

Commission

Keeping European Consumers

2011 Annual Report on the operation of the Rapid Alert System for non-food dangerous products **RAPEX**

Health and Consumers The Directorate-General for Health and Consumers of the European Commission manages the Rapid Alert System for non-food dangerous products (RAPEX).

This report describes the activities of RAPEX in 2011.

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Luxembourg: Publications Office of the European Union, 2012

ISBN 978-92-79-20736-5 ISSN 1830-8821 DOI 10.2772/6642

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Keeping European Consumers Safe

2011 Annual Report

on the operation of the Rapid Alert System for non-food dangerous products **RAPEX**



Foreword

I am very pleased to present the eighth Annual Report on the RAPEX system. This Report presents an overview of the main developments in the field of product safety in 2011. Since its start in 2004, the RAPEX system has consistently proved its value in exchanging information on dangerous products between Member States' authorities and the European Commission and in protecting consumers' health and safety.

Throughout the last eight years, the number of notifications on dangerous products has increased year after year. In 2011, for the first time, we witnessed a decrease in the number of notifications. This decrease, which occurred mainly in the first quarter of the year, may be due, partly, to budget cuts and subsequent resource constraints in the national administrations. Despite the pressure on resources, the Member States and the Commission are committed to exploring ways to uphold a high level of enforcement of product safety legislation.

The decrease in the number of notifications could also indicate that the RAPEX system has reached a certain level of stability and maturity, and that the more active use of the risk assessment guidelines has led to the streamlining of notifications, with improvements in their quality.

Our focus will continue to be on the constant improvement of the efficiency of the system through effective follow-up actions.

Tackling product safety problems at source is an efficient way of reducing the number of unsafe products entering the EU market. In this respect, active cooperation between the EU and the Chinese product safety administration has continued to yield tangible benefits. The Report shows that, thanks to this cooperation in 2011, the number of notifications regarding products of Chinese origin decreased further, representing 54% of the total notifications. In 2011, there were also important developments in standardisation that will contribute to strengthening the safety of consumers. One of the main achievements was the EU-wide requirement to introduce reduced ignition propensity (RIP) cigarettes, which rapidly self-extinguish when left unattended, thus reducing the risk of fire and injuries.

The accomplishments described in this Report are the result of the continued cooperation between all the parties involved. As before, in 2011 market surveillance authorities in the Member States demonstrated a consistently constructive approach and commitment, as did economic operators and international partners sharing the same goal – to ensure the safety of consumers. I am sure that the results that we have achieved through our common efforts in 2011 will continue to motivate us to strengthen the enforcement of product safety legislation in 2012 and beyond.

John Dalli

European Commissioner for Health and Consumer Policy

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CHAPTER 1

RAPEX Activity in 2011 Executive Summary

The role of RAPEX in supporting product safety

RAPEX¹ (the Community Rapid Information System for non-food products) is key to ensuring that European consumers have confidence that the products they are buying are safe. It is a system which allows EU Member State market surveillance authorities and the European Commission to share information about dangerous products found on the European market quickly and efficiently and to inform consumers about potential risks to their health and safety. RAPEX is established under Article 12 of the General Product Safety Directive (2001/95/EC, the "GPSD")².

With the entry into force of Regulation (EC) No 765/2008 in January 2010, the scope of the RAPEX system was extended to risks other than those affecting the health and safety of consumers (i.e. risks to health and safety in the workplace, the environment and security) and also to products intended for professional use.



The main objective of the RAPEX system is to ensure that only safe products are put on the European Single Market. Its success relies not only on close cooperation between national market surveillance authorities and the Commission but also on rigorous enforcement of appropriate legislation, a commitment to safety from all economic operators in the supply chain – from design to delivery – and close cooperation between the EU and its international trading partners.

What was achieved in 2011?

For the first time since 2004, when the current RAPEX system was put in place, the **total number of measures taken against dangerous products** and reported by Member States through RAPEX decreased compared to the previous year (from 2,244 in 2010 to 1,803 in 2011). This represents a reduction of **20%**.

Past growth in the number of notifications has been seen positively, resulting as it did from increased attention given to product safety by authorities and companies, a greater number of market surveillance actions carried out jointly by several national authorities and the effect of training and seminars provided by the Commission for different stakeholders. The decrease in 2011 can be attributed to various factors. First, a number of targeted joint enforcement actions by Member States came to an end. These may have increased the number of notifications in certain product categories in previous years. Second, resource constraints due to budgetary restrictions may have affected Member States' activity level. Moreover, a wider and more thorough use of the RAPEX risk assessment quidelines in 2011 allowed Member States to identify the correct

¹ A detailed description of how the RAPEX system functions can be found in Chapter 5. A Glossary of the technical terms used in this report can be found in Chapter 6.

² OJ L 22, 26.01.2010, p.1.

level of risk posed by specific products at an earlier stage and to focus their notifications on those products posing the most serious risks. Accordingly, while fewer numbers of notifications were received, their quality and reliability were enhanced. Higher quality notifications facilitate Member States' follow up actions against dangerous products.

In any case, the number of notifications should not be taken as the only indicator of enforcement activity. Member States and the Commission have consistently reaffirmed the importance of RAPEX and their commitment to maintaining a high level of product safety in Europe.

The most notified product category this year is **clothing, textiles and fashion items** (27%), followed by toys (21%), which was previously at the top. **Injuries, chemical risks and strangulation** were the most commonly notified risks in 2011.

The number of RAPEX notifications concerning products of **Chinese** origin, although remaining high (54%), represents a decrease compared to 2010 when it was 58% (this was the second consecutive year in which this figure has dropped.) The high number of notifications concerning products of Chinese origin is mainly explained by the significant market share of Chinese-manufactured products in the consumer goods sector. Nonetheless, over recent years, reinforced cooperation with the Chinese authorities has yielded positive returns - improved traceability of products, for instance, has provided more scope for corrective measures to be taken in China, contributing to the downward trend. The European Commission remains committed to these joint efforts with the Chinese authorities to help tackle safety at source.

Enforcement and compliance by businesses

2011 was marked by **the strengthening of market surveillance cooperation** between national authorities across the EU. Under the umbrella of the Product Safety Enforcement Forum of Europe, or "Prosafe", 19 Member States have applied for a single grant for joint enforcement actions covering four products (childcare articles, fireworks, lawn-mowers and battery chargers) and a series of thematic activities. The Commission awarded **EUR 1.7 million** to the project. In addition, thirteen exchanges of officials took place in 2011.

The Commission also convened an informal expert group on product traceability composed of experts from industry, consumer organizations and national market surveillance authorities. The objective of this group is to develop a series of non-regulatory recommendations to stakeholders - economic operators and market surveillance authorities alike on how to improve traceability, drawing on the state of the art in different sectors. Concretely, the group will try to understand what could be done to allow market surveillance authorities get the information they need from economic operators in order, in turn, to share this information with their EU counterparts via more complete RAPEX notifications. The group's informal recommendations on best practices will be laid out in a final report delivered at the end of its two years of work.

In 2011, the Commission organised **RAPEX train**ing seminars for national market surveillance and customs authorities to strengthen their knowledge of the RAPEX system and to improve enforcement capacity. Seminars were held in Luxembourg,





Lithuania, France, Latvia, the United Kingdom and Romania. In addition, market surveillance authorities increasingly applied the RAPEX risk assessment method published in early 2010 as part of the RAPEX Guidelines and the related IT tool was improved.

Since its launch in 2009, operation of the **GPSD Business Application**, an on-line information exchange system for producers and distributors of consumer products, has proved successful. In 2011, 215 notifications sent through the application by producers and distributors were accepted by the competent national authorities. This constitutes an increase of 62% – an extra 133 notifications – compared to 2010.

Developments relating to specific products and risks

Cigarettes left unattended are a leading cause of fatal fires. Work to introduce to the **EU reduced ignition propensity (RIP) cigarettes**, which rapidly self-extinguish when left unattended, was completed with the publication of the references of the two relevant standards in the Official Journal on 17 November 2011. These new EU-wide requirements, similar to those already applied in Finland as well as in the United States, Canada and Australia, are expected to save hundreds of lives every year. The Commission's communication campaign on the issue reached up to 90 million Europeans and highlighted that, while the new standards reduced the risk of fire associated with cigarettes, tobacco remained the largest avoidable health risk in Europe.

The European Commission extended the validity of Decision 2006/502/EC for an additional period of 12 months, until 11 May 2013, in order to maintain the requirement that **cigarette lighters** be child-resistant and that novelty lighters be banned from the market. In addition, a study was launched to identify technical parameters or test methods with a view to the further revision of the standard EN 13869:2002 'Lighters – Childresistance for lighters – Safety requirements and test methods'. Since **Dimethyl fumarate (DMF)**, an anti-mould chemical substance that is strongly sensitising and can cause severe skin lesions, continued to be identified in consumer products under RAPEX, the European Commission proposed to Member States to extend the validity of the one-year, temporary, extendable ban on DMF under the GPSD for a third time. A permanent ban under the REACH legislation is expected to enter into force in the first half of 2012.

