of the Market Surveillance Regulation, which provides that 'Market surveillance authorities shall exercise their powers and carry out their duties independently, impartially and without bias'.

[194] ECHA – Forum for Exchange of Information on enforcement (2017) Strategies and minimum criteria for enforcement of Chemical Regulations.

This criterion is not specified as a separate criterion in the Forum paper. Criteria applicable in other areas of the legislation however contain provisions in this regard, such as the requirement for competent authorities to have 'arrangements in place to ensure that staff performing official controls are free from any conflict of interest' in Article 5 of Regulation (EU) 2017/625.

Criterion 3: General obligation to ensure effectiveness of controls

Criterion 3: Authorities must have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of the official control system and of its implementation.

This general criterion aims to ensure that effectiveness of controls is considered by the competent authority in all aspects of the organisation of the control system, in the planning and execution of controls and in taking enforcement actions. This general criterion leaves to Member States the choice of the appropriate procedures and means to implement it. It may be verified by an EAC e.g. by reviewing information provided as part of Article 117 reporting exercise, enforcement strategies, control programmes, documented procedures, reports on controls, through checking how individual controls are carried out and the Member State's own procedures to review the effectiveness or their control system. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not spelled out as a specific and separate legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. However, an obligation to maintain a system of official controls implies that this system should be effective. In that sense, recital (121) of the REACH Regulation explains that 'in order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures. The necessary inspections should be planned, carried out and their results should be reported'. Furthermore, Article 121 REACH requires that 'Member States place adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner'. Similarly, recital (59) of the CLP Regulation states that 'Member States should put in place effective monitoring and control measures to ensure compliance with this Regulation'. Recital (18) of the PIC Regulation refers to the need to 'ensure effective control and enforcement'. The Market Surveillance Regulation does not include such a general requirement but requires in Article 11 that market surveillance authorities perform an 'effective market surveillance within their territory of products made available online and offline' and in Article 14 that Market surveillance authorities exercise their powers 'efficiently and effectively'.

This criterion is included in the Forum paper, which recommends putting in place an effective management structure and arrangements (section 3.2 Organisation of enforcement). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement for competent authorities to have 'arrangements in place to ensure the effectiveness of official controls; their impartiality, quality and consistency' in Article 5 of Regulation (EU) 2017/625.

Criterion 4: Powers and competences of authorities responsible for controls

Criterion 4: Authorities responsible for controls must be given the investigation and enforcement powers necessary for the application of the REACH Regulation.

- Subcriterion 4.1: Powers conferred to enforcement authorities must include the following:
  - The power to require dutyholders to provide relevant documents, data or information in any form or format and to take or obtain copies of such documents, data or information
  - The power to carry out unannounced on-site controls and physical checks

- The power to enter any premises used by the dutyholder
- The power to take samples for further testing
- The power to start investigations on their own initiative based on complaints or reports of incidents
- The power to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk
- The power to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists
- The power to impose penalties

This criterion aims to ensure that officers performing controls have the necessary investigation and enforcement powers to adequately control and enforce the REACH Regulation, including by taking or seeking preventive or remedial measures and sanctions. Clarity on the powers of controllers is necessary both to ensure the effectiveness of the control system and provide for a clear and fair process for all dutyholders. To ensure that the criterion may be applied in different national institutional and administrative systems, Member States should have the possibility to provide that these powers are exercisable by enforcement authorities directly, through other competent authorities or other public authorities as appropriate or by application to courts competent to grant the necessary decision. This criterion might be controlled by an EAC e.g. by reviewing national legislation, regulations or official documents if these powers are not laid down in national legislation or indirectly, e.g. by verifying what actions are in practice taken by enforcement authorities and whether reasons for not having taken some other might be in practice due to some potential limitation in powers. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a specific legal requirement for competent authorities in the REACH Regulation the CLP Regulation, the PIC Regulation and the POPs Regulation. However, these regulations all require Member States to lay down provisions on penalties applicable for infringement of the provisions of the regulations and to take all measures necessary to ensure that they are implemented (Article 126 of REACH, Article 47 of CLP, Article 28 of the PIC Regulation and Article 14 of the POPs Regulation). Minimum investigation and enforcement powers of market surveillance authorities are however provided in Article 14 of the Market Surveillance Regulation.

‘Member States may provide for the power to be exercisable in one of the following ways, as appropriate:

- (a) directly by the market surveillance authorities under their own authority;
- (b) by recourse to other public authorities in accordance with the division of powers and the institutional and administrative organisation of the Member State in question;
- (c) upon application to courts competent to grant the necessary decision to approve the exercise of that power, including, where appropriate, on appeal, if the application to grant the necessary decision was not successful. (Article 14(3)).

‘The powers conferred on market surveillance authorities under paragraph 1 shall include at least the following:

- (a) the power to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product, including access to embedded software in so far as such access is necessary for the purpose of assessing the product's compliance with applicable Union harmonisation legislation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored, and to take or obtain copies thereof;
- (b) the power to require economic operators to provide relevant information on the supply chain, on the details of the distribution network, on quantities of products on the market and on other product models that have the same technical characteristics as the product in question,

where relevant for compliance with the applicable requirements under Union harmonisation legislation;
- (c) the power to require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites, where the information in question is related to the subject matter of the investigation;
- (d) the power to carry out unannounced on-site inspections and physical checks of products;
- (e) the power to enter any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator's trade, business, craft or profession, in order to identify non-compliance and to obtain evidence;
- (f) the power to start investigations on market surveillance authorities' own initiative in order to identify non-compliances and bring them to an end;
- g) the power to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk;
- (h) the power to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled;
- (i) the power to impose penalties in accordance with Article 41;
- (j) the power to acquire product samples, including under a cover identity, to inspect those samples and to reverse engineer them in order to identify non-compliance and to obtain evidence;
- (k) the power, where no other effective means are available to eliminate a serious risk:
  - (i) to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface;
  - or (ii) where a request according to point (i) has not been complied with, to require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures (Article 14(4)).

Market surveillance authorities may use any information, document, finding, statement, or any intelligence as evidence for the purpose of their investigations, irrespective of the format in which and medium on which they are stored (Article 14(5).

This criterion is not specified as a separate criterion in the Forum paper but is implied in several sections (in particular section 3.4.4. Enforcement actions). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement for competent authorities to have 'the legal powers to perform official controls' and 'legal procedures in place to ensure that staff have access to the premises of, and documents kept by, operators' in Article 5 of Regulation (EU) 2017/625.

Criterion 5: Efficient and effective cooperation, communication and coordination within and between authorities responsible for controls

Criterion 5: Member States must ensure efficient and effective cooperation, communication and coordination within authorities responsible for controls and between authorities responsible for controls when several authorities have been designated.

- Subcriterion 5.1: When several authorities have been designated, Member States must ensure efficient and effective coordination between all enforcement authorities and with customs authorities
- Subcriterion 5.2: Member States must ensure efficient and effective coordination across different levels of administration (national, regional, local)
- Subcriterion 5.3: If several authorities are responsible for controls, Member States must ensure that the respective responsibilities of those authorities are clearly defined and that appropriate communication and coordination mechanisms are established to enable those

authorities to collaborate closely and exercise their responsibilities effectively
- Subcriterion 5.4: Member States must have working cooperation mechanisms for integrated enforcement of related legislations so that, to the extent possible, controls are holistic and cover related legislative duties (such REACH, CLP, OSH).
- Subcriterion 5.5: Member States must communicate relevant information to enforcement and competent authorities in other Member States, in particular related to cross-border compliance issues.

This criterion aims to ensure higher effectiveness of controls (through clear responsibilities and consistent approach to controls), higher efficiency and focus of resources, and decreased burden for operators and authorities. This criterion might be controlled by an EAC e.g., by checking, among other elements, that:

- National enforcement authorities have clear mandates and responsibilities (defined in legislation, statuses, policy documents) and duplication of responsibilities is avoided.
- Formal and unambiguous provisions or arrangements for cooperation, communication and coordination between enforcement authorities, and between enforcement authorities and competent authority(ies) and/or customs authorities as appropriate, are established and implemented. These can for instance take the form of memoranda of understanding and describe the scope and process for cooperation and exchange of information, including process for information exchange on non-compliant dutyholders, or principle for coordination of control activities (such as joint inspections).
- Mechanisms for exchange of information and coordination of enforcement between enforcement authorities, and between enforcement authorities and competent authorities(ies) and/or customs authorities, have been set up and implemented. Such mechanisms can include formal working groups or networks gathering all authorities for regular meetings, information exchange and alert systems through electronic channels, joint inspections planning etc.
- Evidence showing coordination and exchange of information in practice, in particular cases
- Evidence of integrated controls and cooperation with authorities responsible for related pieces of legislation

As for other criteria, it can also be checked indirectly, e.g., when the EAC may find that weaknesses in the system/procedures providing for coordination/cooperation or in their implementation were the reasons that lead to an identified shortcoming that affected the effectiveness of the control system. This may include:

- Whether there are gaps in practice, as regards aspects of legislation to be enforced due to lack of clarity or coordination on the responsible authority.
- Whether in practice, should there be shortcomings concerning official controls detected those may be linked to lack of clear/effective cooperation and coordination mechanisms or to their implementation.

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Several experts from Member States' authorities commented that a sub-criterion included in the survey requiring Member States to have 'a single authority responsible for contacts with the Commission / ECHA and other Member States' was too restrictive and not in line with how communication with the Commission and ECHA is established by Member States – for instance, the Forum member and the alternate Forum member may come from different authorities and representatives of different authorities can be involved in enforcement projects. This sub-criterion was therefore removed from the description of Criterion 5 above. Based on received feedback, the requirement to have working cooperation mechanisms for integrated enforcementwith authorities responsible for controls of other pieces legislation (e.g., OSH), was more clearly formulated in the criterion.

This criterion is at least partially a legal requirement for competent authorities in the REACH Regulation. Article 122 of the REACH Regulation requires that 'competent authorities cooperate with each other in the performance of their tasks under this Regulation and give the competent authorities of other Member States all the necessary and useful support to this end'. This requirement is however not as specific and prescriptive than the criterion described above. The same requirement is provided in Article 43 of the CLP Regulation, but not in the PIC and POPs Regulations.

Clear responsibilities and the establishment of coordination mechanisms are legal requirements in the Market Surveillance Regulation. Article 10 requires that 'where there is more than one market surveillance authority in their territory, Member States shall ensure that the respective duties of those authorities are clearly defined and that appropriate communication and coordination mechanisms are established to enable those authorities to collaborate closely and exercise their duties effectively'.

Cooperation, information exchange and coordination between enforcement authorities is highlighted as an important criterion in the Forum paper (section 3.2 Organisation of enforcement, section 4 Co-operation and co-ordination between enforcing authorities, and Annex I, criterion A1 and A2). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirements to 'ensure effective coordination between all authorities involved' in Article 4 of Regulation (EU) 2017/625 or the requirement to 'designate a single authority that coordinates the control activities of all national control authorities' in Article 5 of Regulation (EC) 1224/2009.

Criterion 6: Resources

Criterion 6: Authorities responsible for controls must have the necessary resources, including sufficient budgetary resources, competent personnel, expertise, and equipment for the proper performance of their responsibilities.

- Subcriterion 6.1: Authorities responsible for controls must have, or have access to a sufficient number of trained staff to perform controls.
- Subcriterion 6.2: Authorities responsible for controls must have, or have access to sufficient budgetary resources to organise and perform controls
- Subcriterion 6.3: Authorities responsible for controls must have, or have access to appropriate equipment to perform all necessary controls
- Subcriterion 6.4: Authorities responsible for controls must have, or have access to appropriate IT capacity and tools for the planning, execution, reporting and follow-up of controls
- Subcriterion 6.5: Authorities responsible for controls must have, or have access to an adequate laboratory capacity for analysis, testing and diagnosis
- Subcriterion 6.6: Authorities responsible for controls dedicate sufficient resources for the involvement in the exchange of information and coordination of enforcement via the Forum for Exchange of Information for Enforcement.
- Subcriterion 6.7: Authorities responsible for controls must regularly review their resource needs and take action as appropriate to address gaps and needs.

This criterion aims to ensure that appropriate human, financial and technical resources are made available to enforcement authorities to complete their duties, which is a prerequisite for effective enforcement activities. This criterion was mentioned as one of the criteria that was difficult for competent authorities to fulfil by some EU control systems; Member States' competent authorities also mentioned in the survey that enforcement resources were generally scarce. Based on the feedback received, the requirement that Member States dedicate sufficient resources for their involvement in the Forum was added.

Several experts consulted commented that this criterion will be difficult to assess by an EAC as what is considered 'sufficient' resources is not defined in absolute terms with a concrete benchmark against which Member States could be compared and recommendations could be made. However, the criterion refers to whether the necessary resources to implement the necessary controls are in

place. While the criterion is the same for all Member States, the resources that are necessary in quantitative terms are different for each Member State. The EAC might verify e.g. whether in practice not all necessary controls are planned or implemented in a Member State, or not efficiently implemented, whether this may be linked to lack of necessary resources. Another element to verify within this criterion is to check whether authorities responsible for controls regularly assess their overall capacity and resource needs, based on their enforcement strategy and control programmes, and take appropriate action to address gaps and needs identified. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Placing 'adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under the REACH Regulation in a timely and effective manner' is a legal requirement in the REACH Regulation (Article 121). It is however not included as a specific legal requirement in the CLP, PIC and POPs Regulations. It is also a legal requirement in the Market Surveillance Regulation. Article 10(5) requires that 'Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, such as a sufficient number of competent personnel, expertise, procedures and other arrangements for the proper performance of their duties'.

The provision of adequate resources for enforcement is considered as an important criterion in the Forum paper (section 3.2 Organisation of enforcement and Annex I, criterion A6). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirements for competent authorities to have or have access to 'an adequate laboratory capacity', 'a sufficient number of qualified and experienced staff', and 'appropriate facilities and equipment' in Article 5 of Regulation (EU) 2017/625 or the requirement to 'allocate adequate financial, human and technical resources' to competent authorities in Article 5 of Regulation (EC) 1224/2009.

Criterion 7: Training

Criterion 7: Controllers must receive appropriate training enabling them undertaking their duties competently and performing official controls in a consistent manner.

Subcriterion 7.1: More specifically, controllers must receive appropriate initial and on the job training on control methods and techniques and other core technical or enforcement skills.
Subcriterion 7.2: If several authorities are responsible for controls, effective coordination of training programmes must be implemented, as appropriate.

This criterion is linked to the criterion above related to resources as it aims to ensure that appropriately trained staff is available for performing official controls. This criterion might be controlled by an EAC e.g. by checking, among other elements, that:

- Types and content of training programmes available to controllers are documented and cover both field-specific technical knowledge and core enforcement competencies.
- Frequency of on-the-job training is appropriate.
- Provided training and attendance to training are documented in reports.
- Number of training sessions and trainers are sufficient in relation to the number of controllers.
- Attendance to training is appropriate.
- How the above works in practice, e.g. where potential shortcomings on controls may be identified, whether they may be linked to lack of training/information/knowledge of the staff carrying out the controls or to problems as regards trainings provided.

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

According to feedback received from some experts from Member States authorities, requiring the coordination of training programmes when several enforcement authorities are appointed may not be suitable in Member States where authorities responsible for enforcement have different legal mandates to address specific aspects of EU legislation. According to them, in such cases, training needs may be different and, in their views, it would be more effective that each authority sets up its own training programme. Nevertheless, the fact that different authorities may be responsible for controls seems an argument in favour of coordinating training programmes as the Member State should ensure the consistency of controls. This does not preclude that training programmes may address specific needs for the control of specific aspects of the legislation.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. This criterion is not a legal requirement in the Market Surveillance Regulation, although training programmes and exchanges of personnel are activities that are in the mandate of the Union Product Compliance Network, created by the Regulation, which provides a platform for coordination and cooperation between enforcement authorities of the Member States and the Commission.

Training of inspectors is a stated criterion in the Forum paper (section 3.2 Organisation of enforcement, Annex I, criterion A.6). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement that 'staff performing official controls receive, for their area of competence, appropriate training enabling them to undertake their duties competently', 'receive regular additional training as necessary' and receive training on control methods, techniques and procedures' in Article 5 of Regulation (EU) 2017/625.

