Guidance Document on Peer Reviews under Reg. (EU) 2019/1020

Contents

1   Introduction

This guidance document describes a methodology in order to carry out peer reviews under Article 12 of Market Surveillance Regulation (EU) 2019/1020 (hereinafter referred to as Regulation). Peer reviews shall be organised for Market Surveillance Authorities (MSAs) wishing to participate in such reviews. The main goal is to share best practices among them in order to increase the effectiveness of market surveillance activities throughout the Single Market in the different sectors.

Peer review is intended as a voluntary review of the organisation, functioning and performance of an authority by other authorities, in order to strengthen the consistency of market surveillance activities in relation to the application of the Regulation and in accordance with Article 12 of the Regulation.

According to Article 12 of the Regulation:

> *1. **Peer reviews** shall be organised for market surveillance authorities wishing to participate in such reviews, in order to strengthen consistency in market surveillance activities in relation to the application of this Regulation.*
> *2. The Network shall **develop the methodology** and the rolling plan for peer reviews among participating market surveillance authorities. When establishing the methodology and the rolling plan, the Network shall take into consideration, at least, the number and the size of market surveillance authorities in the Member States, the number of personnel available and other resources for performing the peer review, and other relevant criteria.*
> *3. Peer reviews shall cover **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.*
> *4. The outcome of the peer reviews shall be **reported to the Network.***

Note 1: The abbreviations (and definition) used in this document are listed in Annex 1.

Note 2: This guidance document is meant to be revised based on comments and feedback collected in the frame of peer review rounds. Such a revision may be formally requested by the EUPCN (European Union Product Compliance Network).

2   Scope

The peer reviews shall be organised for MSAs volunteering to be reviewed. In general, a peer review shall involve at least two MSAs from one single sector (Annex 2) and the corresponding ADCO (Administrative Cooperation Group of Market Surveillance Authorities as referred to in Article 30(2) of the Regulation) at a time (Annex 2). In case a MSA to be peer reviewed has competencies in more than one product sector, the MSA may be peer reviewed for several sectors, in accordance with Section 3.2.

3   Description of the peer review process

The following chapters describe the different steps in the peer review process. The following main steps were identified and described in this guidance document:

1. Expression of interest by MSA;
2. Expression of budget and resources estimation;
3. Organisation of the peer review;
4. Execution of the peer review;
5. Peer review report to the visited MSA(s);
6. Peer review summary report to the ADCO and Partnership;
7. Report of the ADCO to the EUPCN;
8. Feedback from the peer review;
9. Review of the effectiveness of the peer review system.

3.1   Expression of interest by MSA

In February of each year, the Commission (Chair of the EUPCN) shall inform the EUPCN about the budget available to perform a given number of peer reviews in the following year. A dedicated call for the expression of interest (EoI) by the MSA volunteering to be peer reviewed will be launched by the EUPCN in March. The peer review process timeline is illustrated in Annex 3.

The call shall be coordinated by the SLOs (Single Liaison Offices as referred to in Article 10(3) of the Regulation) in the Member States. Each SLO shall announce the call within its national MSAs and promote their participation to the peer reviews. In addition, the ADCOs may promote the call within its members (during the plenary meeting or via email). SLOs shall collect the EoIs received from the MSAs by 31st of May. Each EoI should specify:

- MSA name (organisation), country and email address of the MSA contact person, including relevant national coordinating authorities, if appropriate;
- Sector(s) and activities to be included in peer review, specifying the relevant EU legislation(s);
- Relevant ADCO(s).

Only EoIs received before the given deadline shall be taken into consideration.

SLOs send all the EoIs received to the Partnership by 30th of June.

The Partnership collects all the EoIs and groups them in lists per sector. The resulting lists of EoIs are sent to the respective ADCOs by 31st of July.

Note: In case of EoIs for sectors where there is no ADCO, then possible peer review is coordinated by the EUPCN.

As the peer review process is voluntary, any MSA can withdraw their participation providing a justification.

