



EUROPEAN COMMISSION



Directorate-General for
Health & Consumers

Keeping European Consumers Safe

2009 Annual Report

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

RAPEX





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

This report describes the activities of RAPEX in 2009.

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Keeping European Consumers Safe

2009 Annual Report

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RAPEX

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The RAPEX weekly overviews can be consulted at:

<http://ec.europa.eu/RAPEX>

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Foreword



Dear readers,

I am proud to present the 2009 RAPEX Annual Report in my role as Commissioner for Health and Consumer Policy.

This report provides an overview of the main activities carried out by the European Commission and EU Member States in the area of consumer product safety during the past year.

It shows that, continuing the upward trend, almost 2 000 notifications of dangerous products were identified in 2009. This result is remarkable for two reasons. Firstly, it proves that the enforcement of product safety legislation is constantly improving, resulting in a bigger share of dangerous products being removed from the market. Secondly, it confirms that protecting the health and safety of European consumers is a non-negotiable priority for the Member States, even in times of economic crisis.

RAPEX has enhanced safety in almost all aspects of our daily life: in the products we use at home, for leisure, for fun, for our children, for travelling. To ensure that the RAPEX network performs like clockwork, its machinery was simplified and modernised in 2009. The new RAPEX guidelines adopted last year will improve the efficiency of the system and the more modern and transparent risk assessment method, which is now available, should help providing a more consistent approach across the EU.

The 2009 report is the last in which the RAPEX system will cover only consumer products and risks to consumers' health and safety. As of January 2010, with the entry into force of Regulation (EC) No 765/2008/EC of the European Parliament and of the Council, setting out the requirements for accreditation and market surveillance relating to the marketing of products, the scope of the RAPEX system extends to certain non-consumer products and to risks other than those affecting the health and safety of consumers (i.e. risks to health and safety in the workplace, the environment and security risks). This shows even more the potential and capability of the RAPEX system.

The success of RAPEX is attributable to the goodwill and valuable contribution made by all participants in the system. I would therefore like to thank both the authorities in the Member States for their continuous work and increased involvement in pan-European cooperation, and the economic operators who ensure the safety of products sold and take measures, on their own initiative, against dangerous products. We have to ensure that these efforts, together with the RAPEX website, help to inform, empower and generate the confidence of European consumers in the internal market.

John Dalli
European Commissioner for Health and Consumer Policy



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RAPEX activity in 2009 – executive summary

1



The role of RAPEX in supporting product safety

RAPEX¹ (the Community Rapid Information System for non-food consumer products) is a system which allows market surveillance authorities in EU Member States and the European Commission to share efficiently information about dangerous products found on the European Market and to inform consumers about potential risks to their health and safety.

The main objective of the RAPEX system is to ensure that only safe consumer products are placed on the European Internal Market. The success of RAPEX not only relies on close cooperation between national market surveillance authorities and the European Commission, but also on appropriate legislation and rigorous enforcement, safe product engineering and production, commitment from all economic operators in the supply chain and close cooperation between trading partners.

What was achieved in 2009?

The total number of measures taken against dangerous products and reported through RAPEX by Member States was 1 993, which represents a **7% increase** compared to 2008. The constant growth in the number of notifications over the past six years is due to an increased awareness and attention given to product safety by national authorities and the business sector, more frequent and more effective controls of consumer products on the market and joint market surveillance actions carried out by national authorities.

Toys, clothing and textiles and motor vehicles were the product categories for which the highest number of notifications was issued, while **chemical risks, injuries and choking** were the most common risks. A good number of these notifications related to products containing Dimethyl fumarate (DMF), following a Community Decision banning this sensitising biocide in consumer products.

China was indicated as the country of origin in approximately 60% of the RAPEX notifications, which is also explained by the significant market penetration of Chinese-manufactured consumer products in European markets, while 20% of the notified products were manufactured in the **European Union**.

Enforcement

On 16 December 2009, the Commission adopted Decision 2010/15/EU laying down **the new guidelines for the management of the Community Rapid Information System 'RAPEX'**, established under Article 12, and of the notification procedure established under Article 11 of Directive 2001/95/EC ('the new RAPEX guidelines'). The guidelines identify more precisely and comprehensively the scope of the two procedures, clarifying the notification criteria and the various stages and aspects of the notification and reaction procedures.



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

A modern and transparent risk assessment method is now available for use within RAPEX, which should help to provide more consistent risk assessments.

2009 was again a successful year for **market surveillance cooperation in Europe**. PROSAFE, an informal network of national market surveillance officers, presented, on behalf of the Member States, **five proposals for new joint actions** on helmets, baby-walkers, child-appealing appliances, sun beds and lighters. The Commission awarded co-funding to all of them, for a total amount of EUR 1.2 million. **The exchange of officials programme** attracted 22 applications, more than double the level of participation in 2008.

The European Commission has organised **RAPEX seminars** for national market surveillance and customs authorities to strengthen their knowledge of the RAPEX system and to improve the overall enforcement capacity of the Member States. In 2009, these seminars took place in Romania and Cyprus.

Compliance by businesses

In May 2009, the Commission introduced a new on-line system in the product safety area for producers and distributors called "**Business Application**", with the objective of simplifying the procedure for producers and distributors to fulfil their obligations. In total, 44 notifications were sent by economic operators in 2009 and all Member States have been notified in at least one of the situations.

2009 was characterised by strenuous efforts in view of the revised Toy Safety Directive, focused mainly on the training of economic operators on forthcoming changes to the regulatory framework. These efforts also resulted in the publication before Christmas of 12 toy safety tips for consumers.



Developments relating to specific products and risks

Decision 2009/251/EC adopted on 17 March 2009 requires Member States to ensure that any consumer product containing **Dimethyl fumarate (DMF)**, an anti-mould chemical substance that is strongly sensitising and can cause severe skin lesions, is not placed or made available on the market. This Decision applies until 15 March 2010 and is expected to be extended for subsequent periods until a permanent measure is in place.

Following the adoption of Decision 2009/490/EC determining the safety requirements **for personal music players**, a mandate to develop **new safety standards** for these products in order to avoid the risk of hearing damage, was sent to the European Electrical Standardisation Committee (CENELEC) in September 2009.

The European standardisation organisation CEN started its work on the revision of European standard EN 13869-2002: Lighters – Child-resistance for lighters – safety requirements and test methods. While the revision is pending, the Commission has adopted a follow-up Decision 2009/298/EC extending, for the third time, the validity of the requirements put in place in 2006, thus prohibiting the sale of **non-child resistant and novelty lighters to consumers** until March 2010.

In 2009, the Commission worked actively with the Member States and CEN to achieve completion of the mandated work on a European standard on ladders, a tool consistently ranking in the "Top-10" list of most dangerous utensils and tools found in the home in Europe.

Work to introduce in the EU **reduced ignition propensity (RIP) cigarettes**, which rapidly self-extinguish when lay down unattended, have also been progressing within the standardisation organisations concerned.

In June 2009, the Member States agreed with the Commission on the safety requirements for **baby bath articles and childproof locks for windows and balcony doors**. In October 2009, the Member States similarly agreed with the Commission on the requirements for the safety **of five products commonly used in the sleep environment of newborns and young children**. These requirements are the first step towards submitting the relevant mandates to CEN. All these products are linked to a significant number of accidents, including fatal ones, involving children.

International cooperation

2009 saw further strengthening of the collaboration between the Commission's Directorate-General for Health and Consumers and the **Chinese** Administration for Quality Supervision, Inspection and Quarantine (AQSIQ). The annual meeting of the market surveillance/consumer product safety working group took place in Beijing. A roundtable discussion on the impact of the financial crisis on product safety in China took place, showing that, despite many negative effects, it has resulted in a positive influence on product quality and safety, through consolidation in the industry and more focus on testing and assurance efforts.

In November 2009, the Council authorised the European Commission to open negotiations with the **United States of America** for an agreement on cooperation and information exchange in the area of consumer product safety. During 2009, the toy safety working group established between the European Commission and the Consumer Product Safety Commission (CPSC) of the United States of America met three times.

The European Commission has also been taking an active part in discussions in the **OECD and other fora and networks** on enhancing consumer product safety information sharing.



RAPEX statistics

2.1 Notifications

2.1.1 Total number of notifications

Situation in 2009

In 2009, the European Commission distributed 1 993 notifications through the RAPEX system:

- **1 699** of these notifications were distributed to Member States as notifications under Article 12 of the GPSD (preventive or restrictive measures taken by competent national authorities or voluntarily by economic operators with regard to products presenting serious risks to the health and safety of consumers, e.g. stopping or banning of sales, withdrawals from the market, recalls from consumers);
- 11 notifications were distributed to Member States under Article 11 of the GPSD (measures taken by competent national authorities with regard to products posing moderate risks);
- 283 notifications were distributed to Member States for information purposes, as they did not qualify for distribution under either Article 12 or Article 11.

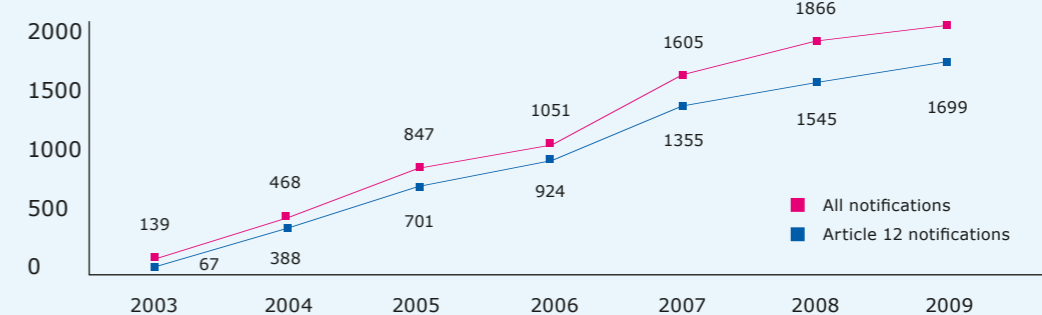


Figure 1 – Total number of notifications



Comparison with previous years

Figure 2 – Number of notifications 2003–2009



The total number of notifications validated by the European Commission has risen gradually over the past years: the number of notifications has more than quadrupled between 2004 (468) and 2009 (1 993).

In 2009, the total number of notifications rose by 7% (1 993 notifications distributed in 2009 compared to 1 866 in 2008). Since 2004, the numbers have grown constantly (81% in 2005, 24% in 2006, 53% in 2007 and 16% in 2008), fuelled in part by the enlargements of 2004 and 2007. In 2008 and 2009, the system stabilised at around 2 000 notifications.

The number of Article 12 notifications has grown by 10% compared to 2008 (1 699 notifications were distributed in 2009 compared to 1 545 notifications in 2008). In 2008, the number of Article 12 notifications had increased by 14% compared to 2007.

The total number of notifications distributed through the RAPEX system concerning products posing a serious risk is rising every year. This is due to increased awareness and attention given to product safety by national authorities and the business sector, more frequent and more effective controls of consumer products on the market, joint market surveillance actions carried out by national authorities and, finally, to several training actions and seminars provided by the European Commission for different stakeholders.

The number of notifications distributed for information purposes only has decreased by 9% compared to 2008 (283 notifications distributed in 2009 compared to 311 notifications in 2008). This results mainly from the fact that notifications submitted by Member States to the Commission were of better quality. In particular, the notified products and risks posed by them were better identified, thus other Member States could undertake necessary follow-up activities with regard to these products.

In the following charts, the figures concern only notifications that were distributed through the RAPEX system under Article 12 of the GPSD (1 699 notifications). Notifications distributed through the system under Article 11 of the GPSD, and notifications sent for information purposes, are not covered by the detailed statistics below.

2.1.2 Notifications by notifying country

In 2009, 26 EU Member States and Norway sent notifications through the RAPEX system. The following five most frequently notifying countries accounted for 47% of all notifications:

- Spain (220 notifications, 13%),
- Germany (187 notifications, 11%),
- Greece (154 notifications, 9%),
- Bulgaria (122 notifications, 7%),
- Hungary (119 notifications, 7%).



