

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 2012.

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The RAPEX weekly overviews can be consulted at: http://ec.europa.eu/rapex

 $Luxembourg: Publications \ Office \ of \ the \ European \ Union, \ 2013$

ISBN 978-92-79-26091-9 ISSN 1830-8821 DOI 10.2772/62237

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Keeping European Consumers Safe

2012 Annual Report

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

RAPEX



<u>Foreword</u>

I am proud to present the 2012 Annual Report on the RAPEX system which presents the main developments in product safety for the year 2012. This Report shows how consumers benefit from the increasing cooperation and determination of the Commission, the Member States and international partners in relation to market surveillance and their commitment to exclude dangerous products from the market.

Since its creation in 2004, the RAPEX system has been instrumental in protecting European consumers' health and safety. It has provided the necessary platform for the essential exchange of information on dangerous products between Member State authorities and the European Commission.

If in 2011 there was a decrease in the total number of RAPEX notifications, 2012 marks the return of an upward curve. This increase may be accredited to the increased circulation of dangerous products, or, more hopefully, to the tireless determination of the Member State authorities and the Commission to remain vigilant and proactive in the protection of consumer safety.

The increase in notifications may also be attributed to the improved and updated IT system for RAPEX, which better facilitates the work of the authorities in the Member States and the Commission. This year has seen significant updates to the RAPEX system and we continue to strive to improve both the efficiency and the visibility of results through effective follow-up action and communication.

2012 was a challenging year for product safety. The Commission's efforts, such as the co-financing of joint actions on market surveillance, training seminars and exchanges of officials, as well as work to promote coherence throughout the network, including the development of standardisation mandates, all contributed to success and improvements. In 2013, the Commission proposes modernised and further

streamlined legislation with a view to further cooperation efficiencies and cost savings in the years to come.

Improving global cooperation continues to be a high priority. In 2012 the launch of the OECD Global Recalls Portal set an important milestone for the promotion of consumer protection worldwide.

Tonio Borg

European Commissioner for Health and Consumer Policy

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CHAPTER 1

RAPEX Activity in 2012 Executive Summary

The role of RAPEX in supporting product safety

RAPEX¹ (the EU Rapid Information System for non-food products) is the system which allows EU Member States and the European Commission to share information quickly and efficiently about dangerous products found on the European market and to inform consumers about potential risks to their health and safety. RAPEX is established under Article 12 of Directive 2001/95/EC (the General Product Safety Directive – GPSD).²

With the entry into force of Regulation (EC) No 765/2008 on accreditation and market surveillance³ in January 2010, the scope of the RAPEX system

was extended to risks other than those affecting the health and safety of consumers (e.g. 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 placed on the European Single Market. Its success relies not only on close cooperation between national market surveillance authorities and between them and the Commission but also on rigorous enforcement of legislation, 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.



A detailed description of how the RAPEX system functions can be found in Chapter 4. A Glossary of the technical terms used in this report can be found in Chapter 5.

² OJ L 11, 15.1.2002, p. 4–17.

³ OJ L 218, 13.8.2008, p. 30–47.

What was achieved in 2012?

In 2012, the total number of measures taken against dangerous products and reported through RAPEX by Member States was 2 278. Unlike in 2011, when there was a 20% decrease as compared with the previous year, the number of RAPEX notifications continued the previous upward trend with an increase of 26%, returning to around the 2010 level.

The number of RAPEX notifications depends on controls carried out on products on the EU market which are triggered by different factors such as complaints, accidents, risk prioritisation, new products, etc.

Clothing, textiles and fashion items (34%), followed by toys (19%), were again the most common product categories concerned. Injuries, chemical risks and strangulation were the most commonly notified risks.

The number of RAPEX notifications concerning **products of Chinese origin** remains high **(58%)** and slightly increased as compared with 2011 (54%). The high number is mainly due to the significant market share of Chinese products in the consumer goods sector. Nonetheless, closer cooperation with the Chinese authorities over recent years appears to have had a positive impact, e.g. in terms of improved product traceability. The Commission remains committed to joint efforts with the Chinese authorities to help promote safety at source.

Enforcement and compliance by businesses

To be highlighted for 2012 is the closer cooperation between Member States in the field of market surveillance. With financial support from the Commission, market surveillance authorities across the EU have continued their joint efforts to improve cooperation on enforcing product safety rules and taking effective action against dangerous and non-compliant products. Under the umbrella of the Product Safety Enforcement Forum of Europe (Prosafe), the new project in 2012 focused on childcare articles, fireworks, lawn mowers and battery chargers. Authorities from 19 Member States participated and the total budget for the project was EUR 2.4 million.

In addition, more than twenty exchanges of officials between national authorities were supported in 2012.

This approach will be maintained: in December 2012, the Commission, Prosafe and 24 Member States signed an agreement on new joint actions and exchanges of officials in 2013.

The informal expert group on product traceability (made up of experts from industry, consumer organisations and national market surveillance authorities) continued its work in 2012. Its objective is to develop a series of non-regulatory recommendations to economic operators and market surveillance authorities on how to improve traceability, drawing on state of the art input from various sectors. Ultimately, this should contribute to better identification of dangerous products, leading to more effective corrective actions and more complete RAPEX notifications. The group will conclude its work in 2013 and set out its recommendations on best practices in a final report.

In 2012, the Commission organised RAPEX training seminars in Germany, Malta, Lithuania and Poland to increase national market surveillance and customs authorities' familiarity with the RAPEX system and improve enforcement capacity. Market surveillance authorities increasingly applied the RAPEX risk assessment method published as part of the RAPEX Guidelines in early 2010 and for which the Commission improved the relevant IT tool.

In May 2012, the Commission finalised the development of a new IT application for the RAPEX system to replace the one that had been in use since 2004. The new system (GRAS-RAPEX) has proven to be a stable and user-friendly application which allows many more authorities to participate in RAPEX and considerably speeds up the daily work of those who use it.

In order to raise awareness among manufacturers and other economic operators and to address commonly recurring safety shortcomings in certain products (children's clothes, novelty lighters, food imitating products and pushchairs) identified in the framework of the RAPEX system, the Commission prepared several short **videos** made available to stakeholders, including those in China.

The GPSD Business Application, an online information exchange system whereby producers and distributors of consumer products communicate with the national authorities, has worked well since its launch in 2009. In 2012, 247 notifications were accepted by the competent national authorities, which constitutes an increase of 15% (32 notifications) as compared with 2011.

Developments relating to specific products and risks

The Commission started the process of extending the validity of Decision 2006/502/EC for a further 12 months, until 11 May 2014; this requires cigarette **lighters** to be child-resistant and bans novelty lighters. The study on Lighters – Child-resistance for lighters – Safety requirements and test methods should be completed in spring 2013, in time for the planned revision of standard EN 13869 by the European Committee for Standardisation (CEN).



⁴ Commission Regulation (EU) No 412/2012. OJ L 128, 16.5.2012, p. 1

The references of two new European standards which address the risk of hearing loss from excessive sound levels from **personal music players** (EN 60065:2002/A12:2011) and EN 60950-1:2006/A12:2011) were published in the Official Journal of the European Union under the GPSD at the beginning of 2012.

Discussions with the Member States on the definition of the safety requirements for consumer laser products under the GPSD continued with a view to mandating the European Committee for Electrotechnical Standardisation (CENELEC) to revise the relevant European standard. The main concern is the risk of damage to eyesight from powerful handheld.

The European standardisation organisations were mandated to develop European standards under the GPSD to address certain risks posed to children by internal blinds, corded window coverings and safety devices as well as for stationary training equipment, for gymnastic equipment and for bicycles, bicycles for young children and luggage carriers for bicycles.

International cooperation

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) also continued in 2012. In particular, the third Trilateral EU-China-US Consumer Product Safety Summit took place on 28–29 June 2012 in the United States, the main topic being 'Product safety surveillance from factory to front door: a cooperative effort'.

Under the chairmanship of the European Commission's Health and Consumers Directorate-General, the International Consumer Product Safety Caucus (ICPSC) met in February in the USA and in October in Brussels. This forum brings together, from around the world, regulatory and market surveillance authorities dealing with consumer product safety and facilitates international cooperation and the exchange of information on consumer product safety issues. Some of the discussion focused on commonalities in product tracking and traceability requirements. In an ICPSC forecasting exercise, the participants (from almost 30 countries) also provided information on their future work plans.

The Global Recalls portal developed under the auspices of the OECD Working Party on Consumer Product Safety was officially launched in Brussels on 19 October as part of the International Product Safety Week. It allows authorities from across the world to highlight common portal information about unsafe products that have been taken off the market, thus allowing a more complete picture of risks addressed.

Product Safety and Market Surveillance Package

The Commission made significant progress on the Product Safety and Market Surveillance Package. This consists of legislative and non-legislative measures, including proposals for a new General Product Safety Regulation and a Single Market Surveillance Regulation and a market surveillance action plan for 2013–15. It is expected that the Package will be adopted by the Commission at the beginning of 2013 and then undergo the legislative procedure in the European Parliament and the Council.



CHAPTER 2

RAPEX Statistics

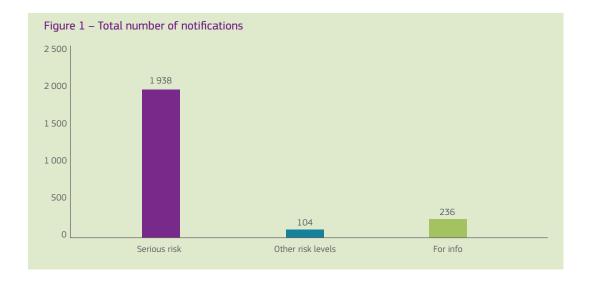
- 2.1 Notifications on products posing a risk to the health and safety of consumers
- 2.1.1 Total number of notifications

Situation in 2012

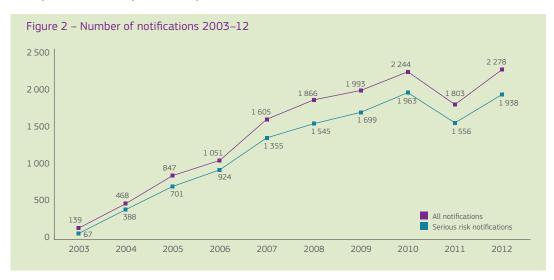
In 2012, the Commission distributed through the RAPEX system 2 278 notifications on consumer products posing risks to health and safety; of these:

 1 938 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;

- 104 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; and
- 236 were distributed to Member States for information purposes only as they did not qualify for distribution on either of the above-mentioned legal bases.



