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Subject:	ANNEXES to the Commission Delegated Regulation 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 Annexes 1 to 2.

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ANNEXES 1 to 2

ANNEXES

to the

Commission Delegated Regulation

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

ANNEX I

RULES ON ACCESS TO AND OPERATION OF THE SAFETY GATE RAPID ALERT SYSTEM, INFORMATION TO BE ENTERED IN THAT SYSTEM AND NOTIFICATION REQUIREMENTS

1. TYPES OF NOTIFICATIONS THROUGH THE SAFETY GATE RAPID ALERT SYSTEM

1.1. Serious risk notification

Where a Member State is to notify through the Safety Gate Rapid Alert System a corrective measure taken in accordance with Article 26(1), point (a), of Regulation (EU) 2023/988 or in accordance with Article 20 of Regulation (EU) 2019/1020, the relevant national authority shall prepare and submit a notification. Such notification shall be classified in the Safety Gate Rapid Alert System as ‘serious risk notification’.

1.2. Other risk notification

National authorities may notify the Commission about corrective measures referred to in Article 26(3) of Regulation (EU) 2023/988 by using the Safety Gate Rapid Alert System. In that System such notification shall be classified as ‘other risk notification’.

1.3. Notification for information

National authorities may notify, by using the Safety Gate Rapid Alert System, an envisaged corrective measure under Article 26(2) of Regulation (EU) 2023/988 when the national authority considers such notification necessary with regard to the urgency of the risk to the health or safety of consumers or other end users. Such notifications shall be classified in the System as ‘notification for information’.

1.4. Follow-up notifications

Notifications to be submitted by other Member States through the Safety Gate Rapid Alert System in accordance with Article 26(7) of Regulation (EU) 2023/988 shall be classified in that System as ‘follow-up notifications’.

1.5. Alerts sent by the Commission

The Commission may use the Safety Gate Rapid Alert System to inform the Member States pursuant to Article 26(8) of Regulation (EU) 2023/988. Such information shall be classified in that System as ‘Commission alerts’.

2. INFORMATION TO BE INCLUDED IN NOTIFICATIONS SUBMITTED BY NATIONAL AUTHORITIES THROUGH THE SAFETY GATE RAPID ALERT SYSTEM

2.1. The elements to be included in the notifications are listed in points 2.2. and 2.3. Notifications submitted by national authorities through the Safety Gate Rapid Alert System shall be as complete as possible. Where the required information is not available to the notifying Member State at the time a notification is submitted, this shall be clearly indicated and explained by the notifying Member State. Once the missing information becomes available, the notifying Member State shall update its notification in accordance with point 4 of this Annex.

2.2. Notifications covered by points 1.1 to 1.3 shall include the following:

(a) information on the safety requirements applicable to the notified product:

(i) the reference to the applicable Union and national legislation and, where relevant, standards;

(ii) the proof of conformity, where relevant;

(iii) the certificates, where relevant and available;

(b) a risk description of the notified product, including:

(i) description of the risk explaining the defect of the product and how it leads to the risk;

(ii) the risk category;

(iii) the risk level;

(iv) the description of the results of laboratory or visual tests, where applicable;

(v) the test reports, including the date of the tests, and certificates providing non-compliance of the notified product with the safety requirements, where applicable;

(vi) a risk assessment, in accordance with Annex II;

(vii) where applicable, information on known accidents or incidents;

(c) information on the taken or envisaged corrective measures, in particular:

(i) the type of the measure (compulsory or voluntary);

(ii) category (for example, withdrawal from the market, recall);

(iii) geographical scope;

(iv) when available, date of entry into force and duration of the measure (for example, permanent, temporary);

(v) when available, the URL link to the recall notice;

(d) indication of whether a notification, part thereof and/or attachments thereto are confidential and, if relevant, a request for confidentiality accompanied by a justification for such a request;

(e) information identifying the product concerned, including when available:

(i) the indication of whether the product is a consumer or professional product;

(ii) the product category;

(iii) the OECD portal category;

(iv) the product name;

(v) the brand;

(vi) the model or the type number or both;

