

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)

- Article 1 The guidelines for the management of the European Union Rapid...
Article 2 Decision 2010/15/EU is repealed.
Article 3 This Decision is addressed to the Member States.
Signature

ANNEX

GUIDELINES FOR THE MANAGEMENT OF THE EUROPEAN UNION RAPID INFORMATION...

PART I

SCOPE AND ADDRESSEES OF THE GUIDELINES

1. Scope, objectives and update
 - 1.1. Scope
 - 1.2. Objectives
 - 1.3. Update
2. Addressees of the Guidelines
3. Products
 - 3.1. Products covered by these Guidelines
 - 3.1.1. Products covered by the GPSD
 - 3.1.2. Products covered by Regulation (EC) No 765/2008
 - 3.2. Products not covered by these Guidelines
4. Measures
 - 4.1. Types of measures
 - 4.2. Categories of measures
 - 4.3. Requirements of the measures
 - 4.4. Exclusion of generally applicable compulsory measures
5. Risk Levels
 - 5.1. Serious risk
 - 5.2. Less than serious risk
 - 5.3. Risk assessment method
 - 5.4. Assessing authority
6. Cross-border effects
 - 6.1. International event
 - 6.2. Local event

PART II

EU RAPID INFORMATION SYSTEM 'RAPEX'
ESTABLISHED UNDER ARTICLE 12 OF...

1. Introduction
 - 1.1. Objectives of RAPEX
 - 1.2. Components of RAPEX
2. Notification criteria
 - 2.1. Mandatory participation in RAPEX: Article 12 of the GPSD and Article 22...
 - 2.2. Non-mandatory participation in RAPEX: Article 11 of the GPSD and Article...
3. Notifications
 - 3.1. Types of notification
 - 3.1.1. Notifications
 - 3.1.2. Notifications for information
 - 3.2. Content of notifications
 - 3.2.1. Scope of data
 - 3.2.2. Completeness of data
 - 3.2.3. Updating of data
 - 3.2.4. Responsibility for the information transmitted
 - 3.3. Actors and roles involved in the notification process
 - 3.3.1. Economic operators
 - 3.3.2. Member States authorities
 - 3.3.3. Authorities in charge of external border controls
 - 3.3.4. European Commission
 - 3.4. Workflow
 - 3.4.1. Creation of a notification
 - 3.4.1.1. By a national authority
 - 3.4.1.2. By the Commission
 - 3.4.2. Submission of notifications to the Commission
 - 3.4.3. Examination of notifications by the Commission
 - 3.4.3.1. Correctness
 - 3.4.3.2. Completeness
 - 3.4.3.3. Validation of notifications without a detailed risk assessment
 - (a) Notifications of products posing chemical risks
 - (b) Notifications of cosmetic products
 - (c) Notification of other products
 - 3.4.3.4. Requests for additional information
 - 3.4.3.5. Investigation
 - 3.4.4. Validation and distribution of notifications
 - 3.4.5. Publication of notifications
 - 3.4.5.1. Disclosure of information as a general rule
 - 3.4.5.2. Exceptions to the general rule
 - 3.4.5.3. Requests for confidentiality
 - 3.4.5.4. Handling of notifications covered by confidentiality
 - 3.4.5.5. Withdrawal of request for confidentiality
 - 3.4.6. Follow-up to notifications
 - 3.4.6.1. Follow-up to the different types of notification
 - 3.4.6.2. Objectives of the follow-up activities

