Product Safety and Market Surveillance Package

Prague, 25 September 2013

European Commission

The Package:

- Communication on More Product Safety and Better Market Surveillance in the Single Market
- Proposal for a Regulation on Consumer Product Safety
- Proposal for a Regulation on Market Surveillance
- Multi-annual action plan for market surveillance: 20 actions for safer and compliant products
- Report on the Implementation of Regulation (EC) No 765/2008

I. Consumer Product Safety

Proposal for a Regulation

General

- GPS Directive → CPS Regulation
- Market surveillance provisions of the GPSD (incl. RAPEX) moved to the proposed MSR
- Repeal of GPSD and of Directive 87/357/EEC on food-imitating products → concept of food-imitating products in Art. 6(1)(e) of the proposal)

Scope

Chapter I: All consumer products including:

- "Second hand" products
- Products to which consumers are exposed in the context of a service provided to them

but excluding:

- Products to be repaired or reconditioned before being marketed prior to being used
- Products listed in Art. 2(3) (e.g. pharmaceuticals, food & feed, animals, plants …)

Scope 2

Chapters II – IV: Non-harmonised consumer products only

Obligations of economic operators

- Alignment with obligations in sector-specific pieces of EU harmonisation legislation (toys, LVD, machinery, etc.)

Procedures for standard-setting

- Alignment with horizontal standard-setting rules under Regulation 1025/2012 on European standardisation

Final provisions

General safety requirement

Art. 4: Only safe products to be made available

- Basic principle of GPSD is kept

Art. 5: Presumption of safety

- Compliance with health and safety requirements of Union harmonisation legislation
- Compliance with EN standards referenced in accordance with GPSD/CPSR
- Compliance with national health and safety requirements

- **Art. 6: Safety assessment**
  - In case of non-harmonised consumer products

Product identification and traceability

- **Art. 7: Indication of origin (all consumer products)/Origin marking**
  - Products from the EU and from third countries
  - Based on Community Customs Code (non-preferential origin)
- **Art. 8: Manufacturers (non-harmonised consumer products)**
  - Identification of the product: type, batch or serial number or other element allowing the identification of the product
  - Identification of the manufacturer: name, registered trade name/registered trade mark and address

Product identification and traceability 2

Art. 10: Importers (non-harmonised consumer products)

- Verification of labelling (identification of product and manufacturer)
- Identification of the importer: name, registered trade name or registered trade mark and address

Art. 11: Distributors (non-harmonised consumer products)

- Verification of labelling (identification of product and manufacturer/ importer)

Product identification and traceability 2

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Product identification and traceability 3

- **Art. 14: Identification of economic operators**
  - … who has supplied them with the product
  - … to whom they have supplied the product

- **Art. 15: Empowerment for Commission to adopt delegated/implementing acts**
  - Economic operators to establish/adhere to electronic system of traceability
  - Products or categories of products susceptible to bear serious risk

Technical documentation

Content

- Description of the product,
- Manufacturer's risk analysis and risk management
- List of European standards, national requirements or other relevant documents applied

Access

- Manufacturers + to be made available to public authorities on request (for 10 years)

Aim

- Documentation of manufacturers' own safety assessment
- Information to authorities for their risk

Information obligations

Manufacturers, importers and distributors are obliged to:

- Notify authorities of **unsafe** consumer products
- Exception: "**isolated cases**" (codification of pt. 3.3. of Guidelines for notification of dangerous products by producers and distributors ("business guidelines") laid down in Commission Decision 2004/905/EC)

Standard-setting procedures

Promotion of use of EN standards in support of general safety requirement ('presumption of safety')

Standardisation request ('mandate') by implementing act

- Development of standards or identification of existing standards
- Safety requirements to be included directly in the mandate
- Appropriate consultation of experts of Member States in the field of consumer product safety
- Vote by the Committee under the Standardisation Regulation

- **Publication of standard's reference** in OJ (no formal measure required)

Standard-setting procedures 2

Formal objection procedure

By any Member State or by the European Parliament

Decision on formal objection by implementing act

- Appropriate consultation of experts of Member States in the field of consumer product safety
- Vote by the Committee under the Standardisation Regulation

- Alignment with the procedures of **Regulation 1025/2012** on European standardisation

II. Proposal for Market Surveillance Regulation

- Improving **cross-border action and cooperation**
- **Simplification: 3** → 1

→ **More collaborative, joint-up system for market surveillance**

Main elements:

- Collects together the market surveillance rules
- Almost all products are subject to the same rules
- Procedures for the notification by Member States will be streamlined

→ **Single** market surveillance system for **almost all** products**,** based on **one** legislative act

1. Scope:

- All consumer products and harmonised products (Article 2(1))
- All products for controls on products from 3rd countries, unless different rules (Article 2(2))
- **Totally excluded:** food, feed, animal health, etc.
- **Partially excluded:** medicinal products, medical devices and substances of human origin; transportable pressure equipment

2. Market surveillance obligation Art.4

- **Member States** carry out market surveillance (subsidiarity principle)
- **Obligations:**

1. Ensuring that products presenting a risk are not made available on the Union market
2. Reporting every year
3. Publication of results

3. Market surveillance authorities (MSA)

- Each MS shall establish/designate MSA + ensure resources and means
- Each MS: appropriate mechanisms for exchange of information, cooperation and coordination
- Information about MSA:

➢ Each MS → Commission → other MS

➢ Each MS → public

4. Their obligations

- Perform checks + record in the ICSMS

→ The Commission may adopt implementing acts

- Alert users + cooperation with economic operators
- Independently, impartially and without bias
- Proportionality
- May enter the premises of economic operators + take samples of products

