



Council of the  
European Union

194946/EU XXVII. GP  
Eingelangt am 29/08/24

Brussels, 29 August 2024  
(OR. en)

12923/24

CONSOM 269  
COMPET 856  
CHIMIE 66  
MI 759  
CYBER 243  
JAI 1279  
DELECT 159  
DIGIT 189

## COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 August 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 6023 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 27.8.2024 supplementing Regulation (EU) 2023/988 of the European Parliament and of the Council with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk

Delegations will find attached document C(2024) 6023 final.

Encl.: C(2024) 6023 final



EUROPEAN  
COMMISSION

Brussels, 27.8.2024  
C(2024) 6023 final

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 27.8.2024**

**supplementing Regulation (EU) 2023/988 of the European Parliament and of the Council with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

The Safety Gate Rapid Alert System enables information on measures against dangerous non-food products to be circulated quickly among the national authorities responsible for product safety in the EU. The system was originally established under the name ‘RAPEX’ by Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety. On 13 December 2024, this Directive will be repealed and replaced by Regulation (EU) 2023/988 (‘General Product Safety Regulation’). Articles 25 and 26 of the Regulation contain new and updated provisions on the Safety Gate Rapid Alert System (new name of the existing ‘RAPEX’ system).

To ensure uniform rules for the functioning of the Safety Gate Rapid Alert System and the assessment of risks posed by products, uniform operating rules and a risk assessment methodology have been set out in Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’. These risk assessment criteria and operating rules of the RAPEX system need to be updated to take account of the provisions and objectives of the General Product Safety Regulation especially regarding the Safety Gate Rapid Alert System. That is the purpose of this delegated regulation.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The criteria currently specified in the risk assessment guidelines in Commission Implementing Decision (EU) 2019/417 are crucial to ensure that the Safety Gate Rapid Alert System works effectively and efficiently and that product safety rules are applied consistently in the EU Single Market.

With the entry into force of Regulation (EU) 2023/988 on general product safety, the previous risk assessment methodology needs to be adjusted and its application to products covered by EU harmonisation legislation, that are also subject to notification through the Safety Gate Rapid Alert System in case they pose a serious risk, be clarified.

To gather input for a modernised risk assessment methodology from all relevant stakeholders, the Commission set up an expert working group, which operated as a sub-group to the Consumer Safety Network established under Article 10 of Directive 2001/95/EC.

Member States’ representatives were informed of the creation of this subgroup at the meeting of the Consumer Safety Network on 11 May 2023. The subgroup was officially established in June 2023, with membership open to all Member States’ authorities that expressed an interest in being involved in its work. The following countries sent representatives: Belgium, Czechia, Denmark, Germany, Ireland, France, Lithuania, Luxembourg, Poland, Slovakia, Finland and Sweden.

The subgroup was also opened up to those with observer status in the Consumer Safety Network. ANEC (‘the European consumer voice in standardisation’) and BEUC (the European Consumer Organisation) actively participated too. Several independent experts and industry experts who showed interest were also admitted to the working group and provided valuable input.

The subgroup met four times between June and December 2023 and results were regularly reported back to both representatives of Member States in the Consumer Safety Network and

to Member States's representatives from the EU Product Compliance Network set up under Regulation (EU) 2019/1020 on market surveillance and compliance of products.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

Article 26(10) of the General Product Safety Regulation requires the Commission to adopt delegated acts to specify various aspects of the Safety Gate Rapid Alert System, namely: access to it, how it will operate, what information is to be entered in it, requirements for notifications in it and risk assessment criteria.

Against this background, Annex I to the delegated regulation sets out rules on the operation of the Safety Gate Rapid Alert System, on the information to be entered into the system and other operational provisions. The rules specify the processes for sending notifications through the Safety Gate Rapid Alert System, validating them in the system (i.e., transmitting them to the Member States) and updating, removing, or withdrawing them. They also concern the publication of selected information of the notifications on the Safety Gate Portal.

Annex II of the delegated regulation provides the criteria and methodology for assessing the level of risk posed by a product covered by this delegated regulation. The methodology contains an explanation of the steps to take during a risk assessment. The methodology ensures the correct use of the risk assessment criteria and, consequently, a correct determination of the level of risk by the Member States with respect to products notified through the Safety Gate Alert System. Annex II further sets out cases in which a product can be systematically presumed as posing a serious risk without the need for an individual risk assessment.

The operating rules and the risk assessment criteria should apply to products falling within the scope of the General Product Safety Regulation and of Regulation (EU) 2019/1020 of the European Parliament and the Council of 20 June 2019 on market surveillance and compliance of products. Specifically, the operating rules and the risk assessment criteria should apply to the health and safety risks posed to consumers by products subject to Regulation (EU) 2023/988 and to the health and safety risks posed to end-users by products subject to (EU) 2019/1020. The Regulation should also apply to the risks to other public interests as regards products covered by Regulation (EU) 2019/1020. Given the specific nature of those other public interests protected by Union harmonisation legislation, the criteria for the assessment of the level of risk to those interests should take into account the specific objectives and requirements of the applicable Union harmonisation legislation and therefore could differ from the criteria for the assessment of the level of the health and safety risk. As regards the assessment of risks to public interests other than health and safety protected by Union harmonisation legislation, it should be recalled that the administrative cooperation groups play a special role as, in accordance with Article 32(2), point (g), of Regulation (EU) 2019/1020, as it is their task to facilitate the sector-specific evaluation of products subject to Union harmonisation legislation, including risk assessments.