Criterion 8: Coordination of enforcement

Criterion 8: Authorities responsible for official controls actively contribute to the exchange of information and coordination of enforcement at the EU level via the Forum for Exchange of Information for Enforcement in ECHA.

Subcriterion 8.1: Authorities responsible for controls contribute to the exchange of information and coordination of enforcement through their participation in the Forum enforcement projects
Subcriterion 8.2: Authorities responsible for controls contribute to the exchange of information and coordination of enforcement through active involvement in Forum discussions, consultations and conclusions
Subcriterion 8.3: Authorities responsible for controls contribute to the exchange of information and coordination of enforcement through their involvement in the Forum working groups
Subcriterion 8.4: Authorities responsible for controls contribute to the exchange of information and coordination of enforcement by taking active lead in the preparation of Forum initiatives by chairing Forum working groups

This criterion aims to ensure that Member States participate in the efforts to achieve coordinated enforcement at EU level. The EAC may control this criterion against the following indicators:

- Member States' participation in Forum projects
- Contribution to consultations & discussions
- Appointing experts to participation to Forum working groups
- Appointing experts as chairs of Forum working groups

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion was added based on feedback received on the preliminary list of criteria to enable the EAC to make recommendations to Member States on their degree of involvement in the work of the Forum.

All Member States have the legal obligation to appoint a member of the Forum (Article 86 of the REACH Regulation). The Forum carries out activities in relation to all regulations (REACH, CLP, PIC and POPs Regulation).

Criterion 9: Internal and external audits

Criterion 9: Authorities responsible for controls should carry out internal audits or have audits carried out on themselves and take appropriate measures to take account of the results of those audits.

- Subcriterion 9.1: All authorities responsible for controls are subject to internal or external audits at reasonable frequency.
- Subcriterion 9.2: Audits should cover all official controls and other official activities of the authorities.
- Subcriterion 9.3: The audit body must be independent, and audits must be carried out in a transparent manner and subject to independent scrutiny.

This criterion aims to verify that criteria relevant to competent authorities are fulfilled and that official controls are carried out according to planned arrangements. This criterion might be controlled by an EAC by reviewing, among other elements, that:

- Audits are effectively carried at a reasonable frequency.
- The audit body or team is independent from the staff involved in managing or supervising the control systems being audited.
- Independence and transparency are guaranteed by a clear mandate given to the audit body or team including the purpose, responsibilities, authority and accountability of the audit body or team, and providing it with adequate powers to carry out the audits.
- Independent scrutiny is a regular and planned process, external to the audit body or team.
- Appropriate actions are taken based on the conclusions of the audit.

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. This criterion is not a legal requirement in the Market Surveillance Regulation, although Article 10(5) requires Member States to ensure that market surveillance authorities have the necessary 'procedures and other arrangements for the proper performance of their duties'.

Reviewing the performance of the enforcement systems, including through audits, is recommended in the Forum paper (section 3.6 Reviewing performance). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement that 'competent authorities carry out internal audits or have audits carried out on themselves and take appropriate measures in the light of the results of those audits' in Article 6 of Regulation (EU) 2017/625.

4.2.3 Criteria related to controls

4.2.3.1 Planning of controls

Criterion 10: Enforcement strategy

Criterion 10: Member States must adopt a multiannual enforcement strategy setting goals, objectives and key enforcement principles.

- Subcriterion 10.1: The Enforcement Strategy is common to all authorities responsible for controls
- Subcriterion 10.2: the enforcement strategy contains the following elements: 1) policy objectives, 2) organisation for effective, efficient, transparent and systematic enforcement, 3) planning enforcement activities, 4) taking enforcement measures, 5) progress monitoring and measurement, 6) procedures for review, evaluation and update of the enforcement strategy, 7) reporting on enforcement.
- Subcriterion 10.3: the enforcement strategy ensures that enforcement is risk-based, effective, efficient (avoids duplication and minimises burden), proportional, focused on compliance promotion, transparent and impartial.
- Subcriterion 10.4: the enforcement strategy identifies priority areas for controls and includes the enforcement activities planned in particular in those areas.
- Subcriterion 10.5: the enforcement strategy establishes a process for including non-routine/reactive control activities – in addition to routine activities – and set aside resources for them, as prioritisation should not prevent that emergency situations are effectively addressed.
- Subcriterion 10.6 the Enforcement Strategy is regularly reviewed and revised.

This criterion aims to ensure that enforcement is planned to respond to defined objectives, prioritised based on risk assessment, coordinated and executed effectively and consistently throughout the Member State. This criterion might be controlled by an EAC by checking, among other elements, that:

- there is a multiannual Strategy and its content includes all the elements covered by the criterion;
- Whether the organisation and controls planned are suitable for achieving the objectives set out
- Whether it is implemented as foreseen and the reasons if not the case
- the strategy is reviewed and revised at an appropriate frequency.

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Some experts from Member States' authorities considered that an enforcement strategy may be more appropriate at the level of the authority than the Member State – as competent authorities may have different mandates and areas of responsibility and should keep the control over their own strategy. However, this criterion aims to ensure the efficiency and consistency of the control system as regards all aspects of the REACH Regulation and in the whole Member State. It is not limited to the control of specific aspects of REACH or controls at national, regional or local level for which specific authorities may be appointed. Partial and not coordinated sectorial approaches would not be sufficient to address this aim. This criterion however does not intend to prescribe which authority(ies) within the Member State should be appointed or at what level an enforcement strategy should be adopted. Whatever the level(s) or authority(ies) chosen for its design, the Member State should ensure that the Strategy and its implementation is consistent across the Member State, taking also into account coordination with authorities dealing with other related areas (e.g. OSH). This criterion does not prevent that a national strategy is based on the coordination/complementarity of several strategies, as far as consistent and efficient control and enforcement of the REACH Regulation is ensured in the Member State. .

This criterion is a legal requirement in the Market Surveillance Regulation. Article 13 requires that 'each Member State shall draw up an overarching national market surveillance strategy, at least every four years', starting from July 2022. According to Article 13, the national strategy must 'promote a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of Union harmonisation legislation within the territory of the Member State'. 'All sectors covered by the Union harmonisation legislation and all stages of the product supply chain, including imports and

digital supply chains', must be considered in the national strategy.

Although not a specific legal requirement for competent authorities in the REACH, CLP, PIC and POPs Regulations, a strategy for enforcement at national level is foreseen in the Forum paper (section 3, Elements of an enforcement strategy for the Regulations; section 3.4.1, Enforcement programmes; and Annex I, criterion B.1 to B.5)–. Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement for a multi-annual national control plan laid down in Article 109 of Regulation (EU) 2017/625.

Criterion 11: Scope of controls

Criterion 11: The planning of controls must cover operators at any stages of the manufacturing, use and placing on the market, all products, ways of placing on the market, and all legal obligations in the legislation.

- Subcriterion 11.1: Controls must cover operators at any stages of the manufacturing, use and placing on the market – manufacturers, importers, only representatives, distributors, and downstream users. The scope of the control will include legal requirements relevant to the role of the dutyholder.
- Subcriterion 11.2: Controls must cover products from Member States and from third countries.
- Subcriterion 11.3: Controls must cover all ways of placing on the market, including online sales.
- Subcriterion 11.4: Control must cover all legal obligations in the legislation imposed on operators..
- Subcriterion 11.5: Authorities responsible for controls must establish and keep up to date a list of operators that are subject to official controls or have access to a list drawn up by other authorities where appropriate.

This criterion aims to ensure that competent authorities consider, when developing their control programmes all aspects and operators subject to obligations in REACH and do not overlook some groups of dutyholders or legal obligations. It however does not preclude risk-based prioritisation of controls (as described below). In relation to this criterion an EAC may verify, among other elements, enforcement strategies and control programmes, reports on controls and horizontal analyses, and how controls are implemented in practice. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Some experts from Member States' competent authorities indicated that the structure of the legislation and enforcement administration in some Member States may prevent that official controls cover all legal obligations under REACH, because these obligations fall under the mandates of different authorities. This may indicate a misunderstanding of this criterion, which only reflects that all legal obligations laid down in REACH must be subject to the control and enforcement of a Member State and therefore should be considered within the relevant control programme. The criterion does not point at which authority or authorities a Member State may appoint for the enforcement of each obligation. As required by Art. 121 REACH (and also reflected under criteria 1 within this study) Member States are required to appoint the competent authorities or competent authorities responsible for performing the tasks allotted to competent authorities under this Regulation. This includes the task to control and enforce REACH requirements and all REACH requirements must be enforced.
There are no specific legal requirements in relation to the scope of controls in the REACH, CLP, PIC and POPs Regulations. The Market Surveillance Regulation provides some requirements in relation to the scope of market surveillance activities in particular in relation to ways of placing on the market. Article 11 provides that market surveillance authorities must conduct their activities to ensure 'effective market surveillance within their territory of products made available online and offline

with respect to products that are subject to Union harmonisation legislation'.

This criterion is included in the Forum paper in section 3.1.1 (Analysis of the risk of non-compliance), Annex I, criterion C(a) and (b), and Annexes II to V. Subcriteria 11.3 and 11.4 are however not specifically included separate requirements. Regulations in other areas also specifically define the scope of the controls to be performed. In addition to general criteria for controls, Regulation (EU) 2017/625 contains requirements specific to the area of legislation controlled, e.g. products of animal origin, food and feed, plant health, animal welfare, plant protection products (Articles 18 to 27). These specific requirements define more specifically what official controls performed by Member States should control in each area. Article 74 of Regulation (EC) 1224/2009 defines the elements that competent authorities' officials should in particular verify during a control (such as legality of the fishing gear, the stowage plan and the separate stowage of species, the marking of gears, and the information on the engine).

Criterion 12: Risk-based planning

Criterion 12: Priorities and frequencies of controls must be defined on a risk-based assessment.

- Subcriterion 12.1: the risk assessment takes into account:
  - The extent of the risks for the human health and the environment of a non-compliance
  - The probability of noncompliance in certain sectors / types of dutyholders
  - Level of knowledge on compliance levels of a specific sector or product type (areas where knowledge is lacking could be prioritised in view of gathering knowledge)
  - Position / responsibility of the operator in the supply chain and volume of substances manufactured/imported or distributed
  - Operators' past control records
  - Essential requirements as prioritised in the Enforcement Strategy – i.e. requirements that are the most significant in ensuring that objectives of the legislation are met
  - The Forum's work programmes and planned enforcement projects

This criterion aims to ensure the effectiveness of the control system by requiring enforcement authorities to focus their resources on the dutyholders, sectors / products, legal obligations that bear the highest risks of non-compliance. This criterion might be controlled by an EAC by checking, among other elements, enforcement strategies and control programmes, reports on controls and horizontal analyses and verifying how controls are planned and implemented in practice and whether reasons for shortcoming may be linked to the application of risk prioritisation. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

One expert from a Member States' competent authority indicated that assessing the general compliance levels on the market – without risk-based prioritisation – should also be allowed for sectors and product-types where implementation problems and probability of non-compliance are less know, making risk-based assessment more difficult. It is our understanding that, if the probability of non-compliances cannot be well assessed for a sector or a product type, this criterion would not prevent a Member State to carry out controls in view of assessing the general compliance levels on the market, as it is an important element to consider in risk prioritisation. The sub-criterion was slightly rephrased to include, among the various elements to consider, the level of knowledge on compliance levels of a specific sector or product type.

This criterion is not a legal requirement in the REACH, CLP, PIC and POPs Regulations.

The Market Surveillance Regulation requires the application of a risk-based approach to controls. Article 11(3) requires that 'in deciding on which checks to perform, on which types of products and on what scale, market surveillance authorities shall follow a risk-based approach taking into account the following factors:

- (a) possible hazards and non-compliance associated with the products and, where available, their occurrence on the market;
- (b) activities and operations under the control of the economic operator;
- (c) the economic operator's past record of non-compliance;
- (d) if relevant, the risk profiling performed by the authorities in charge of the control on products entering the Union market;
- (e) consumer complaints and other information received from other authorities, economic operators, media and other sources that might indicate non-compliance'.

Risk based planning of controls is highlighted as a critical criterion in the Forum paper in section 3.1.1 (Analysis of the risk of non-compliance), 3.1.2. (Priority criteria) and Annex I, criterion B3, which provides indicative criteria for risk-based prioritisation of controls. Criteria applicable in other areas of the legislation also contain provisions in this regard. Article 9 of Regulation (EU) 2017/625 provides that 'competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency'. Article 5(4) of Regulation (EC) 1224/2009 provides that 'Member State shall ensure that control, inspection and enforcement are carried out […] on the basis of risk management.

4.2.3.2 Implementation of controls and reporting

Criterion 13: documented processes and procedures

Criterion 13: Authorities responsible for controls perform control activities according to documented processes and procedures, which ensure impartiality, quality and consistency of controls.

- Subcriterion 13.1: Documented procedures must cover:
  - Tasks and responsibilities of controllers, requirements to be controlled
  - Control methods and techniques, sampling procedures, including laboratory analysis and testing, interpretation of those results and ensuing decisions
  - Promotion of dutyholders' knowledge and understanding of their duties during controls
  - Actions to be taken by controllers following controls
  - Procedures for investigating complaints relating to risks or non-compliance as soon as possible after receipt, and follow-up actions if risk is determined
  - Procedures for investigating accidents or incidents without undue delay after these come to the notice of the relevant authorities, and follow-up if risk is determined
  - Impartiality of staff and fairness of control process
  - Confidentiality obligations for staff carrying out controls

This criterion aims to ensure consistency in the execution of controls by a competent authority by introducing standard protocols and control methods that must be applied by all controllers. This criterion might be controlled by an EAC by e.g. checking, among other elements, that:

- All authorities have complete documented procedures (standard operating procedures, guidance/instruction, checklists)
- Documented procedures are followed when control activities are performed

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation.

This criterion is not a specific legal requirement in the Market Surveillance Regulation, although Article 10(5) requires Member States to ensure that market surveillance authorities have the

necessary 'procedures and other arrangements for the proper performance of their duties'.

This criterion is not specified as a separate criterion in the Forum paper although consistency in the application of the enforcement strategy is a principle included in section 3.5 (Progress monitoring and measurement of performance). Criteria applicable in other areas of the legislation however contain provisions in this regard, such as the requirement that 'competent authorities perform official controls in accordance with documented procedures' in Article 12 of Regulation (EU) 2017/625.

Criterion 14: Control methods

Criterion 14: Authorities responsible for controls perform their activities by means of documentary checks, physical on-site checks and laboratory checks, as appropriate to guarantee the effectiveness of controls. Authorities responsible for controls may perform controls with or without prior notice as necessary.

- Subcriterion 14.1: Authorities responsible for controls perform their activity in a consistent manner, while leaving some margin to controllers to form their opinion on compliance or to adapt the methods to specific situations
- Subcriterion 14.2: Authorities responsible for controls perform their activities as much as possible in such a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary.

This criterion aims to provide for a wide range of activities that controls may involve and also to ensure consistency in the way they are implemented. This criterion might be controlled by an EAC by reviewing, among other elements, control programmes, documented procedures, or reports on controls and horizontal analyses, how controls are implemented in practice, and whether reasons for shortcomings might be linked to control methods. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. Article 11 of the Market Surveillance Regulation requires that 'Market surveillance authorities perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples'.

This criterion is included in the Forum paper in section 3.4 (Enforcement process) and Annex I, criterion C. Subcriterion 14.2 is included in section 3.1 (Policy objectives and priorities). Criteria applicable in other areas of the legislation also contain provisions in this regard. Article 14 of Regulation (EU) 2017/625 provides that official control methods and techniques include as appropriate: inspection of equipment, premises, animals and goods etc.; examination of documents and records; interviews with operators and staff etc. Article 9(5) of Regulation (EU) 2017/625 provides that 'official controls shall be performed as much as possible in such a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary'.

Criterion 15: Reporting on controls

Criterion 15: Authorities responsible for controls must report on all controls performed and their outcomes.