- 3.4.6.3. Follow-up techniques
 - (a) Checks on the market
 - (b) Cooperation with business associations
 - (c) Publication of RAPEX data via the internet or other electronic...
 - (d) Online checks
- 3.4.7. Withdrawal/removal of notifications
 - 3.4.7.1. Permanent withdrawal of a notification from RAPEX
 - 3.4.7.1.1. Situations where withdrawal of a submitted or validated notification is...
 - 3.4.7.1.2. Request for permanent or temporary withdrawal by Member States
 - 3.4.7.1.3. Content of the request for permanent or temporary withdrawal
 - 3.4.7.1.4. Decision to withdraw
 - 3.4.7.2. Temporary removal of a notification from the RAPEX website
 - 3.4.7.2.1. Situations where temporary removal is possible
 - 3.4.7.2.2. Request for temporary removal by Member States
 - 3.4.7.2.3. Content of the request for temporary removal
 - 3.4.7.2.4. Decision to remove
 - 3.4.7.2.5. Re-publishing of a notification temporarily removed
- 3.4.8. Notifications older than ten years
- 3.5. Timing and deadlines for notifications
 - 3.5.1. Timing of the notification
 - (a) Compulsory measures
 - (b) Voluntary measures
 - 3.5.2. Deadlines
 - 3.5.3. Emergency situations
- 4. Follow-up activities
 - 4.1. Communication of follow-up activities
 - 4.2. Content of follow-up notifications
 - 4.2.1. Scope of data
 - (a) A notified product has been found on the market
 - (b) Different risk assessment
 - (c) Additional information
 - 4.2.2. Completeness of follow-up notifications
 - 4.2.3. Updating of validated follow-up notifications
 - 4.2.4. Responsibility for follow-up notifications
 - 4.2.5. Response to follow-up notifications
 - 4.3. Actors and roles involved in follow-up activities
 - 4.3.1. Economic operators
 - 4.3.2. Market surveillance authorities
 - 4.3.3. European Commission
 - 4.4. Workflow
 - 4.4.1. Creation and submission of a follow-up notification by a Member...
 - 4.4.2. Examination of follow-up notifications by the Commission
 - 4.4.2.1. Correctness and completeness
 - 4.4.2.2. Requests for additional information

- 4.4.3. Validation and distribution of follow-up notifications
- 4.4.4. Permanent withdrawal of a follow-up notification from RAPEX
- 4.5. Deadlines for submitting follow-up notifications
- 4.6. Requests for confidentiality
- 5. RAPEX networks
 - 5.1. RAPEX National Contact Points
 - 5.1.1. Organisation
 - 5.1.2. Tasks
 - 5.2. RAPEX networks established at EU and national levels
 - 5.2.1. The RAPEX Contact Point Network
 - 5.2.2. RAPEX networks established at national level
 - 5.3. RAPEX internal communication tools, practical and technical arrangements for RAPEX...
 - 5.3.1. Languages
 - 5.3.2. RAPEX online tools
 - (a) RAPEX system
 - (b) ‘Product Safety Business Alert Gateway’
 - (c) Collaborative space
 - (d) ‘RAG tool’
 - 5.3.3. Contact details
 - 5.3.4. Operation of RAPEX outside regular working hours

PART III

APPENDICES

1. Fields and information included in notifications
2. Fields and information included in follow-up notifications
3. Notification scheme
4. Deadlines for member states
5. Deadlines for the Commission

RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS

1. Introduction
2. Risk assessment — an overview
 - 2.1. Risk — Combination of hazard and probability
 - 2.2. A risk assessment in three steps
 - 2.3. Some useful tips
 - Seek information
 - Make a sensitivity analysis of your risk assessment
 - Let others check your risk assessment
 - Document your risk assessment
 - Several hazards, several injuries — but only one risk
 - Can risks cumulate?
 - Compliance with limit values in legislation and standards
 - Specific risk assessment guidelines in specific cases
3. Building a risk assessment step by step
 - 3.1. The product
 - 3.2. The product hazard
 - Hazard identification by tests and standards
 - Products may still present a risk even though they do...
 - 3.3. The consumer
 - 3.4. Injury scenario: Steps leading to injury(ies)

- 3.5. Severity of injury
- 3.6. Probability of injury
- 3.7. Determination of risk
4. From risk to action: how to manage risk responsibly
5. How to prepare a risk assessment — in brief
 1. Describe the product and its hazard.
 2. Identify the type of consumer you want to include in...
 3. Describe an injury scenario in which the product hazard(s) you...
 4. Determine the severity of the injury.
 5. Determine the probability of the injury scenario.
 6. Determine the risk level.
 7. Check whether the risk level is plausible.
 8. Develop several injury scenarios to identify the highest risk of...
 9. Document and pass on your risk assessment.
6. Examples
 - 6.1. Folding chair
 - 6.2. Socket protectors
 - 6.3. Sensitivity analysis

Table 3 Severity of injury

Introduction

Glossary of terms

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

- (1) [OJ L 11, 15.1.2002, p. 4.](#)
- (2) [OJ L 218, 13.8.2008, p. 30.](#)
- (3) Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) ([OJ L 22, 26.1.2010, p. 1.](#))