MEMO/11/

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Questions and answers on the 2010 RAPEX Report

1. WHAT IS RAPEX?

RAPEX is a European rapid alert system for dangerous products. It ensures that information about dangerous products withdrawn from the market and/or recalled from consumers anywhere in Europe is quickly circulated between Member States and the European Commission, so that appropriate action can be taken everywhere in the EU. **30 countries** currently participate in the system. The participating countries are all the European Union countries and the EFTA/EEA countries: Iceland, Liechtenstein and Norway.

What type of measures can be taken?

The most common measures are a ban/stop on sales, withdrawal of a dangerous product from the market, providing information to consumers about the risks related to the use of the product, or recall of a dangerous product from consumers.

What is covered by RAPEX?

The scope of RAPEX covers dangerous **non-food products** intended for consumers (e.g. a toy, a cosmetic, clothing) and for professionals (e.g. a power drill, a machine, a construction product) which pose a serious risk to various public interests, such as 'health and safety of consumers', 'environment' (risk for trees, water, air, soil, etc from dangerous chemicals contained in a product), 'health and safety at the workplace' and 'public security'.

The RAPEX system covers the **majority of non-food products**. Other categories of products, such as food and feed, pharmaceuticals and medical devices are excluded from its scope as they are covered by other specific alert systems, similar to RAPEX.

What are obligations of national authorities?

National authorities ensure that businesses respect their obligation to place only safe products on the market. They must designate authorities which can take measures to prevent or restrict the marketing or use of dangerous products. Each country designates a national RAPEX Contact Point which coordinates the system at national level and submits information to the Commission about dangerous products found on its own market. The information received and validated by the Commission is rapidly circulated to the national Contact Points for appropriate action. The results of these activities are reported back through the system.

What are the obligations of producers?

Producers (i.e. manufacturers and importers) are responsible for placing only safe products on the market. Once aware that a product is dangerous, a producer must immediately take measures to prevent further risks to consumers. National competent authorities must also be informed about the safety problem, clearly identifying the product in question, the risks it poses and the information necessary to trace it. This information is then conveyed via the RAPEX system to the Commission and other countries participating in the RAPEX system if the product poses a serious risk.

2. RAPEX IN 2010

What were the most significant developments in 2010?

There were three main developments:

- Enhanced market surveillance activities by national authorities
- Extended scope for RAPEX
- New tools

First of all, enhanced market surveillance activities were undertaken by national authorities including through specific joint projects. The total number of notifications through RAPEX rose by 13% (from 1993 in 2009 to 2244 in 2010).

There was a particular increase in the number of notifications on dangerous clothing and textiles (from 395 notifications in 2009 to 625 notifications in 2010) following the joint market surveillance action on cords and drawstrings in children's clothing, which saw the participation of nine Member States.

Secondly, in 2010, **RAPEX extended its scope covering new categories of products** (products for professionals) and **risks to new types of public interests** ('environment', 'health and safety at the workplace' and 'public security').

Thirdly, in 2010, the **new RAPEX Guidelines** were used for the first time, as was the new upgraded risk assessment method for consumer products which helped market surveillance authorities in terms of accuracy and efficiency. A new information technology (IT) tool further eased the risk assessment process.

3. RAPEX RESULTS 2010

What were the main findings in 2010?

In 2010, a total of 2244 notifications on dangerous products posing risks to the health and safety of consumers were submitted thought the RAPEX system by Member States. This constitutes 13% more notifications than in 2009 (1993 notifications). Of the 2244 notifications, 1963 notifications concerned products which posed a serious risk to consumers. (Other notifications refer to moderate risk or information only).

Which EU countries notified most cases?

The following five Member States accounted for 47% of all RAPEX notifications on products posing a serious risk to the health and safety of consumers last year:

- Germany (204 notifications, 10%),
- Bulgaria (192 notifications, 10%),
- Hungary (191 notifications, 10%),
- Cyprus (178 notifications, 9%),
- Greece (159 notifications, 8%),

In 2010, 19 countries[1] increased their activity in the RAPEX system.

The most frequently notified products in 2010 were:

- clothing, textile and fashion items (625 notifications, 32%),
- toys (488 notifications, 25%),

[1] Belgium, Bulgaria, Germany, Estonia, Ireland, Greece, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Austria, Portugal, Slovenia, Finland, and Romania

- motor vehicles (175 notifications, 9%),
- electrical appliances (158 notifications, 8%),
- childcare articles and children's equipment (72 notifications, 4%).