When only one MSA is identified for a sector, the ADCO shall evaluate the case and provide an opinion. However, if it is not possible to organise a peer review of the identified MSA, the ADCO must provide a justification.

If more than one candidate MSA is identified for the same sector, the ADCO shall establish a priority list.

If the number of concerned ADCOs exceeds the maximum number of peer reviews foreseen, mutual agreement on the peer reviews to be performed shall be reached among ADCOs. When no agreement can be reached, the EUPCN shall be consulted to set a priority. In addition, any decision by an ADCO not to organise a peer review shall be justified.

By 30th of September, the ADCOs shall submit their list of MSAs to be peer reviewed to the Partnership.

The Partnership shall submit the compiled list of the MSAs to be peer reviewed to the EUPCN by 31st of October.

The EUPCN shall evaluate and formally approve in December the list submitted.

On behalf of the EUPCN, the Partnership shall set up and maintain an overview table of peer reviewed MSAs per sector and country to ensure that all MSAs wishing to participate from the different countries and sectors are included in the peer review process over the years.

3.2 Organisation of the peer review

Once the MSAs to be peer reviewed in the following year have been selected for specific sectors, the corresponding ADCOs shall set up the peer reviews. The peer review process timeline is illustrated in Annex 3.

3.2.1 Peer review Team

The peer review Team (the Team) shall consist of at least two peer reviewers from one or more MSAs, other than the MSA to be peer reviewed, in order to guarantee an objective review. The Team should contain a peer reviewer for the MSA processes and technical peer reviewer(s) for the sector specific aspects.

Note: The peer review of an MSA covering several sectors can be considered as a combination of several peer reviews. The composition of the Team will depend on the location(s) (one or several) of the activities to be reviewed and on the number of sectors involved. An "extended" Team should be set up accordingly by all the ADCOs concerned.

The selection of peer reviewers is subject to an assessment by the ADCO. Any potential conflict of interest between them and the MSA to be peer reviewed shall be evaluated and assessed by the ADCO. The peer reviewers shall be competent staff working at another MSA, but do not need to be ADCO members. Technical peer reviewer(s) shall have adequate working experience in the sector including practical operation in the market surveillance. The ADCO shall evaluate the competence of the peer reviewers in administrative (general peer reviewer) or technical matters (technical peer reviewer). The peer reviewers shall be familiar with the provisions of Reg. (EU) 2019/1020, Reg. (EC) 765/2008 and relevant sector/product specific EU legislation(s).

Note: "Adequate working experience in the sector", is proven by specific knowledge of conducting market surveillance activities and measures, procedures, sampling methods, evaluation of testing results. Moreover, previous experience in conducting peer reviews is an asset.

If no peer reviewers are identified, the ADCO shall inform the EUPCN about the impossibility to perform the peer review.

The Partnership will design and organise a dedicated on-line training for peer reviewers and inform the EUPCN accordingly.

Once the Team has been selected by the ADCO, the Team composition is proposed to the MSA to be peer reviewed for approval. In case of objection, a clear justification needs to be given by the peer reviewed MSA to the ADCO. Based on the justification received, the ADCO may decide to change the peer reviewers in the Team. When the Team composition is approved, the Team, the peer reviewed MSA and the Partnership are informed by the ADCO (February year +1 at the latest).

The Commission shall inform the Team about (i) the budget available, (ii) the financial rules and (iii) the deadlines for the peer review report and summary report.

Note: the budget foreseen will cover the costs endured by the Team, namely travel tickets (travel hours not included), accommodation, daily allowance, and peer review work paid at an hourly rate. Translation services are to be provided by the MSA to be peer reviewed.

The Partnership shall inform the Team about the process for peer review to be implemented and present the checklist to be used.

The confidentiality of the information received in the frame of the peer review shall be assessed and decided between the team and the peer reviewed MSA. The team and the peer reviewed MSA shall not disclose any confidential information to third parties.