In order to avoid the risk of hearing loss, especially for young people, new European safety standards to provide protection against excessive sound levels from **personal music players** were published by CENELEC at the beginning of 2011. A transition period for the transposition of the standards at national level will come to an end on 24 January 2013. As of this date, affected companies should have started to apply the new standards to their products.

Discussions took place with Member States during the course of 2011 on the definition of the safety requirements to be addressed by European standards for **laser products intended for consumers** – such as **laser pointers**. These products can pose a risk of damage to consumers' sight as well as other consequences of their misuse, in particular in relation to aviation safety. In order to clarify the situation at the European level, it is proposed to give a mandate to the European standards organisation CENELEC to update the relevant European standard EN 60825-1 (2007) including all potentially dangerous products.

On 27 July 2011, the European Commission adopted a three decisions setting out safety requirements to be addressed by future European standards. The first seeks to address certain risks posed to children by internal blinds, corded window coverings and safety devices. The purpose of this decision is to strengthen the requirements of standard EN 13120: 2009 for internal blinds and draw up new standards for corded window coverings in general in order to eliminate the risks of children being strangled. The other decisions cover gymnastic equipment and stationary training equipment. On 29 November 2011, the Commission adopted a further decision on safety requirements for bicycles, bicycles for young children, and luggage carriers for bicycles.

Developments of standards relating to products for which specific harmonisation legislation exists are reported separately by the Commission; this report focuses on work carried out by the Health and Consumers Directorate-General, pursuant to the GPSD.

International cooperation

This year, the Commission's intensive bilateral and trilateral regulatory cooperation with the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) and the United States Consumer Product Safety Commission (CPSC) has continued. In particular, in November 2011, an EU-China-US Trilateral Consumer Product Safety Roundtable took place in Beijing in the framework of the EU-China Trade project (EUCTP). The roundtable discussed effective ways to promote awareness of EU and US consumer product safety requirements to parties involved in design, manufacturing and export controls in China.

The European Commission's Health and Consumers Directorate-General held the chairmanship of the **International Consumer Product Safety Caucus (ICPSC)** throughout 2011 and will continue to do so in 2012. This forum, the members of which are regulatory and market surveillance authorities dealing with consumer product safety from around the world, facilitates international cooperation and the exchange of information on consumer product safety issues. In 2011, the ICPSC met three times, in the United States, France and Korea.

The OECD Working Party on Consumer Product Safety continued its activities in 2011. A Commission representative is one of the working party's vice-chairs. In 2011, a web portal with an inventory of product safety issues and events around the world was established. Through this portal, information on product safety matters can be easily exchanged between participating countries. Work also started on the establishment of a global data pool of product recalls.

The European Commission also continues to provide technical assistance in the field of product safety to candidate countries, potential EU accession countries and interested European Neighbourhood Policy (ENP) countries. **CHAPTER 2**

RAPEX Statistics

2.1 Notifications on products posing a risk to the health and safety of consumers

2.1.1 Total number of notifications

Situation in 2011

In 2011, the Commission distributed through the RAPEX system **1,803** notifications on consumer products posing risks to health and safety:

 1,556 of these notifications were distributed under Article 12 of the GPSD and Article 22 of Regulation (EC) No 765/2008. These are preventive or restrictive measures on products presenting a serious risk to the health and safety of consumers. They can either be taken by national authorities, e.g. stopping or banning of sales, or carried out voluntarily by economic operators, e.g. withdrawal from the market, recalls from consumers.

- 58 notifications were distributed to Member States under Article 11 of the GPSD and Article 23 of Regulation (EC) No 765/2008. These concern measures taken by national authorities with regard to products posing risks classified as less than serious. Notifications under Article 23 of Regulation (EC) No 765/2008 may also concern voluntary measures by economic operators.
- 189 notifications were distributed to Member States for information purposes only as they did not qualify for distribution under either of the above-mentioned legal bases.



The total number of notifications validated by the Commission rose steadily in recent years, increasing more than fourfold for instance between 2004 (468) and 2010 (2,244).

In 2011, for the first time since the start of the operation of the current RAPEX system, the total number of notifications decreased by 20% (1,803 notifications, down from 2,244 in 2010). This is compared with annual increases of 81% in 2005, 24% in 2006, 53% in 2007, 16% in 2008, 7% in 2009 and 13% in 2010.³

The number of notifications of products presenting a serious risk (i.e. under Article 12 of the GPSD and Article 22 of Regulation 765/2008) was 21% lower than in 2010 (1,556 versus 1,963). In 2010, that had risen 16%.

The number of notifications distributed for information purposes only has decreased by 22% compared to 2010 (189 notifications compared to 243). The reduction in the number of such notifications is also due to the fact that notifications submitted by Member States to the Commission are constantly improving in quality. In particular, the notified products and the risks they pose are better identified, meaning that other Member States are better able to find the products on their markets and take action to protect consumers. In the following charts, the figures concern only notifications on consumer products posing a serious risk which are distributed through RAPEX under Article 12 of the GPSD and Article 22 of Regulation (EC) No 765/2008. Notifications distributed under Article 11 of the GPSD and Article 23 of Regulation (EC) No 765/2008 and notifications sent for information purposes are not covered.

2.1.2 Notifications by notifying country

In 2011, 27 EU Member States, plus Iceland and Norway, sent notifications through the RAPEX system. Only one participating country (Liechtenstein) did not submit any notifications.

The following five most frequently notifying countries accounted for 47% of all notifications:

- Spain (189 notifications, 12%)
- Bulgaria (162 notifications, 10%)
- Hungary (155 notifications, 10%)
- Germany (130 notifications, 8%)
- United Kingdom (105 notifications, 7%).



Comparison with previous years





Comparison with previous years

In 2011, half of the participating countries notified fewer dangerous products than in 2010. However, the gap between the countries with the highest and the lowest number of notifications remained almost the same as in the previous year. This is reflected in the fact that the total share of the five most frequently notifying countries (i.e. Spain, Bulgaria, Hungary, Germany and the United Kingdom) is still 47%, as in 2010.







Figure 7 – The five most frequently notifying countries in 2010

It should be stressed that RAPEX statistics do not reflect all market surveillance activities carried out in Member States. Legitimate reasons may exist for the fact that some measures taken against dangerous products in Member States do not result in notifications sent to the RAPEX system. Some products, for instance, are not sold outside of the Member State concerned. The participation rate of countries in RAPEX is the result of various factors, such as the different way in which the national market surveillance networks are organised, the different size of the countries, and the different production and market structures that exist across the EU. The Commission has undertaken several actions in 2010 and 2011 in order to facilitate the participation of Member States in RAPEX, including the publication of the new RAPEX Guidelines, the development of a new risk assessment application with an improved IT tool and the organisation of several RAPEX seminars.

2.1.3 Notifications by product identifier

2.1.3.1 Product category of the notified product

The product categories most frequently notified through the RAPEX system in 2011 were:

- Clothing, textiles and fashion items (423 notifications, 27%)
- Toys (324 notifications, 21%)

- Motor vehicles (171 notifications, 11%)
- Electrical appliances and equipment (153 notifications, 8%)
- Cosmetics (104 notifications, 7%).

These categories of consumer products accounted for 74% of all products notified in 2011. This year the product category "Clothing, textiles and fashion items" was the most notified (27%), followed by "Toys" (21%). Both categories account together for almost half (48%) of all notifications distributed through the RAPEX system in 2011.

The significant escalation in the number of RAPEX notifications on clothing, textiles and fashion items over the last two years results mainly from enhanced market surveillance activities undertaken by national authorities following, in particular, the launch of the joint market surveillance action on cords and drawstrings in children's clothing, which saw the participation of nine Member States. A second factor leading to the prominence of this category in the findings of non-compliance was the adoption of Commission Decision 2009/251/ EC on dimethyl fumarate (DMF)⁴, which is a strong novel sensitizer found to have been used as an anti-mould treatment especially in shoes, some textiles and furniture. This proves that riskfocused measures and joint prioritisation of certain types of products in the surveillance actions taken by Member States result in resources being well spent, in terms of finding dangerous products that could be harmful to consumers.

⁴ OJ L 74, 20.3.2009, p. 32–34







Figure 10 – The five most frequently notified product categories in 2011



2.1.3.2 Traceability – brand and model numbers of the notified product

1,308 notifications validated in 2011 (84%) concerned products for which both the brand and the type/model number were known, which ensures a better identification and therefore traceability of the notified products. In 14% of the cases, either the brand or the type/model number was known. In only 30 cases (2%) both the brand and the type/ model number were unknown.

Figure 12 – Number of notifications in which brand and model numbers are known/unknown

	Type/number of model Known	Type/number of model Unknown	Total
Brand Known	1,308	126	1,434
Brand Unknown	92	30	122
	1,400	156	1,556

Figure 13 – Notifications in which brand and model numbers are known/unknown (%)



2.1.3.3 Country of origin of the notified product

In 54% of all notifications sent through the RAPEX system in 2011 (i.e. 839 notifications), the country of origin of the notified products was China (including Hong Kong). That this number is still very high results from the significant market penetration of Chinesemanufactured consumer products in European markets. Products are checked according to the same, stringent safety requirements regardless of their origin, usually based on typical risks associated with the product category. The consistent intensification of contacts with the Chinese administration and businesses is yielding significant returns in terms of improved product identification and traceability for corrective measures and will continue.