- Subcriterion 15.1: authorities responsible for controls must draft a report The report must contain:
  - Data on the control (date, name of the controller(s), purpose and scope of the control, details of the dutyholder, control methods applied, etc.)
  - The findings and outcomes of the control and identification of non-compliances
  - Conclusion on whether any further actions from the authority should follow, such as formal enforcement or further controls
  - Corrective actions that controllers require the dutyholders to take as a result of the control, and deadlines given to dutyholders to comply.
- Subcriterion 15.2: Reports must be communicated to the dutyholder with an explanation of what action they are required to take to ensure compliance.
- Subcriterion 15.3: Reports must be recorded in writing or in electronic format and kept by the authority in an accessible and retrievable format.
- Subcriterion 15.4: Content of reports should facilitate gathering of data for the Member State reporting on enforcement under Article 117 of REACH, including gathering of statistical data.

This criterion aims to ensure appropriate recording of controls carried out and their follow-up where non-compliances have been found.
This reporting can also contribute to the gathering of data on controls, including statistical data, that may feed in horizontal analysis at national level (see section 2.3.11) and Article 117 reporting. This criterion might be controlled by an EAC e.g., by reviewing, among other elements, processes in place for reporting on controls, the database of control reports, the completeness and quality of reports, whether reports have been transmitted to dutyholders, and whether reasons for shortcomings in the system may be linked to reporting. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

The feedback received from Member States authorities' experts indicated that requiring the production of a control report on all controls (which may include various activities, including purely desktop assessments or Customs controls on products) would be excessively resource-intensive for competent authorities. In addition, it was mentioned that this criterion was hindering the ability of inspectors to provide verbal advice only, which is provided for in the legislation in some Member States. Nevertheless, written records of controls performed, their outcome and, where relevant, follow up, play an important role in ensuring legal certainty, equal treatment and an effective implementation of the right of defense. Comments were also received that a link should be made between this criterion and the reporting exercise under Article 117 of REACH as recording and reporting on individual controls can facilitate the EU reporting. This link was added in sub-criterion 15.4.

This criterion is not specified as a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation.

Under the Market Surveillance Regulation, Member States have an obligation to report into the information and communication system, developed by the Commission, all relevant information, including results of testing, measures taken by market surveillance authorities, corrective action taken by economic operators concerned, when a compliance check of products entering the EU

market has taken place (Article 34 of the Market Surveillance Regulation). Every year, Member States must submit to the Commission detailed statistical data covering controls on products entering the EU market by customs authorities and market surveillance authorities (Article 25(6)).

This criterion is included in the Forum paper in section 3.4.5 (Reporting on enforcement activities to the duty holder) and Annex I (criterion D). Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement for competent authorities to draw up written records of every official control and inform operators of any non-compliance identified during the control in Article 13 of Regulation (EU) 2017/625. A similar requirement is included in Article 76 of Regulation (EC) 1224/2009, in which officials performing the controls are required to draw up an inspection report after each inspection and forward it to their competent authorities; findings from the inspection is also provided to the operator, who has the possibility to comment. The operator's comments must be reflected in the inspection report (Article 76(2) of Regulation (EC) 1224/2009).

Criterion 16: Follow-up on controls

Criterion 16: When non-compliances are identified, authorities responsible for controls must require the dutyholder to take appropriate corrective action to bring the non-compliance to an end within a given period of time and prevent further occurrences of such non-compliance, and follow-up with the dutyholder.

- Subcriterion 16.1: The corrective action to be taken by the dutyholder may include:
  - Rectifying the non-compliance
  - Stop selling, withdrawing or recalling products from the market and notifying the public
  - Destroying non-compliant products
- Subcriterion 16.2: The corrective action must be proportionate to the non-compliance and take into account the nature of the non-compliance and the dutyholder's past track record.
- Subcriterion 16.3: Authorities responsible for controls provide the dutyholders with a notification of their decision concerning the action or measure to be taken.
- Subcriterion 16.4: Authorities responsible for controls must establish appropriate procedures for verifying that the corrective action that was to be taken by economic operators has been taken, including through follow-up controls once the deadline given to the dutyholder has passed.

This criterion aims to ensure that remedial actions are taken to end non-compliances identified through official controls, thereby ensuring the effectiveness of the control system. This criterion might be controlled by an EAC by reviewing, among other elements, that:

- appropriate follow-up procedure is in place allowing the monitoring of implementation of corrective action;
- appropriate monitoring tools (including IT) are in place to allow the effective monitoring of deadlines for corrective actions given to dutyholders and organise follow-up controls;
- whether shortcomings in the controls system may be linked to lack of or insufficient follow-up.

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. As per Article 11(7) of the Market Surveillance Regulation, market surveillance authorities must establish 'procedures for verifying that the corrective action that was to be taken by economic operators has been taken'. Article 16(2) further requires that where market surveillance authorities find that a product does not conform to Union harmonisation legislation, 'they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk within a period they specify'. 'The corrective action required to be taken by the economic

operator may include, inter alia:

- (a) bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;
- (b) preventing the product from being made available on the market;
- (c) withdrawing or recalling the product immediately and alerting the public to the risk presented; (d) destroying the product or otherwise rendering it inoperable;
- (e) affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;
- (f) setting prior conditions for making the product concerned available on the market;
- (g) alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market (Article 16(3)).

This criterion is also included in the Forum paper in section 3.4.4. (Enforcement actions) and Annex I, criterion C(l) and D. Criteria applicable in other areas of the legislation also contain provisions in this regard. Article 138 of Regulation (EU) 2017/625 provides that 'where a non-compliance is established, the competent authorities shall take […] appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance'. Similarly, Article 85 of Regulation (EC) 1224/2009 provides that where an infringement is detected during or after an inspection, the competent authorities of the inspecting Member State must take appropriate measures against the master of the vessel or any other legal or natural person responsible for the infringement.

Criterion 17: Enforcement measures and penalties

Criterion 17: When dutyholders fail to take corrective actions or if the non-compliance persists, authorities responsible for controls must take appropriate measures to bring the noncompliance to an end and when justified, impose penalties

- Subcriterion 17.1: Measures may include :
  - Verbal or written advice
  - Administrative measures/orders
  - Withdrawal/recall of products from the market, confiscation or seizure, ban of sale/use, or destruction of non-compliant products
  - Fines
  - Prohibition of activities e.g., by suspension of business licence
  - Withdrawal of the activity permit
  - Referral to state prosecutor office
- Subcriterion 17.2: Enforcement measures and penalties must be proportional to the risk caused by the non-compliance. Their severity should be adjustable to take account of the following:
  - The hazard presented by the substance, the tonnage of substance placed on the market
  - The magnitude of risks to human health or the environment,
  - The extent of the contravention
  - The size of the duty holder and its position in the supply chain
  - The history of inspection of the dutyholder – whether the contravention is part of a pattern
  - The intention of the duty holder in non-compliance – whether the contravention results from mistakes or negligence, if it results from the actions of a third person, whether the dutyholder took action to avoid the contravention
  - The level of cooperation and willingness to act of the dutyholder
  - The duration of non-compliance
- Subcritrion 17.3: Measures and penalties available must allow for effective enforcement of all duties and all duty holders under REACH.
- Subcriterion 17.4: Measures and Penalties must be sufficiently severe to ensure a deterrent effect and increase in case of recidivism or aggravating circumstances.

This criterion aims to bring to an end non-compliances identified through official controls and to sanction non-compliant activities. Penalties also have a deterrent effect on non-compliance. Enforcement measures thereby aim to ensure the effectiveness of the control and enforcement system and the compliance with REACH. It is critical for the effectiveness of the control system and is one criterion in the list that was mentioned as being the most often failed by Member States (for instance, Member States not taking action to bring non compliances to an end is the criterion that led to most infringement procedures initiated by DG SANTE). This criterion might be controlled by an EAC by reviewing, among other elements, the range of enforcement measures and penalties competent authorities have at their disposal, whether they are proportional, effective and dissuasive, and evidence that such measures and penalties were adopted by the authorities in cases of non-compliance. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

The REACH, CLP, PIC and POPs Regulations all require Member States to lay down provisions in national legislation establishing effective, proportionate and dissuasive penalties for infringement of the Regulations, and take all measures necessary to ensure that they are implemented (Article 126 of the REACH Regulation, Article 47 of the CLP Regulation, Article 28 of the PIC Regulation, Article 14 of the POPs Regulation). Article 16(5) of the Market Surveillance Regulation provides that 'If the economic operator fails to take corrective action or where the non-compliance or the risk persists, market surveillance authorities shall ensure that the product is withdrawn or recalled, or that its being

made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly'. Article 41 requires Member States to lay down provisions on effective, proportionate and dissuasive penalties applicable to infringements of the Regulation and of Union harmonisation legislation listed in Annex II of the Regulation that impose obligations on economic operators, and to take all necessary measures to ensure that they are implemented.

This criterion is detailed in the Forum paper in section 3.4.4. (Enforcement actions), which provides examples of formal enforcement measures/actions. Regulations in other areas also contain similar provisions on effective, proportionate and dissuasive penalties (Article 139 of Regulation (EU) 2017/625, Article 89 of Regulation (EC) 1224/2009).

Criterion 18: Right of appeal and formal complaints

Criterion 18: Provisions for making formal complaints and for appealing decisions taken by authorities as a result of controls must be provided for in national law.

- Subcriterion 18.1: Procedures to appeal enforcement decisions are in place, are easily accessible and are well publicised.
- Subcriterion 18.2: Procedures allowing dutyholders to make formal complaints on the implementation of a specific control are in place, easily accessible are well publicised and complaints are addressed.

This criterion aims to ensure a clear and fair process for all dutyholders by guaranteeing their right to appeal a decision and file a complaint. This criterion might be controlled by an EAC by reviewing, among other elements, provisions in the national law and evidence that the procedures are well-publicised (through channels that dutyholders regularly go to) and easily accessible. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, CLP Regulation, the PIC Regulation and the POPs Regulation. This criterion is also not a legal requirement in the Market Surveillance Regulation.

This criterion is not specified as a separate criterion in the Forum paper. Criteria applicable in other areas of the legislation however contain provisions in this regard. Article 7 of Regulation (EU) 2017/625 provides that 'decisions taken by the competent authorities […] concerning natural or legal persons shall be subject to such persons' right of appeal in accordance with national law'.

Criterion 19: Transparency

Criterion 19: Authorities responsible for controls must perform their activities with a high level of transparency and must make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls.

- Subcriterion 19.1: Authorities responsible for controls make available to the public, including through publication on the internet, information on enforcement authorities, their mandate, tasks and responsibilities and ways to contact them.
- Subcriterion 19.2: Authorities responsible for controls make available to the public, including through publication on the internet, aggregated data on controls performed (type, number, outcome), cases of non-compliance identified, measure taken to remedy those non-compliances and penalties imposed, through, for instance, the publication of an annual report (see 'horizontal analysis' below), without revealing any confidential information related to dutyholders. The extent of information made publicly available is left to the discretion of the

competent authority.

This criterion aims to ensure transparency towards operators with regards to the organisation of controls and to increase public trust in the effectiveness of national enforcement systems. This criterion might be controlled by an EAC by reviewing, among other elements, the availability and easy access to information online. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Based on the feedback received from Member States' authorities that information gathered through controls could be sensitive and the publication of official reports could lead to unwanted effects or misuse of information by dutyholders, the criterion was revised to include that the extent of information made publicly available is left to the discretion of the competent authority.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation, and the POPs Regulation, although all regulations contain legal requirements for reporting on enforcement activities carried out by Member States (see above). Reporting requirements may not fully replace the criterion as they do not lead to the publication of easily accessible information in the national language.

Requirements under the Market Surveillance Regulation mentioned above (Article 34) may not fully replace the criterion as they relate to exchange of information between Member States.

Subcriterion 19.1 is included as a separate criterion in the Forum paper (Annex I, criterion A3). Subcriterion 19.2 is recommended in section 3.5.1 (Enforcement reports) of the Forum paper, for example to inform the public about actions taken in relation to non-compliances. Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement in Article 11 of Regulation (EU) 2017/625 that competent authorities 'perform official controls with a high level of transparency and, at least once a year, make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls'.

4.2.4 Criteria related to quality management and evaluation

Criterion 20: Horizontal analysis

Criterion 20: Results from controls are analysed horizontally, in the form of, for instance, an annual enforcement report, to provide an overall picture of the level of compliance at national level, which may inform the planning of future controls.

- Subcriterion 20.1: The horizontal analysis assesses main areas of non-compliances and of the underlying factors behind non-compliances.
- Subcriterion 20.2: Conclusions from the horizontal analysis are taken into account by competent authorities when planning future controls.
- Subcriterion 20.3: Results from the analysis are shared within the competent authority.
- Subcriterion 20.4: The horizontal analysis includes collecting the data needed for the Member State report required under Article 117 of REACH.

This criterion aims to ensure that results of controls inform the prioritisation and the planning of future controls. It may also facilitate reporting. This criterion might be controlled by an EAC by reviewing, among other elements, the availability of (annual) reports and evidence that conclusions are incorporated in planning of controls. It is to note that these are only potential examples and do

not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Based on feedback received, the criterion was revised to include a link to the Member State report required under Article 117 of REACH, which contains a section on enforcement requiring Member States to report on overall numbers of controls and level and causes of non-compliances.

This criterion is not as such a legal requirement for competent authorities in the REACH Regulation, although reporting on enforcement is mandatory as per Article 117(1). Similarly, this criterion is not as such a legal requirement in the CLP Regulation, the PIC Regulation, and the POPs Regulation, although all regulations contain legal requirements for reporting on enforcement activities carried out by Member States (Article 46 of the CLP Regulation, Article 22 of the PIC Regulation and Article 13 of the POPs Regulation). These obligations are however primarily intended for EU level reporting and do not require that this information is used for future control prioritisation and planning by Member States.

Under the Market Surveillance Regulation, Member States have an obligation to report into the information and communication system, developed by the Commission, all relevant information, including results of testing, measures taken by market surveillance authorities, corrective action taken by economic operators concerned, when a compliance check has taken place (Article 34 of the Market Surveillance Regulation). This obligation is however primarily intended for sharing information across Member States and does not require that this information is used for future control prioritisation and planning.

Collating information from individual control reports into horizontal analysis is recommended in the Forum paper (section 3.5.1 Enforcement reports) for both communication and Article 117(1) reporting purposes. Criteria applicable in other areas of the legislation contain provisions in this regard, such as the requirement for Member States to submit every year to the Commission a report setting out the outcome of official controls performed in the previous year under the multi-annual national control plans, the type and number of cases of non-compliance, the measures taken, including enforcement action and the results of such measures in Article 113 of Regulation (EU) 2017/625. In addition, Article 111(2) requires Member States to regularly update their multi-annual national control plans taking into account the outcomes of official controls.

Criterion 21: Quality control and control verification procedures

Criterion 21: Authorities responsible for controls must have quality control and control verification procedures in place.

- Subcriterion 21.1: Quality control and control verification procedures establish routine checks to ensure that control programmes are implemented as planned, that plans are effective to address their objectives and that controls are implemented according to documented procedures.
- Subcriterion 21.2: Authorities responsible for controls should take corrective actions when issues have been identified during quality control. .
- Subcriterion 21.3: Outcomes of the quality control procedures may lead, as appropriate, to revising the organisation and functioning of the control system, documented procedures for controls and control methods and techniques.

This criterion aims to ensure the good functioning of the control system and ensure that shortcoming identified are addressed. This criterion might be controlled by an EAC by reviewing, among other elements, quality control / verification procedures in place and evidence that outcomes of quality controls lead to changes in control procedures where appropriate. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Some feedback received from experts from Member States' authorities pointed to the possibility that a quality control system may apply to a whole entity . It is to note that it is up to the Member State to decide whether they want to apply a single set of quality control and verification procedures for the whole control system or procedures specific to each competent authority to fulfil this criterion. Feedback was received that such quality control procedures are resource-intensive and this criterion might create significant administrative burden for Member States' competent authorities.
This criterion is not a legal requirement for competent authorities in the REACH Regulation the CLP Regulation, the PIC Regulation and the POPs Regulation. This criterion is not a legal requirement in the Market Surveillance Regulation.

This criterion is not specified as a separate criterion from 'internal evaluation' (criterion 22 below) in the Forum paper but is addressed in its section 3.5 (Progress monitoring and measurement of performance), which recommends setting up tools for periodical monitoring and measurement of the progress achieved. Criteria applicable in other areas of the legislation also contain provisions in this regard, such as the requirement for competent authorities to have control verification procedures in place in Article 12 of Regulation (EU) 2017/625.