3.2.2 Means to execute the peer review

Different means may be used for the execution of the peer review such as: document sharing, on-line interviews, on-site interviews and visits. The Team selects the proper means in line with the available budget, practical considerations related to the activities to be included in the peer review, the allocated time for the peer review and the size of the Team. Hybrid approaches may be used in which the peer review is organised partly on-line and partly on-site. The means proposed by the Team need to be agreed with the MSA to be peer reviewed.

This MSA should provide some preliminary information to the Team before the start of the peer review process, in line with the non-exhaustive checklist prepared by the Partnership and provided to the Team (Annex 5). Additional information may be requested by the Team to perform the peer review.

3.2.3 Activities to be covered during the peer review

During a peer review, only certain (preselected) activities are to be included. Therefore, it is up to the Team and MSA to be peer reviewed to select the activities considered as most relevant for the peer review. This may depend, for example, on the allocated time for the peer review, the size of the MSA and the sector(s) covered as well as the presence or absence of laboratory activities.

The selected activities subjected to peer review shall be assessed for consistency, effectiveness and best practices in line with Article 12 of the Regulation and relevant sector regulations. The following topics should be considered (non-comprehensive list):

- Sample selection strategy (related to product and/or economic operator);
- Use of checklists for conducting the inspections;
- Sampling methods;
- Use of ICSMS (input and follow-up);
- Evaluation of testing results;
- Risk assessment (e.g. identification, analysis, evaluation, complaint management);
- Compliance assessment (e.g. formal and technical requirements);
- Enforcement management procedures;
- Cooperation mechanism (e.g. Customs, Associations, other MSAs);
- Other national legislative provision(s);
- Document control.

Examples of MSA activities (non-comprehensive list) that should be covered during the peer review are presented in Annex 4.

3.2.4 Timetable and date for the peer review

The timetable allocated to carry out the peer review is first prepared by the Team (February year +1), then discussed and agreed with the MSA to be peer reviewed. The ADCO shall be informed accordingly.

Timetable includes the starting date of the peer review, the date(s) and duration allocated to the different means (e.g. visits, meetings, interviews), the schedule for the reporting and the end date of the peer review. The time expressed in hours shall include the time allocated for the preparation, for the execution, and for the drafting of the reports of the peer review. This time will depend on the budget available, the size of the MSA and the (number of) sectors and activities to be included in the peer review, the size of the Team and the means used for execution.

The peer review shall be executed by end of June year+1.

Note:

- It is recommended to perform the peer reviews in April or May year+1 (if possible).
- Five to seven working days per peer reviewer are estimated for the peer review process for one sector in one MSA, including preparation (ca. 0.5 day), execution (ca. 2 d) and finalisation of the peer review report (ca. 3 d) and summary report (ca. 0.5 d). Travelling time is not included.

3.3 Reports on the peer review

The outcome and the observations done during the peer reviews are presented in two separate reports: (i) Peer review report and (ii) Peer review summary report. The peer review process timeline is illustrated in Annex 3.

3.3.1 Peer review report

Following the execution of the peer review, the Team shall provide a peer review report to the peer reviewed MSA. The report shall give a clear overview of the activities included in the peer review and it shall list best practices observed during the peer review. The report may also contain constructive recommendations for improvement and implementation of best practices.

The confidentiality of the report shall be assessed and decided between the team and the peer reviewed MSA. The team and the peer reviewed MSA shall not disclose any confidential information to third parties.

The Team shall provide a draft version of the report to the peer reviewed MSA for commenting in a timely manner, and not later than end of August year+1 after the execution of the peer review. The peer reviewed MSA can review and comment the report. These comments shall be evaluated by the Team before implementation. In case of disagreement, both opinions shall be included in the peer review report. However, the conclusions and recommendations are the responsibility of the Team.

The Team shall provide the final version of the report to the peer reviewed MSA not later than end of September year + 1 after the execution of the peer review. The report shall be approved by the peer reviewed MSA and the Team before its final adoption.

3.3.2 Peer review summary report

Following the adoption of the peer review report, the Team shall provide a peer review summary report to the ADCO and Partnership in a timely manner, and not later than end of September year + 1. In addition, the Team shall provide the summary report to the Commission as a deliverable foreseen in the contract.