293 notifications (19% of all notifications sent through RAPEX) concerned products originating from the 27 EU Member States and 3 EFTA/EEA countries. This is consistent with the data from previous years (17% in 2010, 20% in 2009, 20% in 2008, 22% in 2007 and 21% in 2006).

128 notifications (8% of all notifications sent through RAPEX) contained no information about the

country of origin of the notified product. Nevertheless, this figure should be seen as a significant improvement in the operation of the RAPEX system as even though this figure is slightly higher than the 7% recorded in 2009, it is lower than the 10% recorded in 2010. In fact, it remains a very low level given that, in 2004, the number of cases with an unidentified country of origin was as high as 23%. The overall drop indicates that market surveillance authorities in Europe are increasingly aware of the importance of finding identification data that is helpful to partner authorities in other Member States and, ultimately, in the country of origin of the product.

In most cases, market surveillance authorities are able to take corrective measures if both the country of origin and sufficient product identification (such as a reliable barcode or brand and type/number of model) are known. Since the brand and type/ number of model were indicated in the case of only 84% of products notified in 2011, there is still room for improvement in educating manufacturers and importers on the importance of traceability in the supply chain. The work of the informal expert group on product traceability is expected to be helpful in this sense⁵.



⁵ http://ec.europa.eu/consumers/safety/projects/ongoing-projects_en.htm







Figure 17 - Notifications by country of origin of the notified product (%) - comparison previous years

2.1.4 Notifications by type of risk

The five most frequently notified risk categories were:

- Injuries (481 notifications, 26%)
- Chemical (347 notifications, 19%)
- Strangulation (275 notifications, 15%)
- Choking (224 notifications, 12%)
- Electric shock (216 notifications, 12%).

These five risk categories account for 84% of all notified risks.

It should be noted that some RAPEX notifications concern products presenting more than one risk. For example, a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to excessive levels of a restricted substance. The total number of notified risks is accordingly higher than the total number of notifications. On the basis of RAPEX data, it can also be concluded that each product category is likely to expose consumers to specific types of risk. For example, the main risks arising when playing with unsafe toys are choking (often associated with the presence of small parts) and reactions to chemicals (often associated with the presence of significant amounts of chemical substances such as certain phthalates, lead and other heavy metals), while the most common risk for electrical products is electric shock, often combined with the risk of fire.









2.1.5 Notifications by type of measure

922 of the 1,556 RAPEX serious risk notifications concerned compulsory preventive and restrictive measures ordered by national authorities (60% of the total). In 598 notified cases (38%), economic operators took preventive and restrictive measures on a 'voluntary' basis, i.e. they complied with their legal obligations without the formal intervention of a national authority. In 36 cases (2%), 'voluntary' actions were complemented by compulsory measures taken by the national authority. In this situation, even though an economic operator has ceased selling a product, national authorities still believe further action needs to be taken and accordingly order, for example, the product to be withdrawn from the market or recalled from consumers who have already bought it.







Jan-Dec 2011	Compulsory measures	Voluntary measures	Compulsory and voluntary	Total
Belgium	1	7		8
Bulgaria	156	6		162
Czech Republic	9	4		13
Denmark	15	33		48
Germany	9	107	14	130
Estonia	16	2		18
Ireland		29		29
Greece	22	47		69
Spain	153	35	1	189
France	20	64	7	91
Italy	26	1		27
Cyprus	64	8	1	73
Latvia	25	2	1	28
Lithuania	17	3		20
Luxembourg	9			9
Hungary	155			155
Malta		33		33
Netherlands	19	21		40
Austria	1	13		14
Poland	19	32		51
Portugal	33	21		54
Romania	28	2		30
Slovenia	3	16	2	21
Slovakia	27	9	2	38
Finland	65	12	1	78
Sweden		14		14
United Kingdom	28	70	7	105
Iceland		1		1
Liechtenstein				0
Norway	2	6		8
	922	598	36	1,556

Figure 24 – Number of notifications by type of measure per country (absolute values)

Comparison with previous years

In 2011, the share of cases in which measures were initiated by the authorities remained the same as in 2010: six out of ten measures are now ordered by the authorities.



2.1.6 Notifications initiated by the activities of the customs authorities

136 notifications processed in the RAPEX system in 2011 concerned measures that were adopted by customs authorities, representing 15% of the total of 922 compulsory measures taken. These measures consisted mainly of rejections of imports.

The Member State figures for this category of notifications may appear to indicate that customs authorities are more active in tackling imports of dangerous products in some countries than others. However, this does not give a full picture of the activity of customs authorities across the EU, since in many other countries measures in which customs have played an important role are in fact taken directly by market surveillance authorities themselves, acting in liaison with the customs authorities. Furthermore, customs authorities also have their own information sharing mechanisms and not all of their reporting goes through RAPEX.

2.2 Reactions on products posing a risk to the health and safety of consumers

2.2.1 Total number of reactions

In 2011, EU Member States and the EFTA/EEA countries sent a total of 2,100 reactions to all notifications distributed through RAPEX. 2,059 reactions were sent in response to notifications concerning a serious risk (98%); 19 reactions concerned notifications of products with lower risk levels (1%); and 22 reactions were sent in relation to notifications sent for information only (1%). The number of reactions received per notifications received at least 10 reactions.

In the following charts, the figures only concern reactions to notifications concerning a serious risk (2,059 reactions).



2.2.2 Reactions by reacting country 2.2.3 Reactions by notified product

In 2011, all Member States, plus Norway and Iceland, sent reactions to RAPEX notifications. Only Liechtenstein did not send a reaction to any RAPEX notifications.

The following five countries accounted for 42% of all reactions:

- Netherlands (237 reactions, 12%)
- Sweden (178 reactions, 9%)
- Portugal (164 reactions, 8%)
- Denmark (136 reactions, 7%)
- Slovenia (122 reactions, 6%).

Notifications concerning motor vehicles generated the most reactions (69%). Almost 90% of all reactions concerned RAPEX notifications related to the following five product categories:

- Motor vehicles (1,415 reactions, 69%)
- Toys (137 reactions, 7%)
- Electrical appliances and equipment (85 reactions, 4%)
- Clothing, textiles and fashion items (64 reactions, 3%)
- Protective equipment (57 reactions, 3%).











2.2.4 Reactions by type of notified risk

More than half of the reactions received were sent in response to notifications about consumer products posing a risk of injuries (1,380 reactions, 63%) or fire (328 reactions, 15%). These two risks are clearly linked to motor vehicles, which accounted for 69% of all reactions received.

The five risk categories most frequently included in the reactions were:

- Injuries (1,380 reactions, 63%)
- Fire (328 reactions, 15%)
- Chemical (124 reactions, 6%)
- Electric shock (86 reactions, 4%)
- Choking (80 reactions, 4%).

Some reactions concerned products that present more than one risk: therefore the total number of risks associated with the reactions (2,192) is higher than the total number of reactions submitted for products posing a serious risk (2,059).





2.2.5 Reactions by type of reaction

In the majority of reactions received (1,864 reactions, 91%), Member States stated that the notified product was found on their market and that adequate preventive or restrictive measures had been adopted at national level. In 82 reactions (4%), the reacting country requested or provided additional information on the case. In only 9 reactions, the reacting country did not agree with the information provided in the notification. These disagreements mainly related to the conclusions of the risk assessment presented by the notifying Member State. In 104 reactions (5%), Member States informed the Commission that the notified product was not found on their market (this kind of reaction is not formally required).





2.2.6 Measures taken by reacting countries

In the majority of cases in which the reacting country found the notified product on its market (1,864 reactions), the measures taken were also indicated. In 72 cases (4%), those measures were taken by the national authorities (compulsory measures) and in 1,772 cases (95%) they were

taken by economic operators (voluntary measures). In 2 cases, it was indicated that compulsory as well as voluntary measures were taken. In 18 cases (1%), no measures were indicated.

Since January 2011, the RAPEX website mentions next to each notification those countries which found the product on their market and took restrictive measures.





2.3 The new notifications and reactions on professional goods and other risks

2.3.1 Notifications on professional goods and other risks

Following the entry into force of Regulation (EC) No 765/2008 on accreditation and market surveillance on 1 January 2010, Member States have an obligation to notify the Commission about measures taken in relation to professional products as well with regard to consumer products that pose a serious risk other than to health and safety (such as environmental risks, security risks, electromagnetic disturbance risk, etc.). An interim solution was used (until the new RAPEX IT system is operational) for the distribution and storage of these notifications.

- 2 notifications were distributed to Member States under Article 23 of Regulation (EC) No 765/2008 (non-serious risk);
- 6 notifications were distributed to Member States for information purposes as they did not fulfil the criteria of either Article 22 or Article 23, although the information contained therein was deemed of interest to market surveillance authorities.

Despite the European Commission's efforts to encourage Member States to send notifications in this area, less progress than expected was achieved compared to the previous year.