Figure 3 – Number of notifications by notifying country (absolute values)

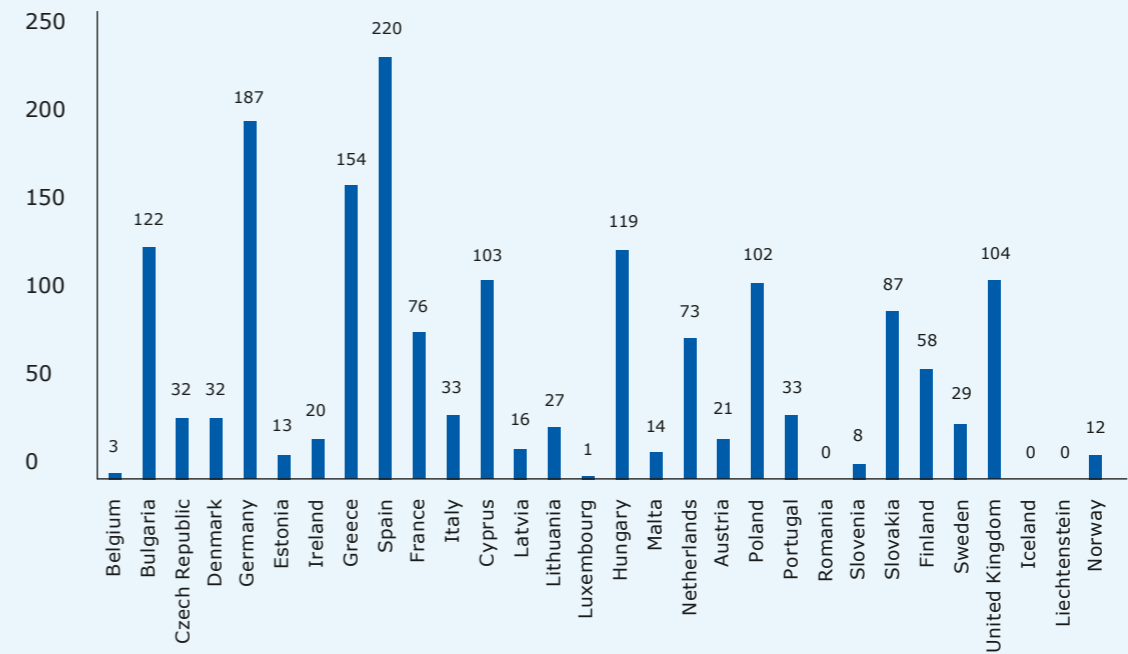
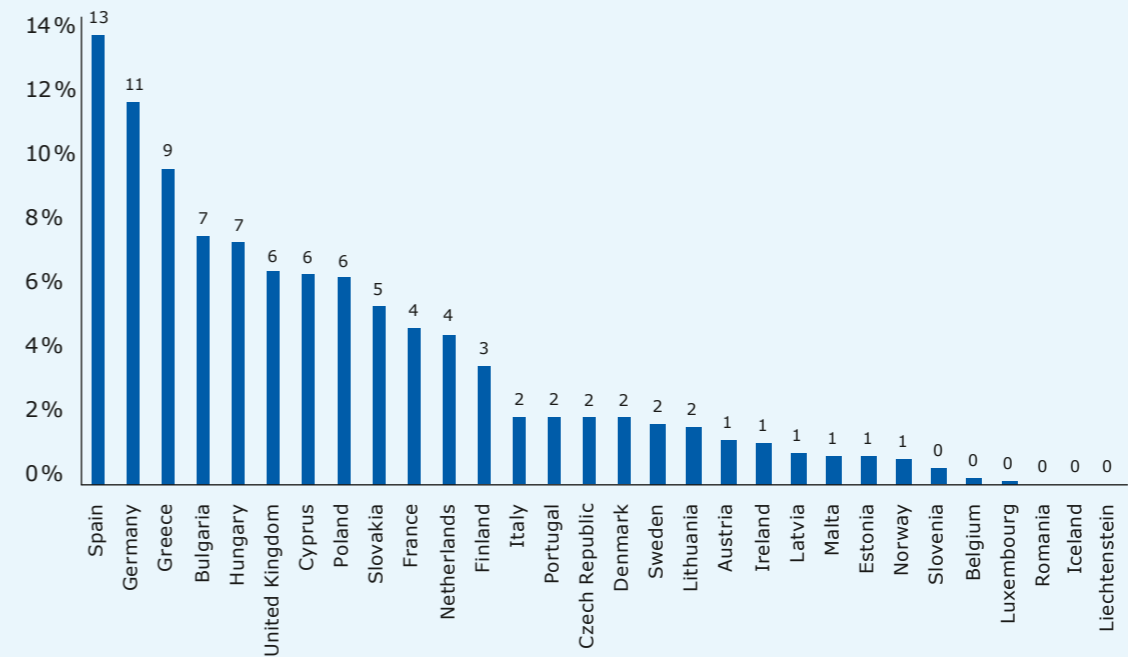


Figure 4 – Notifications by notifying country (%)



Comparison with previous years

In 2009, half of the countries increased their activities in the RAPEX system and notified more dangerous products than in 2008. This year, the gap between the countries with the highest and the lowest number of notifications decreased slightly compared to 2008. This is reflected in the fact that the total share of the five most frequently notifying countries (i.e. Spain, Germany, Greece, Bulgaria and Hungary) decreased from 50% in 2008 to 47% in 2009.

Figure 5 – Number of notifications by notifying country: comparison with previous years

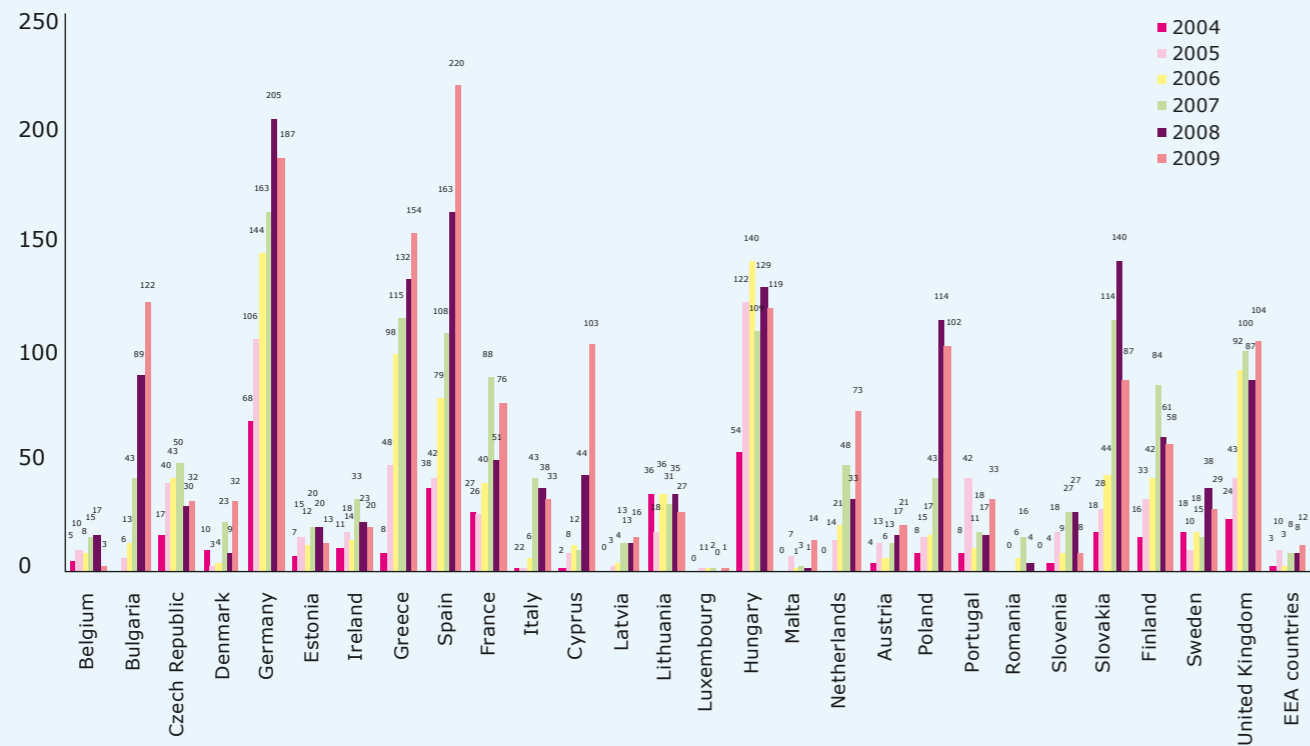


Figure 6 – The five most frequently notifying countries in 2009

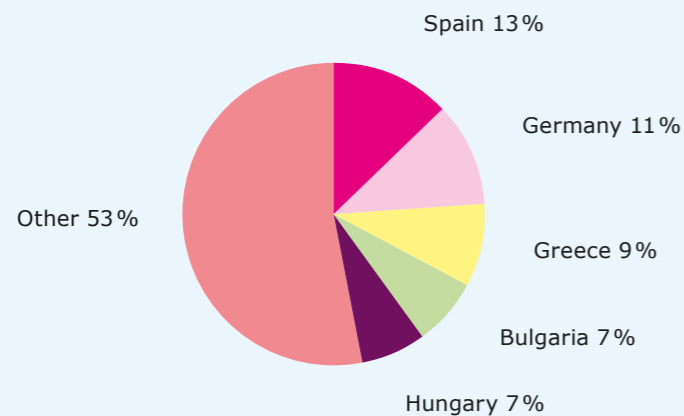
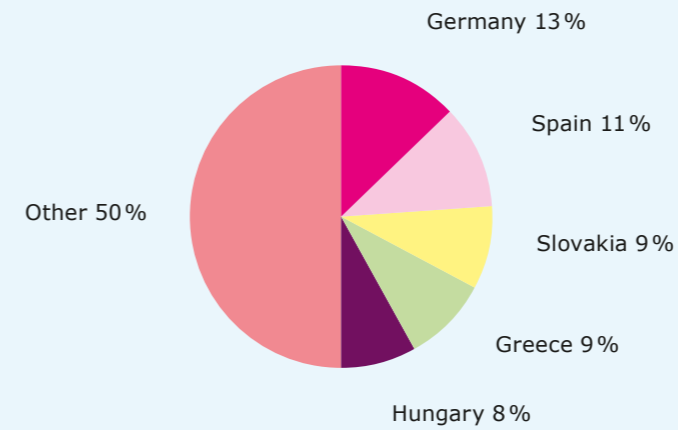


Figure 7 – The five most frequently notifying countries in 2008



It should be stressed that the RAPEX statistics do not reflect all market surveillance activities carried out in Member States. It is normal, and legitimate reasons may exist, that some measures taken against dangerous products in the Member States do not result in notifications to the RAPEX system. 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 European Commission is nevertheless in discussions with the Member States in order to better understand the overall activity level (enforcement indicators), on the one hand, and regularly also checking whether the guidelines it provides to Member States are satisfactory, on the other hand.

2.1.3 Notifications by product identifier

2.1.3.1 Product category of the notified product

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

- toys (472 notifications, 28%),
- clothing, textiles and fashion items (395 notifications, 23%),
- motor vehicles (146 notifications, 9%),
- electrical appliances (138 notifications, 8%),
- cosmetics (86 notifications, 5%).

These categories of products accounted for almost 73% of all products notified in 2009. The product category "toys" remains the most notified (28%) but this year it is closely followed by "clothing, textiles and fashion items" (23%). Both categories account together for more than half (51%) of all notifications distributed through the RAPEX system in 2009.

A significant increase in the number of RAPEX notifications on clothing, textiles and fashion items results mainly from the enhanced market surveillance activities undertaken by national authorities following, in particular, the adoption of Commission Decision 2009/251/EC on DMF² which is a strong novel sensitizer found to have been used as an anti-mould treatment especially in shoes, some textiles and furniture. A second, equally important factor leading to the prominence of this category in the findings of non-compliance was the launch of the joint market surveillance action on cords and drawstrings in children's clothing, which saw the participation of nine Member States. This proves that risk-focused Community level measures and joint prioritisation of certain types of products in the surveillance actions taken by Member States result in well spent resources in terms of finding dangerous products that could be harmful to consumers.

² OJ L 74, 20.3.2009, p. 32-34

Figure 8 – Number of notifications by product category (absolute values)

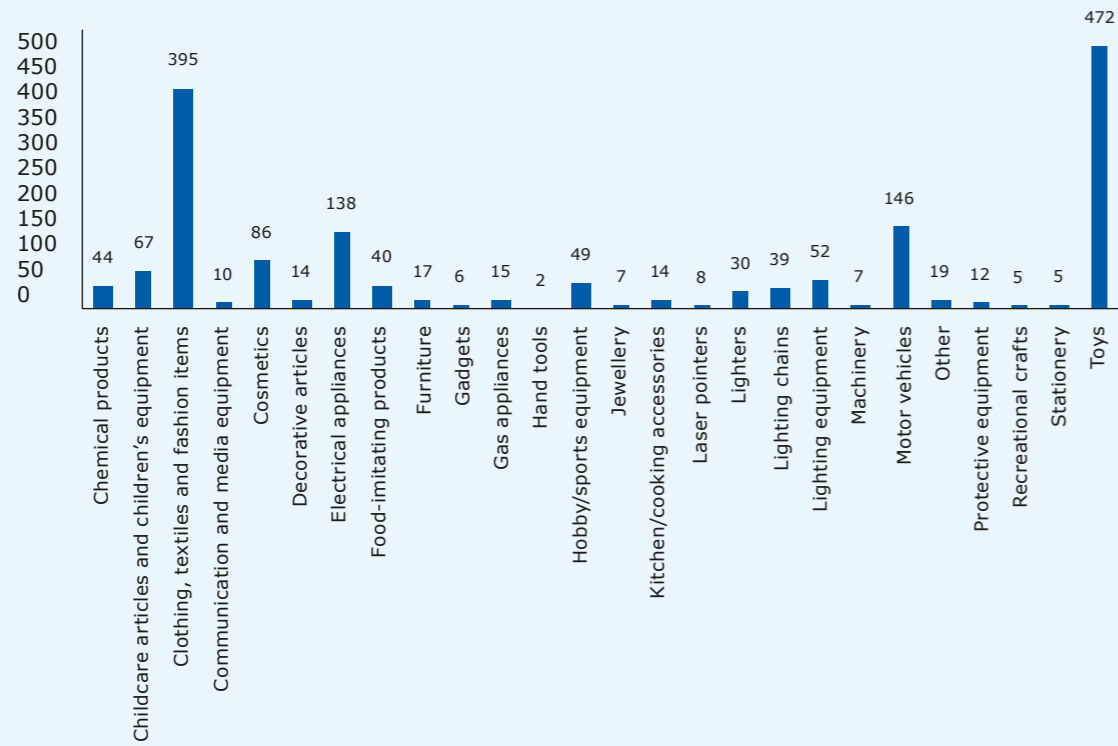


Figure 9 – Notifications by product category (%)

