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Commission Notice

Guidelines for the practical implementation of the Safety Business Gateway under Article 27(2) of Regulation (EU) 2023/988

(Text with EEA relevance)

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1. Introduction

This Notice provides guidelines for the practical implementation of the Safety Business Gateway, and on how businesses and market surveillance authorities can access and use this gateway in line with the General Product Safety Regulation (GPSR)¹.

This Notice is intended purely as a guidance document – only the text of the EU legislation itself has legal force. Any authoritative reading of the law must stem from the text of the Regulation and directly from the decisions of the Court of Justice of the European Union. The information set out in this Notice is of a general nature only and is not specifically addressed to any particular individual or entity.

Neither the European Commission nor any person acting on behalf of the European Commission is responsible for any use that may be made of the following information. The guidance offered may be modified at a later date.

2. What is the Safety Business Gateway?

The Safety Business Gateway is the web portal made available on the Safety Gate Portal through which businesses must inform the Member States' market surveillance authorities about dangerous products and accidents, including the measures or actions taken to address these dangerous products and accidents, as described in Article 9(8), Article 10(2), Article 11(2) and (8), Article 12(4), Article 20 and Article 22 of the GPSR. The use of the Safety Business Gateway is mandatory for businesses to comply with their reporting obligations. Additionally, it can also be used by manufacturers to alert consumers in line with Article 9(9) of the GPSR.

3. Mandatory use of the Safety Business Gateway by businesses

Businesses must use the Safety Business Gateway in certain situations and depending on their role in the supply chain, namely, whether they are acting as an economic operator (meaning the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with the GPSR) or as a provider of an online marketplace.

The submission of notifications, when required by the GPSR, through the Safety Business Gateway is reserved for the economic operators and providers of online marketplaces concerned by the specific product that is subject to the notification, based on Articles 9, 10, 11, 12 and 22 of the GPSR, or on the basis of Article 20 of the GPSR in the case of accidents. Therefore, any

¹ Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) ELI: <http://data.europa.eu/eli/reg/2023/988/oj>

other third parties (e.g. business competitors) are excluded from submitting notifications via the Safety Business Gateway.

The accidents – that economic operators are obliged to notify under Article 20 of the GPSR – relate to occurrences associated with the use of a product that resulted in an individual's death or in serious adverse effects on that individual's health and safety. Those effects can be permanent or temporary, and can include injuries, other damage to the body, illnesses and chronic health effects.² Under Article 20(1) of the GPSR, the use of the Safety Business Gateway to report accidents is an obligation for all products, including those which are also subject to Union harmonisation legislation as defined by Article 3, point (27) of the GPSR.

Manufacturers and authorised representatives

Under the GPSR, the manufacturer has an obligation to inform the market surveillance authorities about a product, if the manufacturer considers or has reason to believe that the product is dangerous (see Article 9(8)(c) of the GPSR) and inform consumers of the corrective measures taken (see Article 9(8)(b) of the GPSR).

Example 1. The manufacturer discovers that the folding chair they produced presents a risk of collapsing under the weight of the user, causing them to fall and get injured. In this scenario, the company then needs to take the necessary corrective measure(s), inform consumers thereof, and inform the market surveillance authorities about this through the Safety Business Gateway.

This obligation also extends to the authorised representative, who must inform the competent national authorities about dangerous products and accidents through the Safety Business Gateway if this has not already been done by the manufacturer (see Article 10(2)(c) of the GPSR).

Moreover, if a manufacturer becomes aware that a product has caused an accident, the manufacturer must report that accident through the Safety Business Gateway (see Article 20(1) of the GPSR), without undue delay from the moment it knows about the accident. If the manufacturer is not established in the EU, the responsible person must ensure that the accident is reported through the Safety Business Gateway.

Finally, manufacturers may use the Safety Business Gateway to alert consumers about dangerous products (see Article 9(8)(c) and Article 9(9) of the GPSR).

Importer

Importers are obliged to report dangerous products in the situations set out below:

- **Products not yet placed on the market.** If the importer detects that a product is dangerous before placing it on the market, the importer must inform the product manufacturer and ensure that the market surveillance authorities are informed through the Safety Business Gateway (see Article 11(2) GPSR). This means that either the

² See Article 20(2) of the GPSR.

manufacturer must send that information via the Safety Business Gateway, or the importer must do so.

- **Products already placed on the market.** If the importer considers or has reason to believe that a product that they have placed on the market is dangerous, the importer must immediately: (i) inform the manufacturer (see Article 11(8)(a) of the GPSR); (ii) ensure that the necessary corrective measures are taken (immediately taking such measures themselves if they have not been taken by the manufacturer) (see Article 11(8)(b) of the GPSR); (iii) ensure that consumers are immediately informed thereof (see Article 11(8)(c) of the GPSR); and (iv) inform the relevant market surveillance authorities through the Safety Business Gateway (see Article 11(8)(d) of the GPSR).

Example 2. A company imports a candleholder. After placing it on the market, the importer identifies that the screws holding the candle can come loose, which may result in the candle falling on the floor, potentially causing a fire or burns. In this scenario, the company must inform the manufacturer of the risk detected in relation to the product and check whether the manufacturer takes the necessary corrective measures, informs the consumers thereof and informs the market surveillance authorities thereof through the Safety Business Gateway. If the manufacturer fails to take effective corrective measures, the importer must take the appropriate corrective measure.

