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D3. Market Surveillance - Directorate D, Networks & Governance

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NOTE FOR THE ATTENTION OF EUPCN MEMBERS

Subject: Article 34(4) of Regulation (EU) 2019/1020 – Data to be entered in ICSMS in relation to investigations on products made available on the market and to products entering the EU market for which the release for free circulation has been suspended

Article 34(4) of Regulation 2019/1020 requires market surveillance authorities (MSAs) to enter in ICSMS certain information in relation to investigations carried out on products made available on the market, as well as in relation to products entering the Union market for which the release for free circulation has been suspended in accordance with Article 26 of the Regulation.

Article 34(4) of Regulation 2019/1020

Market surveillance authorities shall enter into the information and communication system in relation to products made available on the market for which an in-depth check of compliance has been carried out, without prejudice to Article 12 of Directive 2001/95/EC and Article 20 of this Regulation, and where applicable, in relation to products entering the Union market for which the process for the release for free circulation has been suspended in accordance with Article 26 of this Regulation, in their territory, the following information concerning:

(a) measures according to Article 16(5) taken by that market surveillance authority;
(b) reports of testing carried out by them;
(c) corrective action taken by economic operators concerned;
(d) readily available reports on injuries caused by the product in question;
(e) any objection raised by a Member State in accordance with the applicable safeguard procedure in the Union harmonisation legislation applicable to the product and any subsequent follow-up;
(f) where available, failures by authorised representatives to comply with Article 5(2);
(g) where available, failures by manufacturers to comply with Article 5(1).

In the framework of preparations for the implementation of Regulation 2019/1020, several Single Liaison Offices have raised questions concerning the interpretation and practical application of this provision with respect to products entering the Union market for which the process of release for free circulation has been suspended. These questions essentially relate to:

- the notion of "in-depth check of compliance" and its practical application;

- the information which MSAs are required to enter in ICSMS where they have been notified of the suspension of release for free circulation by the authorities in charge of the control on products entering the EU (usually customs authorities).

- the role of the future IT interface between national customs systems and ICSMS pursuant to Article 34(7) of the Regulation.

This note provides elements of understanding prepared jointly by the responsible teams in DG GROW and DG TAXUD. It reflects the technical views of the services but does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret EU law.

1. BACKGROUND

Article 34(4) was the result of political compromises achieved by the legislators during the negotiation process that led to Regulation 2019/1020.

In the Commission proposal for the Regulation[1], the proposed Article 34 included two distinct provisions as regards the information to be entered in ICSMS. These provisions were subsequently merged and amended during the negotiations in the European Parliament and Council.

Commission initial proposal for Regulation (EU) 2019/1020

Article 34 (e) and (f):

[Market surveillance authorities shall enter the following information into the system]:

(e) in relation to products made available on the market in their territory, without prejudice to Article 12 of Directive 2001/95/EC and Article 19 of this Regulation, the following information:

- *i. any non-compliance;*
- *ii. the identification of hazards and the economic operator concerned;*
- *iii. any possible risks not restricted to their territory;*
- *iv. the results of testing carried out by them or the concerned economic operator;*
- *v. details of voluntary measures taken by economic operators;*
- *vi. details of restrictive measures taken by that market surveillance authority, where applicable, the penalties imposed;*
- *vii. the outcome of contacts with an economic operator and the follow up by that economic operator;*
- *viii. failures by a person responsible for compliance information to comply with Article 4 (3);*
- *ix. (ix) failures by manufacturers to comply with Article 4(4).*

(f) in relation to products entering the Union market for which the process for the release for free circulation has been suspended in accordance with Article 27, in their territory, the following information:

- *i. any non-compliance;*
- *ii. the identification of any hazards and the economic operator concerned;*
- *iii. the results of testing carried out by them or the concerned economic operator;*
- *iv. details of restrictive measures taken by that market surveillance authority and, where applicable, the penalties imposed;*
- *v. the outcome of contacts with an economic operator and the follow up by that economic operator;*
- *vi. any other control or test reports carried out by or at the request of the market surveillance authority;*
- *vii. any objection raised by a Member State in accordance with the applicable safeguard procedure in the Union harmonisation legislation applicable to the product and any subsequent follow-up.*

[1] COM(2017)795, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2017:795:FIN

Thus, the Commission's initial proposal sheds light on the coverage by Article 34(4) of the Regulation of two different situations relating, on the one hand, to the investigation of products on the domestic market and, on the other hand, to cases of products for which the release for free circulation has been notified to the MSAs.