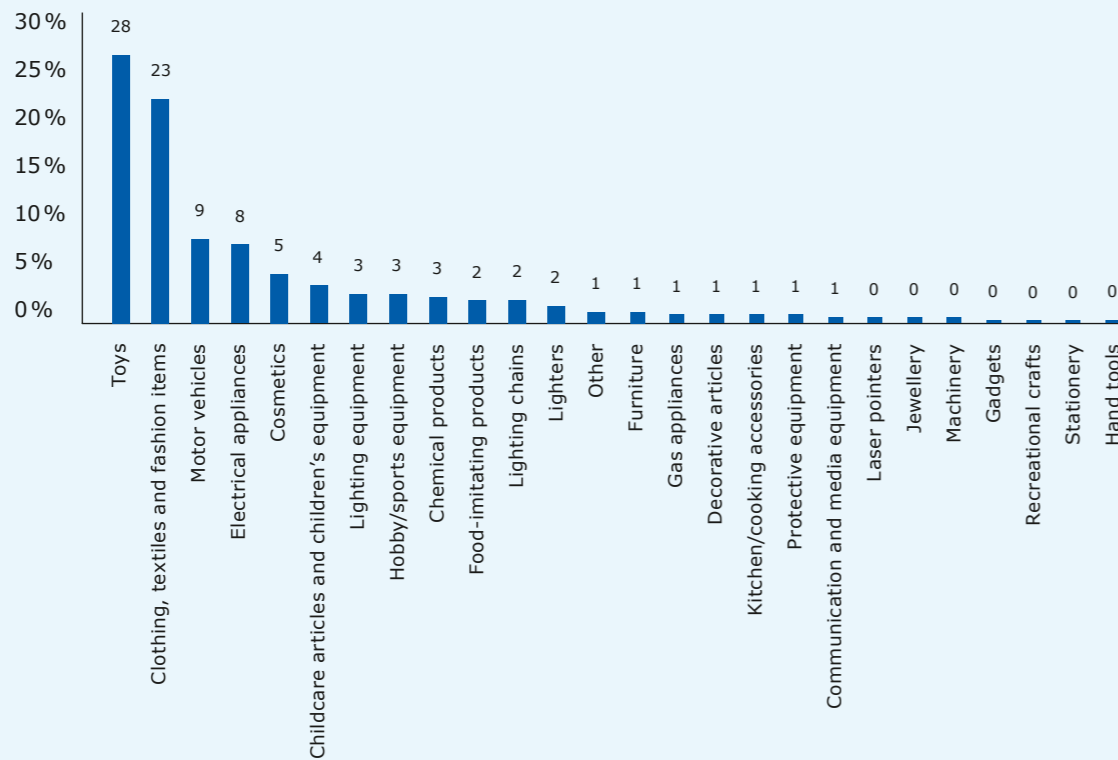


Figure 10 – The five most frequently notified product categories in 2009

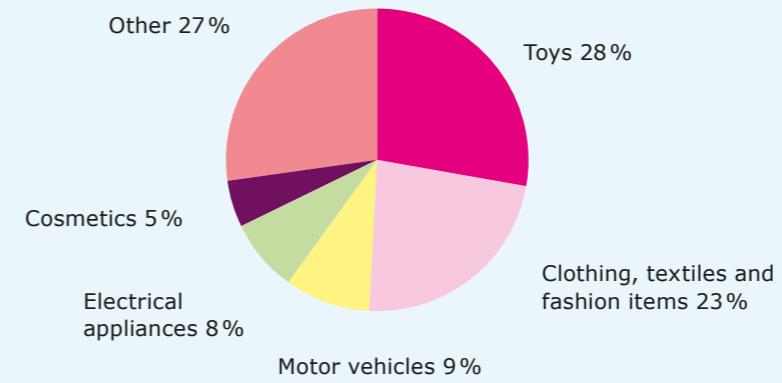
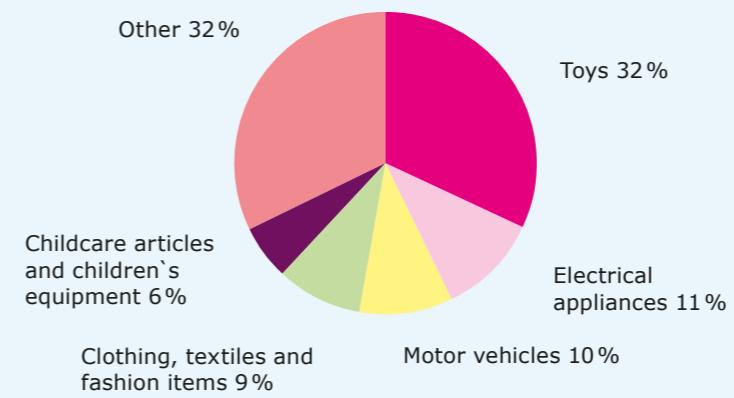


Figure 11 – The five most frequently notified product categories in 2008



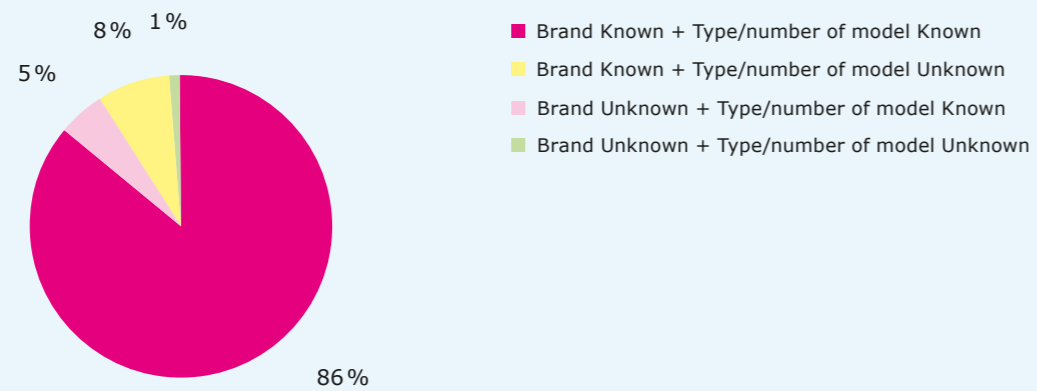
2.1.3.2 Brand and model numbers of the notified product

1 464 notifications validated in 2009 (86%) concerned products for which the brand and the type/model number were both known, which ensures a better identification and thereby traceability of the notified products. Only 16 notifications (1%) were validated concerning products for which both the brand and the type/model number were unknown. In 13% of the cases, either the brand or the type/model number was known.

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

	Type/number of model Known	Type/number of model Unknown	Total
Brand Known	1 464	133	1 597
Brand Unknown	86	16	102
	1 550	149	1 699

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



2.1.3.3 Country of origin of the notified product

In 60% of all notifications sent through the RAPEX system in 2009 (i.e., 1 013 notifications), China (including Hong Kong) was indicated as the country of origin of the notified products. The high number of RAPEX notifications concerning Chinese products results from the significant market penetration of Chinese-manufactured consumer products in European markets. Products of all origins are checked in the same way, usually based on risks associated with the product category or typical hazards. In addition, the constant intensification of our contacts with Chinese authorities and businesses is yielding significant returns in terms of improved product identification and traceability (see specific section in Chapter 4)

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

124 notifications (7% of all notifications sent through RAPEX) contained no information about the country of origin of the notified product. This figure should be seen as a significant improvement in the operation of the RAPEX system, as the number of cases with an unidentified country of origin has decreased from 23% in 2004 to 7% in 2009. This is an indicator that the market surveillance authorities in Europe are increasingly aware of the importance of not only taking the incriminated product off the outlets in their country but also finding out the traceability data helpful to authorities in other countries and ultimately in the country of origin of the product.

Figure 14 – Number of notifications by country of origin of the notified product

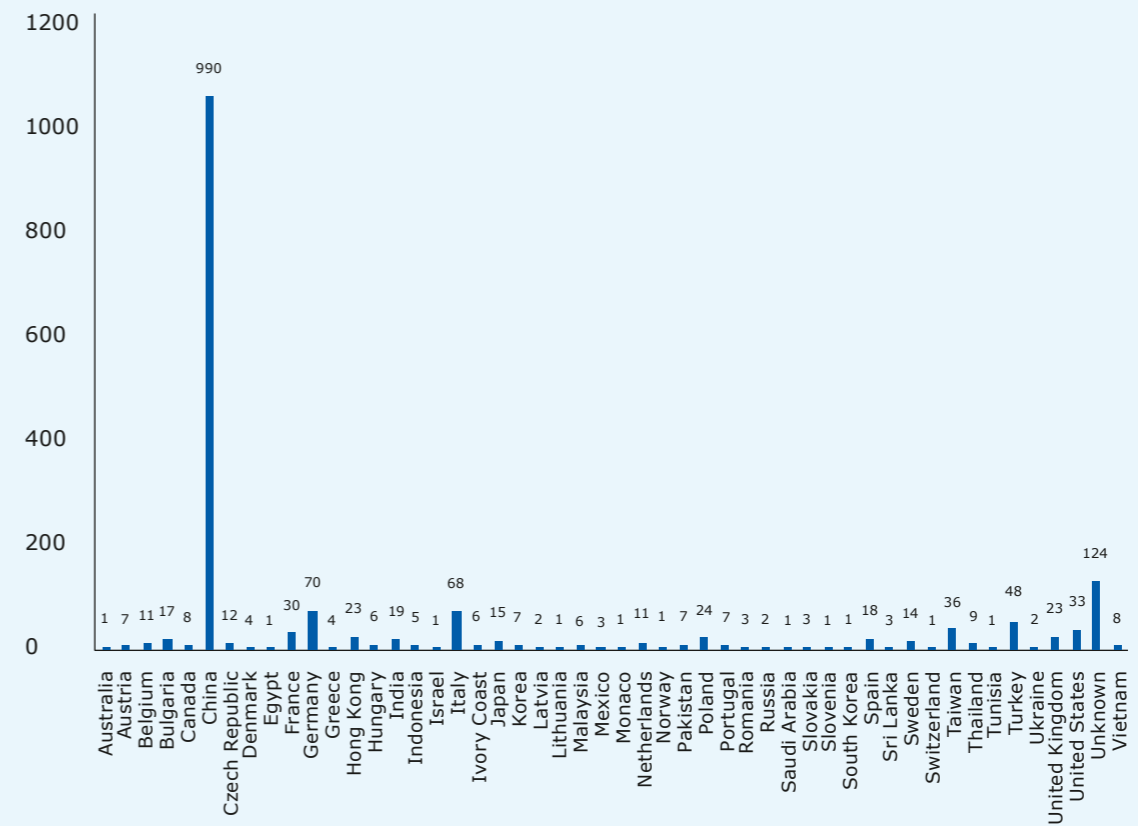


Figure 15 – Notifications by country of origin of the notified product (%)

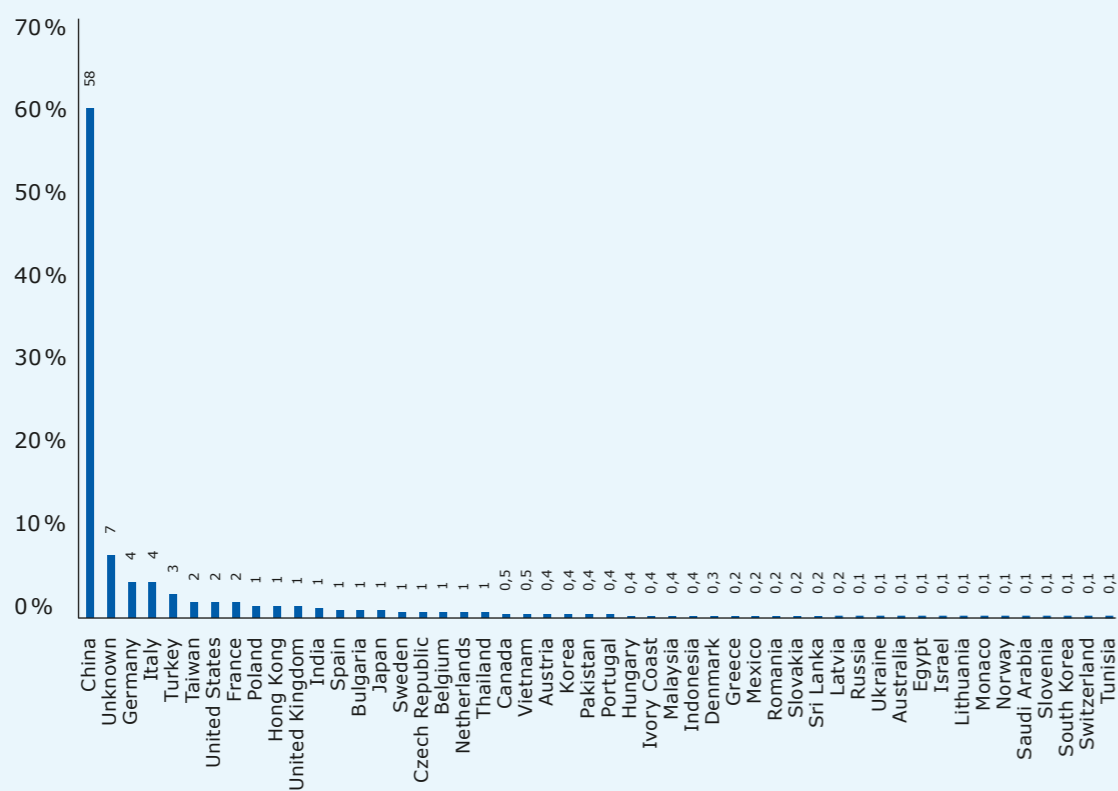


Figure 16 – Notifications by country of origin of the notified product (%)