- **Accident reporting.** If the importer has knowledge of an accident caused by a product that they placed or made available on the market, the importer must, without undue delay, inform the manufacturer thereof. The manufacturer must then notify the accident via the Safety Business Gateway or instruct the importer to do so. If the manufacturer is not established in the EU, the importer must ensure that the accident is notified (see Article 20 GPSR).

Responsible person

If the manufacturer of the product is not established in the EU, the responsible person within the meaning of Article 16(1) of the GPSR or Article 4(1) of Regulation (EU) 2019/1020 must ensure that an accident of which they have knowledge is notified via the Safety Business Gateway.

Distributor

Distributors are obliged to take action if they consider that a product is dangerous or does not meet the labelling and safety requirements set out in Articles 9(5), (6) and (7) and Article 11(3) and (4) of the GPSR. It may be the case, for example, that the product does not contain information identifying the product, information identifying the manufacturer and importer, or safety information and clear instructions. The distributor must ensure that the market surveillance authorities are immediately informed of such irregularities through the Safety Business Gateway (see Article 12(4)(c) of the GPSR). This means that either the manufacturer or importer must send that information via the Safety Business Gateway or, if they have not done so, the distributor must do it.

Example 3. A company distributes teething necklaces intended for children. After making the product available on the market, the company becomes aware that the necklaces can easily break, resulting in the release of small parts. Children under 36 months could easily put these in their mouth and choke on them. This is an example of a case in which the distributor must ensure that the market surveillance authorities are informed through the Safety Business Gateway (either via a notification from the manufacturer or importer, or by sending this information themselves if the manufacturer or the importer has failed to do so).

When it comes to accidents, a distributor who has knowledge of an accident caused by a product that they placed or made available on the market must, without undue delay, inform the manufacturer thereof. The manufacturer can instruct the distributor to notify product-related accidents via the Safety Business Gateway on their behalf (see Article 20(3) of the GPSR).

Providers of online marketplaces

Providers of online marketplaces are also subject to reporting obligations through the Safety Business Gateway (see Article 22(12), point (d) and point (e)(ii) of the GPSR). Providers of online marketplaces must report to the market surveillance authorities, through the Safety Business Gateway, both dangerous products, of which they have actual knowledge and which were offered on their online interfaces, as well as any accidents caused by a product made available on their marketplace of which they have been informed and which have resulted in a serious risk or actual damage to the health or safety of a consumer. They must also inform the relevant traders and economic operators without delay of the information they have received regarding accidents or safety issues, where they have knowledge that the product in question was offered by those traders through the providers of online marketplaces' interfaces.

Example 4. The provider of an online marketplace is informed via a consumer complaint or by the press that a plastic doll sold on its marketplace contains chemical substances that are not authorised in the EU and poses a risk to the health and safety of consumers. In this scenario, the provider of the online marketplace must inform the EU market surveillance authorities and provide sufficient details about the risk to the health and safety of consumers, through the Safety Business Gateway, and also inform accordingly the trader who offered the product via that provider's online interface.

4. Information received by market surveillance authorities in the Safety Business Gateway

Through the Safety Business Gateway, the market surveillance authorities of the EU Member States receive information from economic operators about dangerous products they have placed or made available on the market and from providers of online marketplaces about dangerous products that have been offered to EU consumers via their online interfaces. They also receive information about accidents caused by a product made available on those interfaces. All this information is analysed by the relevant market surveillance authorities. If the national authorities find a product to be dangerous or otherwise non-compliant with the GPSR, the national market surveillance authorities take appropriate measures. If the product presents a serious risk to the

health and safety of consumers, the national authorities are obliged to notify the product and the relevant measures taken through the Safety Gate Rapid Alert System. If the product presents a less than serious risk, the national authorities must, in any case, inform the Commission and may notify the product and the relevant measures through the same system.

5. Access to the Safety Business Gateway

In addition to the information contained in this Notice, further step-by-step technical information on the practical use of the Safety Business Gateway is provided in the Safety Business Gateway User Manual for Economic Operators and Providers of Online Marketplaces and the Safety Business Gateway User Manual for National Authorities³, which are available on the Safety Business Gateway web portal.⁴

5.1. Where to access the Safety Business Gateway

You can access the Safety Business Gateway through the relevant section of the Safety Gate Portal.

5.2. Who has access to it

The following parties have access to the Safety Business Gateway:

a) Economic operators and providers of online marketplaces

Economic operators and providers of an online marketplace can have access to the Safety Business Gateway in accordance with Article 27(1) of the GPSR. They have access only to information concerning the notifications they submitted.

To access the Safety Business Gateway, an EU login account (the Commission's mandatory authentication service) is necessary.

b) Market surveillance authorities of the Member States

Market surveillance authorities can access the Safety Business Gateway in order to be informed about notifications submitted by economic operators or providers of online marketplaces as referred to under point (a). They need an EU login to access the Safety Business Gateway. Each market surveillance authority has access only to the notifications submitted to their respective Member State(s).

c) The European Commission

The European Commission is the administrator of the Safety Business Gateway. It allows businesses to publish information on its web portal to alert consumers under Article 9(9) of the GPSR.

³ Note that the Safety Business Gateway User Manual for National Authorities manual is only accessible to the market surveillance authorities of the Member States.

⁴ The Safety Business Gateway web portal can be accessed via the Safety Gate Portal.

6. Applicable language regime

The Safety Business Gateway is available in all official languages of the European Union, as well as in Icelandic and Norwegian.