2. HOW TO UNDERSTAND ARTICLE 34(4)

In light of the above, we consider that the requirements laid down in Article 34(4) of Regulation 2019/1020 need to be read in two parts, as follows:

- MSAs shall enter into ICSMS, in relation to products made available on the market for which an in-depth check of compliance has been carried out, the following information: *[points (a) to (g)]*;

- Where applicable, MSAs shall enter into ICSMS in relation to products for which the release for free circulation has been suspended (i.e. for products entering the EU for which there is cause to believe that the product does not comply with the Union law applicable to it or that it presents a serious risk), the following information: *[points (a) to (g)]*.

2.1. Information on products made available on the market for which an in-depth check of compliance has been carried out

The criterion of an in-depth check of compliance, introduced by the Council during the co-decision process, applies exclusively to products investigated by MSAs on the national market. For such cases, all information listed in points (a) to (g) have to be provided, when they are available, by the authority entering the product/cases data in ICSMS. Recital 58 clarifies the cases in which products investigated on the national market must be entered in ICSMS and explains the notion of in-depth check of compliance.

Recital 58

In general, ICSMS should be used to exchange information considered helpful for other market surveillance authorities. This might include checks undertaken in the context of market surveillance projects, regardless of the outcomes of the tests.

The amount of data to be entered in ICSMS should strike a balance between imposing too great a burden, when the efforts for entering the data would exceed the work involved in doing the actual checks, and being comprehensive enough to support greater efficiency and effectiveness on the side of the authorities.

The data entered in ICSMS should also cover simpler checks than laboratory tests only. Nevertheless, there should be no need to include brief visual checks. As a guideline, checks which are individually documented should also be entered in ICSMS.

On this basis, we take the view that products/cases selected for control – whether documentary, physical or testing – should always be registered in ICSMS, unless the checks are so cursory that it would be too cumbersome to register them (e.g. an inspector skimming through an entire website or examining a supermarket aisle of toys to visually check CE markings, without however detecting any non-compliance). As a rule of thumb, any product control that would be registered and individually documented in national market surveillance files or systems should find its way into ICSMS.

2.2. Information on products for which the release for free circulation has been suspended by border authorities

As regards products entering the EU market and for which the release for free circulation has been suspended, the information in points (a) to (g) shall be entered in ICSMS regardless of the type of investigation (no "in-depth check" criterion) but only where applicable.

Thus, if the release for free circulation of a product is suspended, and irrespective of whether the MSAs conclude that the product complies or not, the information in points (a) to (g) shall be registered in ICSMS where they find application in the specific case at hand. For instance, MSAs may have to indicate in ICSMS: (a) the prohibition to placing on the market (Art. 28, to be read also in relation to Art. 16(5)), (b) test reports (even if such tests do not demonstrate non-compliance), (c) corrective action taken by the economic operator concerned, etc.

It is also important to keep in mind that, in accordance with Article 28(1) and 28(2), all products for which the release for free circulation has been refused because they are dangerous or non-compliant have to be registered as such in ICSMS (and also in the Safety Gate/RAPEX in case of serious risk[2]). The Regulation foresees no transition period and these provisions are immediately applicable, even in the absence of an electronic interface.

3. ROLE OF THE FUTURE SINGLE WINDOW INTERFACE

In order to support data exchange between customs authorities and MSAs, and its integration in ICSMS, Article 34(7) of Regulation 2019/1020 provides for the creation of an electronic interface between national customs systems and ICSMS. The interface will allow for the electronic notification in ICSMS of suspensions of release for free circulation and for related exchanges between customs and market surveillance authorities. It should be in place within four years after adoption of the relevant implementing regulation (target date: end 2025). The use of the interface will remain voluntary in accordance with Article 25(4) of the Regulation.

How the system will work in practice once the interface is operational will be examined in the course of the joint IT project launched by DG GROW and DG TAXUD. The current working hypothesis is that notifications of suspension transmitted through the interface would arrive in a specific module or section of ICSMS, where they would be registered separately from the traditional part of the system containing 'Case Information' and 'Product Information' cases (CI/PI). MSAs would then have the ability to decide which cases need to be registered as CI/PI cases in the traditional part of ICSMS, in particular to preserve the consistency of the overall database and compliance with Articles 28(1)-(2) and 34(4) as regards the information to be entered by MSAs in ICSMS.

[2] Serious risk should be understood as covering not only product safety but all serious risks referred to in Art. 26(1)(e): "serious risk to health, safety, the environment or any other public interest referred to in Article 1", meaning "health and safety in general, health and safety in the workplace, the protection of consumers, the protection of the environment and public security and any other public interests protected by that legislation".

Pending the launch of the interface, market surveillance authorities will be responsible as from 16 July 2021 for ensuring that all required information is entered in ICSMS, where the conditions laid down in Articles 28(1)-(2) and 34(4) are met.

(e-signed)
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