Comparison with previous years



The total number of notifications validated by the Commission has risen steadily in recent years, increasing more than fourfold for instance between 2004 (468) and 2010 (2 244). In 2011, for the first time under the current RAPEX system, the total number of notifications fell (by 20%, to 1 803). In 2012, the total number of notifications validated by the Commission rose again, with an increase of 26%, to a record high for RAPEX.

The number of notifications of products presenting a serious risk (i.e. under Article 12 of the GPSD and Article 22 of Regulation (EC) No 765/2008) was 24% higher than in 2011 (1 938 as compared with 1 556).

The number of notifications distributed for information purposes only increased by 25% (236 notifications as compared with 189 in 2011).

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 those sent for information purposes only are not covered.

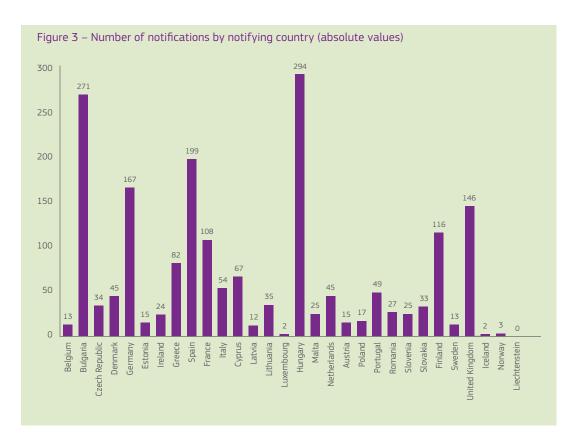
2.1.2 Notifications by notifying country

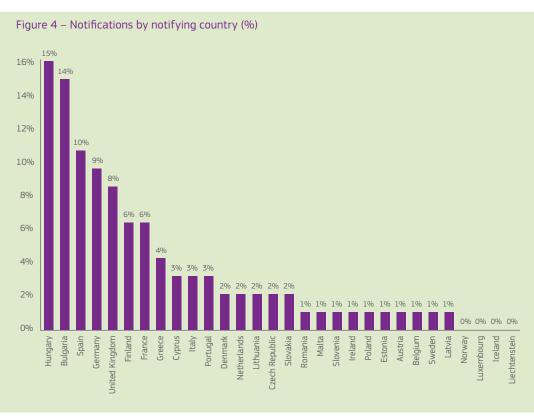
In 2012, all 27 EU Member States, Iceland and Norway sent notifications through the RAPEX system. Only one participating country (Liechtenstein) did not submit any notifications.

The following five most frequently notifying countries accounted for 56% of all notifications:

- Hungary (294 notifications, 15%)
- Bulgaria (271 notifications, 14%)
- Spain (199 notifications, 10%)
- Germany (167 notifications, 9%)
- United Kingdom (146 notifications, 8%).





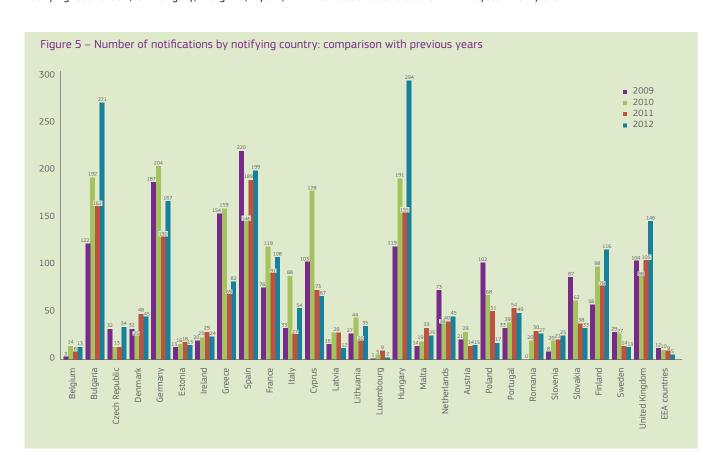


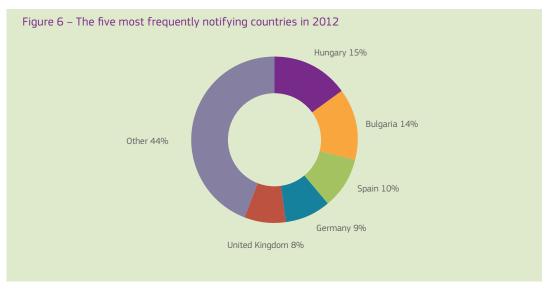
Comparison with previous years

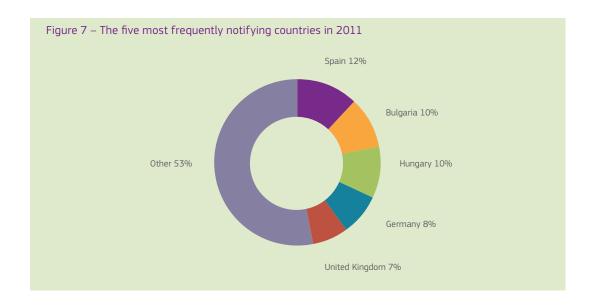
In 2012, half of the participating countries notified more dangerous products than in 2011. The gap between the countries with the highest and the lowest number of notifications became wider as compared with the previous year. This is reflected in the fact that the total share of the five most frequently notifying countries (i.e. Hungary, Bulgaria, Spain,

Germany and the United Kingdom) is 56%, as compared with 47% in 2011.

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. Only the







first notification regarding a dangerous product is validated as a RAPEX notification. 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 2011 and 2012 to help Member States participate in RAPEX: it published the new RAPEX Guidelines, developed a new risk assessment application with an improved IT tool, finalised the new, improved GRAS-RAPEX IT system and organised several RAPEX seminars. More generally, the Commission keeps up the pressure on Member States to carry out market surveillance on an appropriate scale and inform the Commission and other Member States of the results, including by way of submission of RAPEX notifications.

2.1.3 Notifications by product identifier

2.1.3.1 Product category of the notified product

The product categories most frequently concerned by RAPEX notifications in 2012 were:

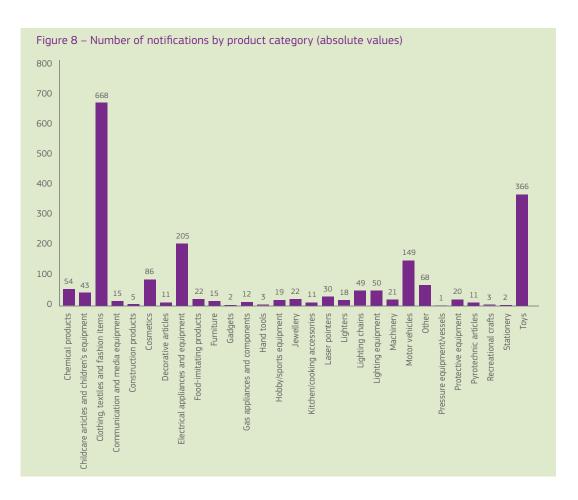
- Clothing, textiles and fashion items (668 notifications, 34%)
- Toys (366 notifications, 19%)
- Electrical appliances and equipment (205 notifications, 11%)
- Motor vehicles (149 notifications, 8%)
- Cosmetics (86 notifications, 4%).

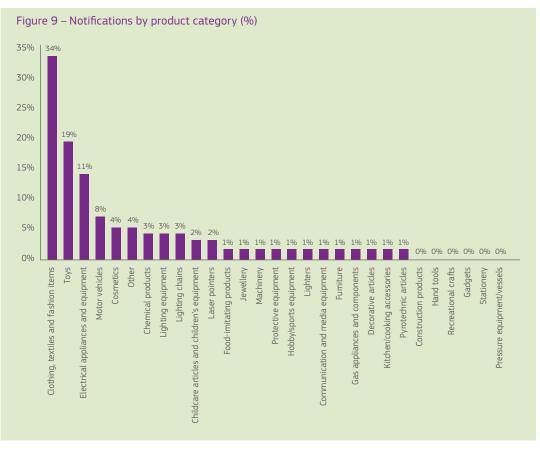
These categories accounted for 76% of all products notified. The two most notified product categories ('Clothing, textiles and fashion items' and 'Toys') together account for more than half (53%) of all notifications distributed through the RAPEX system.

The significant escalation in the number of RAPEX notifications regarding clothing, textiles and fashion items over the last three years results mainly from enhanced market surveillance activities by national authorities following, in particular, the launch of the joint market surveillance action on cords and drawstrings in children's clothing, which involved nine Member States. A second factor leading to the prominence of this category was the adoption of Commission Decision 2009/251/EC on dimethyl fumarate (DMF)⁵ and the subsequent inclusion of the relevant ban in the REACH Regulation⁶. DMF is a strong novel sensitiser found to have been used as an anti mould treatment especially in shoes, some textiles and furniture.

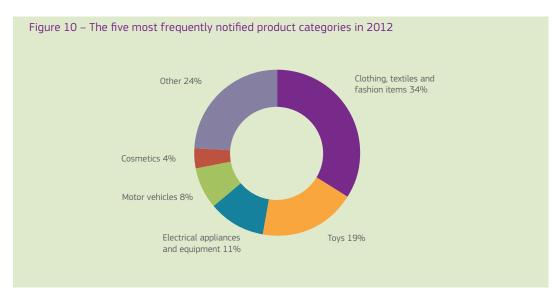
OJ L 74, 20.3.2009, p. 32–34.

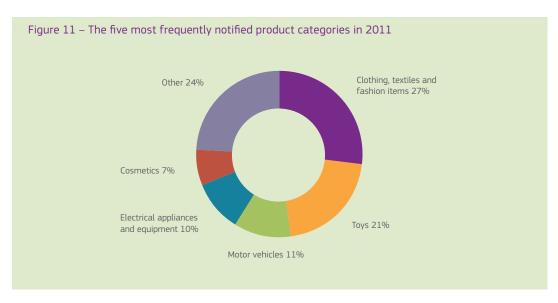
Commission Regulation (EU) No 412/2012 (OJ L 128, 16.5.2012, p. 1).