As regards the 17 notifications on products presenting a serious risk, the main risk categories for these particular RAPEX notifications were the following:



There was a slight rise in the number of these types of RAPEX notifications validated in 2011 and, as a result, the Commission distributed altogether 25 notifications concerning professional products and risks other than health and safety:

- 17 of these notifications were distributed to Member States as notifications under Article 22 of Regulation (EC) No 765/2008 (serious risk);
- Environment (12 notifications, 71%)
- Health & safety (5 notifications, 29%).

Reported environmental risks referred to chemical pollution and CO_2 emissions. These risks concern consumer products such as plastic packages used for toys and a number of fireworks. As regards health and safety risks, the relevant subcategories were injuries, damage to sight and burns. These risks were associated with professional products (e.g. a clipping machine, an electric rollable stable screen, a cryogenic shot blastic system or a feed mixer for agriculture).



Out of these 17 notifications, 5 RAPEX notifications (29%) which were distributed in 2011 related to professional products and 12 validated RAPEX notifications (71%) referred to consumer products.

The following 5 countries sent RAPEX notifications concerning professional goods or other risks:

- Finland (6 notifications, 35%)
- Denmark (4 notifications, 24%)
- The Netherlands (3 notifications, 18%)
- Sweden (3 notifications, 18%)
- Germany (1 notification, 5%).

It can be observed that in the last two years most notifications were sent only from the abovementioned countries.





The notifications concerned the following categories of products:

- Explosive atmosphere equipment and pyrotechnics articles (6 notifications, 35%)
- Machinery (5 notifications, 29%)
- Clothing, textiles and fashion items (2 notifications, 12%)
- Other plastic packages (4 notifications, 24%).

Seven out of 17 serious risk notifications led to compulsory preventive and restrictive measures ordered by the national authorities (41% of the total number). In nine cases (53%), the economic operators took voluntary measures. In one case (6%), compulsory measures were complemented by voluntary actions.



China was indicated as the country of origin of the notified product in the majority of the cases (11 notifications, 65%). The 27 EU Member States accounted for 4 notifications; there was 1 notification concerning a product of which the country of origin was unknown and 1 notification originated from Taiwan.


2.3.2 Reactions to notifications on professional goods and other risks

In 2011, Member States did not send any reactions to the validated notifications on professional goods and other risks. Notifications validated in 2011 were mainly associated with serious environmental risks linked to consumer products and notifications posing a risk to health and safety related to professional products. In most cases, notifications distributed concerned consumer products. Compulsory measures (ordered by national authorities) and voluntary measures



2.3.3 Conclusion on professional goods and other risks

In 2011, the Commission received 70% more RAPEX notifications on professional goods and other risks, indicating, in absolute terms, 10 notifications more than in 2010. The statistics show in particular a very uneven distribution of notifications among Member States, confirming that there is a need to ensure a much more complete and consistent participation of all Member States in RAPEX notifications regarding professional products and risks other than health and safety.

(taken by economic operators) were taken on almost an equal basis. A high share of the dangerous products notified originated from China.

The limited number of notifications in this area might indicate either that Member States are not sufficiently proactive in their controls of the market or that the risks for these products are not as widespread as was originally thought. This will be monitored more closely in 2012.

Key Developments in 2011

3.1 Enforcement and compliance by businesses

Product safety legislation lays down rules that aim to ensure that only safe products are placed on the market. Nevertheless, only through effective enforcement can it be guaranteed that 500 million European citizens are, and feel, protected against serious risks and threats that they cannot tackle as individuals. National market surveillance authorities and the European Commission cooperate at European level to stop unsafe products reaching the marketplace. Product safety legislation also imposes a legal obligation on producers and distributors to notify the national authorities of any dangerous consumer products they know to be placed on the EU market. They can fulfil this obligation in a simple way through the on-line GPSD Business Application.

3.1.1 Market surveillance coordination and cooperation

2011 was marked by the strengthening of market surveillance cooperation between national authorities across the EU. Represented by the umbrella organisation Prosafe, 19 Member States applied for a single joint action grant covering four products (childcare articles, fireworks, lawn-mowers and battery chargers) as well as a number of horizontal core activities. The Commission awarded EUR 1.7 million to the project (70% of the total budget).

Thirteen exchanges of officials took place in 2011.

Three joint market surveillance actions drew to a close, achieving important results:

Toys

Thirteen Member States took part in a joint enforcement project on toys. The main objective of the participants was to ensure that toys for children under 3 years of age are safe from the point of view of small parts, magnets and heavy metals.

The national authorities inspected the premises of 1,400 economic operators and over 14,000 toys were subjected to visual checks. 580 toys were tested against the requirements of the European standard EN 71-1 (small parts and magnets in toys). Furthermore, approximately 2,300 toys sold by 360 economic operators were inspected for the presence of heavy metals and 230 toys were subjected to laboratory tests for compliance with EN 71-3 (migration of heavy metals in toys).

About 35% of the toys selected for laboratory tests failed to comply with the mechanical requirements related to small parts and magnets, while less than 1% of toys failed the heavy metals tests. These dangerous products can expose children to serious health risks and must be removed from the market.

Sunbeds

2011 also saw the end of a joint enforcement project dealing with sunbeds. This project aimed to consolidate the progress made in an earlier joint action on sunbeds implemented in 2008 and 2009. It extended the cooperation already established with the representative organisations of the sunbed industry and the providers of tanning services. It also expanded cooperation with stakeholders by establishing contact with the medical and scientific community involved in diminishing the incidence of skin cancers caused by UV radiation.

Over two years, market surveillance authorities in the eleven participating Member States inspected over 1,000 tanning service providers and manu-



facturers, importers and distributors of sunbeds. Inspectors concluded that consumers are poorly informed and protected (the minimum age limit of 18 is often not enforced and there is a lack of risk information and qualified personnel).

1,396 sunbeds were checked for appropriate labelling and UV radiation. A series of problems were found, such as the absence of CE marking (about 25%), warnings (about 20%) or the indication of maximum UV radiation. More significant is the result of UV radiation measurements which showed that 65% of the inspected sunbeds do not respect the maximum level of 0.3 W/m2, thus posing serious health risks to unsuspecting consumers.

EMARS II

EMARS II (Enhancing Market Surveillance through Best Practice) was a large scale horizontal project, which ran from 2008 until 2011. It aimed to further strengthen cooperation between Member States on consumer product safety by promoting the use of the Rapid Advice Forum, extending the knowledge base, updating market surveillance guidance materials, establishing an EU-wide training programme for market surveillance inspectors and coordinating authorities' input into standardisation.

The activities were successfully finalised in 2011, providing the product safety community with knowledge and experience to be used in the future. Some of the key activities of EMARS II will continue

in 2012 as horizontal components of the abovementioned EUR 1.7 Million project.

3.1.2 Better tools and capacity building

3.1.2.1 IT tool on the risk assessment method

The risk assessment method published in early 2010 as part of the RAPEX Guidelines was increasingly applied by market surveillance authorities throughout 2011. In addition, the related IT tool that facilitates the preparation of risk assessments (http://europa.eu/sanco/rag) was improved and will be available shortly in 22 EU languages.

3.1.2.2 RAPEX seminars

The Commission organises RAPEX seminars on a regular basis for national market surveillance and customs authorities in order to strengthen their knowledge of the RAPEX system and improve their overall enforcement capacity. In 2011, seminars were held in Luxembourg, Lithuania, France, Latvia, the United Kingdom and Romania. Besides the functioning of the RAPEX system and the implementation of the GPSD and Regulation (EC) No 765/2008, an significant part of the seminars was dedicated to workshops on risk assessment and, in particular, the application of the risk assessment guidelines.



3.1.3 RAPEX and other product safety indicators

Eurobarometer opinion surveys

For the fourth consecutive year, the Commission conducted two Eurobarometer opinion surveys covering product safety issues, consulting consumers and retailers about their perception of consumer law enforcement in Europe. The results help to provide a better understanding of what consumers and economic operators know about product safety rules, complaints and the activities of authorities, among other issues.



The surveys showed that 25% of consumers (compared to 20% in 2010) and 19% of retailers (compared to 16% in 2010) thought that a significant number of non-food consumer products sold in Europe were unsafe. There were big differences between Member States, with the highest levels of perceived safety noted in Ireland, Luxembourg, and Denmark, while the most dissatisfied consumers were found in Greece, Romania and Latvia. On average, 8% of the respondents stated that they had been personally affected by the recall of a nonfood product.

A majority of retailers in the EU felt they were wellinformed about the rules and regulations relating to product safety and almost half (46%) of retailers of consumer products declared that they had carried out tests in the past two years to make sure that none of the products they were selling were unsafe.

A majority of retailers in all countries agreed that national public authorities actively monitor and ensure compliance with product safety legislation in their sector.

Consumer Market Scoreboard

The 5th edition of the Scoreboard, "Consumers at Home in the Internal Market" focused mainly on measuring the integration of the Single Market for retail sales and on benchmarking national consumer environments. Product safety was one of the key areas addressed as it plays an important role in building consumer welfare and confidence. The main conclusion drawn, on the basis of broad range of indicators, was that difficult economic conditions have had a big impact on national consumer environments, leading consumers to feel generally less secure.