Criterion 22: Evaluation of the effectiveness of the control system

Criterion 22: Authorities responsible for controls regularly evaluate the effectiveness of the control system.

- Subcriterion 22.1: Authorities responsible for controls regularly evaluate the proper functioning and the effectiveness of the control system, in particular whether the system is set up, organised and implemented in such a way that it ensures the detection of non-compliances, and that corrective action is taken.
- Subcriterion 22.2: The evaluation takes into account the results of internal and external audits (Criterion 9), quality control and verification procedures (criterion 21), horizontal analyses (criterion 20) and feedback of dutyholders (criterion 23).
- Subcriterion 22.3: Conclusions from the evaluation may lead, as appropriate, to revising the organisation of the control system or the enforcement strategy and priorities.
- Subcriterion 22.4: Results from the evaluation are shared within the authority.
- Subcriterion 22.5 (Optional): The evaluation may take into account a set of performance indicators set at national level as they may reflect whether the system was implemented as planned and the outcome of such implementation. Performance indicators may include, inter alia, the share of dutyholders controlled, the overall compliance rate of dutyholders, the number of routine vs non routine activities and their outcomes, the number of follow-up controls and their outcomes. Performance indicators remain the same from one evaluation to the next and are common to all authorities responsible for enforcement.

This criterion aims to ensure a critical review by the competent authority of the effectiveness of the entire control system as designed and implemented, from the strategy and objectives set out, the control programme defined, to the resources and measures put in place and implemented. Shortcomings detected should be corrected and the outcome of such evaluation should feed in the next strategy/planning. This criterion might be controlled by an EAC by checking, among other elements, that:

- Evaluations of the effectiveness of the control process are carried out by relevant authorities responsible for controls.
- Should there be an alert for an important non-compliance, the evaluation addresses the weaknesses in the system that did not prevent it to materialise.
- Actions are taken based on the conclusions of the evaluations and uptake is being monitored

It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot

verifications.

Several experts from Member States considered that establishing internal evaluation procedures as laid down in the criterion would be resource-intensive and might create significant administrative burden for Member States' competent authorities. It is to note that it is up to the Member State to decide on the practical implementation of the evaluation procedure, including on whether they want to apply a single evaluation procedure for the whole control system or procedures specific to each competent authority to fulfil this criterion. Nevertheless, Member States should ensure the consistency and effectiveness of the control system for REACH as a whole.

This criterion is not a legal requirement for competent authorities in the REACH Regulation the CLP Regulation, the PIC Regulation, and the POPs Regulation. This criterion is not a legal requirement in the Market Surveillance Regulation, although Article 10(5) requires Member States to ensure that market surveillance authorities have the necessary 'procedures and other arrangements for the proper performance of their duties'.

This criterion is included in the Forum paper (section 3.5 Progress monitoring and measurement of performance). The paper also refers to the use of appropriate performance indicators (section 3.5.2), which are listed in Annex VII (Member State enforcement indicators). Some of the Regulations considered in other areas include provisions related to the evaluation of the control system. Regulation (EU) 2017/625 includes, in addition to the requirement that competent authorities are subject to internal or external audits (see criterion 9), that competent authorities have 'procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities' (Article 5(1)).

Criterion 23: Feedback from controlled dutyholders

Criterion 23: Authorities responsible for controls should seek feedback from controlled dutyholders after controls, for instance through the dissemination of a feedback questionnaire, and/or have communication channels in place through which controlled dutyholders may ask questions or provide feedback.

This criterion aims to gather critical feedback from controlled dutyholders in view of improving the overall control system. This criterion might be controlled by an EAC by checking, among other elements, the existence and functioning of the feedback mechanism and communications channels. It is to note that these are only potential examples and do not intend to define or prejudge elements or evidence that may be verified by an EAC or audit techniques, including interviews and on the spot verifications.

Several experts from Member States considered that establishing such a feedback system might lead to a significant workload for the authority and may be redundant with existing communication channels through which controlled operators or federations can ask questions following controls. The criterion was revised so that it is not phrased as an obligation and is more flexible to cover communication channels that may already exist in Member States.

This criterion is not a legal requirement for competent authorities in the REACH Regulation, the CLP Regulation, the PIC Regulation and the POPs Regulation. This criterion is also not a legal requirement in the Market Surveillance Regulation.

This criterion is not specified as a separate criterion in the Forum paper or in Regulations considered in other areas.

4.3 OPTIONS FOR IMPLEMENTING THE CRITERIA

The following section assesses possible options for implementing the criteria

4.3.1 Common criteria provided in a guidance document

One option to be considered would be to lay down the enforcement criteria in a guidance document, which may be drafted in consultation with ECHA and the Forum. As the criteria would not be legally binding, the EAC would not have the mandate to require Member States to take corrective actions to remedy identified shortcomings in their control systems and to follow up with Member States on implementation of these corrective actions. The EAC could however still issue recommendations to the Member State's competent authority to improve the effectiveness of its control system. The implementation of the recommendations would depend on Member States' buy-in. This option is therefore likely to result in less Member States taking corrective actions compared to the option of laying down binding criteria, which may be more successful in ensuring the effectiveness of official control systems throughout the EU. This option is also likely to achieve a lower level of harmonisation among Member States' enforcement policies and practices than binding criteria.

In the survey carried out for this study among experts from Member States' competent authorities, around half of the respondents (27 out of 53) did not agree with the option of having binding criteria laid down in legislation. Their answers may have been impacted by their overall opinion of the establishment of an EAC (respondents who disagreed with the establishment of an EAC often disagreed with the introduction of binding criteria and with the relevance of the criteria themselves). Those that commented on the option to lay down criteria in a guidance document, underlined that a guidance would be more flexible to adapt to different enforcement systems and structures at national level, and easier to revise if necessary. As the survey indicated that amending legislation to adopt legally binding enforcement criteria might face strong opposition from Member States, this option, although less effective, may reach a higher level of acceptance among Member States.

Furthermore, such non-binding guidance would have to 'co-habit' with binding enforcement criteria that market surveillance authorities in charge of monitoring REACH 'placing on the market' provisions will have to comply with. This may lead to a complex regime where for certain REACH requirements binding enforcement criteria must be applied by competent authorities whereas for other REACH requirements there would be non-binding enforcement criteria.

According to the above, this is therefore unlikely to be the best option.

4.3.2 Binding common criteria

To become binding, the criteria proposed in section 4.2 should be laid down in EU legislation – for instance directly in REACH or in a new Regulation establishing the EAC. Several options for incorporating the criteria in the legislation are proposed in section 5.1. Binding common criteria would enable the EAC to control their implementation, require Member States to take corrective actions to remedy identified shortcomings in their control systems and follow-up on the implementation of these corrective actions, thereby contributing to the effectiveness of national control systems. Furthermore, the option of legally binding criteria is likely to achieve a higher level of harmonisation of enforcement practices among Member States compared to non-binding criteria laid down in a guidance. In the survey carried out for this study among experts from Member States' competent authorities, about a fourth of respondents (14 out of 53) supported the inclusion of the criteria as binding elements in the legislation. In addition to the fact that binding criteria contribute to harmonisation of enforcement, some of these respondents underlined that binding criteria may increase legal certainty for Member States and may support competent authorities in leveraging more funding for enforcement to ensure compliance with the criteria.

Within the context of setting an EAC, binding common criteria seems, based on the above, the most

adequate option. However, this option will have to consider the interface with the Market Surveillance Regulation.

4.3.2.1 Using only criteria in the Market Surveillance Regulation

Enforcement criteria already included in the Market Surveillance Regulation, are the following:

- Criterion 1 – designation of competent authorities
- Criterion 2 – prevention of conflict of interest
- Criterion 4 – powers of competent authorities
- Criterion 5 – coordination and cooperation between competent authorities
- Criterion 6 – resources
- Criterion 9 – enforcement strategy
- Criterion 10 – scope of controls
- Criterion 11 – risk-based planning of controls
- Criterion 13 – control methods
- Criterion 14 – reporting (only partially as no requirement to share the report with the operator)
- Criterion 15 – follow-up
- Criterion 16 – enforcement measures and penalties

Member State authorities that enforce REACH 'place on the market' provisions (see table 45) are subject to these criteria. Indeed, according to its Article 2(1), the Market Surveillance Regulation applies to the enforcement of requirements on products to be made available on the market or made available on the market 'that are subject to the Union harmonisation legislation listed in Annex I' of the Regulation, in which, among others, the REACH Regulation is listed. The Market Surveillance Regulation therefore applies to obligations in REACH related to substances on their own, in mixtures or in articles placed or to be placed on the market, i.e. provisions which aim to ensure that only compliant products are made available on the EU market.

Table 43: Examples of REACH enforceable requirements related to obligations for products made available on the market that would fall under the enforcement regime of the Market Surveillance Regulation

Article	REACH requirements related to the placing on the market of substances on their own, in mixtures or in articles falling under the enforcement regime of the Market Surveillance Regulation
5	Prohibition on placing on the market of substances on their own, in mixtures or in articles unless they have been registered
8(1) and (2)	A person established outside the Community may designate a person inside the Community as its OR, which will be done through a letter of appointment. The OR will then have to fulfil the obligations for registration imposed on importers. Requirement on a representative to keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the SDS
31	Requirement on a supplier of a substance or a mixture to provide recipient with a SDS
56(1)	Requirements on manufacturers, importers, or downstream users not to place a substance on the market for a use if that substance is included in Annex XIV unless sub-paragraph (a), (b), (c), (d) or (e) are satisfied.
65	Requirement on a holder of an authorisation and downstream users to include the authorisation number on the label before they place the substance or mixture on the market for an authorised use
67(1)	Prohibition on placing on the market of a substance on its own, in a mixture or in an article for which Annex XVII contains a restriction unless the manufacture, placing on the market or use of a substance on its own complies with the conditions of that restriction

Other enforceable requirements under REACH may not fall under the Market Surveillance Regulation. This includes core obligations like:

- The requirement on a manufacturer and importer to inform ECHA of the additional information they would require when a registration reaches the next tonnage threshold

(Article 12(2))
- The requirement on a registrant to apply the appropriate measures to adequately control the risks identified in the CSA (Article 14(6))
- The requirement for registrants to keep their registration up to date without undue delays (Article 22(1))
- The requirements on downstream users not to use a substance otherwise than in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use (56(2))
- The requirement to ensure the respect of the conditions linked to the authorisation for the use of a substance (Article (60(8))
- Certain restrictions concerning the use of substances that may be included in Annex XVII to REACH and that are not related to a requirement that the substance or product containing it needs to comply to be placed on the market

It is to note however that the line between requirements in REACH for products available on the market and other obligations is not always straightforward. The lists above is based on the consultant own assessment and only the interpretation of the Court of Justice has a binding force.

Based on feedback received during the Member State experts focus group, it is most likely that the same enforcement authorities in Member States are in charge of enforcing both REACH 'placing on the market' related requirements and the other enforceable REACH requirements not falling under the Market Surveillance Regulation. Therefore, it should not be a major change for these enforcement authorities to comply with these enforcement criteria for all REACH enforceable requirements. It may in fact limit administrative burden and additional legal complexities. The Market Surveillance Regulation criteria are general and could therefore be easily applied by enforcement authorities in charge of REACH. However, several criteria identified under this section 4 are not reflected in the Market Surveillance Regulation:

- General obligation to ensure effectiveness of controls (criterion 3)
- Training (criterion 7)
- Coordinated enforcement (criterion 8)
- Internal and external audits (criterion 9)
- Right of appeal and formal complaints (criterion 18)
- Transparency (criterion 19)
- Horizontal analysis (criterion 20)
- Quality control and control verification procedures (Criterion 21)
- Internal evaluation (criterion 22)
- Feedback from controlled dutyholder (criterion 23)

Finally, to ensure that the Market Surveillance Regulation enforcement criteria are also applied to enforcement authorities in charge of REACH requirements other than the ones related to the placing on the market, some legal changes are needed to fill this gap as detailed under Section 5.1.1.1.

4.3.2.2 Develop enforcement criteria out of the scope of the Market Surveillance Regulation

Another option would be to set binding enforcement criteria that would only apply within the context of REACH or EU chemical legislation. In such case these criteria would prevail over the ones set under the Market Surveillance Regulation. According to its Article 2, the Market Surveillance Regulation: '*applies to products that are subject to the Union harmonisation legislation listed in Annex I ('Union harmonisation legislation'), in so far as there are no specific provisions with the same objective in the Union harmonisation legislation, which* ***regulate in a more specific manner particular aspects of market surveillance and enforcement'*** [emphasis added]. Such option would ensure more leeway in defining enforcement criteria. For example, under such approach, enforcement criteria not covered by the Market Surveillance Regulation and identified under Task 3

could also be applied by competent authorities in charge of enforcing REACH.

5. PROPOSAL FOR INCORPORATION INTO EU LEGISLATION

5.1 PROPOSAL FOR INCLUDING CRITERIA / STANDARDS FOR MEMBER STATES' CONTROL SYSTEMS IN THE LEGISLATION

The main objective of the study is to identify how to best establish a EAC to ensure compliance with and effective national control and enforcement systems for the REACH Regulation throughout the EU. To this end, some options have been developed (see Section 3). An important element of establishing an Audit Capacity are the criteria against which it will perform its control activities. These have been developed in Section 4.1 – 4.3.

Should the Commission decide to adopt (some of) the enforcement criteria, it needs to assess the most effective way to integrate them in the current (legal) framework. This section investigates several options to do so. The objective that the criteria are used by the Audit Capacity is considered, but also the possibility that the criteria are adopted stand-alone to harmonise enforcement of REACH, CLP, POPs and PIC across the EU.

5.1.1 Incorporation of enforcement criteria in REACH

Enforcement of the provisions of the REACH Regulation by the Member States is addressed in **Article 125** REACH. It requires Member States to maintain "*a system of official controls and other activities as appropriate to the circumstances*".

In addition, **Article 126** obligates Member States to lay down the provisions on penalties for infringement of the REACH provisions and to take all measures necessary to ensure that they are implemented. The penalties provided for must be "*effective, proportionate and dissuasive*".

Member States must appoint a competent authority and allocate adequate resources to enable it to fulfil its tasks in a timely and effective manner, pursuant to **Article 121** REACH. A cooperation between the competent authorities is required under **Article 122** REACH.

Member States are also required to report to the Commission on their activities in relation to enforcement, including the results of the official inspections, the monitoring carried out, the penalties provided for, and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period, according to Article 127 REACH. The common issues to be covered in the reports must be agreed by the Forum. The Commission makes these reports available to ECHA and the Forum.

The REACH Regulation, however, does not specify what elements should be considered in that system of official controls, how it should be organised or the enforcement actions to be taken and merely provides for a minimum framework. It is then left for the Member States to set up more detailed rules. The Forum, which is a body of ECHA and consists of representatives of Member States' competent authorities, aims to exchange information and coordinate enforcement activities among the Member States. In 2017, it adopted "Strategies and minimum criteria for enforcement of Chemical Regulations"[195] providing a framework and general recommendations for developing the national REACH, CLP, PIC and BPR enforcement strategies within the Member States concerned. The document is, however, not legally binding on national enforcement authorities.

When considering enshrining the enforcement criteria in legislation it needs to be assessed whether

[195] ECHA, Strategies and minimum criteria for enforcement of Chemical Regulations, adopted 06/12/2017, available at: https://echa.europa.eu/about-us/who-we-are/enforcement-forum.

this is in line with the subsidiarity principle. The subsidiarity principle provides that, in areas which do not fall within its exclusive competence, the Union is authorised to act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level[196]. At least the following three arguments can be made in favour of adopting enforcement criteria at EU level: First, as mentioned in Section 3.1., studies and data, such as the latest evaluation[197] of REACH, point at a need for increasing compliance and improving enforcement across the Member States. Laying down enforcement criteria that are applicable in all Member States will increase effectiveness of enforcement. Second, the concrete enforcement activities fall within the competence of Member States' national authorities, and this will not change by laying down enforcement criteria.

Third, binding enforcement criteria help ensuring a level playing field and avoid 'forum shopping' by operators. This will improve the functioning of the internal market.