(vii) the barcode;

(viii) the batch or serial number;

(ix) the customs code;

(x) the description of the product and its packaging;

(xi) the total number of items covered by the notification;

(xii) any other information allowing the national authorities to identify the product;

(xiii) specification whether the product is counterfeit;

(f) traceability information, including when available:

(i) information establishing the product's origin (country of origin);

(ii) full contact details of the manufacturer including their name, their registered trade name or registered trademark, their postal and electronic address and their telephone number;

(iii) information on the countries of destination, contact details of importer(s);

(iv) information on distributors of the notified product in Union and retailers;

(v) the name, registered trade name or registered trademark, and contact details, including the postal and electronic address, of the responsible person in the Union in accordance with Article 4 of Regulation (EU) 2019/1020 and Article 16 Regulation (EU) 2023/988;

(vi) copies of orders, sales contracts, invoices, shipping documents, customs declarations, or any other document containing information about actors in the supply chain, where manufacturers and exporters of the notified product are located in third countries;

(vii) indication of where exactly the product has been made available;

(viii) the URL of the offer and its unique identifier, where the product is or has been sold online, and, where applicable, the name of the provider of an online marketplace;

(ix) information on the supply chains of the notified product, including in third countries;

(g) where relevant and available, reference to the information provided through the Safety Business Gateway, including:

(i) information on reported accidents related to the notified product;

(ii) the measures taken by the economic operator;

(h) where relevant, additional information on the context of the notification, including information on whether the measure was taken in the context of a coordinated enforcement activity at Union level or is a result of the complaint of a consumer or any other interested party in accordance with Article 33(4) or information submitted in accordance with Article 34(3) of Regulation (EU) 2023/988.

With regards to the information identifying the product concerned as provided by in point (e), the notification shall specify, if possible, whether the identification data is located directly on the product or packaging where it was placed by the manufacturer, or on labels placed on the product or its packaging by the importer or distributor.

The notification shall be accompanied by pictures showing the product and its packaging including the relevant labels in high-resolution and in colour.

2.3. Follow-up notifications under point 1.4 shall include information that was not included in the original notification, or information which is to be updated or complemented, and information on the follow-up measure or action taken by the national authority submitting the follow-up notification.

Follow-up notifications shall in particular provide detailed information on the risk assessment if the Member State notifying the follow-up measure had a different conclusion on the level of the risk than the Member State that sent the original notification.

3. CHECK OF NOTIFICATIONS BY THE COMMISSION AND PUBLICATION

3.1. In accordance with Article 26(5) of Regulation (EU) 2023/988, the Commission shall check whether notifications submitted by the Member States are complete taking into account the requirements set out in point 2 of this Annex.

If, based on the information contained in the notification, the Commission considers that the notification is complete, the four working day deadline referred to in Article 26(5) of Regulation (EU) 2023/988 shall be triggered by the receipt of the notification.

3.2. The Commission may ask for additional information from the notifying national authorities or ask them to correct their notifications. In such cases the Commission shall set a deadline for complying with such requests.

In accordance with Article 26(5) of Regulation (EU) 2023/988, the four working day deadline set out in that Article shall start only after sufficient additional information is received or the requested correction of the notification is completed.

3.3. Based on the information available to it the Commission shall decide whether to validate a notification, if after the elapse of the deadline referred to in paragraph 2 of point 3.2,

(a) the additional information is not provided;

(b) the provided information is insufficient; or

(c) the correction of the notification is not completed.

3.4. The Commission may change the type of the notification concerned, in line with the categories set out in point 1, upon the validation of that notification and inform the notifying Member State thereof.

3.5. After the validation of a notification, the Commission shall ensure the publication of selected information included in the notification on the Safety Gate Portal.

3.6. The Commission shall not be liable for the correctness and the accuracy of the information provided by national authorities.

4. UPDATE OF NOTIFICATIONS

4.1. Member States shall notify to the Commission without undue delay and through the Safety Gate Rapid Alert System any update, modification or withdrawal of corrective measures notified through the Safety Gate Rapid Alert System.