Enforcement indicators

Based on the data provided by market surveillance authorities in 25 countries, Member States have spent over EUR 100 Million on product safety enforcement in 2010 and employed over 6,000 inspectors.

In the general context of the 2009–2010, most Member States indicated they have increased their efforts to keep unsafe products from the shelves. Despite their more limited resources and economic crisis, more inspections and tests have been carried out, resulting in more corrective decisions taken by the authorities.

3.1.4 GPSD Business Application

Since May 2009, producers and distributors have had the possibility to notify the national authorities of Member States and EFTA/EEA countries about dangerous products through the on-line GPSD Business Application.

The purpose of this application is to simplify the procedure by which producers and distributors fulfil their obligations to notify competent national authorities of any dangerous consumer products they know to be placed on the EU market. The advantage of the application is that producers and distributors



can alert all countries concerned at the same time through one single notification, streamlining and speeding up the process. Access to the secure online database where all the notifications are stored is restricted to competent national authorities only; neither business nor consumers have access to it. In 2011, a total of 215 notifications (including updates) sent through the application by producers and distributors were accepted by the competent national authorities. This constitutes an increase of 62% compared to 2010 (133 notifications).

In 2011, all the Member States and EFTA/EEA countries received notifications via the GPSD Business Application. France, Netherlands, Spain, Germany and Belgium are the Member States most often notified by producers and distributors.

Notifications submitted through the application concerned a range of product categories, including electrical appliances, motor vehicles, toys, children's products and hobby/sport equipment.





3.2

The data provided through the application by producers and distributors was usually complete and of good quality. The notifications contained detailed information regarding a) product identification, b) the risks posed by the product, c) the importers and distributors responsible for marketing and distributing the product in the EU, d) measures taken to protect consumers and e) the incidents reported and complaints received.

For additional information on the GPSD Business Application, including a manual explaining how to prepare and submit a notification and a memo with frequently asked questions, please visit the European Commission's website http://ec.europa.eu/consumers/ safety/rapex/guidelines_business_en.htm

It should be noted that a notification in the Business Application does not replace a RAPEX notification but, as appropriate, is followed by a RAPEX notification made by the lead authority.

Developments relating to specific products and risks⁶

3.2.1 Reduced ignition propensity cigarettes

Cigarettes left unattended are a leading cause of fatal fires. Work to introduce reduced ignition propensity (RIP) cigarettes, which rapidly self-extinguish when left unattended, across the EU was completed with the publication of a reference to the two relevant standards in the Official Journal on 17 November 2011⁷. This provided the presumption of fire safety for all cigarettes manufactured in compliance with the standards. These new requirements, similar to those already applied in Finland, the United States, Canada and Australia, are expected to save hundreds of lives every year. In related communications to the public, the Commission underlined that, while the standards reduced the risk of fire associated with cigarettes, there is no such thing as a safe cigarette and that tobacco remained the largest avoidable health risk in Europe. This message was covered in at least 700 separate media reports, reaching up to 90 million Europeans.

Development of other standards and safety requirements for products for which specific harmonisation legislation exists are reported separately by the Commission; this report focuses on the work of the Health and Consumers Directorate-General.
 OJ L 205, 10.8.2011, p. 31.

3.2.2 Lighters

In order to maintain the requirement that cigarette lighters be child-resistant and the ban on novelty lighters, the European Commission extended the validity of Decision 2006/502/EC for an additional period of 12 months, until 11 May 2013.

A further step was made towards the inclusion, in standard EN 13869:2002 'Lighters – Child-resistance for lighters – Safety requirements and test methods', of testing method(s) for child resistance that avoid the use of child panels. In 2011, CEN requested that the European Commission co-fund a study to identify the technical parameters or methods that are currently available. The study started in November 2011 and should be completed within 12 months. It is expected to provide much-needed information so that work on the revision of EN 13869 can subsequently get underway.

3.2.3 Measures to address risks from Dimethyl fumarate

Since Dimethyl fumarate (DMF), an anti-mould chemical substance that is strongly sensitising and can cause severe skin lesions, continued to be identified in certain consumer products notified under RAPEX in 2011, the European Commission proposed that Member States extend the validity of the oneyear, temporary, extendable ban on DMF under the GPSD for a third time. A permanent ban under REACH is expected to enter into force during the first half of 2012.

3.2.4 Personal music players

Listening to personal music players at excessive volume over time may pose a risk of hearing loss. Young people are particularly at risk. In response to a Commission mandate to the European standardisation bodies given in September 2009, new European safety standards to provide protection against excessive sound levels from personal music players were published by CENELEC at the beginning of 2011 as EN 60065:2002/A12:2011 and EN 60950-1:2006/A12:2011.

The standards are based on a sound level limit of 85 dB. This is a level that is considered to be safe under all conditions of use. There is the possibility however for the user to choose to override the limit so that the sound level can be increased up to a maximum of 100 dB. In this case the user has to be provided with warnings about the risks, which



are repeated after each 20 hours of listening time. At the moment, there is a transition period during which the standards will be transposed at national level. This transition period will finish on 24 January 2013 (the latest date by which conflicting national standards have to be withdrawn). After this date, industry should have started to apply the new standards to their products.

In the meantime, CENELEC is expected to continue with the next step of the mandated work, which is the development of "smart" methods of providing protection against excessive sound pressure levels from personal music players based on the measurement of sound dose.

The new standards are voluntary but, if applied, they will provide a presumption of conformity with the safety requirements of applicable legislation. For this reason, the references of the new standards have been published in the Official Journal under the Low Voltage Directive (2006/95/EC) and the Radio and Telecommunications Terminal Equipment Directive (1999/5/EC). Publication under the General Product Safety Directive (2001/95/EC) is foreseen for early 2012.





3.2.5 Laser products intended for consumers

Products which can project powerful laser beams, such as laser pointers, pose a risk of damage to consumers' sight. There is also considerable concern about their misuse, in particular in relation to aviation safety.

Whilst the relevant European standard EN 60825-1 (2007) requires that the hazard of laser products should be assessed and that appropriate warning labels are displayed, compliance with the standard does not ensure that a laser product is safe. In particular, the standard does not specify which classes of products should or should not be made available to consumers.

Nevertheless, it is widely accepted by national market surveillance authorities that laser pointers higher than Class 2M should not be made available to consumers. There is also legislation in some Member States restricting the marketing of laser products to consumers.

In order to clarify the situation at the European level, it is proposed to give a mandate to the European standards organisation CENELEC to update the standard under Article 4 of the GPSD including all potentially dangerous products.

To this end, discussions took place with the Member States during the course of 2011 on the definition of the safety requirements which would have to be addressed by European standards. The discussions are expected to continue in 2012.

3.2.6 Safety of window blinds

On 27 July 2011, the European Commission adopted a decision setting out safety requirements to be met by European standards to address certain **risks posed to children by internal blinds, corded window coverings and safety devices** pursuant to the GPSD.

The safety of corded window coverings such as blinds or draperies was the topic of several discussions with Member States, standardisation experts and consumer representatives throughout 2011. The European Commission is also working closely with international partner organisations on this issue. The purpose of this decision is to strengthen the requirements of European standard EN 13120: 2009 for internal blinds and draw up new standards for corded window coverings in general, to eliminate the risk of children being strangled.

3.2.7 Training equipment, gymnastic equipment and bicycles

On 27 July 2011, the European Commission adopted two decisions setting out safety requirements to be met by European standards pursuant to the GPSD: a decision on gymnastic equipment⁸ and a decision on stationary training equipment⁹.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:197:0013:0016:EN:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=0J:L:2011:196:0016:0020:EN:PDF

On 29 November 2011, the European Commission adopted a decision setting out safety requirements to be met by European standards for bicycles, bicycles for young children, and luggage carriers for bicycles pursuant to the GPSD.

3.2.8 Children's equipment/childcare articles

In November 2011, a Commission-funded study on childcare articles was finalised. The study includes risk assessments and suggested safety requirements for 11 products commonly used for child and baby care, for which there are no European standards or where the existing relevant standard does not adequately cover the risks. Amongst the products concerned are **children's shoes, bibs, soft slings, baby feeders and nursery pillows**. The European Commission will discuss draft safety requirements with Member States during 2012 with a view to adopting safety requirements and mandates for standardisation work to be carried out by CEN.



3.3 International cooperation towards global governance

3.3.1 Bilateral cooperation

While this section describes cooperation with certain countries in more detail, the Health and Consumers Directorate-General is also engaged in dialogue with many other countries and regional organisations which are not specifically mentioned here.

China

In 2011, regulatory cooperation with China has continued with tangible results as briefly outlined below.

In November 2011, a meeting of the working group on consumer products/market surveillance, set up by the Memorandum of Understanding between the European Commission's Health and Consumers Directorate-General and AQSIQ (General Administration of Quality Supervision, Inspection and Quaran-



tine), took place in China. The authorities exchanged information on consumer product safety issues, such as market surveillance, traceability, standardisation. etc.

RAPEX-China

The RAPEX-China on-line system was established in September 2006 and facilitates regular and rapid transmission of data between the EU and Chinese product safety administrations. The European Commission provides the Chinese authorities with information on consumer products originating from China which have been notified through RAPEX.