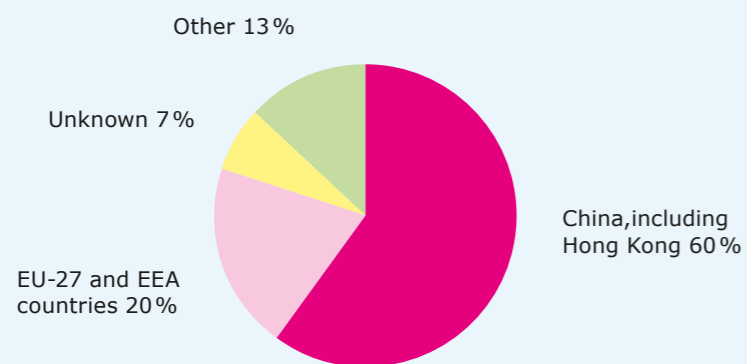
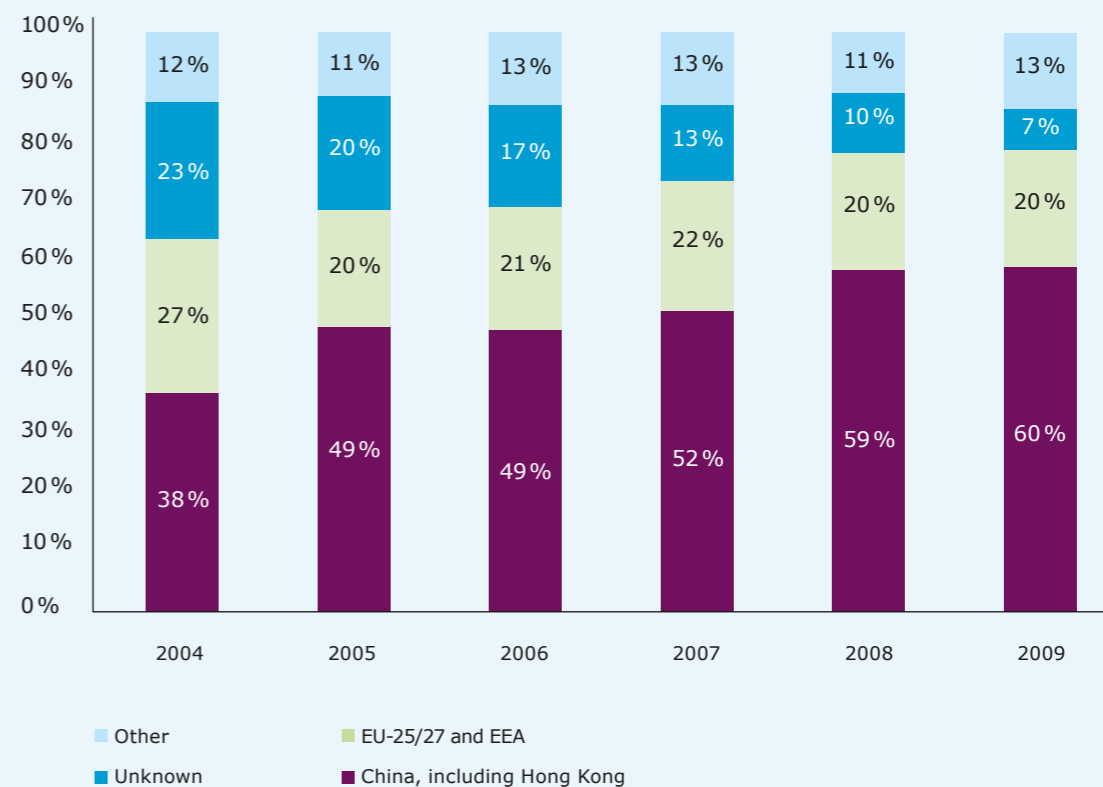


Figure 17 – Notifications by country of origin of the notified product (%) – comparison previous years



2.1.4 Notifications by type of risk

The five most frequently notified risk categories were:

- chemical (493 notifications, 26%),
- injuries (405 notifications, 21%),
- choking (261 notifications, 14%),
- electric shock (214 notifications, 11%),
- strangulation (182 notifications, 10%).

These five risk categories account for 82% of all risks.

It should be noted that some RAPEX notifications concern products presenting more than just one risk (e.g. a toy can pose a choking risk due to small parts and, simultaneously, a chemical risk due to excessive levels of a restricted substance). Therefore the total number of notified risks is higher than the total number of notifications.

On the basis of RAPEX data, it can also be concluded that each product category is likely to expose consumers to specific types of risk. For example, the main risks arising when playing with unsafe toys are choking (often associated with the presence of small parts) and chemical (often associated with high levels of chemical substances such as phthalates, lead and other heavy metals), while the most common risk for electrical products is, quite obviously, electric shock, often combined with the risk of fire.

Figure 18 – Number of notifications by type of risk (absolute values)

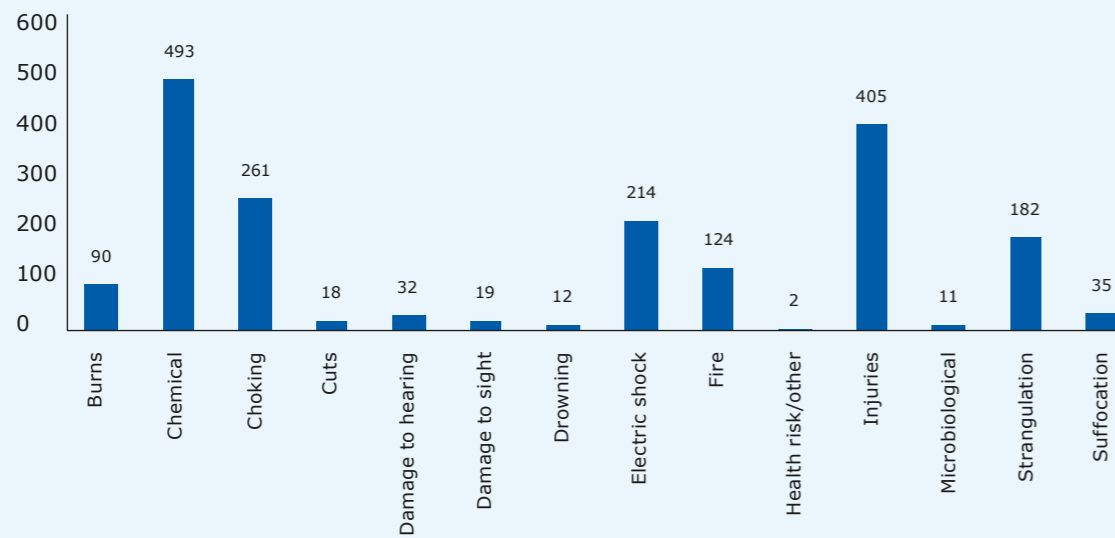


Figure 19 – Notifications by type of risk (%)

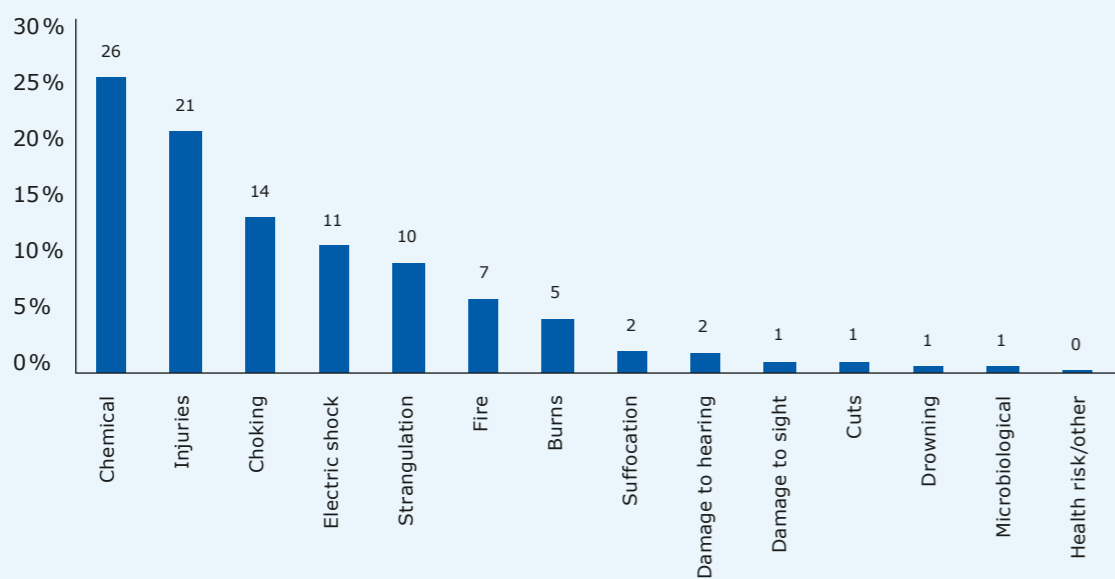


Figure 20 – The five most frequently notified types of risk in 2009

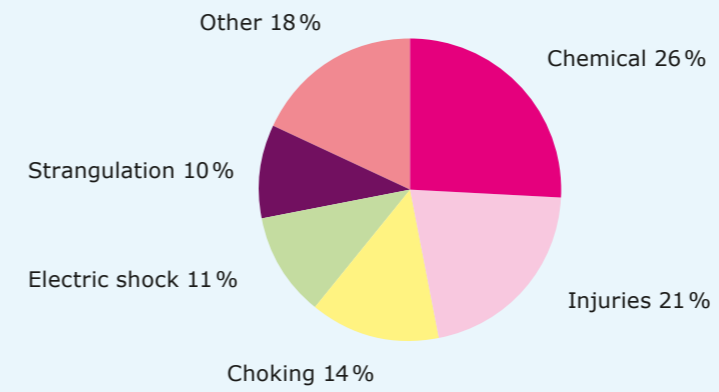
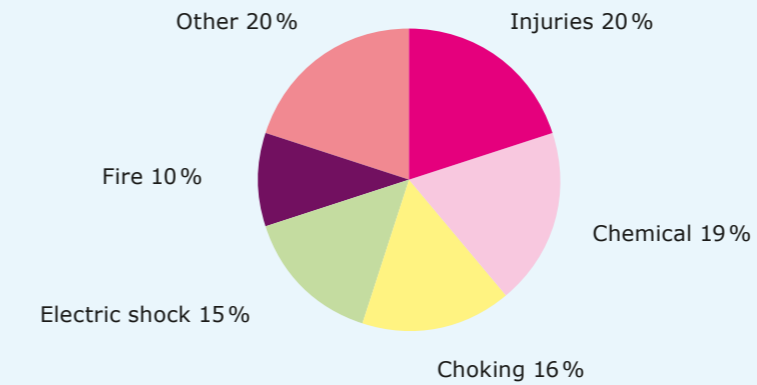


Figure 21 – The five most frequently notified types of risk in 2008



2.1.5 Notifications by type of measure

901 of the 1 699 RAPEX serious risk notifications concerned compulsory preventive and restrictive measures ordered by the national authorities (53 % of the total number). In 752 notified cases (44%), the economic operators took the necessary preventive and restrictive measures on a 'voluntary' basis, i.e. complying with their legal obligations without the formal intervention of a national authority. In 46 cases (3%), compulsory measures were complemented by 'voluntary' actions taken by an economic operator, e.g. the economic operator decides to stop selling the product and the national authorities order that the product be withdrawn from the market or recalled from consumers who may have already bought the product.