4.2. Based on the information received under point 4.1 the Commission shall introduce the notified changes in the Safety Gate Rapid Alert System and, where applicable, publish those changes on the Safety Gate Portal.

5. SPECIFIC RULES CONCERNING FOLLOW-UP NOTIFICATIONS

5.1. In accordance with Article 26(7) of Regulation (EU) 2023/988 Member States, other than the Member State which notified the original corrective measure taken in relation to products presenting a serious risk, shall submit follow-up notifications through the Safety Gate Rapid Alert System, in particular in the following cases:

(a) the Member State carried out a specific market surveillance action in relation to a Safety Gate Rapid Alert System notification but did not find the notified product on its market;

(b) the Member State found the notified product on its market and took a corrective measure;

(c) the Member State found the notified product on its market, but no corrective measures were taken by that Member State;

(d) other actions were taken by the Member State or it obtained additional information on the notification.

Follow-up notifications sent in cases referred to in point (c) shall include explanation why the corrective measures were considered not necessary.

6. REMOVAL OF NOTIFICATIONS FROM THE SAFETY GATE RAPID ALERT SYSTEM AND THE SAFETY GATE PORTAL

6.1. In duly justified cases, Member States may request from the Commission to remove notifications they submitted through the Safety Gate Rapid Alert System.

6.2. If, on the basis of the justification provided by the Member State, the Commission removes the notification from the Safety Gate Rapid Alert System, it shall also remove it from the Safety Gate Portal.

6.3. After 10 years from the validation of the notification by the Commission, the Commission shall ensure that the selected information based on that notification is available to the general public in a separate archive section of the Safety Gate Portal.

ANNEX II

CRITERIA FOR ASSESSMENT OF THE LEVEL OF RISK

1. DEFINITIONS

For the purposes of this Annex, the following definitions apply:

(a) 'harm scenario' means the sequence of events leading to the harm materialising;

(b) 'probability of harm' means the probability that the harm may actually happen;

(c) 'risk management' means the follow-up action which aims to reduce or eliminate a risk identified in a risk assessment.

2. RISKS

2.1. This Annex provides criteria for the assessment of the level of the risk, to allow the Member States to comply with their obligations under Article 26(1) of Regulation (EU) 2023/988 and when submitting notifications through the Safety Gate Rapid Alert System under Article 26(2), (3) or (7) of that Regulation.

2.2. This Annex sets out requirements for the assessment of the health and safety risks of products subject to Regulations (EU) 2023/988 and (EU) 2019/1020 and the assessment of risks to other public interests as regards products covered by Regulation (EU) 2019/1020, in so far as such other public interests are protected by the Union harmonisation legislation.

2.2.1. Risks to health and safety

The requirements concerning the assessment of health and safety risks of products that are placed or made available on the market for consumers and, in the case of products covered by Regulation (EU) 2019/1020, for end users are set out in points 3 and 4 of this Annex.

2.2.2. Risks to public interests other than those referred to in point 2.2.1 as regards products covered by Regulation (EU) 2019/1020

Public interests covered by Union harmonisation legislation extend beyond the health and safety risks referred to in point 2.2.1. to include a broader range of protected interests such as the environment, animals, energy resources, property, public security or economic transactions.

In accordance with Article 19(2) of Regulation (EU) 2019/1020, the assessment as to whether a product presents a serious risk shall take account of the nature of the hazard and the likelihood of its occurrence.

In their assessment of risks to other public interests, Member States shall take into account the specific requirements of the Union harmonisation legislation, including the specific nature of the interests protected by that legislation and the requirements to be fulfilled by the products to ensure the protection of those interests.

Member States shall also take into account that risks to public interests other than health and safety may relate to product hazards that do not cause injury to end users but can generate different types of negative effects or harms that need to be identified and evaluated during the risk assessment, considering the requirements of the Union harmonisation legislation and the public interests they aim to protect.

Points 3 and 4 shall be applied to the assessment of risks to other public interests protected by Union harmonisation legislation, taking into account this point 2.2.2. and the specific requirements and objectives of the Union harmonisation legislation applicable to the risk at issue.