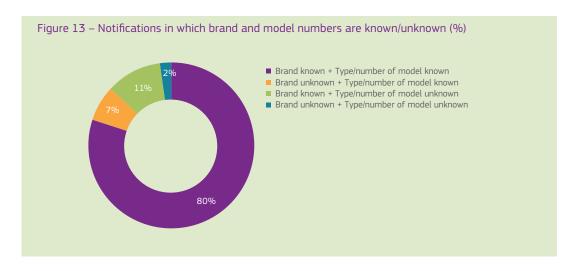
2.1.3.2 Brand and model numbers of the notified product

 $1\,549$ notifications validated in 2012 (80%) concerned products for which both the brand and the type/model number were known, thus facilitating

identification and traceability of the products. In 18% of the cases, either the brand or the type/model number was known. In only 35 cases (2%) were neither the brand nor the type/model number known.

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	1 549	217	1 766
Brand unknown	137	35	172
	1 686	252	1 938





2.1.3.3 Country of origin of the notified product

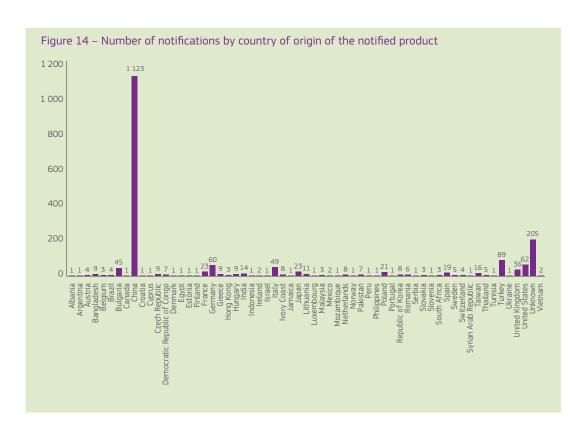
For 58% of all notifications sent through the RAPEX system in 2012 (i.e. 1 126 notifications), the country of origin of the notified products was China (including Hong Kong). Although higher than in 2011 (54%), this still remains in the range of the average observed over the last few years. The high number is due to the significant market penetration of Chinese-manufactured consumer products in European markets. Products are checked according to the same, stringent safety requirements regardless of their origin, usually on the basis of typical risks associated with the product category. The steady intensification of contacts with the Chinese administration and businesses is bearing fruit in terms of improved product identification and traceability, allowing more effective corrective measures. This cooperation will continue.

330 notifications (17% of all notifications sent through RAPEX) concerned products originating in the 27 EU Member States and three EFTA/EEA countries. This is consistent with previous years' data (19% in 2011, 17% in 2010, 20% in 2009, 20% in 2008, 22% in 2007 and 21% in 2006).

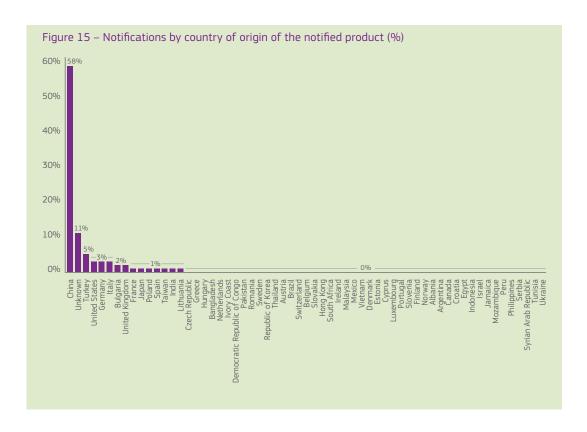


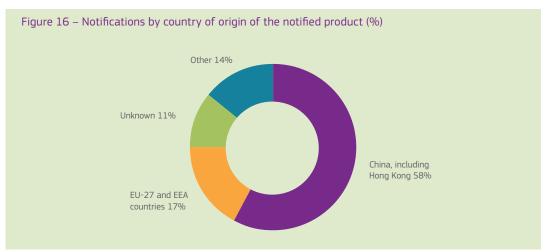
205 notifications (11% of all notifications sent through RAPEX) contained no information about the country of origin of the notified product. This is higher than the 8% recorded in 2011. The Commission must therefore pay more attention to the problem of lack of information on the supply chain.

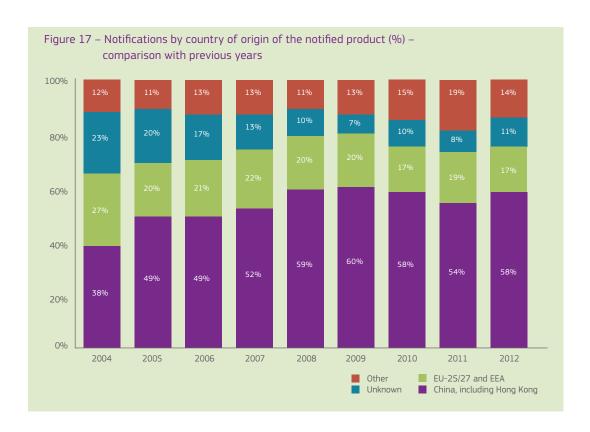
In most cases, market surveillance authorities are able to take corrective measures if both the country of origin and sufficient product identification (such as a reliable barcode or brand and type/number of model) are known. Since the brand and type/number of model were indicated in the case of only 80% of products notified, there is still room for improvement in educating manufacturers and importers as to the importance of traceability in the supply chain. The work of the informal expert group on product traceability is expected help in this respect.⁷



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







2.1.4 Notifications by type of risk

The five most frequently notified risk categories were:

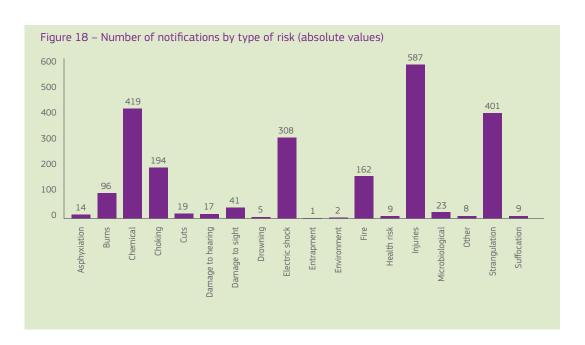
- Injuries (587 notifications, 25%)
- Chemical (419 notifications, 18%)
- Strangulation (401 notifications, 17%)
- Electric shock (308 notifications, 13%)
- Choking (194 notifications, 8%).

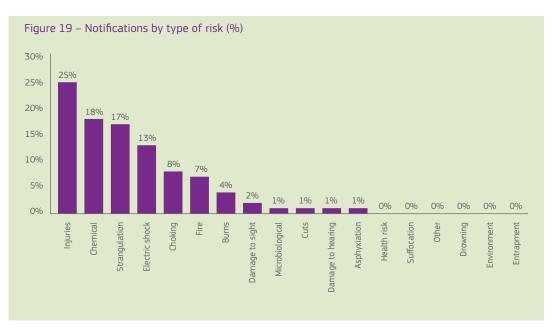
These five risk categories account for 81% of all notified risks.

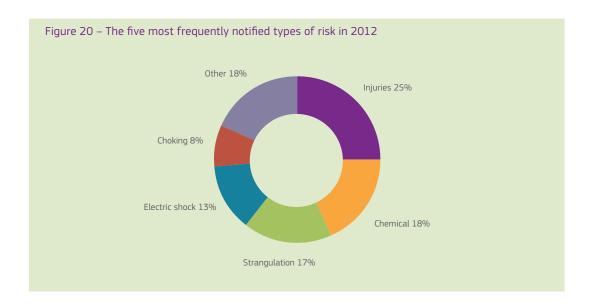
It should be noted that some RAPEX notifications concern products presenting more than one risk. For example, a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to

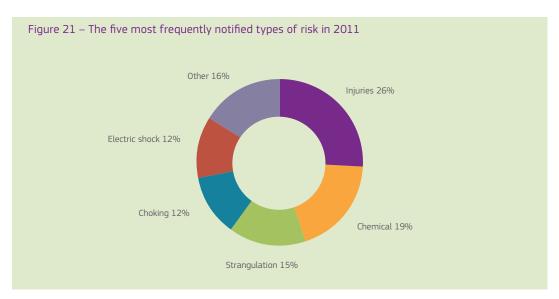
excessive levels of a restricted substance. The total number of notified risks is accordingly higher than the total number of notifications.

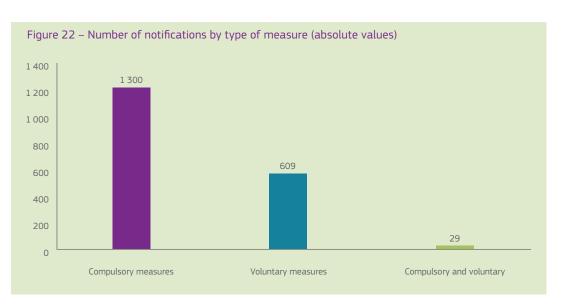
On the basis of RAPEX data, it can also be concluded that each product category is likely to expose consumers to specific types of risk. For example, the main risks with unsafe toys are choking (often associated with the presence of small parts) and reactions to chemicals (often associated with the presence 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

1 300 of the 1 938 RAPEX serious risk notifications (67%) concerned compulsory preventive and restrictive measures ordered by national authorities. In 609 notified cases (31%), 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 29 cases (2%), 'voluntary' actions were complemented by compulsory measures taken by the national authority. In such cases, even though an economic operator has stopped selling a product, the national authorities still believe further action needs to be taken and accordingly order the withdrawal of the product from the market, for example, or its recall from consumers who have already bought it.