Figure 22 – Number of notifications by type of measure (absolute values)

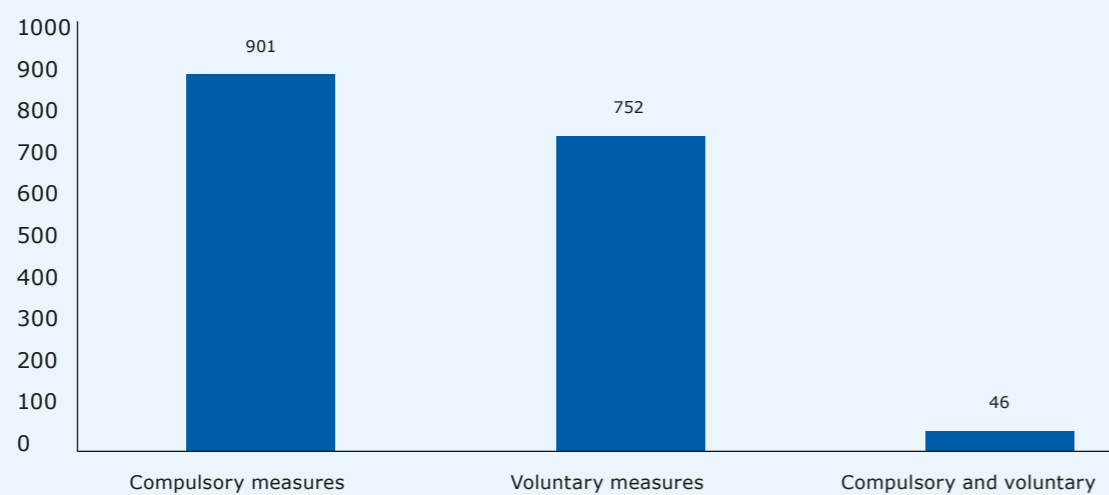


Figure 23 – Notifications by type of measure (%)

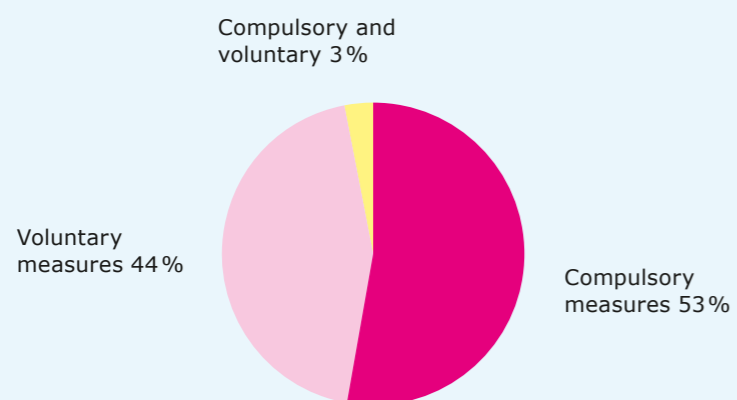


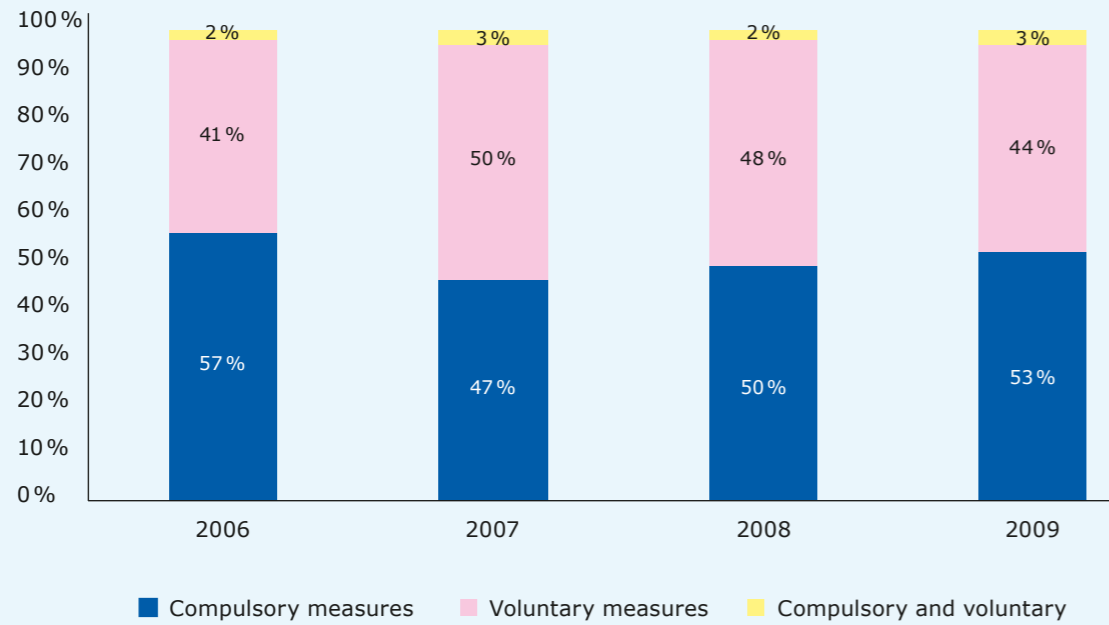
Figure 24 – Number of notifications by type of measure per country (absolute values)

Jan-Dec 2009	Compulsory measures	Voluntary measures	Compulsory and voluntary	Total
Belgium	1	1	1	3
Bulgaria	120	1	1	122
Czech Republic	32			32
Denmark	3	29		32
Germany	19	159	9	187
Estonia	13			13
Ireland	1	19		20
Greece	72	82		154
Spain	200	19	1	220
France	9	64	3	76
Italy	14	16	3	33
Cyprus	70	24	9	103
Latvia	7	9		16
Lithuania	27			27
Luxembourg	1			1
Hungary	115	4		119
Malta	2	12		14
Netherlands	33	38	2	73
Austria	9	12		21
Poland	27	75		102
Portugal	10	23		33
Romania				0
Slovenia	2	6		8
Slovakia	58	17	12	87
Finland	42	15	1	58
Sweden		28	1	29
United Kingdom	7	94	3	104
<i>Iceland</i>				<i>0</i>
<i>Liechtenstein</i>				<i>0</i>
<i>Norway</i>	7	5		<i>12</i>
	901	752	46	1 699

Comparison with previous years

After a decrease in 2007 (from 57% in 2006 to 47% in 2007), the share of cases for which measures have been initiated by the authorities slightly grew again in 2009 (from 47% in 2007 to 50% in 2008 and 53% in 2009). More than half of the measures are now ordered by the authorities.

Figure 25 – Notifications by type of measure (%) – comparison previous years

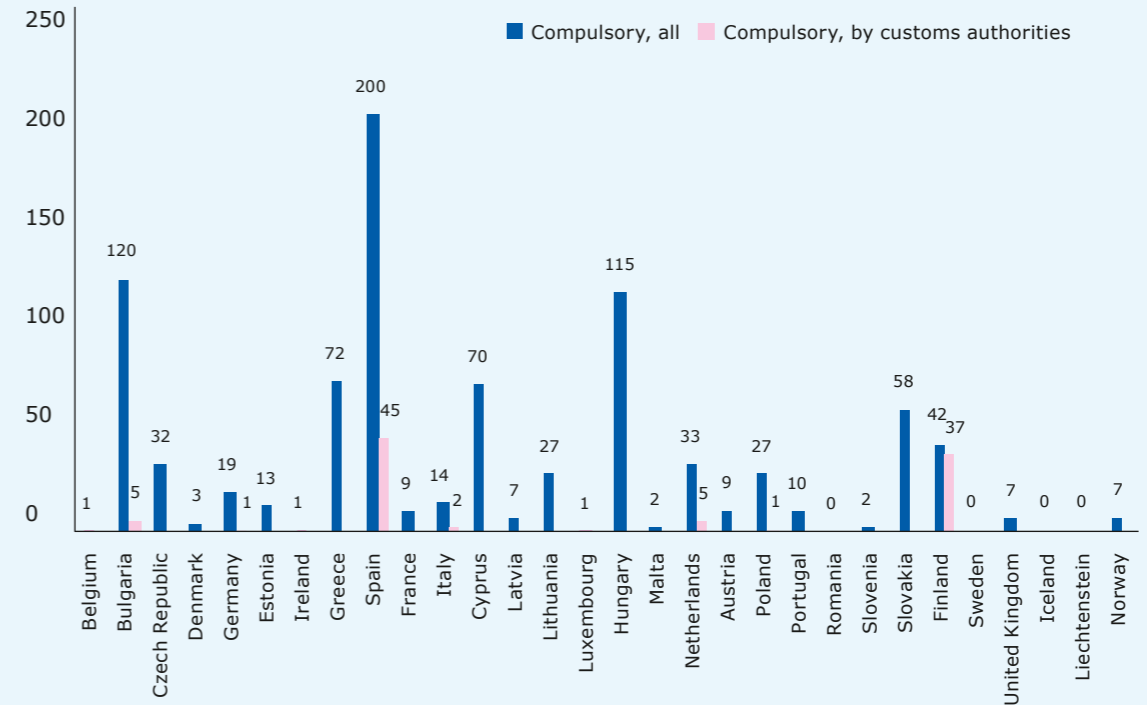


2.1.6 Notifications initiated by the activities of the customs authorities

As stated above, 901 of the 1 699 RAPEX notifications relating to products posing a serious risk concerned preventive and restrictive measures solely ordered by the competent national authorities (53% of the total number). 96 of these 901 notifications (11%) concerned measures that were adopted by the customs authorities (mainly rejection of imports).

This figure indicates that in some countries the customs authorities are more involved in taking the decision to stop the import of dangerous products but it does not give a full picture of the activity of the customs authorities, since in many other countries such measures are taken directly by the market surveillance authorities and are thus reflected in the total figure for compulsory measures notified through the RAPEX system.

Figure 26 – Number of notifications concerning compulsory measures initiated by the customs authorities (absolute values)



2.2 Reactions

2.2.1 Total number of reactions

In 2009, Member States and EFTA/EEA countries sent a total of 1 556 reactions to all notifications distributed through RAPEX. 1 530 reactions were sent regarding Article 12 notifications (98%); no reactions were sent concerning Article 11 notifications (0%); and 26 reactions were sent regarding 'For information only' notifications (2%).

41% of all the Article 12 notifications (i.e. 692 out of 1 699 Article 12 notifications) received at least one reaction.

In the following charts, the figures only concern reactions to notifications that were distributed through the RAPEX system under Article 12 of the GPSD – serious risk (1 530 reactions).

2.2.2 Reactions by reacting country

In 2009, all Member States, plus Norway and Iceland, sent reactions regarding RAPEX notifications.

The following five countries accounted for 38% of all reactions:

- Spain (137 reactions, 9%),
- Slovenia (121 reactions, 8%),
- Poland (113 reactions, 7%),
- Portugal (103 reactions, 7%),
- Netherlands (101 reactions, 7%).



Figure 27 – Number of reactions by reacting country (absolute values)

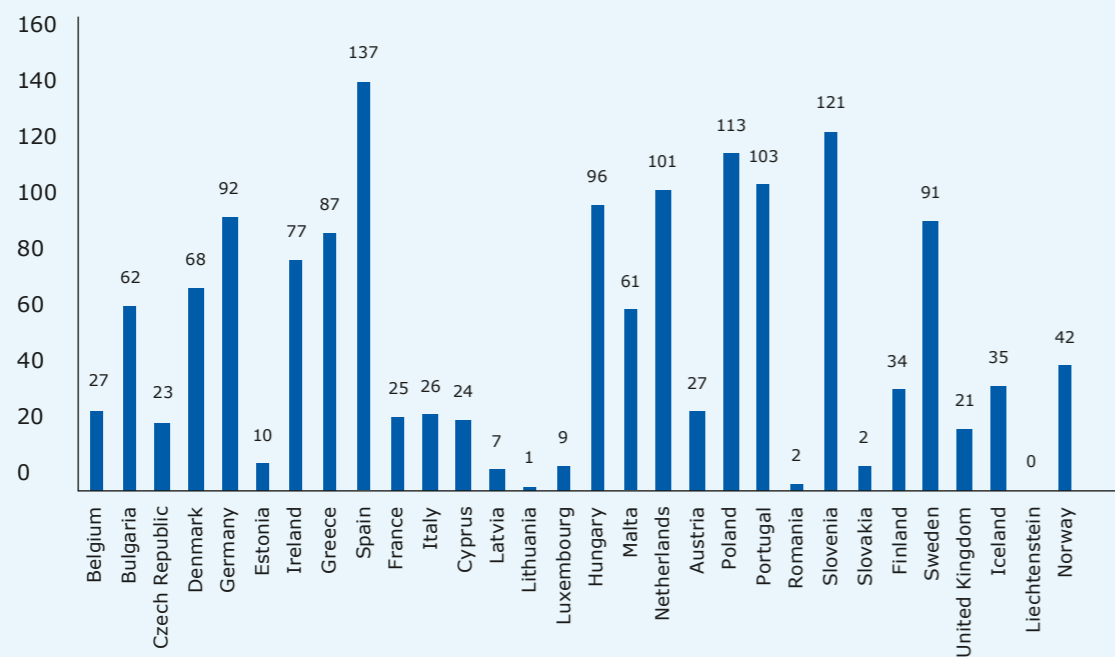
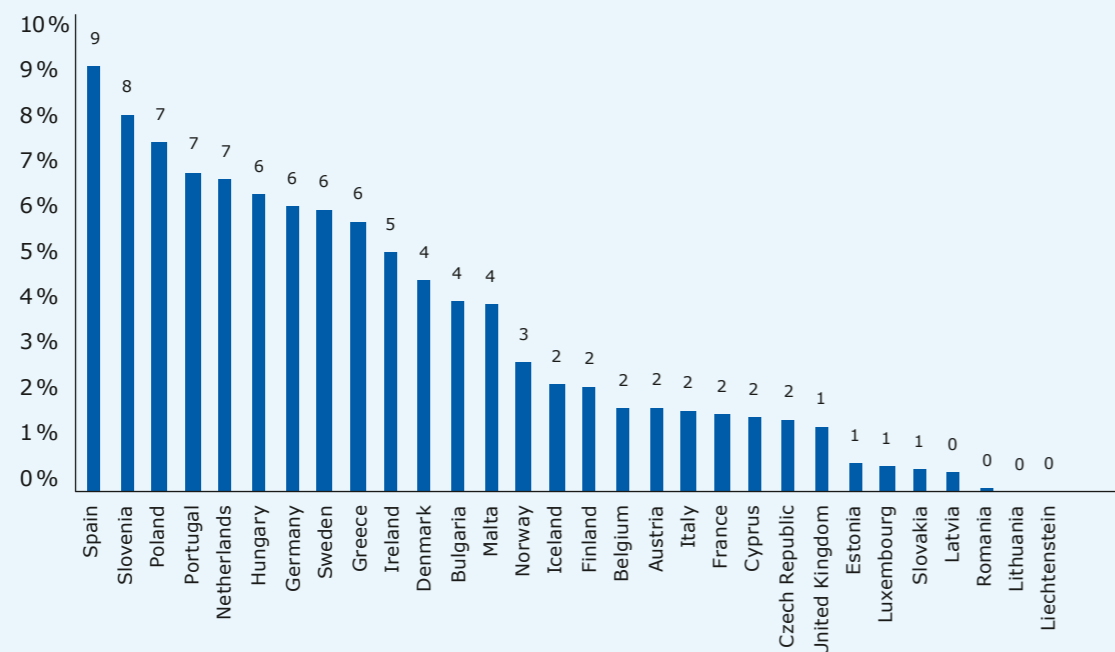