The fact that the legal basis of the REACH Regulation is Article 95 TEC (now: Article 114 TFEU) aiming at the establishment and functioning of the internal market therefore also strengthens this position.

The following scenarios to lay down binding enforcement criteria could be considered by the Commission:

5.1.1.1 Scenario 1: Apply MSR criteria to entire REACH scope

The Commission could opt for applying the same enforcement criteria as set out in the Market Surveillance Regulation to the whole scope of the national control of REACH The advantage of this scenario would obviously be the coherence with the criteria set out in the Market Surveillance Regulation that already apply to most of the scope of the national control of REACH.

This option would ensure a high level of harmonisation of enforcement of REACH among the Member States and would serve as a good basis for audits carried out by the EAC should it be established.

Before the Lisbon Treaty introduced a distinction between 'delegated acts' and 'implementing acts', the making of secondary measures was governed by Article 202 TEC that allowed delegation of the power to the Commission for the 'implementation' of rules, subject to the Comitology procedure.[198] The spectrum of measures that was covered by this empowerment was very broad and included 'pure' rulemaking at the one end and 'pure' implementation on the other.[199]

REACH has not been 'lisbonised' yet, i.e., it has not been adapted to the Lisbon Treaty that put in place two procedures for adopting secondary legislation: the delegated acts procedure and the implementing acts procedure. Therefore, adopting binding enforcement criteria could still be done under the pre-Lisbon regime if it could be considered to implement one or several of the existing REACH provisions on the basis of Article 132 of REACH. Pursuant to that Article, the measures necessary to put the provisions of REACH efficiently into effect should be adopted in accordance with the procedure referred to in Article 133(3). The latter refers to the regulatory procedure provided for in Article 5 and 7 of Decision 1999/468/EC, which has been repealed and replaced by Comitology Regulation (EU) No 182/2011. The advantage of this procedure would be that a lengthy ordinary

[196] Article 5(5) Treaty on European Union (TEU).

[197] COM(2018) 116 final and SWD(2018) 58 final.

[198] Art. 202 EC: "To ensure that the objectives set out in this Treaty are attained the Council shall, in accordance with the provisions of this Treaty: […] confer on the Commission, in the acts which the Council adopts, powers for the implementation of the rules which the Council lays down."

[199] P. Craig, G. de Burca, EU Law, 2020, p.148.

legislative procedure involving European Parliament and the Council could be avoided. Representatives of the Member States would nevertheless be involved and would need to vote on the proposal to be submitted by the Commission. This option does not, however, seem to be in line with the intention of the legislator. As mentioned above, the legislator set merely a very general requirement for Member States to appoint a competent authority and maintain an enforcement system, thereby leaving Member States very much discretion as to how to shape the competent authority and organise the enforcement activities in detail. The enforcement of EU legislation is in general under the competence of the Member States and there is no indication that the legislator wanted to differ from this rule in the case of REACH. The adoption of binding enforcement criteria would therefore not be considered as 'implementing' any of the above-mentioned Articles of REACH.

Therefore, ordinary legislative procedure would be necessary to adopt an amendment of Articles 121 (designation of competent authorities) and 125 (enforcement system) of REACH. The amendment could include a reference to the relevant Articles of the Market Surveillance Regulation, notably Articles 10, 11, 13, 14, 15, 25, 34, respectively. The ordinary procedure is the main legislative procedure of the EU's decision-making system having its legal basis in Article 294 of the Treaty on the Functioning of the European Union (the former Article 251 TEC which is referred to in the REACH Regulation as it predates the TFEU). Due to the involvement of three EU institutions, namely Commission, Council and Parliament, and mandatory procedural rules, the procedure is lengthy (for new legislation it can easily take three years) but may be shortened by informal trialogue discussions.

5.1.1.2 Scenario 2: Adopt a new Annex to REACH

The Commission could set out the enforcement criteria in a new Annex to REACH. This option is particularly relevant for the case the Commission decides also to adopt the criteria developed under Task 3 (see Section 4) and no referencing to the MSR would suffice. As in scenario 2, this would also require an amendment of Articles 121, 122, 125, 126 REACH that would need to refer to the new Annex for it to become effective. The key provision to be amended would obviously be Article 125 on enforcement. It would need to refer to the Annex setting out the specific enforcement criteria. Article 121 would need to refer to the Annex if the latter will contain criteria that concern the competent authority, e.g., regarding the allocation of resources. If the adopted enforcement criteria contain provisions on international cooperation, Article 122 would also need to refer to the Annex. If penalties are specified in the Annex, Article 125 would need to refer to it, too. The legal basis would be the same as for the REACH Regulation, hence Article 95 TEC, now 114 TFEU. This could only be done by ordinary procedure. The ordinary legislative procedure is the main legislative procedure of the EU's decision-making system having its legal basis in Article 294 of the Treaty on the Functioning of the European Union (the former Article 251 TEC which is referred to in the REACH Regulation as it predates the TFEU). Due to the involvement of three EU institutions, namely Commission, Council and Parliament, and mandatory procedural rules, the procedure is lengthy (for new legislation it can easily take three years) but may be shortened by informal trialogue discussions.

As mentioned in Section 4.3.2.2 above, the Market Surveillance Regulation is applicable in so far as the enforcement provisions of REACH are not more specific. No explicit reference in REACH to the MSR would be necessary since REACH would remain lex specialis, just as it is now.

This option would ensure a high level of harmonisation of enforcement of REACH among the Member States and would serve as a good basis for audits carried out by the EAC should it be established.

5.1.1.3 Option 3: Adopt a new Regulation on enforcement of the REACH, CLP, POPs, and PIC Regulations

Since the enforcement criteria developed for REACH could also be used in relation to the enforcement of the CLP, POP and PIC Regulations (see Section 4 above), another option may be to adopt a whole new Regulation laying down enforcement criteria for all four pieces of legislation. This would require a cross-reference in the relevant Articles on competent authorities and enforcement in all the pieces of legislation. As Union legislation enforced by Member States usually contains Articles on enforcement and the competent authorities in charge of it in the last part of the enacting terms, it is not recommended to repeal these Articles in the Regulations subject to this study. It would therefore provide more legal clarity to keep those Articles and to add references to the new Regulation.

The necessary amendment of the Regulations and adoption of the new Regulation would need to follow the ordinary legislative procedure. REACH and CLP Regulations have a common legal basis in Article 95 TEC (now 114 TFEU), which refers to the internal market. The POPs Regulation refers to Article 192(1) TFEU which refers to Article 191 (protection of the environment), while PIC refers to Article 191 (environment) and 207 (common commercial policy). It could be argued that an enforcement Regulation could have a different legal basis than the legislation to be enforced and that Article 114 and/or 191 TFEU could form the legal basis for the new Regulation.

The significant advantage of this option would be that it would not only ensure a harmonised approach to enforcement among Member States concerning REACH but also among the four pieces of legislation. Also, should the criteria need to be updated in the future this would only need to be done once in this document rather than in each Regulation separately.

5.1.2 Incorporation of enforcement criteria in CLP, PIC and POPs

All three Regulations have provisions concerning competent authorities, enforcement, penalties and reporting in place that, as in REACH, merely provide a minimum framework rather than specific enforcement criteria.

CLP Regulation
CLP aims to determine which properties of substances and mixtures should lead to a classification as hazardous for the hazards of substances and mixtures to be properly identified and communicated. The main responsibilities under CLP are that the manufacturers, importers and downstream users classify, label and package substances and mixtures before placing them on the market.

The appointment of competent authorities and enforcement authorities and cooperation between authorities without any reference to resources is regulated in Article 43, general enforcement, including reporting to ECHA, in Article 46, and a general requirement for sanctions in Article 47.

As described for REACH in Section 4 above, the Market Surveillance Regulation applies to the enforcement of requirements on products to be made available on the market or made available on the market 'that are subject to the Union harmonisation legislation listed in Annex I' to the Regulation, in which, among others, the CLP Regulation is listed. The Market Surveillance Regulation therefore applies to obligations in CLP related to substances, mixtures and to certain articles placed or to be placed on the market, i.e. provisions which aim to ensure that only compliant products are made available on the EU market.

PIC Regulation
The Prior Informed Consent Regulation (PIC, Regulation (EU) No 649/2012) mainly implements the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. It regulates the export and import of certain hazardous chemicals and places obligations on companies who intend to export certain categories of chemicals to non-EU

countries or import them into the Union. The Regulation also aims to promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment.

It provides for two main requirements for the export of chemicals, the export notification and the explicit consent of the importing country. The exporter needs to do the notification for all chemicals listed in Annex I prior to the export by introducing it in the database available on the website of ECHA. The notification is checked and validated by the designated national authority (DNA) of the exporter and subsequently sent to the importing country by ECHA.

PIC requires Member States to designate authorities such as customs authorities that have the responsibility of controlling the import and export of chemicals listed in Annex I (Article 18(1)), without specifying on resources, and to lay down the rules on effective, proportionate and dissuasive penalties (Article 28). It also requires Member States to exchange information (Article 20) and report on the controls carried out (Articles 18(3), 22(1)).

POPs Regulation

Persistent organic pollutants (POPs) are regulated worldwide by the Stockholm Convention and the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants. In the European Union these are implemented by the POPs Regulation (Regulation (EU) No 2019/1021). The POPs Regulation aims to protect human health and the environment mainly by prohibiting or severely restricting the production, placing on the market and use of POPs. Other control measures also aim to minimise the environmental release of POPs that are formed as industrial by-products, make sure that stockpiles of restricted POPs are safely managed, and ensure the environmentally sound disposal of waste consisting of, or contaminated by POPs.

The POPs Regulation requires the establishment of a competent authority responsible for the enforcement of the Regulation without specifying on resources (Article 19) and for reporting (Article 13), as well as the establishment of an effective, proportionate and dissuasive sanctions regime (Article 14).

Like REACH and CLP, the POPs Regulation is also listed in Annex I to the Market Surveillance Regulation.

Enforcement provisions

General obligations related to enforcement laid down in the CLP, PIC and POPs Regulations are relatively similar to those laid down in REACH. They cover criterion 1 (designation of competent authorities) and 16 (enforcement measures and penalties). In addition to those, the REACH and CLP Regulations include requirements related to coordination between competent authorities. The REACH Regulation contains a requirement regarding the provision of appropriate resources to competent authorities, which is not included in the other Regulations. There are no contradictory requirements in the Regulations that would prevent from extending the criteria for the REACH Regulation to CLP, PIC and POPs Regulations. Since the criteria essentially relate to the organisation of the control system, control procedures and the evaluation and improvement of the performance of the control system, these criteria should be broad enough to be applicable to the four Regulations.

Implementing acts

The recast of the POPs Regulation has been adopted post-Lisbon, and therefore it already contains references to the Comitology Regulation (Regulation (EU) No 182/2011) which provides for the procedural arrangements for the adoption of implementing acts. Both, CLP and PIC Regulation, have been 'lisbonised'. However, in relation to enforcement, neither delegated nor implementing acts are the appropriate means to specify enforcement requirements for the same reasons as explained above in relation to REACH.

Amendments of the Regulations and guidance

Therefore, the only viable options to lay down binding enforcement criteria are the ones presented for REACH, namely adopting an amendment of the Regulations referring to the enforcement criteria in the MSR, adopting a new Annex for each Regulation setting out the enforcement criteria, or adoption of a new Regulation on enforcement of the REACH, CLP, POP, and PIC Regulations. The same approach would be followed as explained under Section 5.1.1.

As mentioned in Section 4.3.2 and 5.1.1, the most desirable solution from the perspective of contributing to the effectiveness of national control systems and achieving a well-functioning internal market and a high level of protection of human health and the environment would be having binding enforcement criteria in place, be it by amending the Regulations and adding new annexes, be it by adopting an 'enforcement regulation' applicable to all four pieces of legislation.

5.2 PROPOSAL FOR INCLUDING THE THREE OPTIONS FOR A EUROPEAN AUDIT CAPACITY INTO THE LEGISLATION

The three options for a EAC described in Section 3 above do not differ very much from each other in relation to the bodies involved. The main differences lie in the trigger of the audit and its scope. Therefore, the incorporation of the EAC into the legislation subject to the study mostly depends on the scenario chosen to incorporate the enforcement criteria into legislation, as set out in Section 5.1.

Scenario 1 (apply MSR criteria to entire scope of the Regulation) and 2 (adopt new Annex to the Regulation) resemble in that they integrate the changes into the existing four Regulations subject to this study. Should one of these scenarios be chosen, the incorporation of the EAC would therefore also have to be done in the body of the respective Regulation. In scenario 3 (new Regulation on enforcement of the REACH, CLP, POPs and PIC Regulation), the new Regulation would need to include provisions on the EAC.

For all three options for an EAC, provisions would need to be included in the legislative text that defines who the relevant actors are (options 1 and 2: Commission, ECHA, Forum; option 3: Commission, Member States, Forum), the trigger of the audits and its scope. Provisions should also be included setting rules on transparency. The new provisions would need to be placed in the section of the respective Regulation that refers to enforcement.

Regardless of the scenario chosen, changes need to be made in the legislation and new legislation needs to be adopted, respectively, by ordinary procedure. For the same reasons as explained in the previous section, these changes cannot be made by implementing acts.

ANNEX 1: FULL DETAILS OF EUROPEAN AUDIT CAPACITY OPTIONS

This is a modular system and elements in different options could be combined.

Aspects / Options	Trigger of the audit	Scope of the audit	Working methods used	Additional activities	Criteria audited	Follow-up actions	Transparency	Actors	Type of auditors	Evaluation of the EAC control system
Option 1: Comprehensive audit capacity system	Hybrid system: - **General audit programme** - **Specific audit programme** - **Ad hoc targeted control, based on specific concern**	A **combination** of **regular general and specific** audits and **ad hoc targeted** controls **Regular programmed audits** can be of a **general nature**, i.e. covering all aspects of enforcement and of REACH legislation, and all MSs, (e.g. every five years) or of a **specific nature**, i.e. covering certain aspects of enforcement and of the REACH legislation, including recurring problems, and a representative number of MS, as relevant (e.g. a MS audited every five years). **Ad hoc targeted controls** based on specific concerns can be triggered e.g., by an alert, whistleblower, important or recurring problems with the application or enforcement of the rules) Frequency:	The combination of **remote and on the spot verification**, for each audit ('remote verification' means desk based and by online meetings)	Additional complementary activities to the audit may include fact-finding missions	Relevant criteria for national control systems other than those already in REACH (and MSR where applicable) are laid down in the legislation as binding criteria	Detailed recommendations/instructions are provided to the MS identifying the weaknesses to be addressed as regards general and specific aspects of the control system or its implementation MSs are required to take measures to address the shortcomings identified Discussion at the Forum Follow-up mechanism to check action taken by MS Use of information from the audits (e.g. overviews of MS control systems, identification of weaknesses at EU level, input for policy action, scoreboard) e.g. to inform EU policy makers Sharing good practices for other Member States	Publication of all reports (with removal of any confidential data if necessary)	The European Commission to lead, ECHA to provide the technical expertise where appropriate Input (consultation) with Forum in preparing the regular audit programme could be considered within this option	Mix of auditors from the Commission and where appropriate, ECHA, national experts from other Member States enforcement authorities and where needed, external experts via public procurement tenders	External evaluation by independent assessors In addition to internal standard Commission (i.e. under IAS) and Agency controls