AQSIQ has submitted 19 reports to the Health and Consumers Directorate-General on enforcement actions carried out with regard to RAPEX notifications exchanged via RAPEX-China between September 2006 and October 2011.

During this period, AQSIQ has investigated and, where necessary, adopted measures in relation to 1,752 RAPEX notifications. Analyses of the reports received show that, on average, AQSIQ investigates 92 RAPEX cases over a three-month period. Summary analyses are regularly made available at: http://ec.europa.eu/consumers/safety/rapex/index_ en.htm

Challenges

The efficiency of the RAPEX-China system depends heavily on the availability and the correctness of information about responsible Chinese companies transmitted in RAPEX notifications. In 426 (24%) of 1,752 RAPEX cases, AQSIQ was unable to find



the responsible Chinese companies and thus could not adopt appropriate restrictive measures. Explanations from the AQSIQ reports for this include (a) that limited resources and lack of documents do not always allow national authorities to trace the origin of the product, (b) that the information about Chinese companies submitted by the Member States is incorrect or inaccurate, (c) that the Chinese company denies its role in the production or export of a notified product and does not keep any orders, contracts, invoices or other documents which could prove or disprove its involvement, (d) a change of address or bankruptcy of the responsible Chinese company, (e) the great complexity of the multiple trade relations of the responsible Chinese authorities.

The European Commission has reaffirmed the importance of traceability for the effectiveness of the RAPEX-China system and asked national authorities to make all possible efforts during the market surveillance process, in cooperation with economic operators, to establish the contact details of Chinese manufacturers and exporters. If clear information is provided to the Chinese authorities, the distribution of dangerous products can be blocked before they even leave Chinese territory. Accordingly, the problem is tackled in the most effective and efficient way possible – at its source. It has also been indicated that some of the dangerous products subject to AQSIQ's investigations were manufactured by Chinese companies according to improper specifications provided by EU importers. In many cases, EU importers have been found not to specify any safety requirements for the products they purchase, request any tests before shipping products to the EU, or have products approved before shipping them to the EU. These examples show that both the Commission services and the Member States should continue their efforts to informing companies of their obligations under product safety legislation.

United States

While no formal agreements with the USA on consumer product safety have yet been finalised, close cooperation on consumer product safety between the European Commission and the United States Consumer Product Safety Commission (CPSC) continued in 2011. This involved regular information exchange on respective regulatory frameworks, emerging risks and dangerous products. The Toy Safety and Children's Products Working Group established between the European Commission and the CPSC met in June. It discussed recent regulatory developments other matters common to both sides linked to children's products and toy safety.

3.3.2 Trilateral cooperation (EU, USA, China)

Trilateral cooperation on consumer product safety between the European Union, China and the United States continued in 2011. While the EU and the US represent the world's largest markets for consumer products, China is one of the major producers. Cooperative work between authorities responsible for consumer product safety in all three jurisdictions is very important.

In November 2011, an EU-China-US Trilateral Consumer Product Safety Roundtable took place in Beijing in the framework of the EU-China Trade Project II (EUCTP). The roundtable discussed effective ways to raise awareness of EU and US consumer product safety requirements in China among parties involved in design, manufacturing and export controls. Both the EU and the US participated in this exercise because it was deemed important that stakeholders understand the need to check compliance against the requirements of the export destination since they may differ between the two jurisdictions.

3.3.3 Multilateral cooperation

The International Consumer Product Safety Caucus (ICPSC), whose members are regulatory and market surveillance agencies responsible for product safety from around the world, exists to facilitate international cooperation and the exchange of information on consumer product safety issues. Membership of the ICPSC is open to consumer product safety regulators and market surveillance authorities anywhere in the world. The European Commission's Health and Consumer Directorate-General held the chairmanship of the ICPSC in 2011 and will continue to do so in 2012.

In 2011, the ICPSC met three times, in Orlando, Florida (US), in Paris, France and Seoul, Korea. The meeting in Korea took place in conjunction with the meeting of the International Consumer Product Health and Safety Organisation (ICPHSO). At these meetings, discussions continued on product tracking and traceability and on possible further areas of collaboration within the Caucus. In addition, a joint





ICPSC-OECD global product tracking and traceability session was organised at the ICPHSO conference in Korea to discuss how manufacturers, wholesalers, and retailers approach the issue of traceability.

OECD working party

The OECD Working Party on Consumer Product Safety continued its activities in 2011. A representative from the European Commission is one of the working party's vice-chairs.

In 2011, a web portal with an inventory of product safety issues/events around the world was established. Through this portal, information on product safety matters can easily be exchanged between participating countries. This portal, in addition to providing a repository for information, is a mechanism aimed at increasing awareness among regulators about developments and activities in the product safety area worldwide, with a view to better exploiting synergies and avoiding duplication¹⁰.

Multilateral Pilot Project for Closely Aligned Product Safety Requirements

In 2011, the European Commission, together with product safety authorities from Australia, Canada and the United States, launched a pilot project to improve the safety of products through bringing about highly-effective and closely-aligned safety requirements. The pilot project covers selected products which can be dangerous for children: corded window coverings, chair-top booster seats and baby slings.

In launching this project, the participants are looking to agree on a common view of the hazards posed by these products and the safety measures required to address them. From this consensus position, a participating jurisdiction may choose to develop a regulatory approach or it may choose to look to a standards development organization (SDO) affiliated with its domestic market to develop technical standards.

3.3.4 ENP and candidate countries

The European Commission provides technical assistance in the product safety area to candidate countries for EU membership, potential EU accession countries and interested European Neighbourhood Policy (ENP) countries.



¹⁰ So far, one stakeholder also has access (Business and Industry Advisory Committee to the OECD (BIAC)).



3.3.5 Future challenges in international cooperation

The importance of international cooperation is increasing with the globalisation of supply chains and with the phenomenon that similar or even the same products are often found on the markets of different jurisdictions. The European Commission puts great emphasis on international cooperation activities in the consumer product safety area, in particular by recognising that tackling product safety problems at source, whereby product safety issues are addressed at the design and manufacturing phase, is a highly efficient way to reduce the number of unsafe products on the EU market.

Future work will focus on:

Enhancing information exchange

This is an area that continues to be important, both at bilateral and multilateral level. Increased awareness of regulators of developments and activities in the product safety area taking place in other jurisdictions contributes to exploring synergies, avoiding duplication, responding better to emerging issues. Close bilateral relations will continue with China and the US. The European Commission will also maintain its close involvement in the work of the ICPSC and the OECD Working Party. In the latter case, the Commission will participate in the running of the global product safety inventory and the creation of a global recall data pool.

Activities to improve safety at source

The Commission will continue to work on improving safety at source when it comes to consumer products. In this context, it will continue its cooperation with the Chinese authorities, both bilaterally and at trilateral level with the US authorities.

In 2012, the Commission plans to launch a joint surveillance action with the Chinese authorities exploring the idea of seamless surveillance, whereby the EU Member State authorities will cooperate with the Chinese authorities to achieve more efficient control of dangerous products throughout the supply chain.

Ongoing and future challenges

4.1 The legislative package on product safety and market surveillance

On the basis of stakeholder inputs, and in line with the Single Market Act and the Resolution of the European Parliament on the Revision of the General Product Safety Directive and Market Surveillance, Vice-President Tajani and Commissioner Dalli will in 2012 together present proposals for a comprehensive legislative package on product safety and market surveillance. As outlined in the Commission Work Programme 2012, this package will include a new General Product Safety Directive, a new horizontal single Market Surveillance Regulation and a multi-annual market surveillance action plan.

By improving the product safety governance system, the new General Product Safety Directive will make it possible for the Commission and market surveillance authorities in Member States to cooperate more effectively to tackle the challenges of global supply chains and address newly emerging product safety issues. The simplification of the rules on market surveillance will contribute to economic growth by providing businesses with clearer rules that are easier to understand and apply, have lower compliance costs and, more generally, offer a genuine level playing-field for legitimate businesses. Last but not least, it will help provide European citizens with a more homogeneous internal market of safe goods and better protection of health and safety and other relevant public interests (e.g.





environment and security). The multi-annual action plan for market surveillance will explore ways to enhance the implementation and enforcement of the EU market surveillance framework.

4.2 Cooperation with customs authorities

In 2011 the Commission finalised, together with Member State experts on customs and market surveillance, new Guidelines for import controls in the area of product safety. The guidelines will assist authorities to comply with the requirements of Regulation (EC) No 765/2008 related to the controls of products entering the EU market. In the area of RAPEX, cooperation between market surveillance and customs authorities was strengthened in 2011 by the fact that RAPEX notifications considered as containing relevant information for customs officials were distributed via the Risk Information Form (RIF) system. Approximately 50 RAPEX notifications were shared in this way last year.

More details about the RAPEX system

5.1 Objective

The main objective of the RAPEX system is to ensure that information about dangerous non-food consumer and professional products found in one Member State is rapidly circulated among all the other national authorities and sent to the Commission for followup, with the aim of preventing the supply of these products to consumers and professional users.