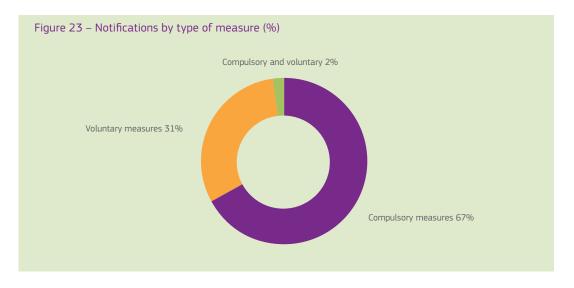
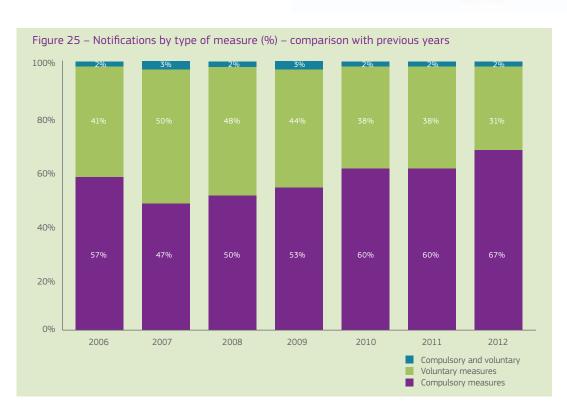


Figure 24 – Number of notifications by type of measure per country (absolute values)

Jan-Dec 2012	Compulsory measures	Voluntary measures	Compulsory and voluntary	Total
Belgium	9	4		13
Bulgaria	271			271
Czech Republic	28	6		34
Denmark	24	20	1	45
Germany	25	134	8	167
Estonia	1	14		15
Ireland	1	23		24
Greece	33	49		82
Spain	174	25		199
France	31	69	8	108
Italy	51	2	1	54
Cyprus	52	15		67
Latvia	3	9		12
Lithuania	29	6		35
Luxembourg	2			2
Hungary	294			294
Malta	4	21		25
Netherlands	44	1		45
Austria		15		15
Poland	4	13		17
Portugal	33	16		49
Romania	27			27
Slovenia		25		25
Slovakia	23	8	2	33
Finland	103	12	1	116
Sweden	3	10		13
United Kingdom	30	108	8	146
Iceland		2		2
Norway	1	2		3
	1 300	609	29	1 938

Comparison with previous years

In 2012, the proportion of cases in which measures were initiated by the authorities was greater than in 2011: 67% as compared with 60%.



2.1.6 Notifications initiated by the activities of the customs authorities

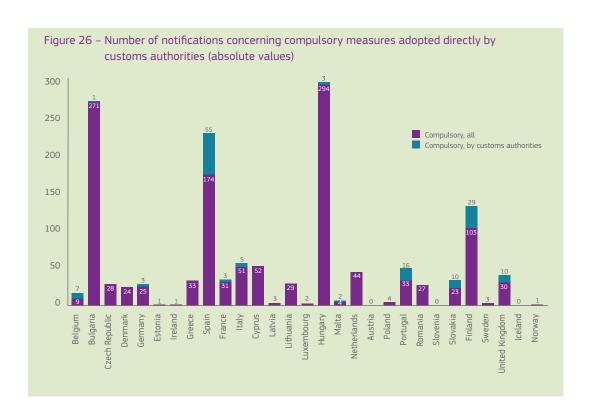
144 notifications processed in the RAPEX system in 2012 concerned measures that were adopted by customs authorities, representing 11% of the total of 1 300 compulsory measures taken. These measures consisted mainly of rejections of imports.

The Member States' figures for this category of notifications may appear to indicate that the customs authorities in some countries are more active in tackling imports of dangerous products than those in others. However, the figures do not give a full picture of the activity of customs authorities across the EU, since in many countries measures in which customs have played an important role are in fact taken directly by market surveillance authorities, acting in liaison with customs. Also, customs authorities 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 2012, EU Member States and the EFTA/EEA countries sent a total of 1760 reactions to all notifications (including those from previous years) distributed through RAPEX. 1700 reactions (97%) were sent in response to notifications concerning a serious risk, 43 reactions (2%) concerned notifications of products with lower risk levels and 17 reactions (1%) were sent in relation to notifications sent for information only. The number of reactions received per notification varied between 1 and 15, with 29 notifications receiving at least 10 reactions. The Commission aims to further strengthen the follow-up of notifications with good traceability data through reactions by Member States. It is also playing a more active role in drawing the attention of certain countries to a notification because certain information appears particularly relevant for them



(e.g. information about an economic operator in the country concerned).

In the following charts, the figures concern reactions only to notifications concerning a serious risk (1 700 reactions).

2.2.2 Reactions by reacting country

In 2012, all EU Member States and EFTA/EEA countries sent reactions to RAPEX notifications.

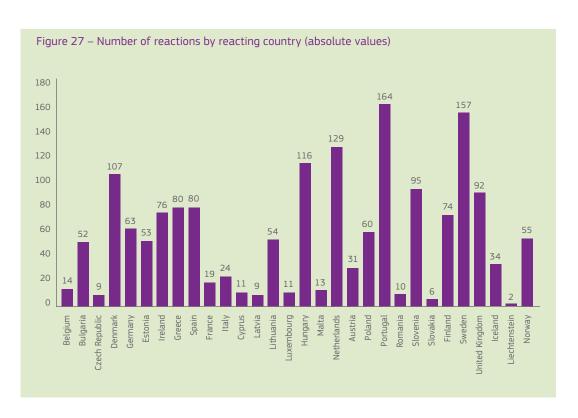
The following five countries accounted for 42% of all reactions:

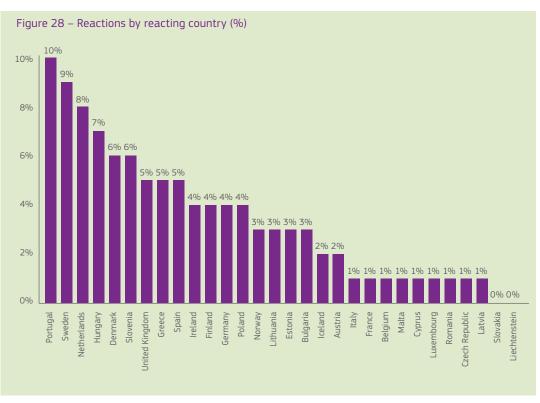
- Portugal (164 reactions, 10%)
- Sweden (157 reactions, 9%)
- Netherlands (129 reactions, 8%)
- Hungary (116 reactions, 7%)
- Denmark (107 reactions, 6%)

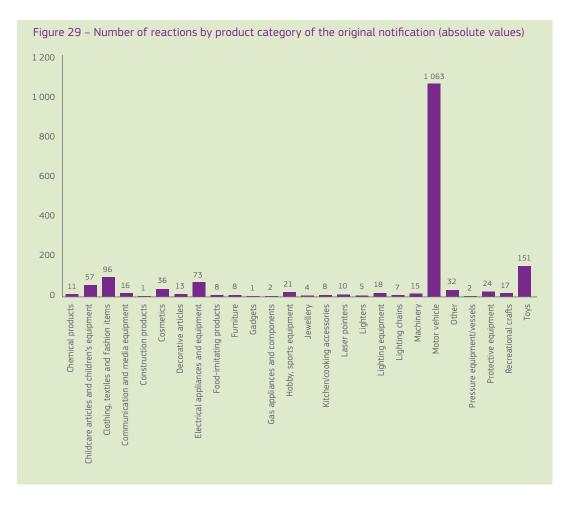
2.2.3 Reactions by notified product

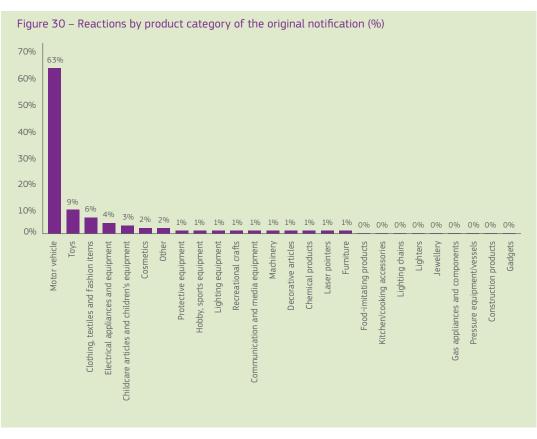
Notifications concerning motor vehicles generated the most reactions (63%). 85% of all reactions concerned RAPEX notifications relating to the following five product categories:

- Motor vehicles (1 063 reactions, 63%)
- Toys (151 reactions, 9%)
- Clothing, textiles and fashion items (96 reactions, 6%)
- Electrical appliances and equipment (73 reactions, 4%)
- Childcare articles and children's equipment (57 reactions, 3%)









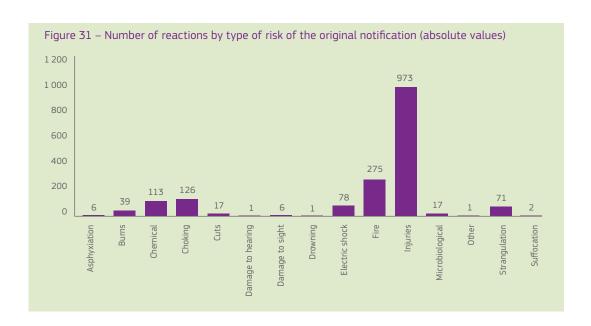
2.2.4 Reactions by type of notified risk

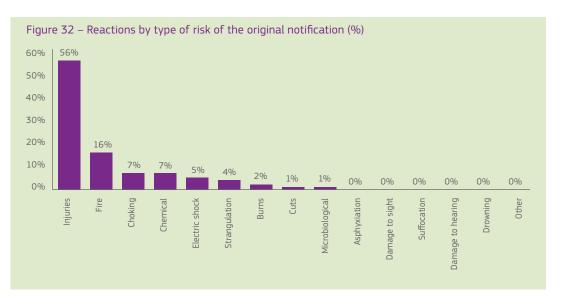
More than half of the reactions received were sent in response to notifications about consumer products posing a risk of injuries (973 reactions, 56%) or fire (275 reactions, 16%). These two risks are clearly linked to motor vehicles, which accounted for 63% of all reactions received.

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

- Injuries (973 reactions, 56%)
- Fire (275 reactions, 16%)
- Choking (126 reactions, 7%)
- Chemical (113 reactions, 7%)
- Electric shock (78 reactions, 5%)

Some reactions concerned products that present more than one risk; therefore the number of risks associated with the reactions (1 726) is higher than the number of reactions submitted for products posing a serious risk (1 700).