The summary report shall give a clear overview of activities included in the peer review and list relevant observations on issues (e.g. best practices, general procedures and horizontal issues when organising and conducting inspections) that other MSAs and ADCOs could find useful.

The content of the summary report shall be assessed and decided between the team and the peer reviewed MSA. The team and the peer reviewed MSA shall not disclose any confidential information to third parties. Therefore, the summary report shall not contain any confidential information.

3.3.3 Report of the ADCO to the EUPCN

According to Article 12(4) of the Regulation (EU) 2019/1020 the outcome of the peer review exercise shall be reported to the EUPCN. The summary report and the feedback (see 3.4) are presented at the EUPCN meeting by the ADCO(s) and the Partnership respectively in December (year+1) at the latest.

3.4 Feedback

The Partnership shall seek feedback from the Team, the peer reviewed MSA and the ADCO(s) involved. The outcome of this feedback should be sent to the ADCO(s), and presented to the EUPCN by the Partnership.

Feedback may include information about best practices, general procedures and issues encountered when organising and conducting reviews. An example of the feedback form is provided in the Annex 6 (will be added as soon as the pilot exercise is finalised).

Based on the received feedback, the EUPCN may decide to modify the peer review process and request the Partnership to revise the guide.

3.5 Review of the effectiveness of the peer review system

According to Article 42(1) of the Regulation, by 31 December 2026 and every five years thereafter, the Commission shall carry out an evaluation of the Regulation. In the context of this evaluation, an evaluation of the effectiveness of the peer review system is also conducted. The evaluation of the effectiveness may be based on – but is not limited to – key performance indicators. In this context, the key performance indicators are

- the number of peer reviews performed in the corresponding period;
- the number of sectors covered;
- the number of Member States involved;
- the number of best practices identified;
- the ratio of positive to negative feedbacks received;
- the number of improvements in market surveillance activities triggered by the peer review.

Example - **Organisation of a pilot peer review**

A pilot peer review could be organised as a proof of concept - applying the process described under chapter 4 – to identify (i) what worked well, (ii) what difficulties were encountered, and (iii) to suggest improvements to be implemented.

The EUPCN could launch an open call to identify an ADCO that volunteers to organise this exercise, with the support of the Partnership. Any volunteering ADCO shall identify at least one MSA willing to be peer reviewed, e.g. ADCO members shall express their interest to participate during the plenary meeting or by email. Based on the replies collected and based on the budget available, the EUPCN will mandate an ADCO to organise the exercise.

The designated ADCO shall formally select the MSA to be peer reviewed and set up the Team in line with chapter 3.2. The Team shall (i) execute the peer review (see 3.2), (ii) draft the review report (see 3.3.1), (iii) draft the summary report (see 3.3.2).

After this exercise the Partnership could seek feedback from the peer reviewed MSA, the Team and the ADCO involved. The outcome of this feedback could then be annexed to the summary report and presented to the EUPCN.

Annex 1. Abbreviations and definitions

ADCO	Administrative Cooperation Group of Market Surveillance Authorities active in the same sector. European cooperation on market surveillance takes place through informal groups of market surveillance authorities, called Administrative Cooperation Groups (Art. 32 of Reg. (EU) 2019/1020).
EUPCN	European Union Product Compliance Network. The EUPCN aims to structure the coordination and cooperation between market surveillance authorities in EU countries, and streamline market surveillance practices within the EU that facilitate the implementation of joint enforcement activities by member state authorities, such as joint investigations (Art. 3 of Reg. (EU) 2019/1020).
MSA	Market Surveillance Authority: An authority of a Member State responsible for carrying out market surveillance on its territory.
Partnership	The established Task Force (operating under EUPCN) on setting up peer reviews according to the 2nd Work Programme 2023-2024 (Section 12 entitled "Mutual Visits and Peer Reviews").
SLO	Single Liaison Office. The single liaison office shall at least be responsible for representing the coordinated position of the market surveillance authorities and the authorities designated under Article 25(1) of Reg. (EU) 2019/1020 and for communicating the national strategies as set out in Article 13 of Reg. (EU) 2019/1020. The single liaison office shall also assist in the cooperation between market surveillance authorities in different Member States, as set out in Chapter VI of Reg. (EU) 2019/1020.
Peer Review	A voluntary review of the organisation, functioning and performance of an authority by other authorities, in order to strengthen the consistency of market surveillance activities in relation to the application of the Regulation and in accordance with Article 12 of the Regulation.