This coordination at European level adds value to national surveillance and enforcement actions and increases the overall safety of consumer goods placed on the European market. Thirty countries currently participate in the system, including all EU Member States and the EFTA/EEA countries: Iceland, Liechtenstein and Norway.

5.2 The legal basis of RAPEX

As of January 2010, two acts, i.e. Directive 2001/95/EC on general product safety¹¹ (GPSD) and Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveil-

lance relating to the marketing of products and repealing Regulation (EEC) No 339/93¹² (Regulation (EC) No 765/2008), provide the legal framework for RAPEX. In addition, in 2010 the Commission introduced new RAPEX Guidelines (Decision 2010/15/ EU¹³), which aim to facilitate the effective and consistent application of the provisions related to the notification procedure.

The RAPEX system is used to exchange information on dangerous, non-food, consumer and professional products, including those covered by "sectoral" Directives (e.g. toys, cosmetics, electrical appliances, personal protective equipment, machinery, motor vehicles), which pose a serious risk to various public interests, such as the health and safety of consumers, health and safety in the work place, the environment, energy efficiency and public security.

While the RAPEX system allows for a rapid exchange of information on dangerous products in order to protect the public interest, some of these sectoral Directives also foresee a procedure known as the Safeguard Clause Procedure. This allows the Commission to check if national measures that

The GPSD is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT

Regulation 765/2008 is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=0J:L:2008:218:0030:0047:en:PDF

The RAPEX Guidelines are available at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418R(01):EN:HTML

¹¹ OJ L 11, 15.1.2002, p. 4.

² OJ L 218, 13.8.2008, p. 30.

¹³ OJ L 151, 30.04.2004, p. 83.

restrict the free movement of products are justified and thus ensure an equal level of public interest protection across the EU.

Sectoral legislation relevant to consumer protection includes:

- Toy Safety Directive 2009/48/EC which replaces Directive 88/378/EEC
- Low Voltage Directive 2006/95/EC
- Machinery Directive 98/37/EC
- Cosmetics Directive 76/768/EEC (Cosmetic regulation 1223/2009 adopted in 2009)
- Motor Vehicles Directive 70/156/EEC
- Personal Protective Equipment Directive 89/686/EEC

in more than one European countries. This obligation is laid down in Article 12 of the GPSD and Article 22 of Regulation (EC) No 765/2008 (see box under point 5.3.2).

What products are concerned by measures notified?

Since the entry into force of the GPSD in 2004, RAPEX has applied only to **non-food consumer products**. However, following the entry into force of Regulation 765/2008 (on 1 January 2010) the scope of the RAPEX system was extended and it now also applies to non-food professional products.

Sectoral Directives are available on the EUR-Lex website: http://eur-lex.europa.eu/. Two guidance documents clarify the relationship between the GPSD and the sectoral Directives. These are available at: http://ec.europa.eu/consumers/safety/rapex/key_docs_en.htm

5.3 When is RAPEX used?

5.3.1 RAPEX Notifications

According to the GPSD and Regulation (EC) No 765/2008, the national authorities of Member States notify the Commission, via the RAPEX system, of those measures taken to prevent or restrict the marketing or use of products which pose a serious risk to the public interest and may be available RAPEX covers products that are made available to users, including products provided to consumers in the context of a service, such as, for example, hairdryers in hotels and sunbeds if operated by the consumer.

The most frequently notified products are: toys, clothing, motor vehicles, electrical appliances, cosmetics, children's equipment, lighting equipment, and hobby/sports equipment.



The RAPEX system does not cover all products. Certain products such as food, feed, medical devices and pharmaceuticals are excluded from the scope of RAPEX because information about such products is exchanged through specific alert systems established at European level. For example, the Rapid Alert System for Food and Feed (RASFF) is used to exchange information about dangerous food and feed.

What measures can be taken?

Through RAPEX Member States highlight dangerous consumer products that are subject both to measures ordered by national authorities and/or actions taken voluntarily by producers and distributors to meet their obligations under the law. The most common measures are sales bans, withdrawal of dangerous products from the market and recalls of dangerous products from consumers.

What is a serious risk?

Products notified through the RAPEX system must pose a serious risk to the public interest. A serious risk is defined as one which requires rapid intervention by the public authorities even though it may concern risks whose effects are not immediate. National authorities are obliged to assess the risks posed by a product they intend to notify using the most suitable method (including the risk assessment method provided in the RAPEX Guidelines), since only those products which pose a serious risk are required to be notified through RAPEX.

What is the cross-border effect?

National authorities of Member States exchange information about dangerous products through RAPEX only if there is evidence or reasonable suspicion that these products can be found on the markets of at least two countries participating in the system.

5.3.2 Other types of information exchanged

Under the GPSD and Regulation (EC) No 765/2008, Member States also exchange other types of information about dangerous products with the Commission. For example, measures ordered by the national authorities in relation to products that present only a moderate risk for consumers are notified under Article 11 of the GPSD and Article 23 of the Regulation (EC) No 765/2008.

Furthermore, Member States exchange information on products posing risks which cannot, however, be correctly identified by national authorities due to insufficient product identification (i.e. the brand, model number, pictures of the product and/or its packaging are not available). These notifications are distributed for information purposes only.

Information exchanged through RAPEX

RAPEX notifications

 Notification under Article 12 of the GPSD/Article 22 of Regulation (EC) No 765/2008: notifications of measures ordered by the national authorities, or actions taken voluntarily by producers or distributors in relation to products presenting a serious risk.

Other information

- Notifications under Article 11 of the GPSD/Article 23 of Regulation (EC) No 765/2008: notifications
 of measures ordered by the national authorities in relation to products presenting a moderate risk.
- Notifications for information: notifications of measures ordered by the national authorities, or actions taken voluntarily by producers or distributors in relation to dangerous products, disseminated for information purposes only, due to insufficient product identification.



5.4 How does RAPEX work?

The RAPEX system relies on close cooperation between the European Commission and the national authorities of the Member States.

5.4.1 Role and obligations of national authorities

Each Member State has designated competent market surveillance authorities and granted them the necessary powers to take measures in order to prevent or restrict the marketing or use of dangerous products. More specifically, the national authorities are competent to take samples of products placed on the market, to test them in laboratories and – in cases where these products pose risks to the public interest – order producers and distributors to stop their sale, withdraw them from the market and/or recall them.

In addition, each country participating in the system has also established a single RAPEX Contact Point, which coordinates the operation of the RAPEX system at national level. When the national authorities or a producer/distributor take measures which prevent or restrict the marketing or use of a product posing serious risks to the public interest, the RAPEX Contact Point submits the following information and details about the product to the Commission by means of a standard notification form:

- Product identification name, brand, model, description, picture
- Risks posed by the product type of risk, results of laboratory tests and risk assessment
- Measures adopted to prevent risks type of measure, scope, duration, date of entry into force
- Distribution channels of the notified product manufacturer, exporter, importer, distributors and countries of destination.

The Commission examines the information provided with regard to its compliance with the GPSD, Regulation (EC) No 765/2008 and the RAPEX Guidelines, and checks its completeness. The result of this process is called "validation". A notification is not validated if another country has already notified measures against the same product and same risk – i.e. if the RAPEX network has already been alerted.

A **notification** consists of information provided by Member States concerning measures or actions taken for products presenting a serious or a moderate risk to the public interests.

A **reaction** is information provided by Member States in response to a "validated" notification. A reaction normally contains information about the presence of the notified product in other Member States and the measures taken therein.



If the examination conducted by the Commission leads to validation, information is circulated to the RAPEX Contact Points in all countries participating in the system. RAPEX Contact Points then forward this information to their competent national authorities, who then check whether the notified product is present on the market and, if necessary, take appropriate action. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the Commission through the RAPEX system. These feedback messages are called "reactions".

5.4.2 Role and obligations of producers and distributors

The RAPEX system is also used to exchange information about the preventive or restrictive actions taken voluntarily by producers and distributors in relation to dangerous products which they may have placed on the market. Voluntary action in this context means measures taken without the intervention of the public authority.

Producers and distributors are in a prime position to assess whether products they place on the market are dangerous because, as professionals, they should have information about the product and have contact with consumers. Therefore, once they become aware that a product is dangerous, they are required under EU product safety law to immediately inform the competent authorities in their country, clearly identifying the product in question, the risk(s) it poses and the information necessary to trace it. They must also inform the authorities of any measures taken to prevent further risk to consumers. First contact with the national authorities should be established as soon as possible and, if necessary, even before all the required information is available.

This information is then conveyed to the Commission by the RAPEX Contact Point via the RAPEX system, and subsequently to the other countries participating in the RAPEX system.

The obligation of economic operators to inform the authorities about dangerous products is a key element in the market monitoring procedure. National authorities are able to monitor whether the companies have taken appropriate measures to address the risks posed by dangerous products and to assess whether additional measures are necessary.

To simplify the practical application of the notification obligation of producers and distributors, the Commission has developed an online application called the GPSD Business Application, which enables economic operators to submit notifications Europe-wide to national authorities via the Internet. For more information on the application, see Chapter 3.1.4.

The diagram below illustrates cooperation between the Commission, the national RAPEX Contact Points and national market surveillance authorities.



