The Rapid Alert System for dangerous non-food products

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Product Safety and Rapid Alert System
European Rapid Alert System for dangerous non-food products – what is it?

System for rapid exchange of information between Member States and EFTA/EEA countries (28+3) and the European Commission about measures and actions taken in relation to products posing a serious risk (food and feed, medical products and devices are excluded)
a) RAPEX Contact Points network at **European level:**
   - 31 RAPEX National Contact Points, 1 per MS/EEA

b) **National RAPEX network:**
   - RAPEX Contact Points
   - Customs authorities
   - Market surveillance authorities
   - Etc.
General principles of EU product safety legislation and its enforcement

- Any product placed on the EU market must be safe
- Economic operators have obligations to comply with this requirement
- Authorities have powers to ensure the legislation is complied with
- The European rapid alert system is a fundamental pillar for a safe single EU market
- Enforcement powers are with the authorities of the EU countries (not Commission)

-General Product Safety Directive
Obligations for producers & distributors

- To place only safe products on the market/supply only safe products
- To ensure proper labelling of products/keep & provide the documentation necessary for tracing the product's origin
- To inform themselves about risks and pass on information
- To inform national authorities about dangerous products they have placed on the market
- To take appropriate actions and cooperate when risks are discovered
Responsibilities of Member States

✓ Ensuring that producers and distributors comply with their obligations
✓ Performance of market surveillance
✓ Establish national market surveillance networks and procedures
✓ Impose preventive and restrictive measures where relevant (sales ban, withdrawal from the market, recall from consumers)
Commission’s role

- Monitor that Member States meet their obligations
- Support a series of activities aimed at ensuring that only safe products are put on the market in Europe, for example by financing coordinated market surveillance activities
- International collaboration
- Recognise standards
- Adopt emergency measures
RAPEX notifications...

...contain information necessary to:

- **Identify the product**
- **Identify the marketing and distribution channels**
- **Trace origin of the product**
- **Determine the related risks**
- **Identify the measures taken to prevent risks**

...and when available,

- **Identify whether the product is counterfeit**
RAPEX process

Defect found
Defect is found by the Manufacturer, Importer, Distributer or National authorities

PSBG Case
PSBG case is logged if the defect is found by Manufacturer, Importer or Distributer

Risk assessment (EC RAG tool)
Detailed risk assessment is made by the National Authorities to evaluate the level of risk (serious/high/medium/low)

RAPEX notification
Notification in RAPEX is submitted by the relevant National Authorities, validated by the EC and published on the web

Measures taken (voluntary/com pulsory)
Customers are notified and relevant measures are being taken to eliminate the defect

Notification follow-up by all MS
All Member States perform follow-up actions to inform consumers and eliminate the defect on their territory

Justice and Consumers
Economic operators: Tools to comply with their obligations

1. Business gateway

2. RAG tool (Risk Assessment Guidelines)

All info at https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm
Business Gateway for Economic Operators

• If a manufacturer or distributor finds out that one of their products on sale is dangerous, they have to inform the competent national authority, in compliance with their obligations under Article 5(3) of the General Product Safety Directive.

• The Business Gateway is an application developed by the Commission for this purpose.

• The submission of notifications through the Gateway is reserved for the producers/distributors of the notified product, or their authorised representative.

• The competent national authority may use the information provided to submit a RAPEX notification if all criteria for this are met.
Authentication via EU login

- In order to login to the Business Gateway system, you need an EU Login account.

**Business Gateway URL:** [https://webgate.ec.europa.eu/gpsd/](https://webgate.ec.europa.eu/gpsd/)
Interface languages

✓ The PSBG application is available in 5 EU languages
PSBG home page for economic operators

Notify a dangerous product to the authorities

Create form
Create and complete your notification here. If you don't have all the information required, save your draft and note down the Case ID. You can retrieve or revise your draft later from the "Case list", before final submission.

Open Case list
Open the Case list to see all your notifications. You can edit or delete drafts and view the notifications you have already submitted to the authorities.

✅ Detailed user instructions
Business Gateway case submission form

Features:

- ✓ Panel view
- ✓ Direct creation and submission of notifications in the application
- ✓ Possibility for Economic Operators to save drafts

Notify a dangerous product to the authorities

1 | Countries concerned
2 | Producer/Distributor submitting notification
3 | Product involved
4 | Risk assessment of the notifier
5 | Corrective actions already taken or planned
6 | Company(ies) in the supply chain which hold affected products
7 | Other
Inclusion of RAG tool

- align risk assessment approaches used by businesses
- align with part b) of the RAPEX guidelines
## Business Gateway case list for economic operators

The Business Gateway is a platform for reporting dangerous products to the authorities. It provides a case list for economic operators to manage and submit notifications of dangerous products.

### Notify a dangerous product to the authorities

**Case list**

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<thead>
<tr>
<th>ID</th>
<th>Submission number</th>
<th>Form language</th>
<th>Created date</th>
<th>Status</th>
<th>Actions</th>
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<td><strong>Edit</strong></td>
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<tr>
<td>125</td>
<td></td>
<td>English</td>
<td>24/04/2018</td>
<td>Draft</td>
<td><strong>Submit</strong></td>
</tr>
</tbody>
</table>

**Status**

- **Submitted**
- **Draft**

**Actions**

- **Edit**
- **Delete**
- **Submit**

**Generate PDFs**
### Business Gateway «Digital Inbox» for National Authorities

#### Product Safety Business Alert Gateway

#### Restricted Area for National Authorities

#### Digital inbox

<table>
<thead>
<tr>
<th>Case ID</th>
<th>Submission</th>
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<th>Responsible</th>
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</tbody>
</table>

**View case details**

**Case status**
Business Gateway statistics

➢ **Before the revamp:**
  • Between 2009 and 2018: submission of +/- 2700 cases

➢ **After the revamp:**
  • In the 2nd Quarter 2018: revamp of the application: it became the Product Safety Business Alert Gateway aka “Business Gateway”
  • Since then, 720 cases have been submitted by economic operators
    o 190 where FR has been identified as Main MS concerned
    o 139 where NL has been identified as Main MS concerned
    o 109 where ES has been identified as Main MS concerned
    o 103 where DE has been identified as Main MS concerned
    o 31 where SE has been identified as Main MS concerned
    o 30 where BE has been identified as Main MS concerned

➢ **Risk level**
  o 213 cases of a serious risk and 147 with high risk have been identified since 2018

➢ **Product categories**
  o 177 notifications on motor vehicles, 121 notifications on electrical appliances, 108 notifications on toys, 28 notifications on childcare articles, 24 notifications on clothing & textile articles...
RAPEX - Confidentiality

"The information made available to the public is a summary of a RAPEX notification and includes only the details specified in Article 16 of the GPSD, i.e. product identification and information about the risks and measures taken to prevent or restrict those risks.

The Commission and the Member States do not disclose whole notifications to the public, especially not detailed risk descriptions with test reports and certificates or detailed lists of distribution channels, as some of this information, due to its nature, is confidential (professional secrets) and needs to be protected."
Public part of the Rapid Alert System

- Public set of data from each notification is published on the Safety Gate public website.
Thank you for your attention!

For more information visit our website:
http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

Or send us an e-mail: just-rapex@ec.europa.eu