Aspects / Options	Trigger of the audit	Scope of the audit	Working methods used	Additional activities	Criteria audited	Follow-up actions	Transparency	Actors	Type of auditors	Evaluation of the EAC control system
		occasional, e.g. around 0-2 control visits in total per year								
Option 2: An audit capacity system	Combination of: - **Specific audit programme** - **Ad hoc targeted control based on specific concern**	**Specific programmed audits** only covering a representative number of MSs (e.g., on certain aspects of enforcement and of the legislation, including on important or recurring problems with the application or enforcement of the rules). On frequency e.g. at least one audit per MS every five years. **Ad hoc targeted controls** based on specific concern can be triggered e.g., by alert, whistleblower, important or recurring problems with the application or enforcement of the rules). Frequency: occasional, e.g. around 0-2 control visits in total per year	Remote only or a combination of **remote and on the spot verification**, where appropriate (on the spot part not to be carried out systematically).	None	Relevant criteria for national control systems other than those already in REACH (and MSR where applicable) are laid down in the legislation as binding criteria	Detailed recommendations/instructions are provided to the MS identifying the weaknesses to be addressed as regards specific aspects of the control system or its implementation MSs are required to take measures to address the shortcomings identified Discussion at the Forum Follow-up mechanism to check action taken by MS	**A summary report** to be published and available to the public and **a more detailed version** sent to the Member Stated audited only and discussed at the FORUM where needed	The European Commission to lead, ECHA to provide the technical expertise where appropriate. Input (consultation) with Forum in preparing the regular audit programme could be considered within this option	Mix of auditors from the Commission and where appropriate, ECHA	Internal evaluation by the Commission (i.e. under IAS) and Agency controls.
Option 3: A minimal control capacity system	Combination of: **a) Ad hoc control capacity only when there is a specific concern**	**a) Ad hoc targeted controls** focusing only on the specific concern that triggered the control (e.g., alert, whistleblower, important, or	**a)**Only combination of remote and on the spot verification The control activity itself could also	No additional activities	Current existing binding criteria in REACH (and in MSR where applicable) Further criteria are laid down in guidance	**a)** Control reports do not include recommendations/instructions, but only identify specific shortcomings to be addressed by the MS	**a) A summary report** to be published and available to the public and **a more detailed version** sent to	a) European Commission	a) Auditors from the Commission,	a) Internal evaluation by the Commission (i.e. under IAS) and Agency controls

Aspects / Options	Trigger of the audit	Scope of the audit	Working methods used	Additional activities	Criteria audited	Follow-up actions	Transparency	Actors	Type of auditors	Evaluation of the EAC control system
		recurring problems with the application or enforcement of the rules) Frequency: occasional, e.g. around 0-2 control visits in total per year	take the form of a fact-finding mission			Lack of recommendations/instructions is without prejudice to the obligation of MSs to take action to ensure compliance with legislation	the Member State visited only and discussed at the FORUM where needed			
	b) Voluntary action: Peer review system (beyond Market Surveillance Regulation, covering all aspects of REACH, arranged voluntarily between MS	**b)** based on voluntary participation from other MS. Scope based on voluntary acceptance Irregular frequency. For CA in MS to decide	**b)** to be agreed based on voluntary acceptance			Follow-up mechanism to check action taken by MS **a) and b)** Discussion at the Forum	**b)** Discussion at the Forum	**b)** Member States CA based on own initiative (FORUM could have a coordination role))	**b)** MS representatives	

ANNEX 2: DETAILED COST ESTIMATIONS FOR THE THREE OPTIONS

Submitted as an Excel file together with this report.

Annex 2 EAC Cost estimations for 3 opti

ANNEX 3: SURVEY QUESTIONNAIRE

Survey to Member States' authorities on criteria / standards for Member States' control systems

About the survey

This survey is part of a study carried out by Milieu Consulting for the European Commission, DG Environment on the establishment of a European Audit Capacity to ensure compliance and effective national control and enforcement of the REACH Regulation and possibly other regulations (CLP, PIC and POPs Regulations). The study aims to 1) identify options to establish a European Audit Capacity to ensure compliance with and effective national control and enforcement systems for the REACH Regulation throughout the EU 2) develop criteria/standards applicable to Member States control and enforcement systems, which would eventually be checked by the European Audit Capacity, and 3) assess the possible extension of the European Audit Capacity to other chemicals legislation.

This survey aims to consult Member States' authorities on the second objective, the development of criteria/standards applicable to Member States control and enforcement systems which are able to ensure their effectiveness and against which the European Audit Capacity could perform its control activities. It is based on a background document (that you can download in the section 'Background document' on the right of the screen), which describes a number of possible criteria and sub-criteria, including examples of elements and evidence that could be checked by an audit capacity without intending them to be exhaustive or to predetermine how an audit activity may be performed in the most efficient way. We encourage you to read the background document before responding to the survey.

You may interrupt your session at any time and continue answering at a later stage. If you do so, please remember to keep the link to your saved answers as this is the only way to access them. Only questions marked with a red asterisk are mandatory. Once you have submitted your answers online, you will be able to download a copy of the completed questionnaire.

We would kindly ask you to respond to the survey by **14 January 2022**.

You can also provide comments to the background document, by sending them to: lise.oules@milieu.be by 14 January 2022.

Privacy statement and use of survey results

Responses to the survey will not be published. Anonymized aggregated results (i.e. not referring to a specific respondent) will be used in the study. Full results (including names of authorities) will however be made available to DG Environment, the recipient of the study.

All personal data gathered for this survey is subject to the conditions laid down in the privacy statement. Please read this carefully before you reply to the survey. Your consent can be withdrawn any time by contacting the data controller, as outlined in the privacy statement.

☐I agree with the personal data protection provisions.

Thank you for participating in the survey.

About your authority

Please provide the name of your authority*

Are you a national enforcement authority?*
- Yes
- No

If you replied 'no' *[the question will only appear to those respondents]***, please explain your role:**

Are you a member of (please tick all that apply)*:
CARACAL
Forum for Exchange of Information on Enforcement
Designated National Authorities for Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals
Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)

Which of the following regulations is your authority responsible for (please tick all that apply)*:
REACH
CLP
PIC
POPs

Level of governance*
National
Regional
Local

Member State*
- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Netherlands

- Norway
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden

Criteria / standards for Member States' control systems

In your opinion, should the European Audit Capacity audit Member States' control and enforcement systems and their implementation against common EU standards?
Strongly agree
Agree
Neither agree not disagree
Disagree
Strongly disagree

Please explain your answer.

If you disagreed or strongly disagreed in the previous question *[the question will only appear to those respondents]***, should the European Audit Capacity audit Member States' control and enforcement systems and their implementation against individual Member State's criteria?**
- Strongly agree
- Agree
- Neither agree not disagree
- Disagree
- Strongly disagree

Please explain your answer. *[the question will only appear to respondents who disagreed or strongly disagreed in the first question]*
If you strongly agreed or agreed, please indicate whether you have such criteria/standards in your Member State, against which your authority could be audited, and if possible, please provide them through a weblink or by uploading the document.

Please upload your document here (1MB maximum).

Should the European Audit Capacity assess the Member States' official control and enforcement system of the REACH Regulation according to the criteria described in the background document? Please rate the relevance of each sub-criterion from very relevant to not relevant.

	Very relevant	Relevant	Moderately relevant	Slightly relevant	Not relevant
1.1 Member States must designate an authority or authorities responsible to organise and/or perform official controls	☐	☐	☐	☐	☐
1.2 Authorities must have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of the official control system and of its implementation					
1.3 Authorities responsible for controls must be given the investigation and enforcement powers necessary for the application of the REACH Regulation	☐	☐	☐	☐	☐
1.4 Member States must ensure efficient and effective cooperation, communication and coordination within authorities	☐	☐	☐	☐	☐

responsible for controls and between authorities responsible for controls when several authorities have been designated					
1.5 Authorities responsible for controls must have the necessary resources, including sufficient budgetary resources, competent personnel, expertise, and equipment for the proper performance of their responsibilities	☐	☐	☐	☐	☐
1.6 Controllers must receive appropriate training enabling them to undertake their duties competently and to perform official controls in a consistent manner	☐	☐	☐	☐	☐
1.7 Authorities must be subject to internal or external audits					
2.1 Member State must adopt an overarching multiannual enforcement strategy setting goals, objectives and key enforcement principles	☐	☐	☐	☐	☐
2.2 The organisation of controls must cover operators at any stages of the manufacturing and placing on the market, all products and all legal obligations in the legislation	☐	☐	☐	☐	☐
2.3 Authorities responsible for controls must use a risk-based approach in deciding which controls to perform and at which frequency	☐	☐	☐	☐	☐
2.4 Authorities have procedure/arrangements to ensure impartiality, quality and consistency of controls	☐	☐	☐	☐	☐
2.5 Authorities responsible for controls perform their activities by means of documentary checks, physical on-site checks and laboratory checks, as appropriate to guarantee the effectiveness of controls. Authorities responsible for controls may perform controls with or without prior notice as necessary	☐	☐	☐	☐	☐
2.6 Authorities responsible for controls must draft reports on all controls performed	☐	☐	☐	☐	☐
2.7When non-compliances are identified, authorities responsible for controls must require the dutyholder to take appropriate corrective action to bring the non-compliance to an end within a given period of time and prevent further occurrences of such non-compliance, and follow-up with the dutyholder	☐	☐	☐	☐	☐
2.8 When dutyholders fail to take corrective actions or if the non-compliance persists, authorities responsible for controls must take appropriate measures to bring the noncompliance to an end and when justified, impose penalties	☐	☐	☐	☐	☐
2.9 Decisions taken by authorities as a result of controls must be subject to right of appeal according to national law	☐	☐	☐	☐	☐
2.10 Authorities responsible for controls must have quality control and control verification procedures in place	☐	☐	☐	☐	☐
2.11 Results from controls are analysed horizontally, in the form of, for instance, an annual enforcement report, to provide an overall picture of the level of compliance at national level, which may inform the planning of future controls	☐	☐	☐	☐	☐
2.12 Authorities responsible for controls must perform their activities with a high level of transparency and must make available to the public relevant information concerning the organisation and the performance of official controls	☐	☐	☐	☐	☐
3.1 Authorities responsible for controls seek feedback from dutyholders on the implementation of controls	☐	☐	☐	☐	☐
3.2 Authorities responsible for controls regularly evaluate the effectiveness of the control system leading to the review, if and as appropriate, of the obligations and competences of the authorities, the control and enforcement strategy, the enforcement priorities, documented procedures for controls and control methods and techniques, the implementation of the controls or the approach to taking enforcement measures	☐	☐	☐	☐	☐

If you considered that some of the criteria listed above are very relevant or relevant *[the question will only appear to those respondents]***, please explain your answer (and please indicate which criteria you are referring to).**

If you considered that some of the criteria listed above are slightly relevant or not relevant *[the question will only appear to those respondents]***, please explain your answer (and please indicate which criteria you are referring to).**

Are there any other criteria applicable to national control systems that you would add to the list, and why? *[visible to all respondents]*

In your opinion, should the standard/criteria for national official control systems be laid down in the legislation as binding elements for such systems?
Strongly agree
Agree
Neither agree not disagree
Disagree
Strongly disagree

If you disagreed or strongly disagreed *[the question will only appear to those respondents]***, should these criteria be laid down as non-binding or guidance for Member States?**
- Strongly agree
- Agree
- Neither agree not disagree
- Disagree
- Strongly disagree

Please explain your answer. *[visible to all respondents]*

Which Regulations should the European Audit Capacity activity cover?
REACH Regulation
CLP Regulation
PIC Regulation
POPs Regulation
Other

Costs and benefits

If a European Audit Capacity were to audit Member States' official control systems, what would be, in your opinion, the costs and/or administrative burden that being subject to an audit would imply for a Member State?

In your opinion, what benefits would audits carried out by a European Audit Capacity bring to Member States?

Additional comments

If you wish to provide any additional comment or input, please provide it below. *[visible to all respondents]*

ANNEX 4: RESULTS OF SURVEY ON CRITERIA / STANDARDS FOR MEMBER STATES CONTROL AND ENFORCEMENT SYSTEMS

The online survey was carried out to gather the opinions of experts from CARACAL, Forum, PIC DNAs and POPs competent authorities on the preliminary list of criteria established by the contractor (provided to respondents as a background document). The survey, together with the background document, were made available to national authorities through the contact points of the different committees and expert groups on 14 December 2021, with a deadline for responses on 14 January 2022.

Profile of respondents

The survey gathered 53 responses, including 35 from experts from national enforcement authorities and 18 from experts from other competent authorities. The majority of responses came from national authorities; one fourth came from regional authorities.

Figure 2: Role in enforcement

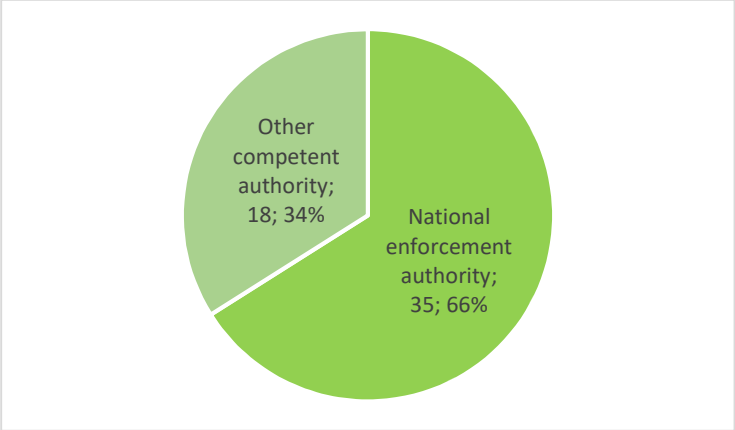
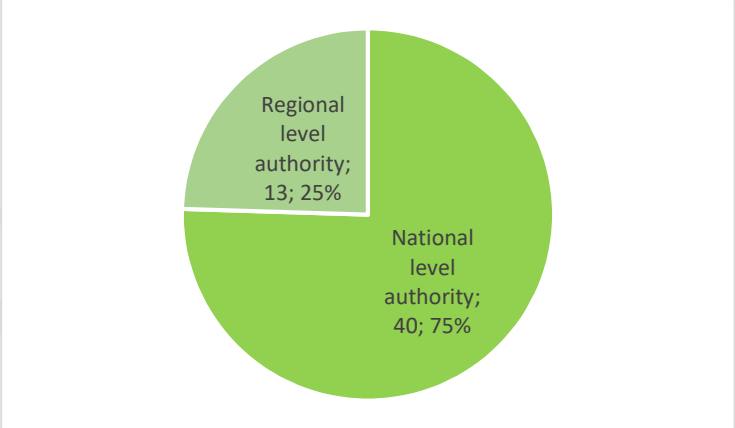
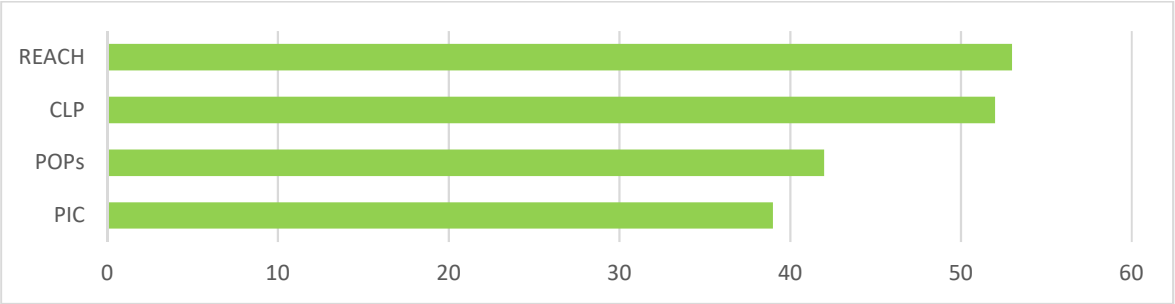


Figure 3: Level of governance



All respondents indicated that their authority is responsible for the REACH Regulation, 52 that their authority is responsible for the CLP Regulation, 42 for the POPs Regulation, and 39 for the PIC Regulation.

Figure 4: Which of the following regulations is your authority responsible for? (n=53, multiple choice possible)



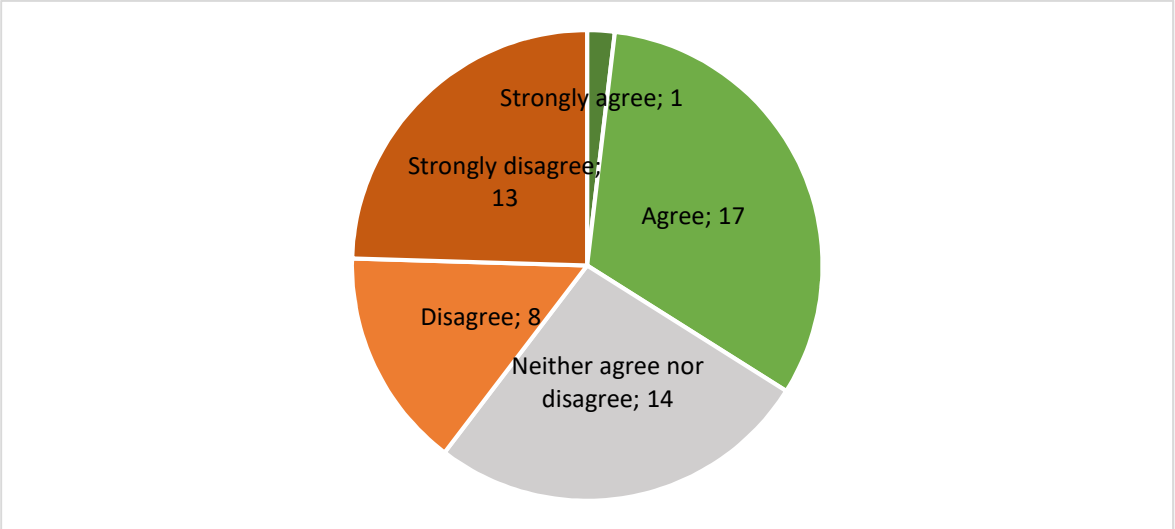
53 responses were received from experts from 27 Member States / EEA countries. About one fourth of the responses (13) come from experts from the same Member State.