Other obligations

- Opportunity for consumers and other interested parties to **submit complaints** + **follow up**
- Verify that corrective action has been taken
- Scientific and technical knowledge
- Adequate procedures
- Confidentiality

5.Obligations of economic operators (Article 8)

1. On request, economic operators + conformity assessment bodies

→ Shall make available to MSA any documentation and information + in a language which can be easily understood

- Provide all necessary information to MSAs

→ **identification** and **tracing** of the product

6. Control of products within the EU (Chapter III)

Procedural flow:

- Checks/information received → MSAs have sufficient reason → risk assessment
- MSAs take consideration of tests and risk assessments that have already been carried out by an economic operator/any other person/ authority including the authorities of other Member States.

Measures taken by the MSA

Where the MSA find that a product = risk

→ **corrective action** by the economic operator

→ the economic operator shall ensure that all corrective action is taken in respect of all products + provide all necessary information

The Commission may adopt **implementing acts** establishing the modalities for the provision of this information (See the Final provisions)

Measures taken by the MSA 2

- **MSA** may **oblige** the economic operators to take corrective actions
- **MSA** may **destroy**/otherwise render inoperable a product = risk
- **MSA** may **charge fees** on economic operators which wholly or partly cover the costs of their activities, incl. testing carried out for the risk assessment.

7. Control of products entering the Union (Chapter IV)

1. Strenghtening controls at external borders

2. Checks → reason → s**uspension of release**

If the product = harmonisation legislation, the formal non-compliance = **sufficient reason**

(a) Not accompanied by required documentation;

(b) not marked or labelled;

(c) CE/other marking = false or misleading manner

EBCAs have to:

→ Immediately **notify** the MSA

In case of **perishable products** to ensure that:

→ the imposed requirements are not incompatible with the preservation of products

If products are **not declared for free circulation** + **reason** that they = risk

→ Inform the EBCAs in the Member State of final destination

7. Control of products entering the Union (Chapter IV)

3. Release:

- 3 working days for MSA
- the economic operator shall rectify the formal non-compliance
- taking full account of test reports or certificates attesting conformity

→ Presumption: the product does not present a risk

Exception: <u>evidence</u> that the product in fact = a risk

8. Exchange of information(Chapter V)

1. RAPEX

- Commission = maintainence;

  MSs = exchange of information
- Single contact point in each MS
- Open to applicant/third countries + international organisations.

Notification: for any corrective action/measure/refusal to release a product

RAPEX - Notification

1. **MS → EC**: risk (all details) + other information

   (!) Use the standard RAPEX notification form

2. **EC → other MSs**

3. **MSs → EC**: the action/measures taken + supplementary information as a follow-up

4. **EC → other MSs**

Information and communication system for market surveillance (ICSMS)

1. **EC** = maintenance
2. **ICSMS = record** of references to notifications of measures/corrective actions made under **RAPEX**
3. **ICSMS = available** for external border control
4. **MSs → ICSMS:** content of information
5. **MSAs recognise** the test reports prepared in other Member States + entered into ICSMS **= avoid double work**

International exchange of confidential information

EC + MSs may exchange confidential information with third countries/international organisations

Basis: bilateral or multilateral confidentiality arrangements based on reciprocity

9. Cooperation (Chapter VI)

European Market Surveillance Forum

- Each **MS =** represented
- Commission's support → **executive secretariat**
- **Tasks:**

- facilitate the exchange of information;
- coordinate the market surveillance programmes

10. Financing (Chapter VII)

1. The EU may finance:

- contributions to guidelines on market surveillance
- technical or scientific expertise
- studies, programmes, evaluations, guidelines, mutual joint visits, development and maintenance of databases, trainings, etc.

2. Protection of the EU's financial interests:

- Prevention, checks, audits and penalties

11. Final provisions (Chapter VIII)

1. The Commission will be assisted by a Committee:

→ Adoption of **implementing acts**

2. **Evaluation:** 5 years after the date of application
3. **Amendments:** from 3 to 1
4. **Entry into force:** 1 January 2015

Budgetary implication

- **In the frame of already envisaged or proposed programmes**

- **Redeployment of existing resources**

→ See the financial statement attached to the proposal

III.
Multi-annual action plan on market surveillance

20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU

→20 actions to be undertaken to the end of 2014

Main actions

Action 2: Maximise the benefits of ICSMS;

Action 3: Create synergies between GRAS-RAPEX and ICSMS;

Action 4: Assess the cost/benefit of an EU accident/injury database (AIDB)

→ Pooling of information stemming from investigations

Newest developments

Action 5: a EU general risk assessment methodology for products;

Action 9: Joint enforcement activities

+ Action 11: More support for 'Administrative Cooperation groups' (ADCOs)

→ Call for proposals Deadline: 30/10/2013

http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=6887&lang=en&title=Call%2Dfor%2Dproposals%3A%2DImplementation%2Dof%2Dthe%2DNew%2DLegislative%2DFramework%2D%2D%2Djoint%2Denforcement%2Dactions%2Dof%2Dmarket%2Dsurveillance%2Dauthorities%2Dand%2Dcustoms

Main actions

Action 12: Products sold on-line

A Working Group will be established

Other groups of actions:

- European dialogue with stakeholders;
- Imroving supply chain supervision;
- More and better controls on products entering the Union

→ To fill gaps and make the surveillance more efficient

Thank you

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