# COMMISSION DELEGATED REGULATION (EU) .../...

of 27.8.2024

## supplementing Regulation (EU) 2023/988 of the European Parliament and of the Council with regard to rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2023/988 of the European Parliament and the Council of 10 May 2023 on general product safety<sup>1</sup>, and in particular Article 26(10) thereof,

Whereas:

- (1) To ensure a proper and efficient functioning of the Safety Gate Rapid Alert System it is essential to provide detailed rules concerning access to and operation of that System, information to be entered in that System and notification requirements and to introduce the criteria for the assessment of the level of risks posed by products.
- (2) In accordance with Article 26 of Regulation (EU) 2023/988, Member States are to, or may, according to the level of the risk posed by the product, notify corrective measures taken or envisaged with respect to dangerous products on the basis of that Regulation and on the basis of Article 20 of Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>2</sup>, for products subject to those two Regulations. Given that Article 26(10) of Regulation (EU) 2023/988, pursuant to which the Commission is to adopt a delegated act specifying, *inter alia*, the requirements for the notifications of such products and the criteria for the assessment of their risk, applies in accordance with Article 2(1) of Regulation (EU) 2023/988 both to products covered by specific Union harmonisation legislation and by Regulation (EU) 2023/988, it is necessary to provide detailed rules for the Safety Gate Rapid Alert System and criteria for the assessment of the level of risk of products subject to both Regulation (EU) 2023/988 and Regulation (EU) 2019/1020.
- (3) In order to facilitate the exchange of information on all dangerous products made available on Union market via a single tool, it should be possible for Member States to communicate on all their envisaged or taken corrective measures with respect to dangerous products, including the measures in relation to products presenting a less than serious risk, via the Safety Gate Rapid Alert System.

<sup>1</sup> OJ L 135, 23.5.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/988/oj>.

<sup>2</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1020/oj>).

- (4) Notifications submitted by the national authorities through the Safety Gate Rapid Alert System should be as detailed as possible to ensure that the product in question can be identified by other authorities who are to or may take follow up measures. Therefore, it is necessary to specify the requirements that those notifications should meet, in particular the information to be provided for different types of notifications.
- (5) Accordingly, the Commission should check the completeness of the notifications taking into account in particular the information to be provided for different types of notifications. At the same time, it should be possible for the Commission to ask for additional relevant information or a correction of the notified information, where necessary, before the Commission validates that notification in the system and by doing so transmits it to the other Member States.
- (6) To ensure that in accordance with Article 34(1) of Regulation (EU) 2023/988 the general public has free of charge and open access to selected information that has been notified through the Safety Gate Rapid Alert System, and notably to information on dangerous products and corrective measures taken in relation to them, the Commission should publish selected information, contained in the notifications sent through the Safety Gate Rapid Alert System, on the Safety Gate Portal.
- (7) Based on information from the Member State which submitted notification, the Commission should update the notifications in the Safety Gate Rapid Alert System. Such updates should only concern the notification on which that Member State indicated an update. To ensure that the information on the Safety Gate Portal is up-to-date, the Commission should also update the information displayed on the Portal or remove it, where appropriate.
- (8) This Regulation should apply to the health and safety risks posed to consumers by products subject to Regulation (EU) 2023/988 and the health and safety risks posed to end-users by products subject to (EU) 2019/1020. This Regulation should lay down the criteria for the assessment of the level of risk of those products.
- (9) This Regulation should also apply to the risks to other public interests as regards products covered by Regulation (EU) 2019/1020. Given the specific nature of those other public interests protected by Union harmonisation legislation, the criteria for the assessment of the level of risk to those interests should take into account the specific objectives and requirements of the applicable Union harmonisation legislation and therefore could differ from the criteria for the assessment of the level of the health and safety risk. As regards the assessment of risks to public interests other than health and safety protected by Union harmonisation legislation, the administrative cooperation groups play a special role as, in accordance with Article 32(2), point (g), of Regulation (EU) 2019/1020, it is their task to facilitate the sector-specific evaluation of products subject to Union harmonisation legislation, including risk assessments.
- (10) In the light of the good experience with the risk assessment guidelines that were included in Commission Implementing Decision 2019/417 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX', of the need to preserve the continuity between the RAPEX and the Safety Gate Rapid Alert System and of the objective of ensuring a correct and effective operation of Safety Gate Rapid Alert System, the criteria for the assessment of the level of risks should also include a methodology allowing the national authorities to assess how a harm or a hazard might turn into a risk and, in that context, how the level of the risk should be assessed and established. That approach ensures the correct use of those criteria and,

consequently, a correct determination of the level of risk by the Member States with respect to products notified through the Safety Gate Alert System.

- (11) The national authorities notifying products through the Safety Gate Rapid Alert System should be able to take account of the fact that in certain situations or as regards products with certain characteristics there is already a well-established evidence, such as statistics, outcomes of market surveillance or risk assessments, allowing to presume the existence of a serious risk posed by such products. In such situations, the national authorities should not be required to submit individual risk assessments for the purposes of the notification through the Safety Gate Rapid Alert System.
- (12) This Regulation should apply from the same date as Regulation (EU) 2023/988,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

The Safety Gate Rapid Alert System shall be operated in accordance with the rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System and notification requirements set out in Annex I.

#### *Article 2*

The level of the risk posed by a product shall be assessed in accordance with the criteria set out in Annex II.

#### *Article 3*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 13 December 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27.8.2024

*For the Commission*  
*The President*  
**Ursula VON DER LEYEN**