Figure 28 – Reactions by reacting country (%)



2.2.3 Reactions by notified product

Notifications concerning motor vehicles generated the most reactions (52% of all reactions). 80% of all the reactions received concerned RAPEX notifications related to the following five product categories:

- motor vehicles (790 reactions, 52%),
- toys (201 reactions, 13%),
- electrical appliances (90 reactions, 6%),
- clothing, textiles and fashion items (83 reactions, 5%),
- childcare articles and children's equipment (56 reactions, 4%).

Figure 29 – Number of reactions by product category of the original notification (absolute values)

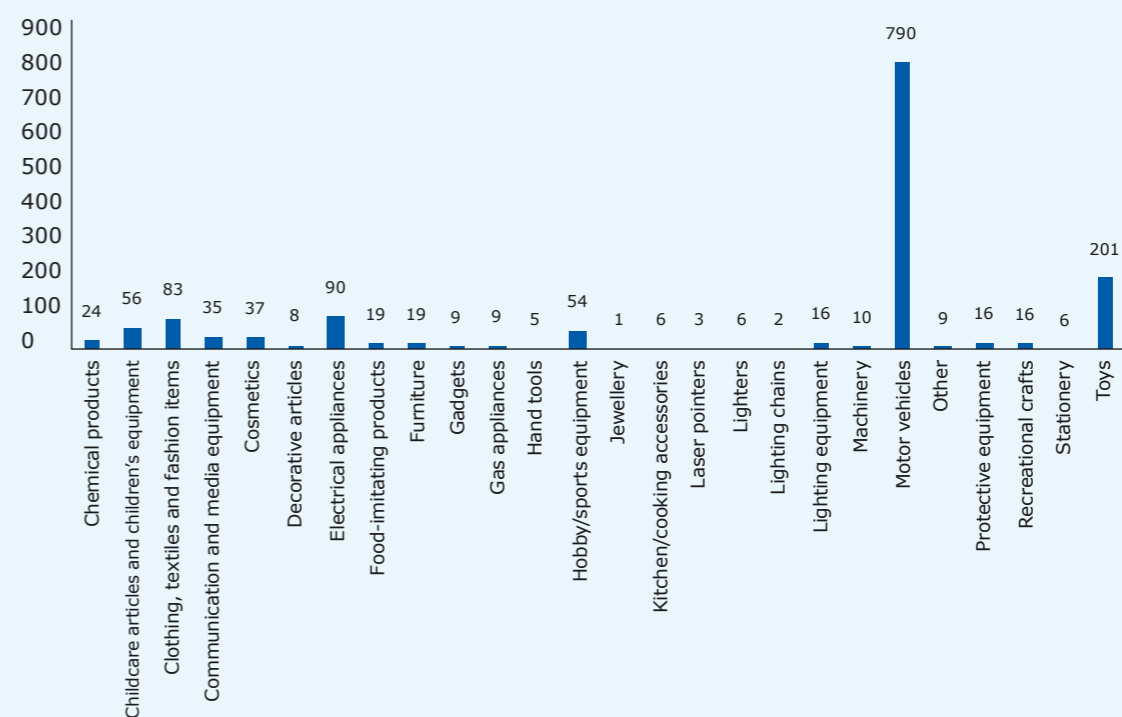
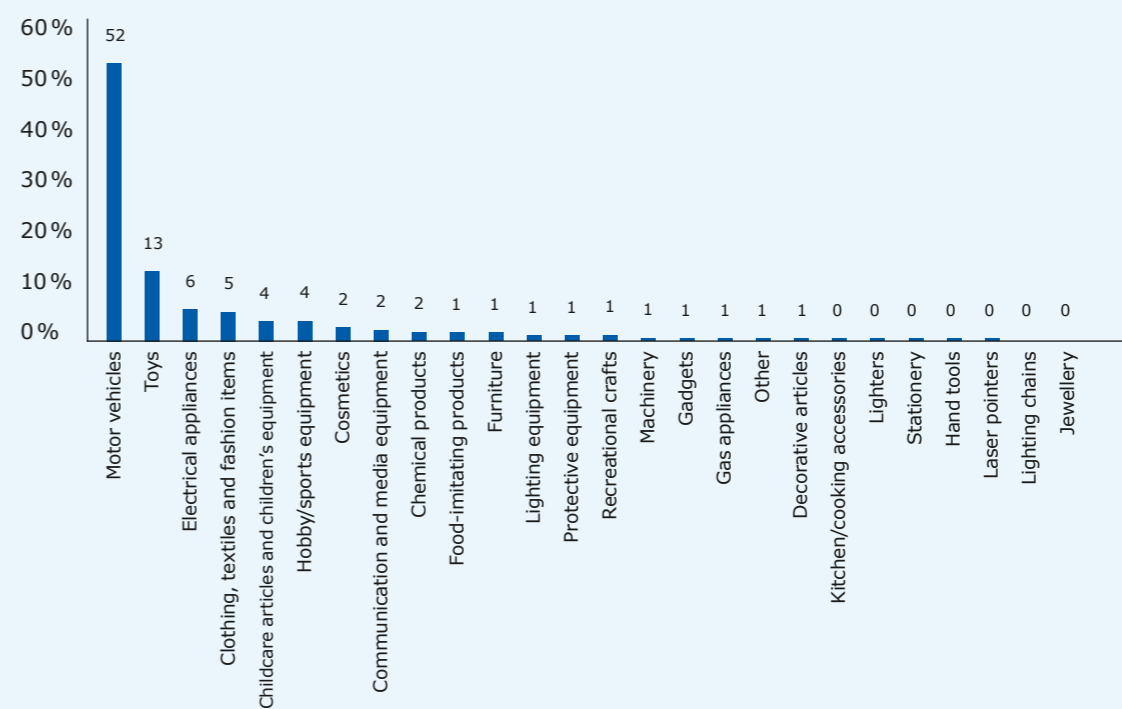


Figure 30 – Reactions by product category of the original notification (%)



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 (870 reactions, 54%) and a risk of fire (195 reactions, 12%). These two risks are clearly linked to motor vehicles, which accounted for 52% of all reactions received.

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

- injuries (870 reactions, 54%),
- fire (195 reactions, 12%),
- chemical (175 reactions, 11%),
- choking (127 reactions, 8%),
- electric shock (75 reactions, 5%).

Some reactions concerned products that present more than one risk: therefore the total number of risks in the reactions (1 605) is higher than the actual number of reactions to Article 12 notifications (1 530).

Figure 31 – Number of reactions by type of risk of the original notification (absolute values)

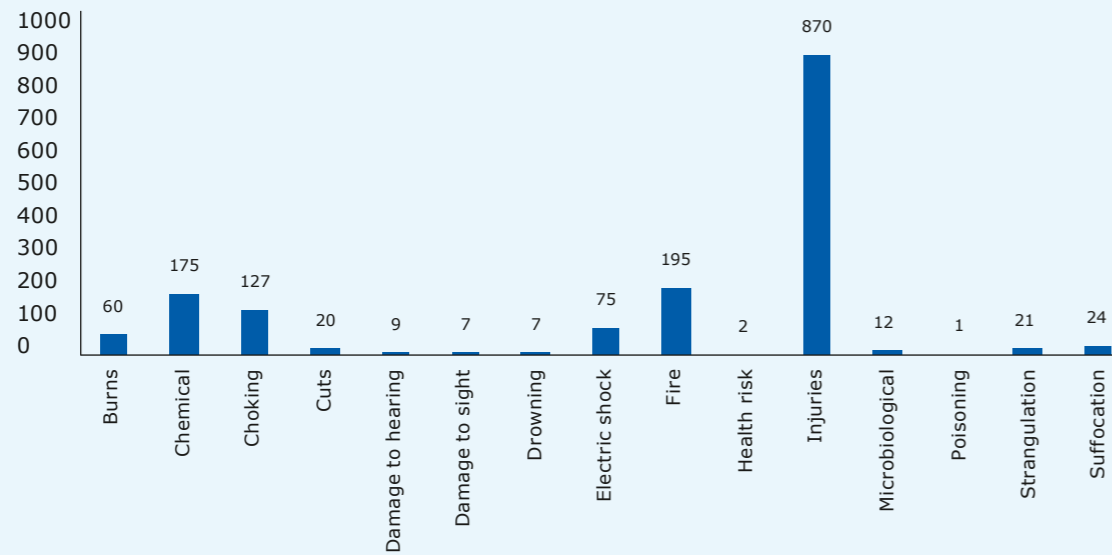
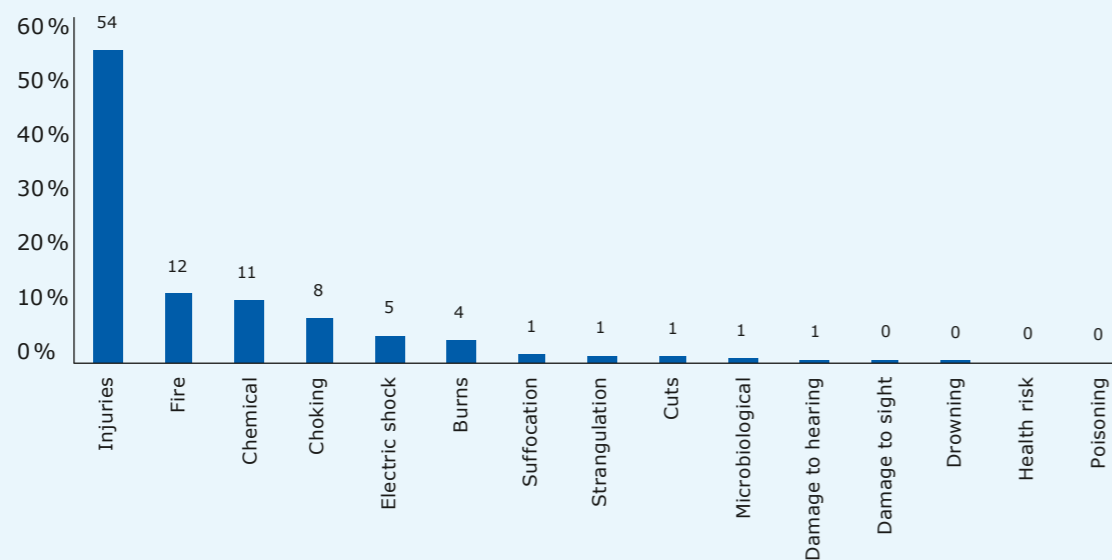


Figure 32 – Reactions by type of risk of the original notification (%)



2.2.5 Reactions by type of reaction

In the majority of reactions received (1 392 reactions, 91% of all reactions), Member States stated that the notified product was found on their market and that adequate preventive or restrictive measures were adopted at national level. In 15 reactions (1% of all reactions), the reacting country requested or provided additional information on the case. In 27 reactions (2% of all reactions), the reacting country did not agree with the information provided in the notification, mainly with the conclusions of the risk assessment presented by the notifying Member State. In 96 reactions (6% of all reactions), Member States informed the Commission that the notified product was not found on their markets.

