

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)

Status: This is the original version (as it was originally adopted).

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.

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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

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Other complementary information

Section 3: Confidentiality

Is the follow-up confidential? *

Scope of confidentiality

Justification

Annexes

Photos (product, packaging and label)

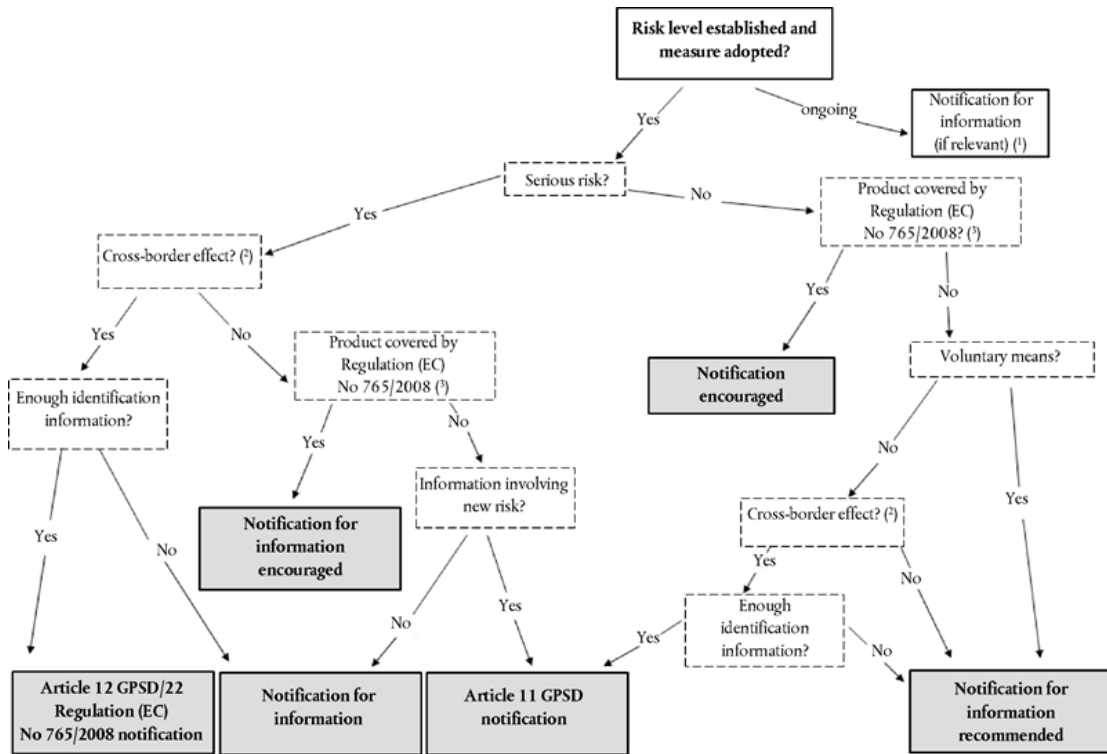
Test reports and risk assessments

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 |

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

| | | | |
|---|---------------|------------------------------------|--|
| | | | — 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 |

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| | | | |
|---|-------------------------|---|--|
| | | 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.