3. SEQUENCE WHEN ASSESSING THE LEVEL OF THE RISK

In order to comply with their notification obligations under Article 26(1) of Regulation (EU) 2023/988 and when submitting notifications under Article 26(2) or (3) of that Regulation, Member States shall follow the steps set out in this point, to:

(a) analyse how certain hazards may translate to potential harms;

(b) determine, with the factoring in of the probability, the level of risk in relation to products.

Member States are not obliged to follow steps from this point in cases listed in point 4.1.

3.1. Assessment of the anticipated harm scenario

3.1.1. National authorities shall assess the scenario in which the intrinsic product hazard may generate a harm. Such intrinsic product hazard shall be determined by referring to the extent of the adverse effect a product can cause for users.

3.1.2. A harm scenario shall be established by describing in detail:

(a) how the hazard leads to the harm;

(b) the severity of the harm caused.

3.1.3. When assessing the anticipated harm scenario, the national authorities shall consider that that a harm may vary in severity, depending on several factors such as the intrinsic hazard of the product, the way the product is used or may be used by the user, or the type of user who uses the product.

3.2. Harm scenario: steps leading to harm(s)

3.2.1. Different harm scenarios may be generated depending on the number of factors that need to be taken into account when determining the risk of a product. Member States shall start with a scenario where an intended user is using the product in accordance with its foreseeable use.

3.2.2. Where the product displays several hazards, harm scenarios shall be developed for each of them.

3.2.3. A harm scenario shall consist of the analysis of at least the following steps:

(a) the product has a defect or can lead to a dangerous situation during its foreseeable lifetime;

(b) the defect or dangerous situation results in an accident or adverse effect on an individual’s health or safety (or on other protected public interests, where applicable in accordance with point 2);

(c) the accident or adverse effect results in a harm.

3.2.4. Based on a case-by-case analysis, Member States may divide the steps referred to in point 3.2.3 into further steps, up to a maximum of five steps, to demonstrate how the product hazard can lead to harm.

3.2.5. Given that each step referred to in points 3.2.3 and 3.2.4 may reduce the event of probability considerably, Member States shall ensure that those steps are clear, concise and illustrate the shortest path to harm.

3.3. Severity of the injury or harm

3.3.1. The severity of the injury or harm to the health and safety of users may depend on the following elements:

(a) the type of hazard;

(b) how powerful the hazard is;

(c) how the hazard affects the user;

(d) what body part is injured;

(e) what impact the hazard has on one or several body parts;

(f) the type and behaviour of the user.

In order to assess the severity of the consequences, national authorities shall set objective criteria for their assessment, considering on the one hand, the level of medical intervention needed, and, on the other hand, the consequences to the further quality of life of the user.

3.3.2. Where several harm scenarios are considered in the risk assessment, the severity of each harm shall be classified separately and considered through the entire risk assessment process.

3.3.3. The severity of injuries or harms shall be classified into four levels, depending on the reversibility of an injury or harm, i.e., whether recovery from an injury or harm is possible and to what extent.

Member States shall apply the classification set out in this table when assessing the level of the risk of a product.

	Severity description	
Harm level	Health /safety harm	Other harm
4	Life-threatening: harm or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10% of disability.	Large negative effect, irreversible in several aspects, whether or not acute.
3	Severe: harm or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.	Significant negative effect, significant effort to reverse by specialist intervention, irreversible without this intervention and effort.

2	Moderate: harm or consequence for which a visit to the hospital may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than 6 months, and recovery is more or less complete.	Negative effect, reversible within a certain period, specialist intervention is required.
1	Minor: harm or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.	Negative effect, usually completely reversible within the short term without specialist intervention.

3.3.4. In exceptional cases, including those linked to cultural or climate specifics, Member States may deviate from the classification set out in point 3.3.3. In such cases Member States shall provide the justification for the deviation in the risk assessment accompanying the relevant notification.

3.3.5. Where applicable in accordance with point 2., harms to other protected interests may also be classified according to a similar four level gradation to what as set out in point 3.3.3, in more abstract terms.