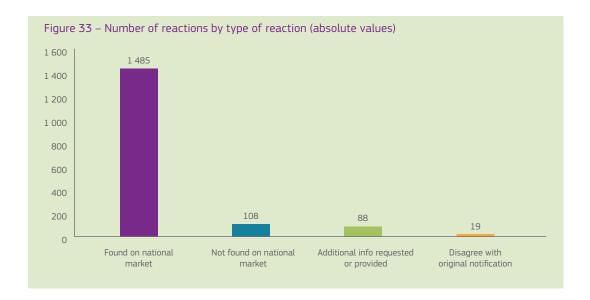
2.2.5 Reactions by type of reaction

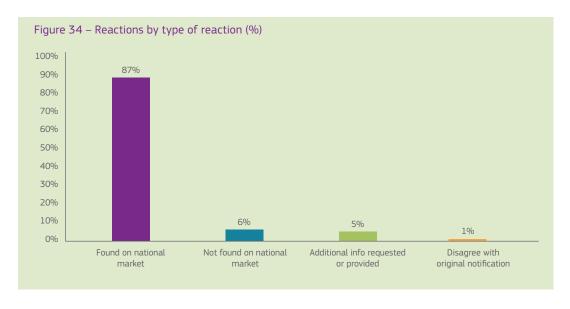
In the majority of reactions received (1 485 reactions, 87%), Member States stated that the notified product was found on their market and that adequate preventive or restrictive measures had been adopted at national level. In 88 reactions (5%), the reacting country requested or provided additional information on the case. In only 19 reactions (1%) did the reacting country not agree with the information provided in the notification. These disagreements related mainly to the conclusions of the risk assessment presented by the notifying Member State. In 108 reactions (6%), 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 (1 485 reactions), it also indicated what measures were being taken. In 79 cases (5%), the measures were taken by the national authorities (compulsory measures) and in 1 398 cases (94%) by economic operators (voluntary measures). In three cases, it was indicated that both compulsory and voluntary measures were being taken. In five cases, no measures were indicated.

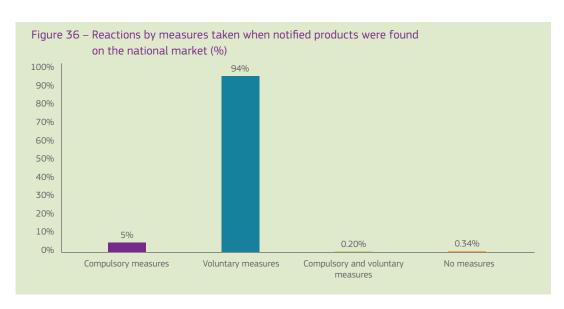
Since January 2011, the RAPEX website has indicated next to each notification those countries which found the product on their market and took restrictive measures.











2.3 Notifications and reactions on professional goods and risks other than those relating to health and safety

2.3.1 Notifications on professional goods and risks other than those relating to health and safety

Since 1 January 2010, when Regulation (EC) No 765/2008 on accreditation and market surveillance became applicable, Member States have been under an obligation to notify the Commission of professional products and consumer products posing a serious risk other than those relating to health and safety (e.g. environmental, security, electromagnetic disturbance risks, etc.). Since the end of May 2012, the GRAS-RAPEX platform has been used for the validation of these notifications.

The number of notifications of this type increased slightly in 2012, with the Commission distributing 37 of them, of which:

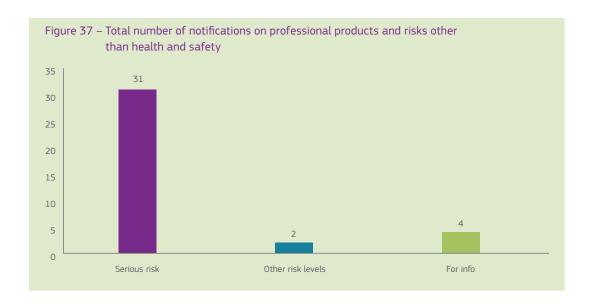
- 31 were distributed to Member States as notifications under Article 22 of Regulation (EC) No 765/08 (serious risk);
- 2 were distributed to Member States under Article
 23 of the Regulation (non-serious risk); and
- 4 were distributed to Member States for information purposes only as they fulfilled the criteria of neither of these Articles, although the information they contained was deemed to be of interest to market surveillance authorities.

The Commission expected the number of notifications to increase significantly as a result of the launching of GRAS-RAPEX. However, although notifications can now be submitted more easily, in a standard format and the Commission regularly reminds Member States of the extended scope of the new system, the number of notifications has not increased as much as anticipated.

The main risk categories for the notifications of this type were the following:

- Environment (18 notifications, 58%); and
- Health and safety (13 notifications, 42%).

Environmental risks concerned chemical pollution, detonation and the release of metals, mainly in relation to consumer products (e.g. plastic packages used for protective equipment/textile items; fireworks). Health and safety risks related in most cases to professional products (e.g. polycarbonate reflectors, light commercial vehicles, cutting attachments for brush cutters and trimmers, side ventilation systems, ammonium nitrate fertiliser, hollow sections for steel constructions, hydraulic rear underrun protections for trucks, professional hair dryers, softice machines, wedge splitters, non-stationary pressure sandblasters, hearing protectors for workers, light trucks and tower cranes). The relevant subcategories were injuries, electric shock/burns and damage to hearing.



The Commission validated 16 notifications (52%) of this type identified as relating to consumer products and 15 (48%) identified as relating to professional products.

The following countries sent notifications of this type:

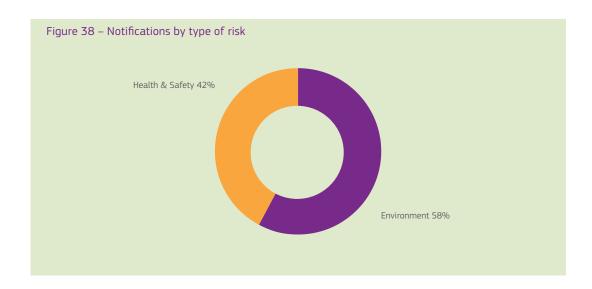
- Finland (12 notifications, 39%)
- Denmark (5 notifications, 16%)
- Germany (5 notifications, 16%)
- Sweden (3 notifications, 10%)
- France (2 notifications, 6%)
- The Netherlands (2 notifications, 6%)
- Ireland (1 notification, 3%)
- Portugal (1 notification, 3%)

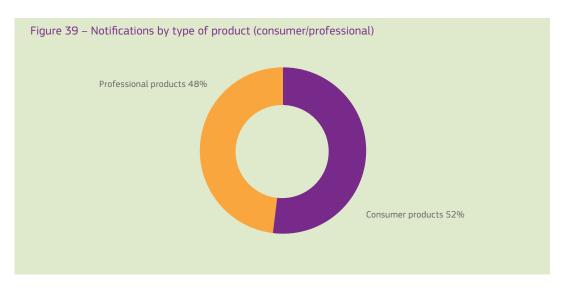
Some Member States (Austria, Belgium, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy,

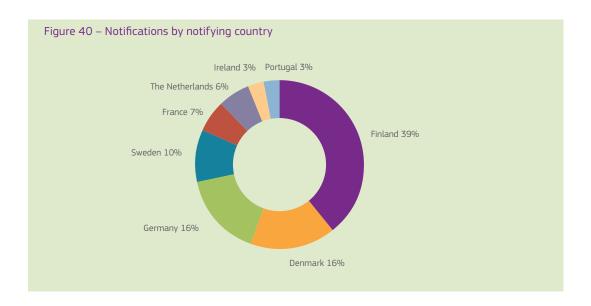
Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia and Spain) have sent no new notifications of this type in the last three years.

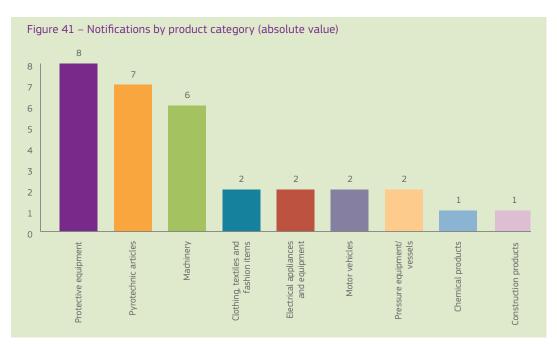
Notifications of this type involved the following categories of products:

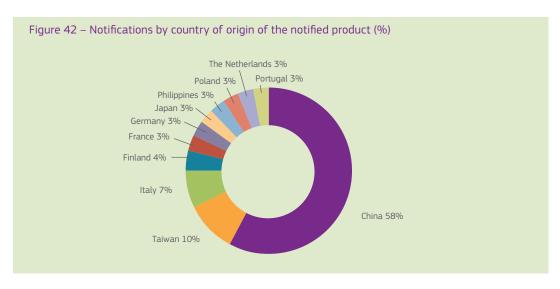
- Protective equipment (8 notifications, 26%)
- Pyrotechnics articles (7 notifications, 23%)
- Machinery (6 notifications, 19%)
- Clothing, textiles and fashion items (2 notifications, 6%)
- Electrical appliances and equipment (2 notifications, 6%)
- Motor vehicles (2 notifications, 6%)
- Pressure equipment/vessels (2 notifications, 6%)
- Chemical products (1 notification, 3%)
- Construction products (1 notification, 3%)

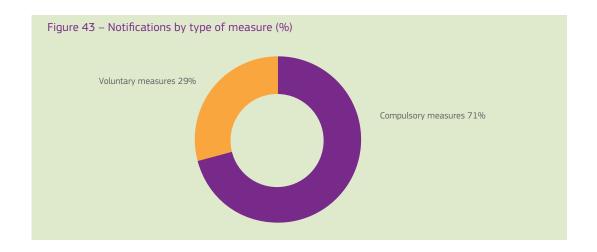












China was indicated as the country of origin of the notified product in the majority of the cases (18 notifications, 58%). In nine cases, the country of origin was an EU Member State, in three it was the Philippines and in one case the product came from Taiwan.

22 serious risk notifications of this type (71% of the total) led to compulsory preventive and restrictive measures ordered by the national authorities. In nine cases (29%), the economic operators took voluntary measures. In no cases were the compulsory measures complemented by voluntary actions.

2.3.2 Reactions to notifications on professional goods and risks other than those relating to health and safety

In 2012, Denmark, Hungary, the Netherlands, Norway, Slovenia and Sweden sent a total of seven reactions to notifications. The products concerned were motor vehicles and pyrotechnics articles which posed risks to the environment and to health and safety.

2.3.3 Conclusion on professional goods and risks other than those relating to health and safety

In 2012, the Commission validated 12 more notifications of this type than in 2011, an increase of 70%. The statistics indicate that not all Member States participate in the submission of RAPEX

notifications regarding professional products and other risks than health and safety.

The notifications concerned environmental risks (linked mainly to consumer products), while notifications presenting risk to health and safety concerned only professional products. The distribution between consumer and professional products was almost equal. In most cases, national authorities took compulsory measures. The products in question originated predominantly in China.