Annex 2: List of sectors

Code sector	List of sector (https://europa.eu/!PrkF8Q)	Code ADCO	ADCO (https://europa.eu/!jq3vRb)
1	Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	30	Market surveillance working group - Medical Device (MDD)
2	Cosmetics	9	ADCO PEMSAC
3	Toys	6	ADCO TOYS
4	Personal protective equipment	28	ADCO PPE
5	Construction	11	ADCO CPR
6	Aerosol dispensers		
7	Simple pressure vessels and pressure equipment	18	ADCO PED
8	Transportable pressure equipment	10	ADCO TPED
9	Machinery	4	ADCO MACHINE
10	Lifts	21	ADCO LIFT
11	Cableways	27	ADCO CABLE
12	Noise emissions for outdoor equipment	2	ADCO NOISE
13	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	22	ADCO ATEX
14	Pyrotechnics	15	ADCO PYROTEC
15	Explosives for civil uses	17	ADCO CIVEX
16	Appliances burning gaseous fuels	29	ADCO GAR
17	Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement	20	ADCO MEASURING INSTRUMENTS (MI)
18	Electrical equipment under EMC	19	ADCO EMC
19	Radio equipment under RED	25	ADCO RED
20	Electrical appliances and equipment under LVD	23	ADCO LVD
21	Electrical and electronic equipment under RoHS and WEEE and batteries	12	ADCO ROHS
22	Chemicals	5	Forum for exchange of information on enforcement (CHEMICALS)
23	Eco-design and Energy Labelling	7	ADCO ECOD
23	Eco-design and Energy Labelling	31	ADCO ENERLAB
24	Tyre labelling	8	ADCO TYRES
25	Recreational craft	16	ADCO RCD
26	Marine equipment	26	ADCO MARINE EQUIPMENT (MED)
27	Motor vehicles and tractors	32	Forum for exchange of information on enforcement (motor vehicles) (VEHICLE)
28	Non-road mobile machinery	32	NRMM
29	Fertilisers	3	ADCO FERTILISERS
30	Other consumer products under GPSD (optional)		
31	Biocides	14	Forum for exchange of information on enforcement (biocides) (BIOCIDE)
32	Textile and Footwear labelling	13	ADCO TEXTILE
33	Crystal glass		
34	Unmanned aircraft systems	33	ADCO DRONES
35	Packaging and packaging waste	1	ADCO PREPACKAGES
36	Tobacco	24	Expert Group on tobacco control

Guidance Document on Peer Reviews

Year

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
						Year						
COM		Announce - budget, - report deadline										
EUPCN			Launch EoI								Approve list of MSAspr	
SLO			Announce to MSAs & collect EoI			Provide list of MSAs						
Partnership							- Cluster / sector - Send list to ADCO			Compile & submit the list to EUPCN		
ADCO								Evaluate & select the candidate MSAspr. Provide list to Part.				
Team												
MSA to be peer reviewed			Submit EoI									
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
						Year						

Abbreviations used:

ADCOs:	Administrative Cooperation Group of Market Surveillance Authorities active in the same sector
COM	European Commission, represented by DG GROW, chair of the EUPCN
EoI:	Expression of Interest
EUPCN:	European Union Product Compliance Network
Info.	Information
MSA:	Market Surveillance Authority
MSApr:	Market Surveillance Authority to be peer reviewed/Peer reviewed MSA
Part.:	Partnership - the established Task Force
PR:	Peer review
PR.Rep:	Peer review report
SLO:	Single Liaison Office
Sum.Rep:	Summary report