These categories of products accounted for almost 80% of all products posing serious risk notified in 2010.

What are the main risks detected through the RAPEX system?

The risk categories most often notified, which accounted for 82% of all alerts on products posing a serious risk, were:

- injuries (550 notifications, 24%),
- chemical risk (439 notifications, 19%),
- strangulation (356 notifications, 16%),
- choking (330 notifications, 14%),
- electric shock (197 notifications, 9%).

Why have notifications for dangerous goods increased every year?

The increase in the number of notifications can be attributed to **increasing awareness and attention given to product safety by national authorities** and the business sector, more frequent and more effective controls of consumer products on the market, joint market surveillance actions carried out by national authorities, the EU enlargement in 2004 and 2007 and finally to several training actions and seminars provided by the European Commission for different stakeholders. The increase does not mean that there are more dangerous goods on the European market.

What does it show when a country makes a lot of notifications – is it that there are more dangerous products on that particular market?

The number of notifications made by a particular Member State cannot be directly linked to the level of safety of the products on its market. There are many reasons why some Member States may have more notifications than others: very effective surveillance mechanisms, large market, large import volumes etc. In general, it follows that the European countries which have the biggest markets and the greatest number of imported goods, and which also have the highest number of inspectors, find more dangerous goods and thus notify through RAPEX more often than smaller countries.

What measures did the national authorities take in response to the dangerous goods that they found?

The most frequently taken measures with regard to dangerous consumer products in 2010 were: sales ban, withdrawal from the market, recall from consumers and corrective actions.

Where did the largest amount of dangerous products come from in 2010?

According to the RAPEX Report (and taking into account additional information received in 2011), the majority of dangerous products posing serious risks to the health and safety of consumers notified through RAPEX came from outside the EU – (China, Turkey).

China (including Hong Kong) was indicated as a country of origin for 58% (1104 notifications) of notified products.

Dangerous products of European origin accounted for 339 notifications (17%), including 63 products of German origin (3%), 51 products of Italian origin (3%) and 36 products of French origin (2%). The figures show that attention needs to be given to informing European manufacturers and importers on the safety requirements applying to consumer products.

In 2010, the number of cases with an unidentified country of origin has slightly increased to 10% (201 notifications) from 7% (124 notifications) in 2009. Even though this figure is higher than in the previous year, it is still much better than the 2004 figures when it was as high as 23%. Checking the traceability data is helpful to authorities in other countries and ultimately in finding the country of origin and final source of the product.

Is there an increase in the number of notifications on products of Chinese origin?

No; in total 1104 notifications concerned products manufactured in China (including Hong Kong). The number of consumer products (posing a serious risk to the health and safety of consumers) of Chinese origin notified via RAPEX **decreased in 2010 to 58% from 60% in 2009**.

4. SAFETY AT SOURCE

Is 'safety at source' a primary objective?

Yes. Research shows that one of the **largest causes of product recalls are design defects**. This means that the product was unsafe due to the faulty design and not because of some error in the manufacturing of the product.

Companies responsible for the design of the product must make sure they do their homework and design out safety risks from the start. This will significantly improve the chances of producing safe products.

It is important to reach out to **manufacturers** to help them know what requirements they are expected to meet, to know the risks associated with certain products and to understand the importance of design assessments and risk analysis. Manufacturers must ensure that suppliers are trustworthy and provide safe materials and components. They have to control incoming supplies to ensure they don't contain unwanted substances. They need to manage the quality of the manufacturing process and check the final products coming off the conveyor belt. Work must move forward in this direction, for example: continuing to offer hands-on training on the responsibilities of manufacturers; develop broad advice to economic operators; look at trends in common weaknesses in products and share this with partners so that guidance can be given to economic operators on how to avoid these in the future.

What other controls are possible in the journey from 'factory to front door'?

Importers also have an important responsibility – they need to inform their suppliers about the requirements applicable to the products they wish to import. They also need to check that the products they receive indeed comply with these requirements. The sheer volume of sales (e.g. over the internet) make this difficult for everyone concerned and there needs to be more information, training and guidance in this regard.

There must be **effective, proportionate and dissuasive penalties** for importers who repeatedly ignore the rules. This is important to protect consumers and also to protect legitimate businesses that invest in product safety.

5. RAPEX-China system

What is the "RAPEX-CHINA" application?