The Commission expected to receive more notifications in 2012 concerning professional products and risks other than health and safety. The statistics indicate that not all Member States submit notifications of this type and it may be that some national authorities are not aware that this is possible. Therefore, the Commission will continue to remind Member States that they are legally obliged to channel these new notifications through the RAPEX system.



Key Developments in 2012

3.1 Enforcement and compliance by businesses

EU product safety legislation requires that only safe products are placed on the market. However, a Eurobarometer survey conducted in 2012 showed that more than a quarter of consumers think that a significant number of non-food consumer products in Europe are not safe. Effective enforcement of the legislation in place is vital to boosting the confidence of the 500 million European citizens in the safety of products on the market. Cooperation at European level involves market surveillance authorities in the Member States working closely with the Commission to reduce the presence of unsafe products in the internal market. The legislation places producers and distributors under a legal obligation to notify the relevant national authorities if they know that consumer products they have made available in the EU are unsafe. In cooperation with the Member States and other EEA countries, the Commission has provided economic operators with an online GPSD Business Application for this purpose.

3.1.1 Market surveillance coordination and cooperation

With financial support from the Commission, market surveillance authorities across the EU have continued their joint efforts to improve cooperation and monitoring for dangerous and non-compliant products. This is primarily achieved through Prosafe, a non-profit professional organisation for market surveillance authorities and officials throughout the EEA aimed chiefly at improving the safety of users of products and services in Europe.

A project focusing on child-care articles, fireworks, lawn mowers and battery chargers started in January 2012. It brought together authorities from 19 Member States and had a total budget of EUR 2.4 million.

In December 2012, the Commission, Prosafe and 24 Member States signed an agreement for a new project to be launched in January 2013.

Over twenty exchanges of officials between national authorities took place in 2012.

One market surveillance action, Lighters II, was brought to a successful close. Prosafe and its members had carried out joint market surveillance activities on lighters since September 2007 in order to check whether only those that are safe and childresistant are placed on the market and to improve collaboration among market surveillance authorities across the EU. The activities involved 17 Member States.

Under the second project, which started in 2010, the participating market surveillance authorities carried out some 8 000 inspections on lighters at retailers, wholesalers, importers and manufacturers. Customs carried out border inspections on 850 consignments from third countries, checking more than 5 000 lighters. In the framework of this project, 74 models of lighters were tested in an accredited laboratory and in 47% of cases at least one form of non-compliance was found. 9% presented potential risks of injury for the consumers.

3.1.2 Better tools, capacity building and communication

3.1.2.1 GRAS – a new IT system for RAPEX

The Commission finalised the development of the new IT application for the RAPEX system. Replacing the REIS application, which had been in use since 2004, GRAS-RAPEX came into use in May 2012 and has proven to be a stable and user-friendly application. It allows many more authorities to participate in RAPEX and considerably speeds up the daily work of



those who use it. Several new functions (e.g. easier search of notifications, faster communication within the system) make for much greater efficiency.

The new system was made necessary by several developments, including the adoption of the RAPEX guidelines in 2010, the extension of the scope of RAPEX to professional products and to risks other than those relating to the health and safety of consumers, and the steady increase (except in 2011) in the number of notifications.

3.1.2.2 IT tool on the RAPEX risk assessment method

The risk assessment method published in early 2010 as part of the RAPEX Guidelines was again increasingly applied by market surveillance authorities using the relevant IT tool (http://europa.eu/sanco/rag). The tool was particularly improved by being made available in 22 EU languages and Chinese.

3.1.2.3 RAPEX seminars

The Commission organises regular RAPEX seminars to increase national market surveillance and customs authorities' familiarity with the RAPEX system and improve their overall enforcement capacity.

In 2012, seminars were held in Germany, Malta, Lithuania and Poland. Besides the functioning of the RAPEX system and the implementation of the GPSD and Regulation (EC) No 765/2008, a significant part of the seminars was dedicated to training on the new GRAS-RAPEX system, workshops on risk assessment and, in particular, the application of the risk assessment guidelines.

3.1.2.4 Videos on how to avoid the most common safety shortcomings in selected products

In 2012, as part of the international cooperation initiative with the US and China, a set of four videos on product safety was produced. The objective is to ensure that products are designed and manufactured avoiding known risks from the start so that the products are safe when they reach the market. By means of a visual demonstration of the most common problems linked to four product categories (children's clothes, novelty lighters, food imitating products and pushchairs), the videos provide clear guidance to designers, manufacturers and importers on how to avoid the identified risks. They are available in English and Chinese and will be disseminated in 2013 in cooperation with the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ).

3.1.3 RAPEX and other product safety indicators

Eurobarometer surveys

In 2012, the Commission conducted two Eurobarometer surveys covering product safety issues, consulting consumers and retailers about their perception of consumer law enforcement in Europe. The results give an idea of perceptions of product safety rules, complaints, authorities' activities, etc.

The surveys showed that 27% of consumers (2011: 25%) and 14% of retailers (2011: 19%) thought that a significant number of non-food consumer products sold in Europe was unsafe. There were big differences between consumers in different Member States, with the best perceived safety levels in Finland, the UK and Estonia, while the most dissatisfied consumers were found in Greece, Romania and Cyprus.

A majority of the retailers in the EU (85%) felt well-informed about the rules and regulations relating to product safety and almost a half (45%) 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 (82%) agreed that national public authorities actively monitor and ensure compliance with product safety legislation in their sector.

A Eurobarometer survey was carried out in 2012 to ascertain consumers' views on the safety of specific services, with a focus on the following sectors: tourist accommodation, organised outdoor leisure activities, swimming pools, beauty and wellness centres, and amusement parks and fairgrounds. The survey, conducted on a sample of more than 25 000 European citizens in 27 Member States, examines perceptions of risk and consumers' evaluation of safety measures, as well as reported accidents and their main causes.

The results of this survey, published in July, indicate a wide range of use of the services in question and a persistently significant number of accidents. According to the survey, consumers are most likely to report accidents when involved in organised outdoor leisure activities. Children are clearly a vulnerable group, affected by several injuries. The key safety issues reported by the consumers interviewed in the survey related to the lack of information about safety and the lack of qualified staff.

The Commission is likely to launch a wide consultation on the safety of certain services in 2013.

Consumer Markets Scoreboard

In 2012, the Commission published the 7th Consumer Markets Scoreboard, 'Consumers at Home in the Single Market', which analysed consumer conditions in EU Member States and the development of crossborder trade and e-commerce.

Product safety was one of the key areas addressed, as it is an important factor in 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.

3.1.4 GPSD Business Application

Since May 2009, producers and distributors have been able to notify national authorities in EU and EFTA/EEA countries of dangerous products through the online GPSD Business Application, the purpose of which is to simplify the procedure whereby producers and distributors fulfil their obligation (under EU product safety legislation) to notify the competent national authorities of any dangerous consumer products placed on the EU market. The advantage of the application is that all countries concerned are alerted at the same time through one notification, thus simplifying and speeding up the process. Access to this secure online database of all notifications is restricted to the competent national authorities – neither businesses nor consumers have access.

The GPSD Business Application has operated successfully since its launch. In 2012, a total of 247 notifications (including updates) sent through the application by producers and distributors were accepted by the competent national authorities. This constitutes an increase of 15% as compared with 2011 (215 notifications).

In 2012, all the Member States and EFTA/EEA countries were notified via GPSD Business Application, with France, the Netherlands, Germany and Belgium the Member States notified most often.

A Business Application notification may result in a RAPEX notification, but this further step depends on the judgment of the national authorities concerned and is not automatic.

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

The data provided by producers and distributors were usually complete and of good quality. The notifications submitted contained the required information regarding a) product identification, b) the risks posed by the product, c) the importers and distributors responsible for marketing and distributing the product on the EU market, d) action taken to protect consumers, and e) the incidents reported and complaints received.

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

3.2 Developments relating to specific products and risks⁸

3.2.1 Lighters

The validity of Decision 2006/502/EC was extended until May 2013 and the Commission started the process of extending it for a further 12 months, until 11 May 2014; this, in order to maintain the require-

ment for cigarette lighters to be child-resistant and for novelty lighters to be banned.

The study on allowing testing method(s) for child resistance that avoid the use of child panels as regards standard EN 13869:2002, Lighters – Childresistance for lighters – Safety requirements and test methods, progressed further, despite a few months delay due to technical reasons. The study should thus be completed in spring 2013, in time for the planned revision of standard EN 13869 by the European Committee for Standardisation (CEN).

3.2.2 Measures to address risks from Dimethyl fumarate

Dimethyl fumarate (DMF), an anti-mould chemical substance that is strongly sensitising and can cause severe skin lesions, was again identified in consumer products under RAPEX. The permanent ban on DMF⁹ under the REACH Regulation entered into force in June 2012, replacing the temporary ban previously adopted under the GPSD.

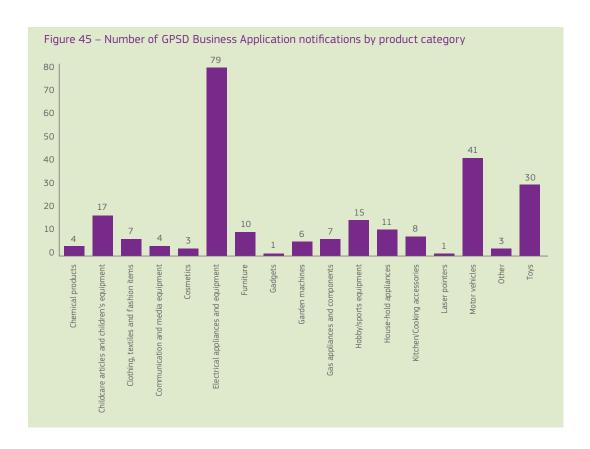
3.2.3 Personal music players

The references of two new European standards for personal music players (EN 60065:2002/A12:2011 and EN 60950-1:2006/A12:2011) were published in the Official Journal under the GPSD at the beginning of 2012. They had previously been published under the Low Voltage Directive (2006/95/EC) and the



Be 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.

Commission Regulation (EU) No 412/2012. OJ L 128, 16.5.2012, p. 1



Radio and Telecommunications Terminal Equipment Directive (1999/5/EC).

