Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334)

ANNEX

GUIDELINES FOR THE MANAGEMENT OF THE EUROPEAN UNION RAPID INFORMATION SYSTEM 'RAPEX' ESTABLISHED UNDER ARTICLE 12 OF DIRECTIVE 2001/95/EC (THE GENERAL PRODUCT SAFETY DIRECTIVE) AND ITS NOTIFICATION SYSTEM

PART III

APPENDICES

1. *Fields and information included in notifications*[(1)]

Fields that will be published on the web are shaded.

Notification Form
Section 1: General information
Case number
Creation date
Validation/distribution date
Notification type *
Notifying country
Full Contact details of the Notifying Authority *
Section 2: Product
Professional / Consumer Product
Product category *
OECD Portal category (if known)
Product (what the product is) *
Name *
Brand *
Type/number of model: *
Batch number/Bar code *
Customs code *
Product and packaging description *
Total number of items covered by the notification (if known) *
Photos:
Section 3: Regulations and standards applicable
Legal provisions (directive, decision, regulation, etc.) *
Standards *

* Indicates a mandatory field.

Proof of conformity *	
Is the product counterfeit? *	
Certificates	
Section 4: Traceability	
Country of origin (where the product manufactured) *	
Countries of destination *	
Full Contact details of the manufacturer or its representative(s) *	
Full Contact details of the exporter(s) *	
Full Contact details of the importer(s) *	
Full Contact details of the distributor(s) *	
Full Contact details of the retailer(s) *	
Is the product (also) sold online?	
Please give details: URL	
Section 5: Risk assessment	
Risk category *	
Risk level	
Summary of test results *	
Description of the technical issue that leads to the highest risk level	
Risk description (how the technical defect leads to the risk) *	
EU Legal provisions and /or Standards against which the product was tested and did not comply with *	
Information on known incidents and accidents *	
Section 6: Measures	
Type of measures adopted *	
If Voluntary:	Type of economic operator taking notified measure(s) *
	Name of economic operator taking notified measure(s) *
If Compulsory:	Name of authority ordering the notified measure(s) *
	Type of economic operator to whom the measure(s) were ordered *
Category of measures *	
Date of entry into force *	
Duration *	
Scope *	

* Indicates a mandatory field.

Has the notification been sent by a producer or a distributor under Article 5(3) of the GPSD? *
URL link to company recall page (if available)
Section 7: Confidentiality
Is the notification confidential? *
Scope of confidentiality
Justification
Section 8: Other
Additional information
Justification for sending ‘Notification for information’
Annexes
Photos (products, packaging and label)
Certificates
Test report and risk assessment
Notification sent by an economic operator through ‘Business Gateway’
Adopted measures
* Indicates a mandatory field.

2. ***Fields and information included in follow-up notifications***[(2)]

Fields that will be published on the web are shaded.

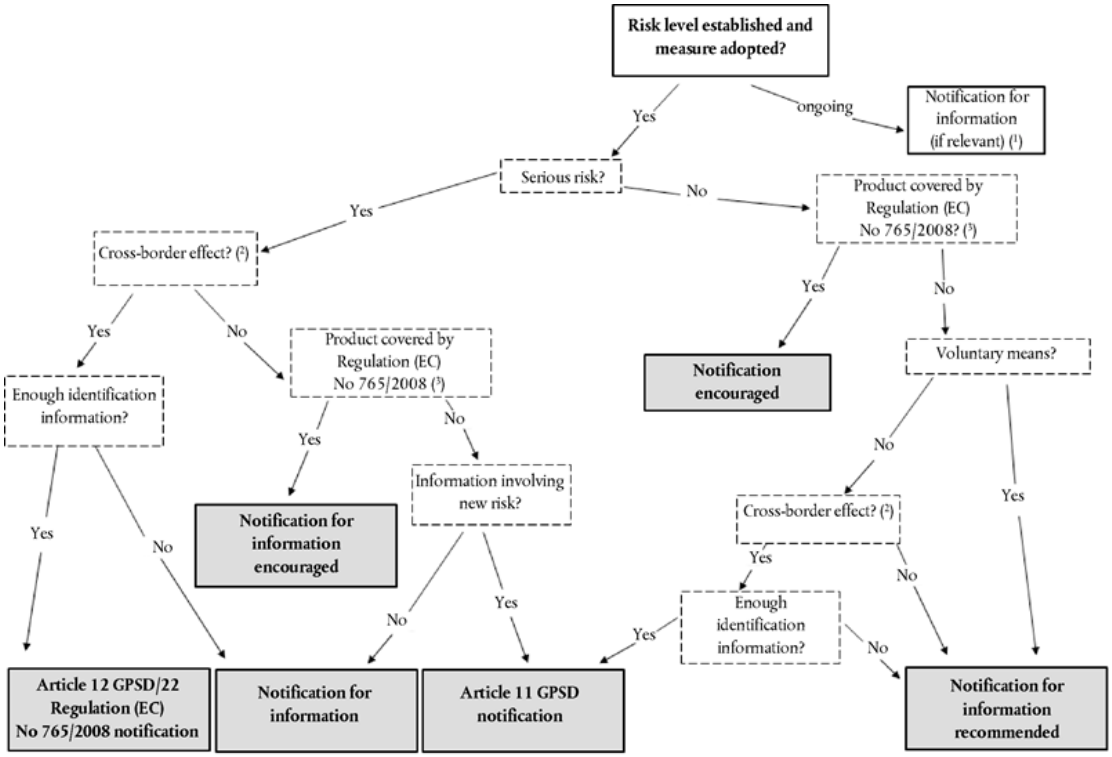
Section 1: General information
Case number
Validated notification type
Notifying country
Creation date
Validation/distribution date
Submission number
Follow up notification number
Reacting country
Full contact details of the notifying authority
Validated notification product category
Notified product
Notified name
Product (what the product is)
* Indicates a mandatory field