Criteria / standards for Member States' control systems

Common criteria vs individual Member States' criteria

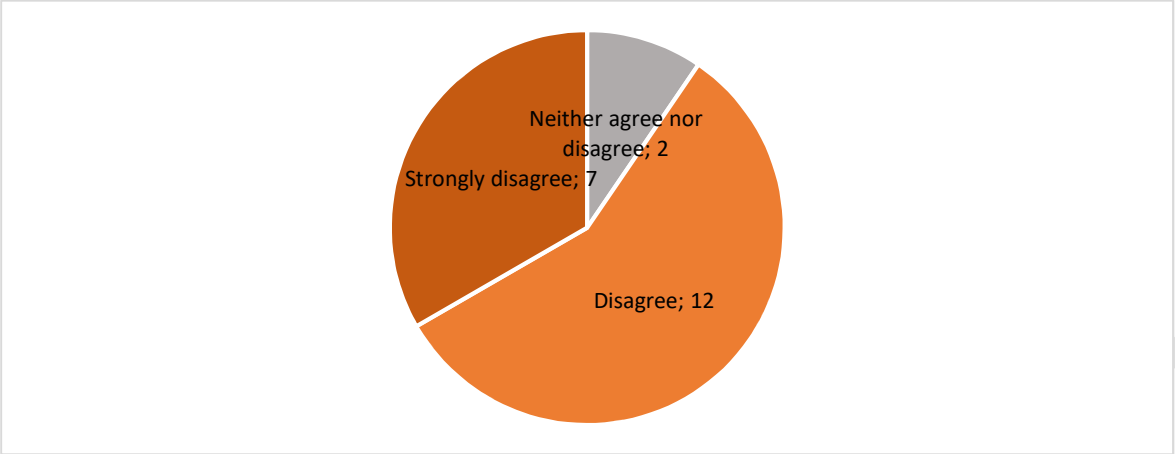
Responses showed a strong division on whether the EAC should audit Member States based on common EU standards.

Figure 5: In your opinion, should the European Audit Capacity audit Member States' control and enforcement systems and their implementation against common EU standards? (n=53)



Respondents that disagreed or strongly disagreed to the use of common EU standards, also indicated that the European Audit Capacity should not audit Member States based on individual Member State's criteria.

Figure 6: If you disagreed or strongly disagreed in the previous question, should the European Audit Capacity audit Member States' control and enforcement systems and their implementation against individual Member State's criteria? (n=21)

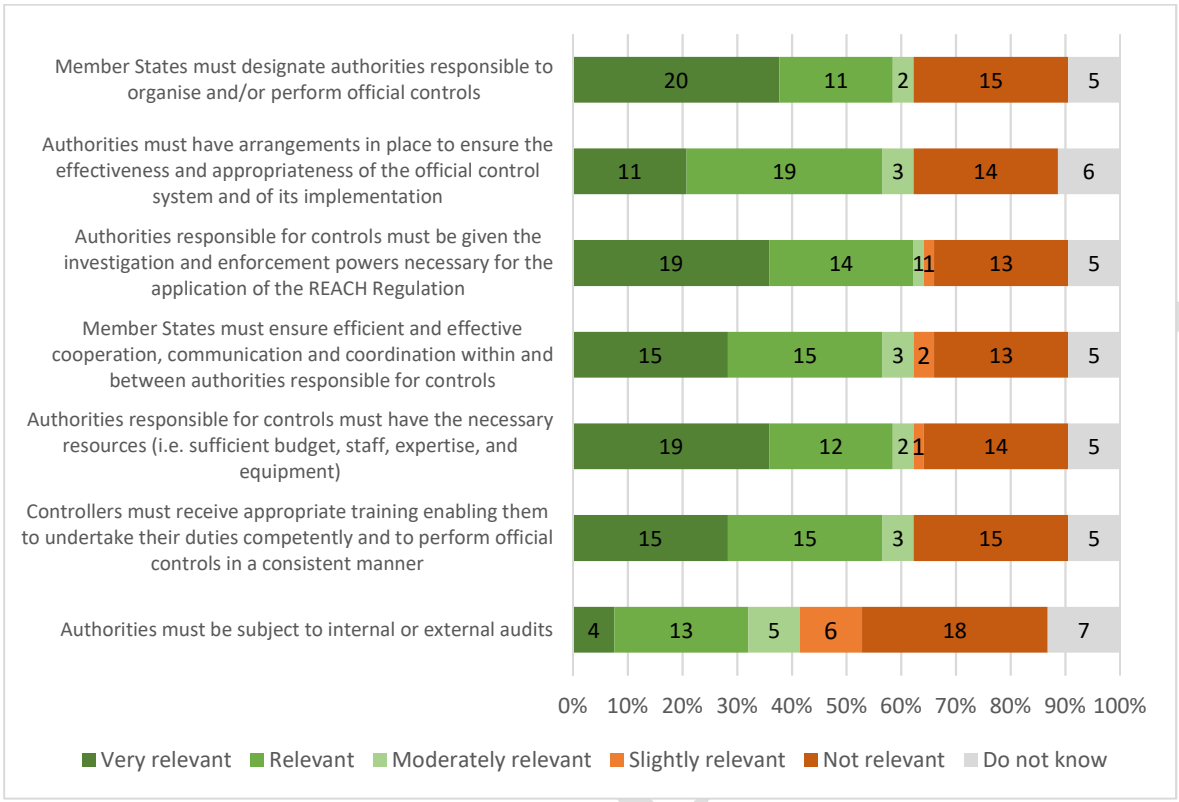


Feedback on the list of common criteria

The scoring the relevance of each criterion is presented below. Responses sometimes reflect a general judgement on the concept of an EAC rather than on each individual criterion (several respondents mentioned that they replied 'not relevant' for all criteria because they considered the establishment of an EAC not relevant).

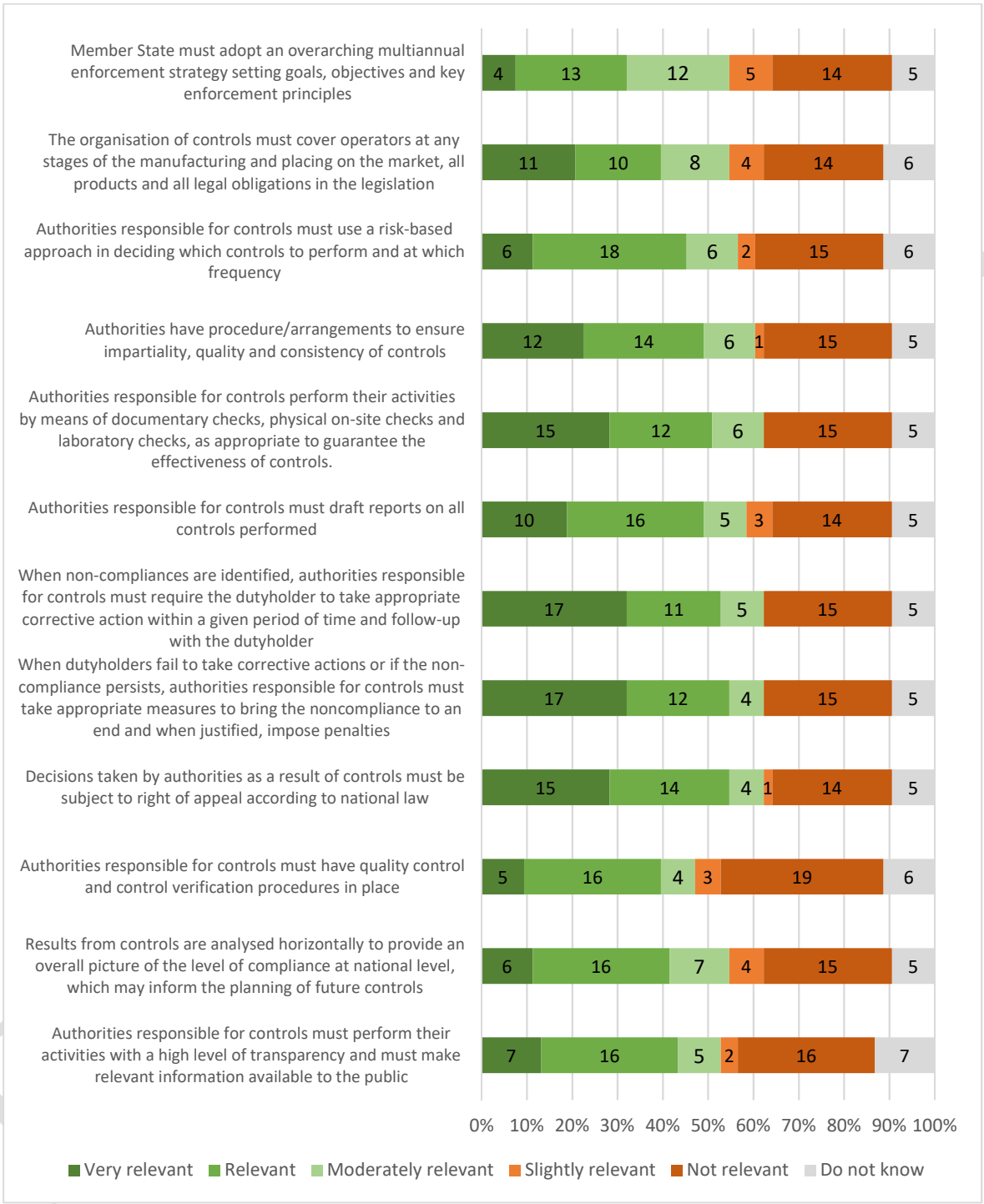
Criteria related to the competent authority

Figure 7: Should the European Audit Capacity assess the Member States' official control and enforcement system of the REACH Regulation according to the criteria described in the background document? (n=53)



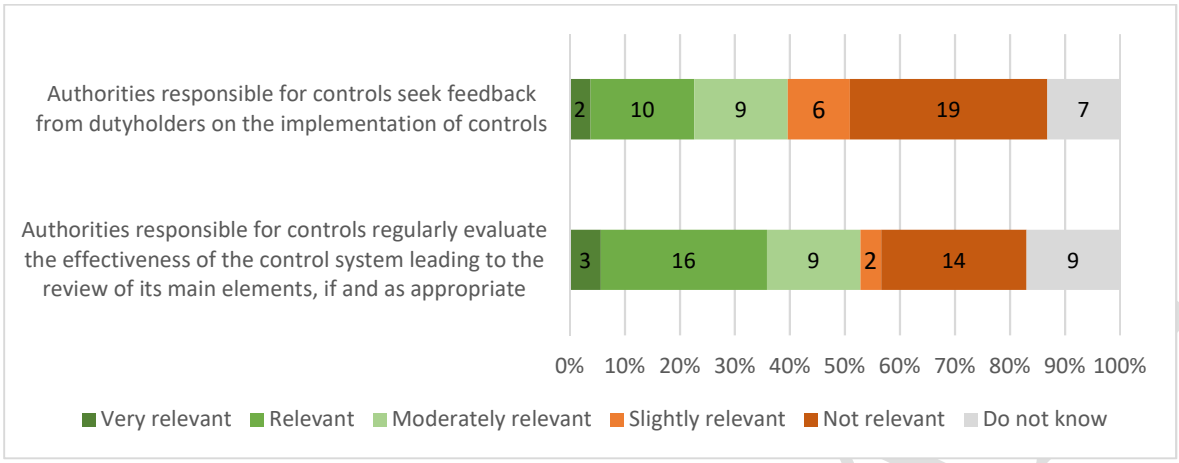
Criteria related to controls

Figure 8: Should the European Audit Capacity assess the Member States' official control and enforcement system of the REACH Regulation according to the criteria described in the background document? (n=53)



Criteria related to evaluation and improvement of the control system

Figure 9: Should the European Audit Capacity assess the Member States' official control and enforcement system of the REACH Regulation according to the criteria described in the background document? (n=53)



Incorporation into legislation vs guidance

Figure 10: In your opinion, should the standard/criteria for national official control systems be laid down in the legislation as binding elements for such systems? (n=53)

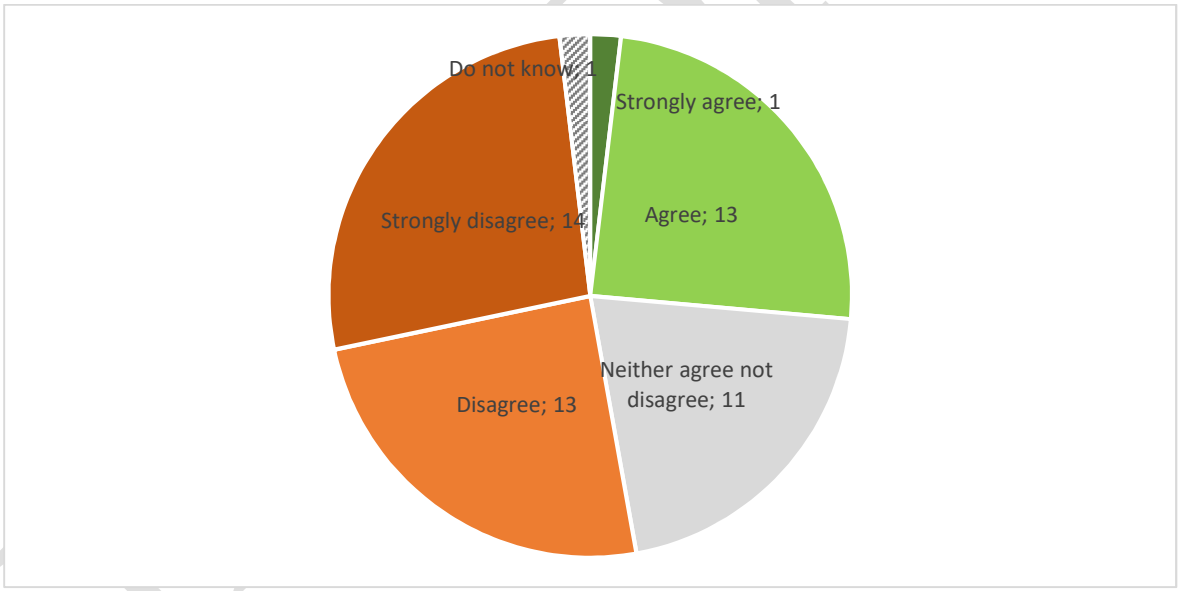
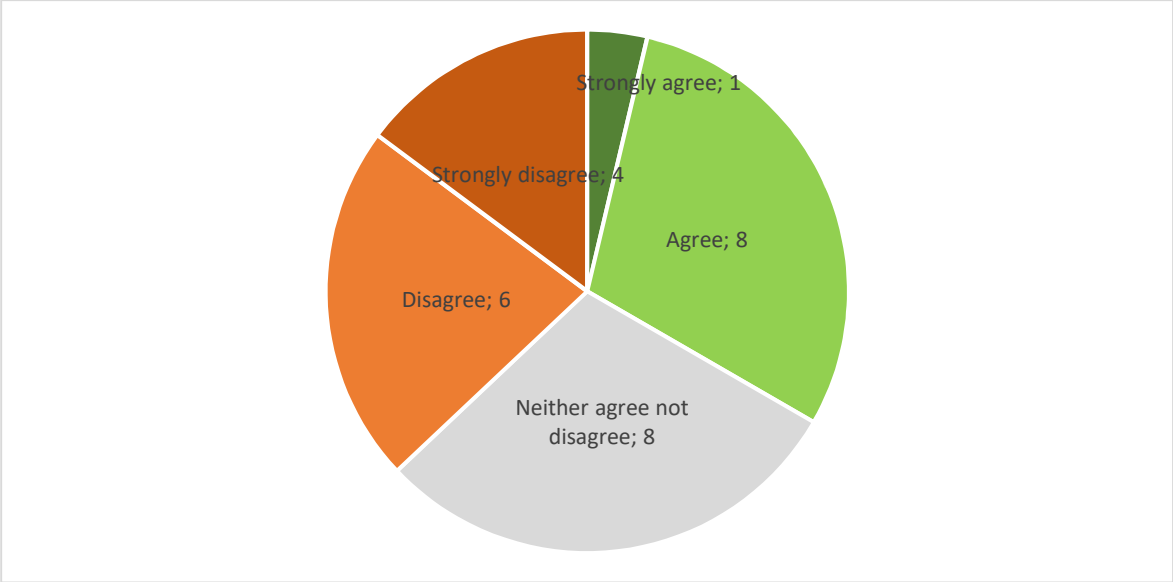
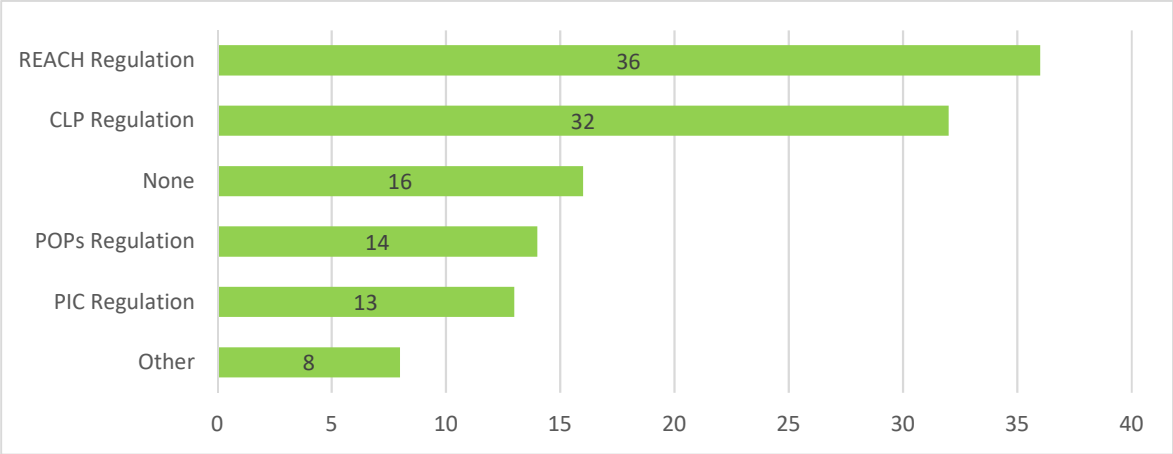