		Year+1										
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
COM									Collect Sum.Rep (contract)			
EUPCN												
SLO												
Partnership		* Team briefing: - budget, - process, - provide checklist							Collect Sum.Rep	Collect feedback from: - Team - MSApr - ADCO	Prepare feedback outcome	Present feedback to EUPCN
ADCO	- Select the PR team - Inform team, MSApr & Part.								Collect Sum.Rep			Present summary report to EUPCN
Team		Prepare (~ 0.5d) - Contact MSApr - organise PR - select activities for PR		Execute PR (~ 2d)			Report (draft and commenting) (~ 3d)		Finalise & submit (~0.5d) * PR.Rep - MSApr * Sum.Rep - MSAp - ADCO - Part)			
MSA to be peer reviewed	Agree on Team composition	* Define - time of PR - activities for PR * Provide logistics		Provide preliminary documentation to Team			Comment draft PR.Rep & Sum.Rep		Approve PR.Rep & Sum.Rep			
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
		Year+1										

Abbreviations used:

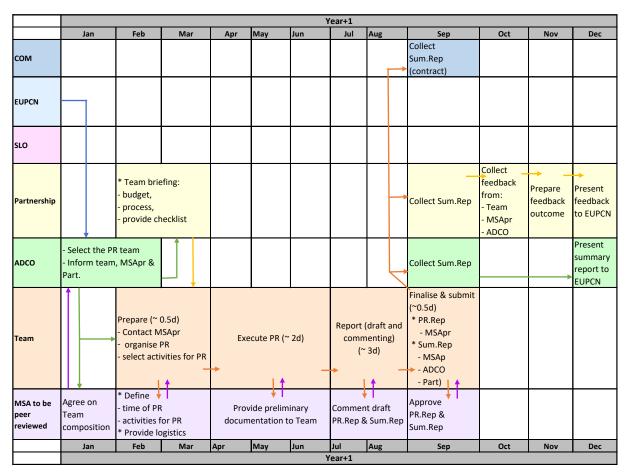|	
ADCOs:	Administrative Cooperation Group of Market Surveillance Authorities active in the same sector
COM	European Commission, represented by DG GROW, chair of the EUPCN
EoI:	Expression of Interest
EUPCN:	European Union Product Compliance Network
Info.	Information
MSA:	Market Surveillance Authority
MSApr:	Market Surveillance Authority to be peer reviewed/Peer reviewed MSA
Part.:	Partnership - the established Task Force
PR:	Peer review
PR.Rep:	Peer review report
SLO:	Single Liaison Office
Sum.Rep:	Summary report

Annex 4: Examples of MSA activities (non-comprehensive list) that can be covered during peer review

Sample selection strategy

- Risk based approach
- Sampling process (product and economic operators)
- Proactive surveillance (e.g. EU and national surveillance projets)
- Reactive surveillance (e.g. consumer complaints, accidents, notification from other MSAs

Product checks and tests

- Use of checklists for conducting the inspections
- Risk assessment (e.g. identification, analysis, evaluation)
- Compliance assessment (e.g. formal and technical requirement)
- Use of testing facilities and procedures related to them
- Evaluation of testing results

Reports and measures

- Methods and ways to contact with the EOs and other parties
- Conducting corrective measures (mandatory and voluntary)
- Use of ICSMS (input and follow-up)
- Enforcement management procedures

Follow-up surveillance and notification

- Verification of corrective measures
- Procedure regarding notification (e.g. Safety Gate, SFG)

Cooperation, legislation and other issues

- Cooperation mechanisms(e.g. Customs, Association, other MSAs)
- Possible national implementing legislation
- Other legislative provision

Annex 5: Checklist for collecting the preliminary information from the MSA to be peer reviewed (will be added as soon as the pilot exercise is finalised)

Annex 6: Template for collecting the feedback (will be added as soon as the pilot exercise is finalised)