Like all European standards, the standards are voluntary, but products that comply with them will benefit from a presumption of conformity with the safety requirements of the applicable legislation with respect to the risk of hearing loss from listening to music at excessive sound levels.

The two-year transition period that followed the publication of the standards, during which time the standards are being transposed at national level, will end on 24 January 2013. After this date, it is expected that manufacturers will apply the standards to their products.

3.2.4 Laser products intended for consumers

Discussions with the Member States on the definition of the safety requirements for consumer laser products under the GPSD continued during the course of 2012 with a view to mandating the European Committee for Electrotechnical Standardisation (CENELEC) to revise the relevant European standard. The main concern is the risk of damage to eyesight from powerful hand-held laser pointers. The discussions are expected to continue in 2013.

3.2.5 Safety of certain window coverings

In 2012, the European standardisation organisations received mandates to develop European standards to address certain risks posed to children by internal blinds, corded window coverings and safety devices. The Commission also worked closely with its international partners – the US, Canada and Australia – on a pilot alignment initiative looking at the obstacles and opportunities for aligning hazard definitions and safety requirements for internal blinds. A 'consensus paper' was adopted containing a description of injuries, risk group, status and scope of existing standards, and some considerations to help inform decision-making.

3.2.6 Children's equipment/childcare articles

The safety of children's seats (chairs, highchairs, chair-mounted seats and table-mounted chairs) was discussed at length with Member States, standardisation experts and consumer representatives. The Commission is expected to adopt safety requirements to be met by European standards for certain children's seats in early 2013. A mandate will then be sent to CEN for the standardisation work to begin.

In parallel, the Commission is leading an international pilot alignment initiative on chair-mounted seats ('boosters') with its partner administrations in the US, Canada and Australia. The Commission expects to focus on setting safety requirements for playground equipment, baby slings and pushchairs in 2013.

3.2.7 Other standardisation mandates and priorities

Further mandates were issued to the European standardisation organisations to develop European standards for stationary training equipment, for gymnastic equipment and for bicycles, bicycles for young children and luggage carriers for bicycles.

The Commission presented the Member States with a rolling plan of products under discussion for possible standardisation, asking them to identify priorities in order to make the best use of limited time and resources. The most likely candidates for standardisation in 2013 are children's shoes, baby slings, portable and fixed goals, pushchairs and barbecue grills. In addition, discussions are underway on safety requirements for alcohol powered flueless fireplaces ('ethanol stoves'). The Commission also has to update the safety requirements for a number of standards that have already been referenced in the Official Journal, such as roller skates, outdoor furniture, buoyancy aids for swimming instruction, etc.

3.3 Ongoing and future challenges

3.3.1 The Product Safety and Market Surveillance Package (revision of the General Product Safety Directive)

Based on the conclusions of the 2009 Report on the implementation of the General Product Safety Directive (GPSD) and in view of the new obligations under Regulation (EC) No 765/2008, the Commission carried out an impact assessment of the revision of the GPSD, including the assessment of the coherence of EU legislation in the product safety area (in particular as regards market surveillance).

On the basis of this impact assessment 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, the Commission made significant progress on the comprehensive legislative Product Safety and Mar-



ket Surveillance Package. This Package, which is due to be adopted in February 2013, will include a new General Product Safety Regulation, a new Single Market Surveillance Regulation and a multi-annual plan for market surveillance in 2013–15.

By improving the product safety governance system, the new Package will enable the Commission and market surveillance authorities in Member States to tackle the challenges of global supply chains, cooperate effectively and address newly emerging product safety risks. The initiative will provide consumers/professional users with a more homogeneous internal market of safe goods and better protection of various public interests (health and safety, environment, security, etc.). A clear set of market surveillance rules, enshrined in a Regulation directly applicable to all Member States, will reduce the current divergence of enforcement practices across the EU. It will also streamline existing procedures so that Member States can do more market surveillance even with reduced resources. Simplification of existing product safety rules will contribute to growth, lower compliance costs and elimination of unfair competition from rogue operators.

It is expected that the Product Safety and Market Surveillance Package will be adopted and submitted to the legislative procedure in the European Parliament and the Council at the beginning of 2013.



3.3.2 Cooperation with customs authorities

With the entry into force of the New Legislative Framework on 1 January 2010, the involvement of customs authorities in enforcing product safety legislation was put on a stronger footing. Further work has had to be done as a result to assist customs officials in fulfilling their new surveillance role.

In 2011, a Working Group composed of customs and market surveillance experts proposed a set of guidelines for implementing the new legislative requirements and a set of check-lists to be used by customs officials when checking the safety of products entering the EU.

In 2012, the Commission proposed a new Roadmap consisting of 26 concrete actions to be taken by the



Commission and the Member States by 2014 to ensure that the product safety customs controls are properly carried out across the EU.

The cooperation between market surveillance and customs authorities was also strengthened in 2012 by the fact that RAPEX notifications which were considered to contain relevant information for customs officials were distributed via the Risk Information Form (RIF) system. Almost 30 notifications were shared last year.

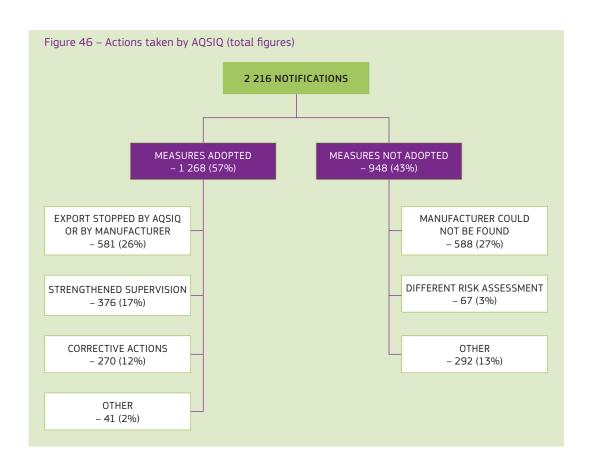
3.4 International cooperation towards global governance

3.4.1 Bilateral cooperation

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

China

The active regulatory cooperation with China continued throughout 2012, resulting in the following tangible results:



RAPEX-China

AQSIQ submitted 23 reports to DG SANCO on enforcement action carried out with regard to RAPEX notifications exchanged via the RAPEX-CHINA system between September 2006 (when the application was established) and August 2012.

During this period, AQSIQ investigated and, where necessary, adopted measures in relation to 2 216 RAPEX notifications. Analysis of the reports received shows that AQSIQ investigates an average of 96 RAPEX cases over a three-month period.

AQSIQ and DG SANCO are convinced that the RAPEX-China system plays an important role in overall cooperation between the EU and China in the field of product safety. Both parties underline the great benefits of the system and the proactive approach followed by DG SANCO and AQSIQ to enhance the safety of Chinese products. The improvement of (a) the level of compliance of consumer products of Chinese origin exported to the EU and (b) the general understanding of product safety rules, policies and

standards among manufacturers, exporters and importers is still the principal objective of the RAPEX-China system.

A good level of product traceability is necessary to ensure that the system operates at its full capacity. Thanks to the information provided through RAPEX-China, the distribution of dangerous products can be blocked before they leave Chinese territory, so that the problem is tackled in the most effective and efficient way, i.e. at its source. Chinese authorities can carry out investigations only with regard to those RAPEX notifications which contain contact details of Chinese companies involved in the manufacturing and export of dangerous products. DG SANCO is still strongly committed to improving the traceability of products in the RAPEX-China system, with the active involvement of the EU national authorities, who seek during the market surveillance process, in cooperation with economic operators, to establish the contact details of Chinese manufacturers and exporters.

Discussions with the Chinese authorities also revealed that some of the dangerous products investigated by AQSIQ were manufactured by Chinese companies according to improper specifications provided by EU economic operators. In many cases, the EU companies failed to specify any safety requirements for purchased products, request any tests or have products approved before shipping them to the EU. These examples show that the Commission and the Member States should continue their efforts to inform companies of the obligations of the product safety legislation.

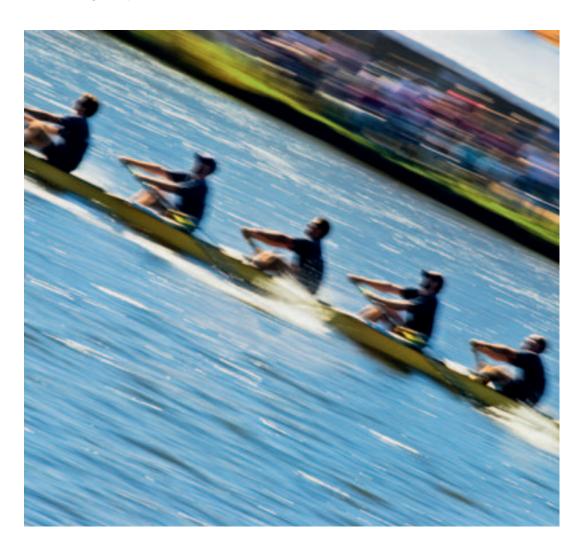
United States

Close cooperation on consumer product safety between the Commission and the United States Consumer Product Safety Commission (CPSC) continued in 2012, involving regular information exchange on the respective regulatory frameworks, emerging risks and dangerous products.

On 10 May, Commission Vice-President Tajani and US Consumer Product Safety Commission Chair Tenenbaum signed a document of recognition of mutual interest in furthering joint cooperation ensuring a high level of children's safety. As a follow up to this, a joint EU-US workshop on regulatory matters and standards was held in the US Congress on 26 June.

3.4.2 Trilateral cooperation (EU, USA, China)

The trilateral cooperation on consumer product safety between the European Union, China and the United States continued in 2012. While the EU and the US represent the world's largest markets for consumer products, China is one of the major producers. Cooperation between the consumer product safety authorities is very important.





The third Trilateral EU-China-US Consumer Product Safety Summit took place on 28-29 June in the United States with the participation of Commissioner for Health and Consumer Policy Dalli, Vice Minister of AQSIQ Sun and CPSC Chairman Tenenbaum. The main topic 'Product safety surveillance from factory to front door: a cooperative effort'. The priorities addressed in the trilateral outline how this initiative will further enhance regulatory cooperation and promote cooperation on 'seamless surveillance'. The joint statement also highlights some specific actions which will help implement the trilateral cooperation, including on product traceability, better information exchange between regulators and the ongoing disseminating of product safety information to industry stakeholders.