Figure 33 – Number of reactions by type of reaction (absolute values)

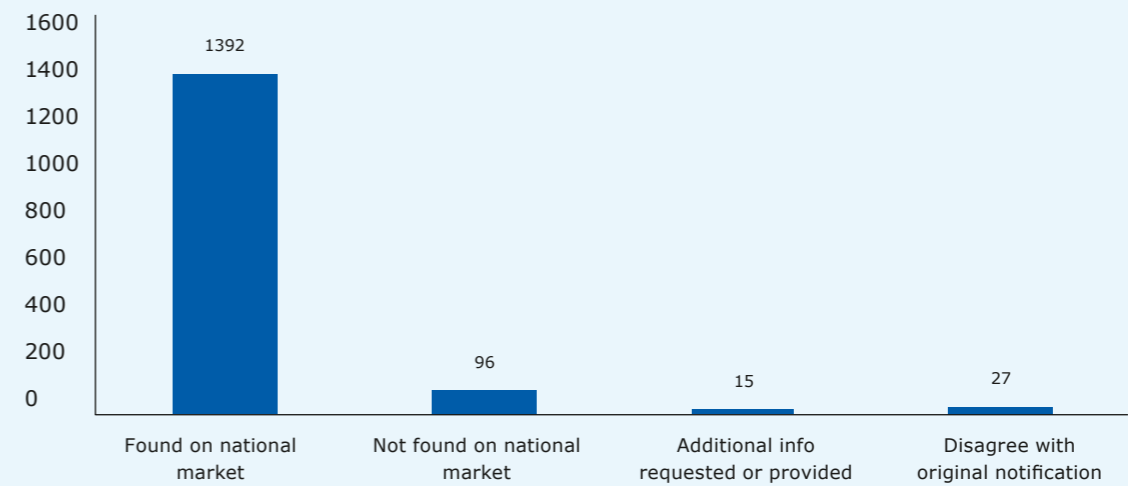
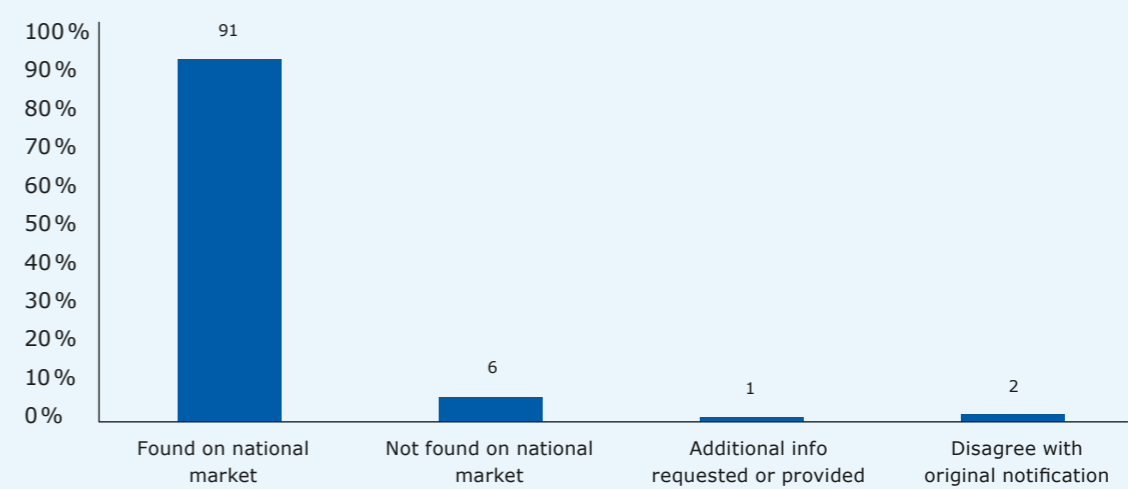


Figure 34 – Reactions by type of reaction (%)



2.2.6 Measures taken by reacting countries

In the majority of cases where the reacting country found the notified product on its national market (1 392 reactions), the measures taken were also indicated. In 80 cases (6%), those measures were ordered by the national authorities (compulsory measures). In 1 171 cases (84%), those measures were taken by the economic operators (voluntary measures). In 15 cases (1%), it was indicated that compulsory as well as voluntary measures were taken. In 126 cases (9%), no measures were indicated.

As it is explained later in this report, the RAPEX website now indicates next to each notification also the countries where measures have also been taken.

Figure 35 – Reactions by measures taken when notified products were found on the national market (absolute values)

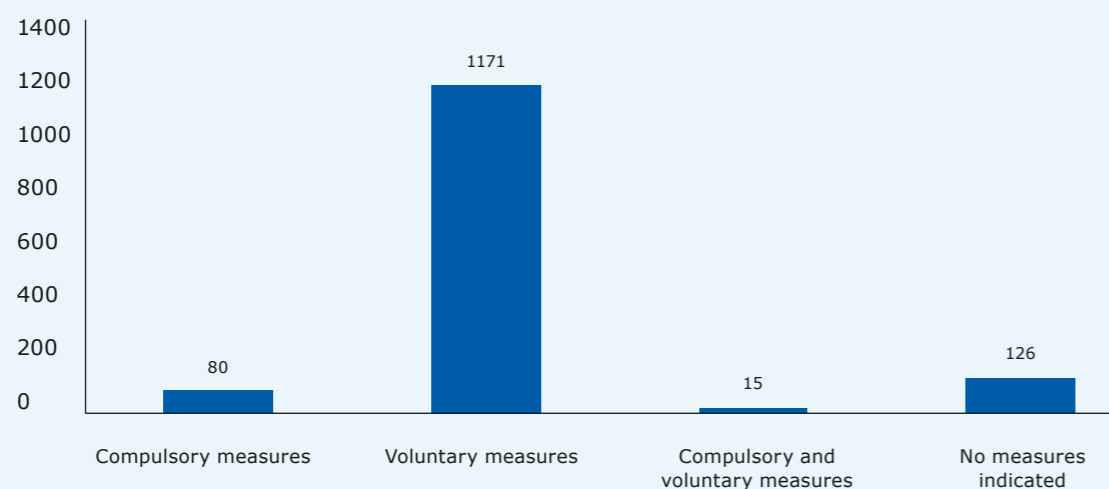
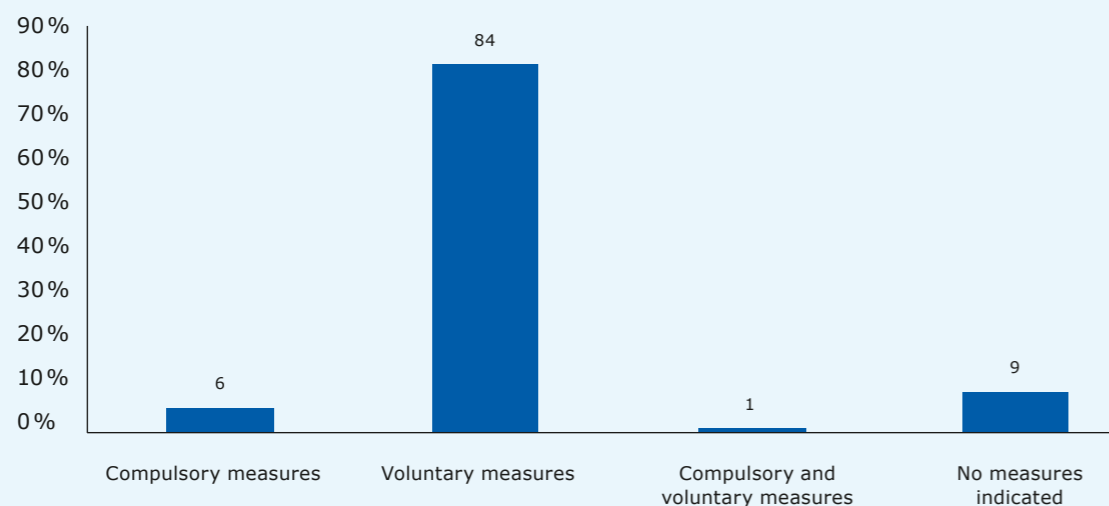


Figure 36 – Reactions by measures taken in the case the products were found on the national market (%)



3.1 Enforcement

To function well, the EU internal market relies on the effectiveness of enforcement. Effective enforcement of product safety legislation ensures that European citizens are protected from serious risks and threats which they cannot tackle as individuals. This is an important determinant in whether or not consumers feel their rights are protected.

National authorities play a key role in enforcement through market surveillance activities and they are responsible for ensuring that every actor on the market respects the product safety rules.

The European Commission plays a coordinating role in enforcement and supports the cooperation between Member State authorities responsible for market surveillance to ensure a level playing field throughout Europe.

3.1.1 The new RAPEX guidelines

On 16 December 2009, the Commission adopted Decision 2010/15/EU laying down the new guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and the notification procedure established under Article 11 of Directive 2001/95/EC³ ('the new RAPEX guidelines'). The new RAPEX guidelines introduced by Decision 2010/15/EU replaced the previous guidelines laid down by Commission Decision 2004/418/EC⁴.

Need for change

Since 2004 (when the previous RAPEX guidelines were adopted), the total number of notifications submitted every year under the RAPEX and Article 11 notification procedures has increased five-fold (to 1 993) and is still growing. Despite the visible achievements of RAPEX as a reliable system recognised worldwide, the Commission and the Member States agreed on the necessity to adopt new, improved RAPEX guidelines.

The decision to revise the RAPEX guidelines was based mainly on the following points:

- the RAPEX Network must be able to respond to change and new challenges, such as: a) the significant increase in the number of notifications sent through RAPEX which have to be followed up in all Member States, b) the need to increase the traceability of dangerous products, by providing more detailed and precise information about the dangerous products notified via RAPEX, c) the need to strengthen and broaden cooperation between market surveillance and customs authorities, and d) enhanced cooperation and exchange of information with third countries, such as China and the US, on dangerous consumer products and corrective measures,
- the forthcoming new on-line application for RAPEX and Article 11 notification procedures called "GRAS/RAPEX", and the newly established application for notifications on dangerous products submitted by businesses, called "Business Application"⁵,
- the agreed procedures must reflect best practices developed over the years by the Member States and the Commission RAPEX Team to ensure even more efficient and effective operation.

³ OJ L 22, 26.1.2010, p. 1

⁴ OJ L 151, 30.4.2004, p. 83

⁵ For more information on "Business Application", please see Chapter 3.2.2

What's new?

While the scope of the RAPEX guidelines remains unchanged under Decision 2010/15/EU (RAPEX and Article 11 notification procedure), the guidelines more precisely and comprehensively:

- identify the scope of the two procedures,⁶
- clarify the notification criteria (including the definition of products and measures covered by and excluded from the notification procedures, a redefined concept of the "cross-border effect", clearer provisions for risk assessment),
- define the various stages and aspects of the notification and reaction procedures (such as the classification of notifications, content of notifications and reactions, examination and validation of notifications and reactions by the Commission, follow-up to notifications), including organisational aspects (such as organisation of RAPEX networks at EU and national levels, tasks of the RAPEX Contact Points, means of communication).



The new guidelines also regulate aspects of the RAPEX system and Article 11 notification procedure which had not previously been subject to specific rules, and which, however, are essential for the functioning of the procedure. Most of these new provisions concern activities which have been regularly (but not always consistently, due to the lack of specific provisions) performed by national authorities or the Commission, including:

- permanent withdrawal of notifications from the system,
- temporary removal of notifications from the RAPEX website,
- information on dangerous products sent by the Commission,
- investigations carried out by the Commission to assess the safety of a product,
- confidentiality rules,
- types of reactions and a reaction form.

Another fundamentally revised element in the RAPEX guidelines is the new improved risk assessment method that was developed by a dedicated working group of Member State experts and is recommended to all national authorities in order to assess the safety of consumer products.

Additional information

Decision 2010/15/EU laying down the new guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC is available on the Commission website: http://ec.europa.eu/consumers/safety/RAPEX/guidelines_states_en.htm

⁶ For more information on the new Risk Assessment Method for consumer products, please see Chapter 3.1.3.1

3.1.2 RAPEX and other product safety indicators

3.1.2.1 Eurobarometers⁷

In 2009, the Commission run two Eurobarometer surveys, consulting both consumers⁸ and retailers⁹ about their perception of consumer law enforcement in Europe. These surveys provided indications about awareness and knowledge of product safety laws, complaints, perceived compliance, and market surveillance activities.

Few consumers indicated that product safety is one of their concerns when making a purchase: 21% had looked for safety-related information in the past twelve months, either on product labels or on the websites of national authorities.

The surveys showed that 25% of consumers (versus 18% in 2008) and 16% of retailers (similar to the percentage in 2008) thought that a significant number of products were unsafe. There were big differences between Member States, the best perceived safety levels occurring in Finland, Ireland and the UK. Overall, a majority of EU consumers (68%) had heard about non-food products being recalled from the market and, on average, 10% of consumers who heard of recalls were personally affected. [58% of the retailers in the EU felt well-informed about the rules and regulations relating to product safety and almost 4 out of 10 (38%) retailers who sell 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 in 2009 agreed that national public authorities actively monitor and ensure compliance with product safety legislation in their sector and about 3 out of 10 (29%) retailers said that authorities had checked the safety of the product they were selling. Furthermore, 12% of retailers reported to have received complaints from consumers about the safety of a product they sold, and 7% said they were aware that their competitors knowingly sold unsafe products in the past year.