The RAPEX-China application was established in 2006 in the framework of the Memorandum of Understanding (MoU) on general product safety between DG SANCO and the Chinese authority responsible for product safety in China - the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ).

Through the RAPEX-China application, the Commission submits information to AQSIQ about dangerous products of Chinese origin found on the EU market and notified through RAPEX. This information allows the Chinese authorities to follow up directly on notifications regarding unsafe products coming from their territory and identify areas where the safety standards are weaker.

Does the Commission get feedback on how the Chinese authorities follow up on the information sent through the "RAPEX-CHINA" application?

Cooperation in the framework of the RAPEX-China system is well-established, as AQSIQ submits quarterly reports to the Commission with the conclusions of the follow up actions undertaken with regard to the data provided through the "RAPEX-CHINA" system.

The information provided in the reports allows the Commission and Member States to monitor and analyse the follow-up market surveillance activities carried out by the Chinese authorities on their territory, and as a consequence allows them to identify and address weak points in the cooperation system. So far, 16 quarterly reports have been provided to the Commission.

How many RAPEX notifications has AQSIQ investigated since the establishment of the "RAPEX-CHINA" application?

AQSIQ has ensured follow-up action with regard to 1499 RAPEX notifications. Analysis of 16 quarterly follow-up reports received so far from AQSIQ shows that over a three-month period AQSIQ investigates on average 94 RAPEX cases. In 851 cases (57%) investigations resulted in preventive or restrictive measures being adopted either by AQSIQ or voluntarily by the Chinese manufacturer/exporter (ex. export stop or strengthened supervision), while in 648 cases (43%) no measures were taken mainly due to the fact that Chinese company responsible for manufacturing and/or exporting products to the EU could not be found.

6. RAPEX data 2010: Safety of goods in a professional context and other risks

In 2010, Member States submitted 20 notifications on restrictive measures taken with regard to the safety of goods used in a professional context (e.g. not for consumers) and measures taken to address risks to public interests other than health and safety of consumers (e.g. environment or security risks), whether the products are used in a professional or by consumers.

Seven of these notifications concern products presenting a serious risk to the environment (chemical pollution and CO_2 pollution) and to the health and safety aspects related mainly to products considered as professional goods (e.g. mobile phones for use in potentially explosive atmospheres).

7. GPSD BUSINESS APPLICATION

What is the "GPSD Business Application"?

The "GPSD Business Application" is an on-line application that was established (in May 2009) by the European Commission to facilitate businesses' obligation to notify Member States' competent authorities of dangerous products made available to consumers on the EU market. Businesses can use this application – instead of traditional methods such as e-mail or fax, to submit their notifications on dangerous products to national authorities of all 27 EU Member States and 3 countries that are parties to the European Economic Area (EEA). Using this application, they can also notify all Member States at the same time.

See https://webgate.ec.europa.eu/gpsd-ba/

When do businesses have to notify dangerous consumer products to national authorities of Member States?

Once a company becomes aware that a product poses a risk to the health and safety of consumers, they must immediately take measures to prevent these risks. They must inform national competent authorities, clearly identifying the product in question, the risks it poses and the information necessary to trace it. This information should be sent to competent authorities in all Member States where the product in question has been marketed.

Is the GPSD Business Application working well?

Yes; since its launch, the GPSD Business Application has proven successful. In 2010, 133 notifications (including updates) sent through the application by producers and distributors were accepted by the competent national authorities. This constitutes an increase of 202% compared to 2009 (44 notifications).

Which products were most frequently notified?

Notifications submitted by producers and distributors concerned: electrical appliances, motor vehicles, toys, children's products and hobby/sport equipment.

Are the 'GPSD Business Application' notifications forwarded via RAPEX?

Yes, they are conveyed via the RAPEX system to the Commission and other countries participating in the RAPEX system.

For more information on the GPSD Business Application

http://ec.europa.eu/consumers/safety/rapex/guidelines_business_en.htm

8. JOINT ENFORCEMENT ACTION ON HELMETS

What was the objective of this joint action by Member States?

The main objective was to ensure that helmets placed on the EU market are safe and carry the appropriate warnings and instructions. It was also an opportunity for surveillance authorities to improve their cooperation and exchange information on sampled products, test methods and results and other practices. The action, which started in December 2009 and ended in November 2010, was co-financed by the Commission under the Consumer Policy Programme (2007-13).