3.4. Probability of harm

3.4.1. Member States shall give each step of the harm scenario established in accordance with point 3.2 a certain probability consideration.

3.4.2. Multiplying probabilities together shall provide the overall probability of the harm scenario.

3.4.3. Member States shall calculate the probability of a harm as a compound probability of all the steps occurring in a particular harm scenario. Where several harm scenarios are developed, Member States shall calculate the probability of each of them.

3.4.4. Member States shall apply the probability index set out in the table.

Probability of occurrence of the harm scenario during the foreseeable lifetime of the product	
Higher or equal to 50%	Very frequent
Between 5/10 and 1/10	Frequent
Between 1/10 and 1/100	Common
Between 1/100 and 1/1000	Occasional
Between 1/1000 and 1/10 000	Unlikely

Between 1/10 000 and1/100 000	Unusual
Between 1/100 000 and 1/1 000 000	Rare
Lower or equal to 1/1 000 000	Extremely rare

3.5. Expressing the probability of the materialisation of the harm

In order to determine the probability of the materialisation of a harm, the probability in a harm scenario may be expressed in the following manner:

(a) quantitatively: the probability may be expressed as a fraction, such as '> 50 %' or '> 1/1 000'.

(b) qualitatively: the probability may be expressed as 'very frequent', 'frequent', as set out in point 3.4.

3.6. Determining the level of risk

3.6.1. The level of risk of a product shall be determined as a combination of the severity of the harm under point 3.3 and the probability of the harm under point 3.4.

3.6.2. Member States shall use the grid set out in this point to assess the combination referred to in point 3.6.1, and determine the level of the risk accordingly as:

(a) serious;

(b) high;

(c) medium, or

(d) low.

Probability of occurrence of the harm during foreseeable lifetime of the product		Severity of harm			
		1	2	3	4
High	>50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S — Serious Risk
H — High risk
M — Medium risk
L — Low risk

3.7. Determination of the level of the risk for different harm scenarios

3.7.1. Where different harm scenarios are assessed in relation to a product, Member States shall determine the level of risk for each of those scenarios.

3.7.2. Where the assessment shows different levels of risks linked to the different harm scenarios, they shall take into account, for the purpose of Article 26 of Regulation (EU) 2023/988, the highest level of risk identified.

3.8. Documentation of the assessment of the level of the risk

Member States shall duly document their assessment of the level of the risk of a product and include this documentation in their notification through the Safety Gate Rapid Alert System, except in cases where a risk is presumed to be serious in accordance with point 4.

4. PRESUMPTION OF SERIOUS RISK

4.1. Risks posed by a product shall be presumed as a serious risk in the following cases:

(a) The product is linked to probable harm levels corresponding to severity levels 3 or 4 referred to in point 3.3 and consumers and end users cannot be reasonably expected to take the necessary precautionary measures to protect themselves or to prevent the materialisation of the risk or they are not informed adequately by the relevant economic operator on how to avoid the risk from materialising. The conditions of the materialisation of the risk need to be inherently linked to the hazard of the product.

(b) The economic operator having placed or made available the product on the market or the provider of an online marketplace having listed it on its online interface has indicated that the product poses a serious risk.

(c) The product has been subject to a recall, withdrawal, or removal of online content based on voluntary measures of economic operators or providers of online marketplaces.

(d) The product contains a chemical substance banned by Union harmonisation legislation or that substance is used in a concentration above the limit established by that legislation.

(e) Where there is well-documented evidence that certain features of the product consistently lead to a serious risk, including the following cases:

(i) small parts detaching from or present in toys or childcare products for children under 36 months;

(ii) highly flammable fancy dress costumes intended for children;

(iii) highly flammable nightwear and nightwear fabrics for children;

(iv) childcare articles posing drowning risk;

(v) drawstrings in the head, neck or upper chest on garments intended for young children;

(vi) electrical products with defective components that can lead to electric shock or fire.

4.2. In cases listed in point 4.1. Member States may submit the notification through the Safety Gate Rapid Alert System without an individual risk assessment.