5.5 The RAPEX website

The Commission publishes weekly overviews of RAPEX notifications on products posing serious risks to consumers, as well as product safety news and information about major events held in the consumer arena, on the RAPEX website: http://ec.europa.eu/ rapex

RAPEX weekly overviews provide information on notified products, the nature of the risks posed and the measures taken to prevent these risks. Information regarding the Member States' reactions to the initial product notifications is also included. This information enables consumers to check whether the products they use or plan to purchase have been subject to RAPEX notifications.

Glossary

AQSIQ

General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

Article 11/Article 23 notification

Notification of measures or actions taken for products presenting a moderate risk according either to Article 11 of the GPSD or Article 23 of Regulation (EC) No 765/2008

Article 12/Article 22 notification

Notification of measures or actions taken for products presenting a serious risk according either to Article 12 of the GPSD or Article 22 of Regulation (EC) No 765/2008

Compulsory measures

Measures ordered by national authorities (e.g. ban of sales, informing consumers, withdrawal from the market, recall from consumers) or by the customs authorities (e.g. rejection of import)

CPSC

United States Consumer Product Safety Commission

EEA countries

(as used in this report) countries that are members of the European Economic Area (EEA) but not members of the European Union, namely Norway, Iceland and Liechtenstein



EU-27

All EU countries

Notification for information

Notification of measures or actions taken which the European Commission disseminates to the National Contact Points for information only because they do not fall under the scope of Article 12 (or Article 22) or Article 11 (or Article 23) of the GPSD (or of Regulation (EC) No 765/2008)

National Contact Point

Representative of the network of all national market surveillance authorities considered by the European Commission as the single contact point for that country

Reaction

Information provided by Member States in response to a "validated" notification. A reaction normally contains information about the presence of the notified product in other Member States and the measures taken therein



Voluntary measures

Corrective measures voluntarily taken by the producer or distributor (e.g. stop of sales, informing consumers, withdrawal from the market, recall from consumers) on the business' own initiative, without the intervention of a public authority

National Contact Details

National RAPEX Contact Points

A list with all the contact details of the national RAPEX Contact Points is available at: http://ec.europa.eu/consumers/safety/rapex/ index_en.htm

Product safety information for consumers per country

Austria

Ministry of Social Affairs and Consumer Protection www.produktsicherheit.gv.at *Austrian Consumers Information Association* (Verein für Konsumenteninformation) www.konsument.at Austrian Road Safety (Kuratorium für Verkehrssicherheit) www.kfv.at *Große schützen Kleine (regional initiative for child safety) www.grosse-schuetzen-kleine.at*

Belgium

www.economie.fgov.be

Bulgaria

Ministry of Economy, Energy and Tourism – in charge of consumer protection www.mi.government.bg *Commission for Consumer Protection www.kzp.bg*

Cyprus

Ministry of Commerce, Industry and Tourism – Competition and Consumers Protection Service www.mcit.gov.cy

Czech Republic

Ministry of Industry and Trade www.mpo.cz *Czech Trade Inspection www.coi.cz* State Health Institute www.szu.cz *Consumers Defence Association – SOS www.consumers.cz*

Denmark Danish Safety Technology Authority www.sik.dk

Estonia Consumer Protection Board www.tarbijakaitseamet.ee

Finland Finnish Safety and Chemicals Agency (Tukes) www.tukes.fi

France

Ministère de l'Economie, des Finances et de l'Industrie – Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) http://www.economie.gouv.fr/dgccrf/

Germany

Federal Institute for Occupational Safety and Health (RAPEX contact point) www.baua.de Federal Office of Consumer Protection and Food Safety (single contact point for cosmetics and daily commodities) www.bvl.bund.de

Greece

Ministry of Labour and Social Security General Secretariat for Consumer Affairs, Directorate of Technical Control www.efpolis.gr

Hungary

Hungarian Authority for Consumer Protection www.nfh.hu Central database on unsafe and prohibited products www.piacfelugyelet.hu

Iceland

Neytendastofa/Consumer Agency www.neytendastofa.is National Consumer Agency www.nca.ie – e-mail: product_safety@nca.ie *Health and Safety Authority www.hsa.ie* Irish Water Safety www.iws.ie

Italy

Ministero dello Sviluppo Economico, Direzione Generale Armonizzazione Mercate e Tutela dei Consumatori, Ufficio D4 Sicurezza prodotti www.sviluppoeconomico.gov.it

Latvia www.ptac.gov.lv

Liechtenstein Amt für Volkswirtschaft (Office of Economic Affairs) http://www.avw.llv.li

Lithuania

State Consumer Rights Protection Authority of Lithuania www.vartotojoteises.lt *State Non Food Products Inspectorate www.inspekcija.lt*

Luxembourg

ILNAS (Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services) www.ilnas.lu

Malta www.msa.org.mt/marketsurveillance/index.html

Netherlands

De nieuwe Voedsel en Waren Autoriteit (Dutch Food and Consumer Product Safety Authority) www.vwa.nl E-mail: meldkamer@vwa.nl

Norway

Directorate for Civil Protection and Emergency Planning www.dsb.no

Poland

Polish Office of Competition and Consumer Protection (Urząd Ochrony Konkurencji I Konsumentów) rapex@uokik.gov.pl email: www.uokik.gov.pl

Portugal

Direcção-Geral do Consumidor (Consumer Directorate General) www.consumidor.pt

Romania

National Authority for Consumer Protection www.anpc.gov.ro

Slovakia

Ministry of Economy of the Slovak Republic www.mhsr.sk *Slovak Trade Inspection www.soi.sk* Public Health Institute of the Slovak Republic www.uvzsr.sk

Slovenia

Market Inspectorate of the Republic of Slovenia www.ti.gov.si/en/ *Health Inspectorate of the Republic of Slovenia www.mz.gov.si/en/* National Chemicals Bureau of the Republic of Slovenia www.uk.gov.si

Spain

Instituto Nacional del Consumo http://www.consumo-inc.es/

Sweden

Swedish Consumer Agency www.konsumentverket.se

United Kingdom

Department for Business, Innovation and Skills www.bis.gov.uk

Important Websites

European Commission

RAPEX: http://ec.europa.eu/rapex

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

EU Commission, Directorate-General for

Health and Consumers: http://ec.europa.eu/dgs/health_consumer/index_ en.htm

EU Commission, Directorate for Consumer Affairs: http://ec.europa.eu/consumers/index_en.htm

EU Commissioner for Consumer Affairs, Mr John Dalli: http://ec.europa.eu/commission_2010-2014/dalli/ index_en.htm

EU Commission, Directorate-General for Enterprise and Industry – "New Approach" Sectoral Directives: http://ec.europa.eu/enterprise/sectors_en.htm

EU Commission, Directorate-General for Taxation and Customs Union: http://ec.europa.eu/taxation_customs/index_ en.htm

Specific products

Lighters:

http://ec.europa.eu/consumers/safety/prod_legis/ prod_legislation_lighters_en.htm

Toys: http://ec.europa.eu/enterprise/toys/index_en.htm

Dimethylfumarate (DMF):

http://ec.europa.eu/consumers/safety/projects/ index_en.htm#dmf

Personal music players:

http://ec.europa.eu/consumers/safety/projects/ index_en.htm#mp3

Consumer product safety regulation/ enforcement agencies

CPSC (US Consumer Product Safety Commission): http://www.cpsc.gov/

AQSIQ (China Administration for Quality Supervision, Inspection and Quarantine): http://english.aqsiq.gov.cn/

Health Canada: http://www.hc-sc.gc.ca/

NITE (Japan, National Institute of Technology and Evaluation): http://www.nite.go.jp/index-e.html

KATS (Korean Agency for Technology & Standards): http://www.kats.go.kr/english/home/home. asp?OlapCode=ATSU15

FCAB (Switzerland, Federal Consumer Affairs Bureau): http://www.konsum.admin.ch/

Product Recalls Australia: http://www.recalls.gov.au/content/index.phtml/ itemId/952401

International consumer safety organisations

ICPHSO (International Consumer Product Health and Safety Organization): http://www.icphso.org/

ICPSC (International Consumer Product Safety Caucus): http://www.icpsc.org/

Market surveillance

PROSAFE: http://www.prosafe.org/

EMARS: http://www.emars.eu/

ICSMS: https://www.icsms.org/icsms/App/index.jsp

Standardisation

ANEC: http://www.anec.org/anec.asp

CEN: http://www.cen.eu/cenorm/homepage.htm

Cenelec: http://www.cenelec.eu/

ETSI: http://www.etsi.org/WebSite/homepage.aspx

The Commission's RAPEX Team

The Commission's RAPEX team can be contacted at:

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Directorate-General for Health and Consumers RAPEX team B232 06/114 B - 1049 Brussels

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European Commission, 2012

Keeping European Consumers Safe

2011 Annual Report on the operation of the Rapid Alert System for non-food dangerous products

Luxembourg: Publications Office of the European Union

2011 - 68 pp. - 21.0 x 29.7 cm ISBN 978-92-79-20736-5 ISSN 1830-8821 DOI 10.2772/6642

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