Name (on the product or the packaging)	
Brand (on the product or the packaging)	
Type/number of model	
Batch number/Bar code (or other information to identify which products are affected)	
Photos (products, packaging and label)	
Section 2: Type of follow-up notification	
Product found *	
Total number of items found (if known) *	
Measures adopted / Measures not adopted	
Type of measures adopted *	
If Voluntary:	Type of economic operator taking notified measure(s) *
	Name of economic operator taking notified measure(s) *
If Compulsory:	Name of authority ordering the notified measure(s) *
	Type of economic operator to whom the measure(s) were ordered *
Category of measures *	
Date of entry into force *	
Duration *	
Scope *	
Adopted measures	
URL link to company recall page (if available):	
Different risk assessment *	
Risk category *	
Summary of the test results (description of technical defects) *	
Indication of legal provisions and standards (with clauses) against which the product was tested *	
Different risk assessment *	
Information on known incidents and accidents *	
Attachments (certificates, test report and risk assessment …)	
Additional information *	
Complementary information on distribution channels and/or product's origin	
Complementary information on the risk assessment	

* Indicates a mandatory field

Other complementary information
Section 3: Confidentiality
Is the follow-up confidential? *
Scope of confidentiality
Justification
Annexes
Photos (product, packaging and label)
Test reports and risk assessments
Certificates
Adopted measures
* Indicates a mandatory field

3. *Notification scheme*



(1) To be upgraded when a measure is adopted.
(2) The notion of cross-border effect should be interpreted in a broad sense (see Part II Chapter 6.1 of these Guidelines).
(3) See Part I, Chapter 3.1 of these Guidelines.

4. *Deadlines for member states*

Member States are required to act within the deadlines indicated unless duly justified

Notification procedure	Action	Deadline

	Notifications	Send ‘Article 12 notification requiring emergency action’		Within 3 days after: — adoption or decision to adopt ‘Compulsory measures’, or — receipt of information on ‘Voluntary measures’.
		Send ‘Article 12 notification’ or Article 22 Regulation (EC) No 765/2008 notification		Within 10 days after: — adoption or decision to adopt ‘Compulsory measures’, or — receipt of information on ‘Voluntary measures’.
		Confirm measures if the notification was sent before deciding to adopt measures		Within 45 days after submission of the notification
		Update to a notification		Within 5 days after receipt of the information on developments requiring changes to a notification
	Follow-up notifications	Ensure follow-up activities to:	‘Article 12 notification requiring emergency action’	Within 20 days after receipt of a notification

		‘Article 12 notification’ and to ‘Notification sent by the European Commission’ as well as Article 22 of Regulation (EC) No 765/2008 notification	Within 45 days after receipt of a notification
	Send follow-up notification to:	‘Article 12 notification requiring emergency action’	Within 3 days after: — the notified product was found on the market, or — the completion of a risk assessment with different results, or — receipt of additional information
		‘Article 12 notification’ and to ‘Notification sent by the European Commission’ as well as Article 22 of Regulation (EC) No 765/2008 notification	Within 5 days after: — the notified product was found on the market, or — the completion of a risk assessment with different

			— results, or — receipt of additional information
		Update to a follow-up notification	Within 5 days after receipt of information or developments requiring changes to a follow-up notification
Notification procedure established under Article 11 of the GPSD	Notifications	Send ‘Article 11 notification’	Within 10 days after adoption of ‘Compulsory measures’
		Update to the notification	Within 5 days after receipt of information on developments requiring changes to the notification

5. ***Deadlines for the Commission***

Notification procedure	**Action**		**Deadline**
EU Rapid Information System ‘RAPEX’ established under Article 12 of the GPSD	Notifications	Validate ‘Article 12 notification requiring emergency action’	Within 3 days after receipt of a notification
		Validate ‘Article 12 notification’ as well as Article 22 of Regulation (EC) No 765/2008 notification	Within 5 days after receipt of a notification
		Validate ‘Notification for information’	Within 10 days after receipt of a notification
	Follow-up notifications	Validate follow-up notification sent to ‘Article 12 notification requiring emergency action’	Within 3 days after receipt of a follow-up notification

		Validate follow-up notification sent to 'Article 12 notification' and to 'Notification sent by the European Commission' as well as Article 22 of Regulation (EC) No 765/2008 notification	Within 5 days after receipt of a follow-up notification
		Validate follow-up notification sent to 'Notification for information'	Within 10 days after receipt of a follow-up notification
Notification procedure established under Article 11 of the GPSD	Notifications	Validate 'Article 11 notification'	Within 10 days after receipt of a notification
	Follow-up notifications	Validate follow-up notifications sent to 'Article 11 notification'	Within 10 days after receipt of a follow-up notification

(**1**) The fields contained in the template may be updated following developments agreed between the Commission and Member States.

(**2**) The fields contained in the template may be updated following developments agreed between the Commission and Member States.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417, Division PART III.