3.4.3 Multilateral cooperation

International Product Safety Week (IPSW) 2012

The Commission hosted the International Product Safety Week in Brussels from 15 to 19 October. A series of events gathered non-food consumer product safety professionals and stakeholders from 43 countries around the globe, representing regulators, industry, consumer organisations, standard-makers and test laboratories.

ICPSC

The International Consumer Product Safety Caucus (ICPSC) exists to facilitate the exchange of information on consumer product safety issues in the area of government policy, legislation and market surveillance, with a view to strengthening cooperation among consumer product safety regulatory

and market surveillance agencies around the world. Membership of the ICPSC is open to such bodies from anywhere in the world. The Commission's DG SANCO held the chairmanship of the ICPSC in 2011 and 2012.

In 2012, the ICPSC met twice: in the USA (Orlando, Florida) on 28 February, and in Brussels, Belgium on 18 October. The meeting in Brussels took place during the International Product Safety Week (15–19 October) and 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 there was also an exchange of views on possible further areas for cooperation within the Caucus. Some of the discussion focused on commonalities in product tracking and traceability requirements, and in an ICPSC forecasting exercise the participants (from almost 30 countries) also provided information on their future work plans.

In a separate strand of activity, the Commission, together with product safety authorities from Australia, Canada and the United States, pursued work on the pilot project to improve the safety of products through bringing about highly effective and closely aligned safety requirements. 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 manage them. A participating jurisdiction may choose to develop a regulatory approach from this consensus position or it may choose to look to a standards development organisation (SDO) affiliated with its domestic market to perform technical standards development from the consensus recommendations. The pilot project covers selected products which can be dangerous for children: chair-top booster seats,

baby slings and corded window coverings. A consensus document was finalised in February for corded window coverings. The working groups on chair-top booster seats and baby slings will continue their work in 2013.

OECD working party

In 2012, the Organisation for Economic Cooperation and Development (OECD) working party on consumer product safety continued its activities, with the Commission taking an active part. A DG SANCO representative was reappointed as one of the working party's vice-chairs and Bureau member.

As part of the meeting of the OECD Working Party on Consumer Product Safety, a risk assessment workshop with stakeholders from governments, businesses, consumers and academia identified the key features of an 'ideal' consumer product risk assessment, many of which are part of the RAPEX risk assessment method. The OECD will be continuing its work on risk assessment.

The OECD Global Recalls portal was officially launched in Brussels on 19 October. It allows authorities across the world to exchange information about unsafe products that have been taken off the mar-

ket. The Global Recalls portal project was developed jointly by the EU and OECD countries including the US, Australia and Canada. With an expected 3 000 product recall notices a year, consumers, businesses and authorities will have access to a pool of information on recalled products, fed on a regular basis by the EU (through RAPEX), US, Canadian and Australian authorities.

On 22 October, the working party on consumer product safety created a group to start work on injury data gathering. The project is aimed at creating and deploying an injury data collection and reporting system for domestic use by jurisdictions throughout the world.

3.4.4 European Neighbourhood Policy and candidate countries

The Commission encourages and supports reform and provides technical assistance in the product safety area in candidate countries, potential candidate countries and interested countries that participate in the European Neighbourhood Policy (ENP). The Commission continues to work closely with these countries, assessing their national legislation with a view to transposing EU product safety legislation





and providing workshops on product safety and the RAPEX system. For instance, a workshop and training session on the RAPEX system was held in Montenegro.

A number of these countries participate in the joint market surveillance actions funded by the Commission and this serves to raise awareness of product safety and market surveillance in the relevant countries.

3.4.5 Future challenges in international cooperation

The importance of international cooperation increases with the globalisation of supply chains and with the phenomenon of often similar products, or the same product, being found on different countries' markets. The Commission puts great emphasis on international cooperation activities in the consumer product safety area; particularly recognising that tackling product safety problems at their source, so that issues are addressed at the design and manufacturing phase, is an efficient way of reducing the presence of unsafe products on the EU market.

Future work will focus on:

• Enhancing information sharing

This is an area that continues to be important both at bilateral and multilateral level. Increased awareness among regulators of developments and activities in the product safety area in other jurisdictions contributes to exploring synergies, avoiding duplications, responding better to emerging issues and thereby making product safety work more effective. Close bilateral relations will continue with China and the US. The Commission will also maintain its high level of involvement in the work of ICPSC and OECD.

• 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 also on a trilateral level together with the US authorities. Next year the Commission is planning to launch a second joint surveillance action with the Chinese authorities, implementing 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 via the supply chain.

More details about the RAPEX system

4.1 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 follow-up, 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 and professional 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.

4.2 The legal basis of rapex

As of January 2010, two acts, i.e. Directive 2001/95/EC on general product safety¹⁰ (GPSD) and Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93¹¹ (Regulation (EC) No 765/2008), provide the legal framework for RAPEX. In addition, in 2010 the Commission introduced new RAPEX Guidelines (Decision 2010/15/EU¹²), which aim to facilitate the effective and consistent application of the provisions related to the notification procedure.

The GPSD is available at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT

Regulation (EC) No 765/2008 is available at:

The RAPEX Guidelines are available at:

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

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

OJ L 11, 15.1.2002, p. 4.

OJ L 218, 13.8.2008, p. 30

¹² OJ L 151, 30.04.2004, p. 83.

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 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

4.3 When is rapex used?

4.3.1 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 in more than one European country. 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 (EC) No 765/2008 (on 1 January 2010) the scope of the RAPEX system was extended and it now also applies to non-food professional products.

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 other 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?

Member States notify through RAPEX 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.

4.3.2 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/professional users 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 may not, 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.

4.4 How does rapex work?

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

4.4.1 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 – to order producers and distributors to stop their sale, withdraw them from the market and/or recall them.

In addition, a single RAPEX Contact Point is established in each country participating in the system, 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.



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 and Notifications under Article 23 of Regulation (EC) No 765/2008 of actions taken voluntarily by producers or distributors 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, or where preventive and restrictive measures have not yet been taken, or in case of local event, or discussion of the level of the risk at EU level is necessary or where there is an uncertainty regarding RAPEX notification criteria.

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.

The Commission examines the information provided with regard to its compliance with the GPSD, Regulation (EC) No 765/2008, sectoral legislation 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.

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'.





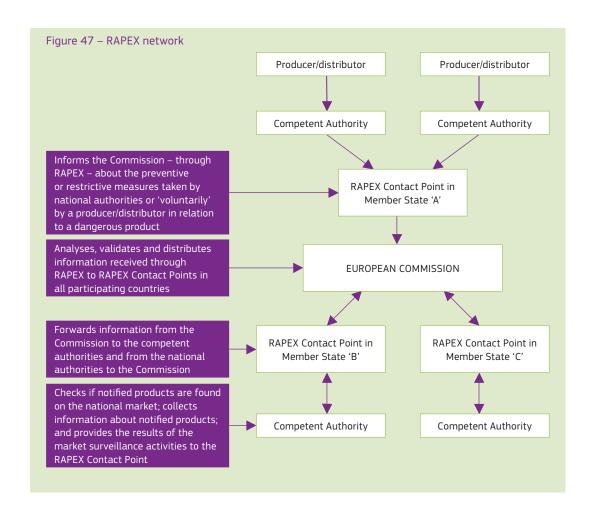
4.4.2 Role and obligations for producers and distributors

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/professional users. Therefore, once they become aware that a product is dangerous, they are required under EU product safety legislation 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/professional users. 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 Europewide to national authorities via the Internet. For more information on the application, see Chapter 3.1.4.

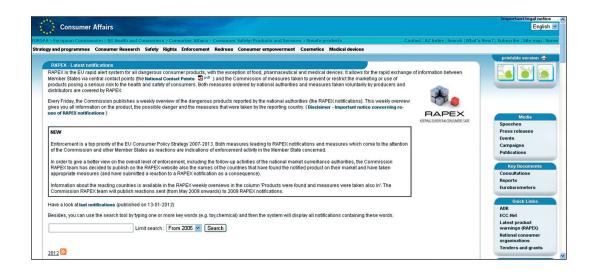
The diagram below illustrates cooperation between the Commission, the national RAPEX Contact Points and national market surveillance authorities.

4.5 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.

In 2013, the Commission will start to publish on the RAPEX website also notifications on products posing less than serious risk as well as on professional products and other risks than health and safety.



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)

GRAS

Generic Rapid Alert System, a general IT platform for all rapid alert systems of the Directorate-General for Health and Consumers

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

Federal 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

Ministry of Economy, SMEs, Self-Employed and Energy 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
Czech Consumers Association TEST www.dtest.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

Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) http://www.dgccrf.bercy.gouv.fr/

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

Ireland

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 e-mail: rapex@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

Malta Competition and Consumer Affairs Authority www.msa.org.mt/marketsurveillance/index.html

Netherlands

Nederlandse Voedsel- en Warenautoriteit (NVWA) Netherlands Food and Consumer Product Safety Authority (NVWA)

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) **www.uokik.gov.pl** email: rapex@uokik.gov.pl

Portugal

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

Romania

National Authority for Consumer Protection www.anpc.qov.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

European Commission, Directorate-General for Health and Consumers:

http://ec.europa.eu/dgs/health_consumer/index_en.htm

European Commission, Directorate for Consumer Affairs:

http://ec.europa.eu/consumers/index_en.htm

EU Commissioner for Consumer Affairs, Mr Tonio Borg:

http://ec.europa.eu/commission_2010-2014/borg/index_en.htm

European 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

Tovs:

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 (General Administration of Quality Supervision, Inspection and Quarantine of P.R.C): http://enqlish.aqsiq.qov.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

OECD Global Recalls Pool:

http://globalrecalls.oecd.org/AboutUs.aspx?lang=En

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/

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

Ceneled

http://www.cenelec.eu/

ETSI:

http://www.etsi.org

The Commission's RAPEX Team

The Commission's RAPEX team can be contacted at:

European Commission

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

E-mail: Sanco-Reis@ec.europa.eu

Tel. (+32-2) 299 40 04 Fax (+32-2) 299 86 37

Mobile phone: (+32-498) 98 04 77

(for use only in case of an emergency during weekends and holidays)



Keeping European Consumers Safe 2012 Annual Report on the operation of the Rapid Alert System for non-food dangerous products

Luxembourg: Publications Office of the European Union 2012 – 68 pp. – 21.0 x 29.7 cm ISBN 978-92-79-26091-9 ISSN 1830-8821 DOI 10.2772/62237

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