Figure 11: If you disagreed or strongly disagreed, should these criteria be laid down as non-binding or guidance for Member States? (n=27)



Extension to CLP, PIC and POPs

Figure 12: Which Regulations should the European Audit Capacity activity cover?



ANNEX 5: FEEDBACK PROVIDED BY EU AND MEMBER STATES' EXPERTS ON CRITERIA AS PART OF THE SURVEY AND / OR THROUGH WRITTEN COMMENTS

Criteria	Feedback received
1.1 Member States must designate an authority or authorities responsible to organise and/or perform official controls	Conflict of interest is not related to the designation of competent authorities and should be removed. If the criterion addresses the designation of enforcement authorities, the sub-criterion should be that "authorities have been given a national legislative mandate" (one national expert) As most MS will have a number of CAs appointed to deal with various aspects, and different chemical Regulations, it will need to confirmed if the Audit is at full MS level, at CA level for CA role or at EU Regulation level. If it is at MS level then audit coordination at MS level may be a significant administrative burden in some Member States (one national expert).
1.2 Authorities must have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of the official control system and of its implementation	
1.3 Authorities responsible for controls must be given the investigation and enforcement powers necessary for the application of the REACH Regulation	Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
1.4 Member States must ensure efficient and effective cooperation, communication and coordination within authorities responsible for controls and between authorities responsible for controls when several authorities have been designated	Additional criterion: Cross-border cooperation with other authorities (one national expert). It is suggested to integrate the aim of integrated enforcement which requires cooperation with authorities responsible for controls of other legislations (e.g. OSH, waste, cosmetics etc.). Easiest way to do it is to propose a new sub criterion: 'Member states strive to integrate enforcement of related legislations so that controls are holistic and cover related legislative duties' (one EU expert). Regarding the sub-criterion: 'When several authorities are responsible for controls, a single authority must be responsible for contacts with the Commission / ECHA and other Member States': 'We are not sure why this should be the case. In many MSs, the Forum member and alternate member are in different agencies for example. Therefore, it is possible that either or both communication with ECHA etc. Additionally invited experts from different authorities involved in projects etc. regularly communicate with ECHA. This sub-criterion is restrictive and not practical' (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
1.5 Authorities responsible for controls must have the necessary resources, including sufficient budgetary resources, competent personnel, expertise, and equipment for the proper performance of their responsibilities	important criterion but difficult to evaluate (how to evaluate "sufficient number" or "sufficient budgetary"?) (one national expert). 'Sufficient' is a vague term. The auditors will find it hard to judge what is sufficient and this is likely to be an area of dispute between auditor and auditee. In addition, if the resource needs are defined by the auditee, based on their current actions (e.g. x controls/year), this criterion will always be fulfilled, unless the auditee organisation itself admits they need more resources. With this definition the auditor would have little basis to recommend that they need more resources. If the EAC audits could not recommend

Criteria	Feedback received
	remedial actions, it would become much less effective. NEAs may need an EAC recommendation to highlight to national decision makers that enforcement needs to better resourced. It is suggested to add a general reference to the guidance that would indicate what is deemed as sufficient. This guidance should set up some external minimal standard (benchmark) which recommends what level of resourcing should be deemed sufficient. For example, a number of controls per year per 100 duty holders in the MS. Alternatively a comparison of level of controls with other MS (per 100.000 inhabitants). Perhaps Milieu would have suggestions for benchmarks based on your review of other EU auditing systems? Such benchmarks could not be put in legislations but could be part of the guidance for the audit that would need to be still developed (one EU expert). It should be added as a sub-criterion that the competent authorities dedicate sufficient resources to Forum activities. It is an important aspect that MS are struggling with – Forum resourcing from MS side should also be covered in the audit (one EU expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
1.6 Controllers must receive appropriate training enabling them to undertake their duties competently and to perform official controls in a consistent manner	Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert). While specific expertise might be needed for "scientific" assessment, the "inspectors" or "controllers" responsible for undertaking inspections and performing duties need to be appropriately trained and have access to expertise. In the criterion in the background doc, we therefore propose that point 1.6.2 ('Controllers must receive appropriate initial and on the job training on control methods and techniques and other core enforcement skills') is therefore sufficient and 1.6.1 ('Controllers must receive appropriate initial training in their area of competence and regular on the job training to keep up to date with their area of competence') can be deleted (one national expert). The sub-criterion 'If several authorities are responsible for controls, effective coordination of training programmes must be implemented and similar training opportunities must be available to controllers in the different authorities involved' is likely to be not relevant to all MS. We don't see benefits if MS have different legislative mandates within a MS or believe co-ordination of training across CA's is relevant for demonstrating that a MS has effective controls. In our MS our Authority has the legal mandate to address certain aspects of REACH but not all aspects of REACH or other EU Chemical Legislation so it would not be relevant for audit purposes (one national expert).
1.7 Authorities must be subject to internal or external audits	Can the implementation of a quality management system for the whole entity and not specific to chemicals controls meet the identified sub-criteria? (one national expert) Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
New criterion added by an EU expert: Authorities actively take part in harmonisation of enforcement at the EU level via the Forum for	The EAC should be able to review and make recommendations on MS's degree of involvement in the work of the Forum. The four sub criteria are the key indicators of the degree of involvement (one EU expert).

Criteria	Feedback received
Exchange of Information for Enforcement in ECHA.	
2.1 Member State must adopt an overarching multiannual enforcement strategy setting goals, objectives and key enforcement principles	Not sure if this will be an effective and efficient use of resources at MS level and relevant in all MS. We support the rationale for an enforcement strategy at CA level to address their areas of responsibility but at a MS level it may not always be the most pragmatic approach if the plan is to extend the scope of this auditing to other Chemical Regulations beyond REACH such as POPs etc. In our Member State, there isn't one authority with responsibility for all chemical legislation and this is the same in other MS. In some cases, a CA may have an enforcement approach that combines a number of pieces of chemical legislation that it has a legal responsibility for. For example, in the Authority we combine REACH, CLP, OSH, PIC activities into our inspections in some instances to be more effective in our inspections (one national expert). The national control authorities are independent from each other. They have their own control strategies and must remain decision makers. We share the desire for transparency on the results of the controls but not on the control strategies which should not be shared before the actual implementation of the controls (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.2 The organisation of controls must cover operators at any stages of the manufacturing and placing on the market, all products and all legal obligations in the legislation	While specific profiling and targeting should be avoided, it should also be noted that a risk-based approach will automatically 'single out' the cohorts/subjects with the higher risk profile. Moreover, the supply chain and the size/population of each cohort per supply chain stage (e.g. manufacturing, placing on the market, etc.) varies across Member States and should therefore be taken into account (one national expert). Regarding the sub-criterion 'controls must cover all legal obligations imposed on operators': due to the way our legislation and enforcement administration is structured, it will not be possible to cover all legal obligations imposed on an operator. CAs need to act within their area of legislative remit and prioritise based on risk. Adopting this approach suggests that all enforcement controls are audits (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.3 Authorities responsible for controls must use a risk-based approach in deciding which controls to perform and at which frequency	It is suggested to add a sub criterion to check whether the controls are really broad and not limited to scope of one enforcement authority (one EU expert). The formalization of this risk assessment is a problem (one national expert). Options to assess the general compliance levels on the market and measure whether there are any changes should also be allowed. This might be important when looking at new product types. Suggested amendment: '2.3 Authorities responsible for controls must use a risk-based approach in deciding which controls to perform and at which frequency for well-known sectors and product types' (one national expert).

Criteria	Feedback received
	Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.4 Authorities have procedure/arrangements to ensure impartiality, quality and consistency of controls	Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.5 Authorities responsible for controls perform their activities by means of documentary checks, physical on-site checks and laboratory checks, as appropriate to guarantee the effectiveness of controls. Authorities responsible for controls may perform controls with or without prior notice as necessary	Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert). Audits without further notice may provoke extended audit times, extending the time consumption of highly priced qualified auditors (one national expert).
2.6 Authorities responsible for controls must draft reports on all controls performed	verbal advice is one of the legislative control measures which can be taken by inspectors where written advice is not required. The requirement to provide a written report for each control undertaken hinders the ability of inspectors to provide verbal advice only. Suggest this is amended to a requirement to record the control undertaken (one national expert). The controls are defined, as per the MS Reporting under Art. 117 of REACH and Art. 46 of CLP requirements, as REACH and CLP controls are understood as inspections or investigations or monitoring, or other enforcement measures carried out by enforcement authorities. These controls include desktop assessments and Customs controls on products. Requiring a report on each of these activities would be excessive and resource demanding. Therefore, we would suggest that this criterion (2.6) is amended to provide a report only where required in follow up to an inspection/where non-compliance is addressed. (one national expert). The request to communicate the report without delay (sub-criterion 2.6.2) seems disproportionate (one national expert). Reporting on all controls performed would result in a great increase of workload for enforcement authorities. These reports are necessary, but depending on the case there should be an assessment of the level of details that they should include (one national expert). Additional sub-criterion suggested: 'Information on controls is collected in a way that facilitates gathering of statistical data for the Member State reporting on enforcement under Article 117 of REACH'. This is an important element for Art 117 reports (one EU expert). Additional suggested sub-criterion: 'Reporting on controls is done in a way that allows calculation of number of controls as recommended by the Forum'. This is needed to facilitate harmonised reporting (one EU expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.7When non-compliances are identified, authorities responsible for controls must require the dutyholder to take appropriate corrective action to bring the non-compliance to an end within a given period of time and prevent further	The legal basis for such actions must be provided, as these may be in significant interference with the member states governance. Therefore the auditing entity must possess the appropriate legal basis (one national expert).

Criteria	Feedback received
occurrences of such non-compliance, and follow-up with the dutyholder	This is already implemented in our country, and we see as very relevant that there is a report allowing to follow our target which is to have each year less cases where there is a non- compliance. This an important indicator (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.8 When dutyholders fail to take corrective actions or if the non-compliance persists, authorities responsible for controls must take appropriate measures to bring the noncompliance to an end and when justified, impose penalties	Regarding the reference to 'verbal and written advice' in the list of enforcement measures: This is contradictory to the need to leave a report in each case as specified in 2.6 (one national expert). Consider removing the division between measures and penalties, because it is fluid. In general, a measure is a tool to ensure that the duty holder complies and a penalty is a "punishment" for non compliance. The same measure (fine) can be used in some MS interchangeably. It is suggested instead to include one list of measures and penalties (one EU expert). Suggestion to add in the list of criteria determining proportionality of the severity of the enforcement measures the duration of the non-compliance. NEAs can only act from the moment they are aware of the noncompliance. But a duty holder may have been uncompliant for 10 years - illegally marketing the substance (or not submitting the required data.) The severity for such long non compliance could be stronger (one EU expert). Suggestion to add as a sub-criterion: 'Measures and penalties available must allow for effective enforcement of all duties and all duty holders under REACH'. We are aware of (few) cases where the NEA is not equipped with appropriate tool/measures/penalties to enforce effectively on certain types of duty holders/duties. The EAC criteria should allow to point that out (one EU expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.9 Decisions taken by authorities as a result of controls must be subject to right of appeal according to national law	This is not a matter of the specific legislation (one national expert). Provision should be provided for in national law (one national expert).
2.10 Authorities responsible for controls must have quality control and control verification procedures in place	Additional admin burden and resource intensive criterion (one national expert). May be difficult to put into practice (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).
2.11 Results from controls are analysed horizontally, in the form of, for instance, an annual enforcement report, to provide an overall picture of the level of compliance at national level, which may inform the planning of future controls	The idea of an annual report is welcomed in principle. Nevertheless, the information gathered by the audit system is delicate and official reports may lead to unwanted effects (e.g. shaming of MS). Therefore, such reports need to be handled with the appropriate care (one national expert). Suggestion to add as sub-criterion: 'The horizontal analysis collects the data needed for the Member State report required under Article 117 of REACH' (one EU expert).
2.12 Authorities responsible for controls must perform their activities with a high level of transparency and must make available to the public relevant information concerning the	This is not a matter of the specific legislation (one national expert). The idea of an annual report is welcomed in principle. Nevertheless, the information gathered by the audit system is delicate and official reports may lead to unwanted effects (e.g.

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organisation and the performance of official controls	shaming of MS). Therefore, such reports need to be handled with the appropriate care (one national expert).
3.1 Authorities responsible for controls seek feedback from dutyholders on the implementation of controls	Difficult to put into practice in our Member State as most of the companies are small-sized enterprises (one national expert) Is it really necessary to set up a procedure for the attention of the controlled operators? All administrations receive messages from professional federations or companies following controls to which we provide answers (one national expert). May lead to a significant workload to the individual authority. In the present MS the personal is very limited and additional workload caused by the audit system may result in a lower coverage of controls in a significant amount.
3.2 Authorities responsible for controls regularly evaluate the effectiveness of the control system leading to the review, if and as appropriate, of the obligations and competences of the authorities, the control and enforcement strategy, the enforcement priorities, documented procedures for controls and control methods and techniques, the implementation of the controls or the approach to taking enforcement measures	Can the implementation of a quality management system for the whole entity and not specific to chemicals controls meet the identified sub-criteria? (one national expert). Important aspect, but not relevant; according to the principle of subsidiarity it is a matter for the Member States and implemented by national legislation and, if necessary, administrative regulations (one national expert).