Who participated?

Participants were market surveillance authorities from nine Member States: Cyprus, the Czech Republic, Germany, Spain, Lithuania, Latvia, the Netherlands, Sweden and Slovenia, together with Iceland and Norway. The joint action was coordinated by

PROSAFE, an informal network of European market surveillance officials and was led by Latvia.

What products were covered by the joint action and why were they chosen?

The joint action focused on four types of helmets used by consumers for **skiing and snowboarding,** for **bike riding** and **skateboarding,** for **horse riding** and for **impact protection for children.** The use of helmets is essential to avoid serious head injuries, and in some countries, it is already mandatory or at least highly recommended to wear them. Therefore, it is very important that the helmets available on the market are safe.

How was this investigation done?

In the period January through July 2010, participants in the Joint Action visited shops in their countries and checked "on the spot" some of the available models, looking for the accuracy of the marking and completeness of the instructions. **367 models** of helmets have been verified in this way.

In addition, **40 models were selected** to be sent to an expert laboratory for testing as set out in the relevant standard. These tests covered the following parameters: **field of vision** (good visibility when the helmet is worn), **shock absorbing capacity**, **durability**, **suitability of retention system to hold the helmet in place** and others. The 40 models (from across the price range and from different countries of origin), sent for laboratory checks were selected by inspectors based on visual inspection and the completeness and correctness of marking and instructions.

What were the results of these checks?

The set of inspections "on the spot" showed that **63% of the examined models did not comply** with the standard requirements for marking, warnings and instructions for use.

The **results** of the laboratory tests on safety aspects revealed that **nearly half of the tested models (18 out of 40) did not comply** with the relevant standard for one or more significant parameters. This does not necessarily mean that half of the helmets sold in Europe are dangerous - the items sent to the lab were not a statistically representative sample, however the results do indicate that more attention needs to be paid to safety requirements.

What were the most common defects on samples checked visually?

- National language not used
- Missing year of fabrication
- Incomplete instructions for use
- Lack of warnings concerning the improper use of helmets
- Unclear indication whether the helmet belonged to Class A or Class B (performance classes for helmets for skiers and snowboarders)

What were the most of the common defects found?

- For helmets for **cyclists and skateboarders**: ineffectiveness of the retention system (to hold the helmet in place) on five models, shock absorption capability on three models and strength of the retention system on two models
- For helmets for **skiers and snowboarders**: insufficient shock absorption capability on four models, resistance to penetration insufficient on three models, ear covers detachable on one model and insufficient strength of the retention system on one model.

- For helmets for **horse riding**: reduced shock absorption capability on three models, insufficient strength of the retention system on two models and resistance to penetration on one model
- For **impact protection helmets** for children: on the two models tested the release force was higher than the one required by the standard.

Are more expensive helmets safer?

Not necessarily. No clear relationship between price and test results could be established. Some models with low or even very low price were compliant and safe, while other models positioned at the top end of the price line were found to be dangerous.

Which rules govern the safety of these helmets?

Directive 89/686/EEC relating to Personal Protective Equipment sets up essential safety requirements which must be met before products may be placed on the European market.

Each product category is covered by European harmonised standards.

- Helmets for alpine skiers and snowboarders are covered by EN1077:2007;
- Helmets for pedal cyclists and for users of skateboards and roller skates are covered by EN1078:1997 and EN1078:1997/A1:2005;
- Equestrian (horse riding) helmets for daily use are covered by EN1384:1996;
- Impact protection helmets for young children are covered by EN 1080:1997.

Who is responsible for the safety of these products?

Manufacturers and importers have primary responsibility for the safety of products they place on the EU market. In addition, other economic operators (e.g. distributors and retailers) also have specific responsibilities with respect to the safety of helmets.

What action can the Commission take in order to improve the safety of products on the market and designed to be used by consumers?

The Commission has co-financed this specific joint project (70%), in which eleven countries participated (under the Consumer Policy Programme 2007-13). The main role of the Commission is to facilitate the cooperation between Member States by providing a platform (the joint actions) in which different authorities plan and carry out their work related to specific products in a coordinated way. This reduces risks for consumers and enables businesses to operate in a level playing field across the internal market.

For information visit **website** **http://ec.europa.eu/consumers/safety/news/index_en.htm** **(available from 12/5 at 12.15)**

To view the **weekly reports or search for specific data:** www.ec.europa.eu/rapex

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