3.1.2.2 Consumer Market Scoreboard

In 2009, the Commission published the second edition of the "Consumer Markets Scoreboard"¹⁰, a publication that monitors the performance of markets in terms of economic and social outcomes for consumers. Product safety is one of the five key areas, as it plays an essential role in building consumer welfare and confidence.

The main conclusion from this edition, which focuses on services, is that consumers are less satisfied and experience more problems with services than with goods markets.

The third section of the Scoreboard, "Country Consumer Statistics", provides detailed figures and a brief analysis on enforcement and consumer empowerment in the 27 Member States. Regarding product safety, in addition to RAPEX statistics, several enforcement indicators collected from the Member States authorities were made public (e.g. total budget for market surveillance or the number of inspectors).

⁷ http://ec.europa.eu/consumers/strategy/facts_eurobar_en.htm

⁸ Flash Eurobarometer 282 – Attitudes towards cross-border sales and consumer protection

⁹ Flash Eurobarometer 278 – Business attitudes towards enforcement and redress in the internal market

¹⁰ http://ec.europa.eu/consumers/strategy/facts_en.htm#CMS

3.1.2.3 Enforcement Indicators

As the Commission plays a coordinating role in product safety enforcement in the EU and is responsible for checking that Member States comply with their Treaty and regulatory obligations, it is important that it understands the enforcement activities and capabilities of each Member State.

An expert group composed of members of the GPSD (General Product Safety Directive) and CPC (Consumer Protection Cooperation) committees was set up in 2009 to identify a set of the most suitable enforcement indicators.

Some general findings of this project:

- Despite limited budgetary and human resources, the national authorities responsible for market surveillance are making great efforts to ensure the safety of products placed on the European Internal Market.
- In several Member States, such detailed information as required in the questionnaire is not collected, resulting in their inability to provide any reliable reply.

Statistically significant results will be included in the special section dedicated to enforcement of the 3rd Consumer Market Scoreboard, due to be published in March 2010.



3.1.3 Better tools and capacity building:

3.1.3.1 Risk assessment methodology

The new draft Risk Assessment Guidelines (RAGs) for consumer products were finalised and included in the RAPEX Management Guidelines and adopted at the end of 2009. A modern and transparent risk assessment method is now available for use within RAPEX, which should help to provide more consistent risk assessments.

As regards chemicals, the RAGs recommend the use of specific risk assessment methods. Assessing, for example, the risk posed by N-Nitrosodiethanolamine (NDELA), which is classified as carcinogenic, requires the development of very detailed knowledge of consumer exposure scenarios. Its presence in cosmetics such as shower gels, mascara or hand cleaning cream has led to different risk assessments within RAPEX, ranging from a "serious" to "negligible" risk. In order to level out these differences, a specialised expert group was convened in late 2009. It has taken the first steps towards finding a solution, and the matter is expected to be concluded in 2010.

3.1.3.2 Market surveillance coordination and cooperation

2009 was again a successful year for market surveillance cooperation in Europe. PROSAFE, an informal network of national market surveillance officers, presented, on behalf of the Member States, five proposals for new joint actions on helmets, baby-walkers, child-appealing appliances, sun beds and lighters. The Commission awarded co-funding to all of them, for a total amount of EUR 1.2 million. The exchange of officials programme attracted 22 applications, an increase of over 100% compared to last year.

Three other joint actions (for lighters, sun beds, and cords and drawstrings in children's clothing) presented their final results during workshops in Brussels. These actions have shown a significant level of coordination activity and good results, including:

For lighters:

In the 13 participating Member States, almost 3 000 inspections were carried out by national market surveillance authorities, and Customs Authorities inspected close to 8 000 incoming consignments. As a result, measures were taken against more than 600 models of lighters (representing millions of individual products) because they were found to be dangerous or because the economic operator did not possess the required technical documentation.

For sun beds:

The 10 market surveillance authorities participating in the sun bed cross-border action carried out investigations at more than 350 locations and inspected more than 550 sun beds. The results showed that guidance to consumer in tanning studios is seldom provided and is often not verifiable; labelling of sun beds fails to comply in at least 20% of cases; and the maximum Erythemally Weighted Irradiation (EWI)¹¹ values for sun beds are violated in at least one out of every 7 sun beds made available at tanning services.

For cords and drawstrings in children's clothes:

Participating market surveillance authorities in 11 Member States carried out more than 3 500 inspections, mainly at retailers, checking more than 11 000 garments. As part of their border controls, customs authorities inspected approximately 60 consignments of clothes. As a result, measures were taken to remove more than 1 400 garments from the market, the majority of which intended for small children (0–7 years), as they did not comply with the safety provisions laid down in the relevant European standard EN 14682.



Following a successful joint seminar in Austria in 2008, cooperation between customs and market surveillance authorities further increased in 2009. This was particularly evident in the various joint actions in which customs officials participated, such as those concerning lighters and a project in the Baltic Sea Region focussing specifically on the cooperation between market surveillance and border control authorities. Moreover, first steps were taken to develop specific guidance for customs authorities on how to deal with consumer product safety issues in their daily work. This action will continue in 2010.

3.1.3.3 RAPEX seminars

The European Commission organises RAPEX seminars for national market surveillance and customs authorities to strengthen their knowledge of the RAPEX system and to improve the overall enforcement capacity of the Member States. In 2009, training sessions took place in Romania and Cyprus. Between 2006 and 2009, 25 countries benefited from RAPEX seminars.

Several Member States have already expressed an interest in hosting a RAPEX seminar in 2010, also in light of the entry into force of the New Legislative Framework and the parallel application with the GPSD, the new RAPEX guidelines and the new risk assessment method.

¹¹ Erythemally Weighted Irradiation (EWI) – a measure for Ultra Violet radiation

3.2 Compliance by businesses

3.2.1 Partnerships with the private sector

Following the signing, in 2008, of two voluntary agreements with the toy sector, 2009 was characterised by strenuous efforts in view of the revised Toy Safety Directive, focused mainly on the training of economic operators on forthcoming changes to the regulatory framework. The Commissioner met with toy representatives in November 2009 to take stock of progress made with the implementation of the agreements. The meeting underlined the commitment of the toy sector to continue its efforts to ensure toy safety and also resulted in the publication of 12 toy safety tips for consumers before Christmas.

3.2.2 GPSD Business Application

In May 2009, the Commission introduced a new on-line system in the product safety area for producers and distributors called "Business Application".

Objective

The application was established to simplify the procedure for producers and distributors to fulfil their obligation (as laid down in Article 5(3) of the GPSD) to notify the competent national authorities of any dangerous consumer products placed on the EU market. This secure on-line system allows producers and distributors to download a notification form which they can use to submit information about dangerous products to the database of the application, where it becomes available to the competent authorities of Member States and EEA countries. The application, therefore, makes it possible for producers and distributors to alert all countries concerned at the same time in one step, thus simplifying and speeding up the process. Access to the database where all the notifications are stored is restricted to the competent national authorities only, and neither business nor consumers have access to it.

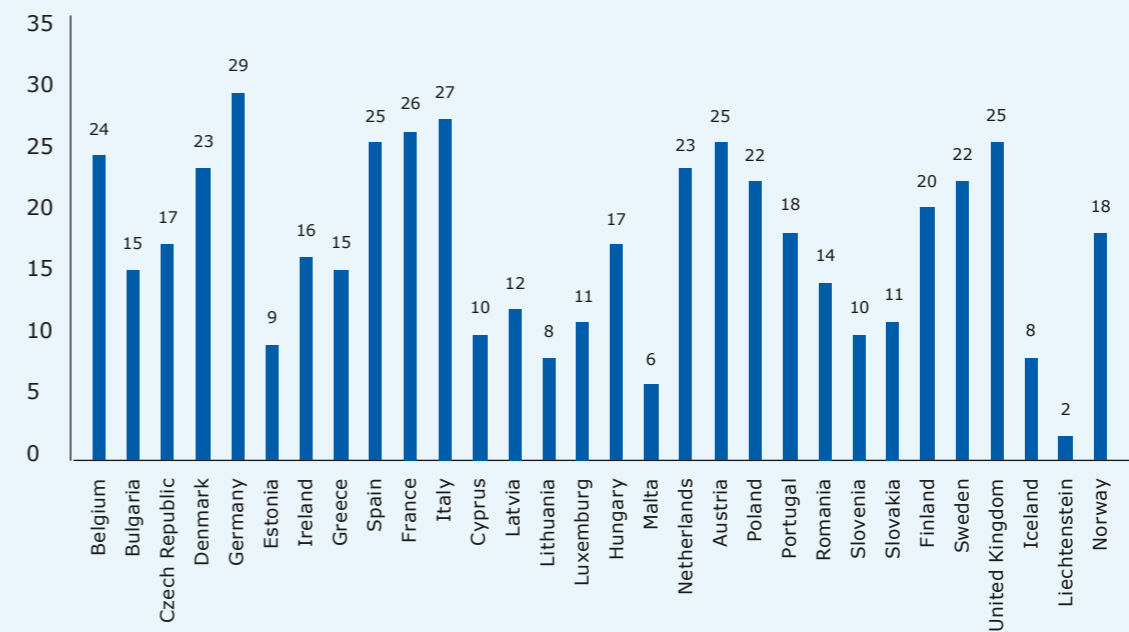
First experience

Since its launch, operation of the "Business Application" has proved successful. In total, 44 notifications (including updates) sent through the application in 2009 by producers and distributors have been accepted by the competent national authorities.

In 2009, all the Member States and EEA countries have been notified via "Business Application". Germany, Italy, France, Spain, Austria and United Kingdom are the Member States most often notified through the application by producers and distributors.

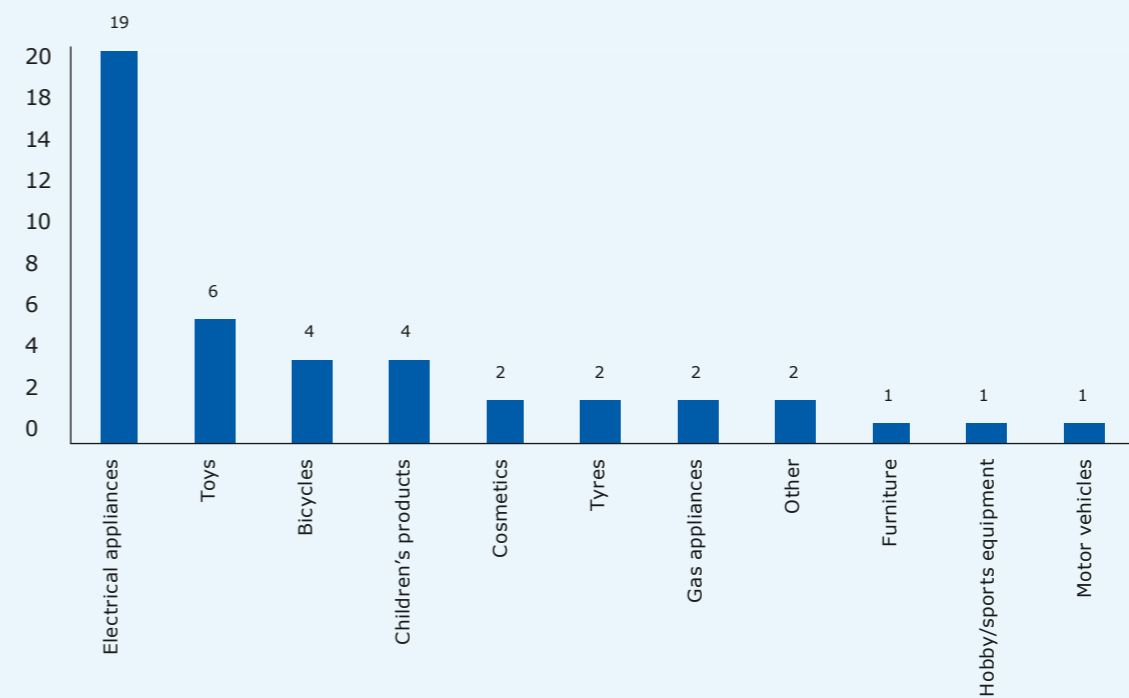


Figure 37 – Number of notifications received by country



Notifications submitted through the application concerned 11 different product categories, including electrical appliances, toys, children's products, cosmetics.

Figure 38 – Number of notifications by product category



The data provided through the application by producers and distributors was in most cases complete and of good quality. The notifications submitted contained detailed information regarding a) the 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.

Additional information

For additional information on "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/guidelines_business_en.htm

3.3 Developments relating to specific products and risks

3.3.1 Measures to address risks from Dimethyl fumarate (DMF)

A Community Measure under Article 13 of the GPSD, initiated at the end of 2008, was adopted in March 2009 in the form of Decision 2009/251/EC¹². It requires Member States to ensure that any consumer product containing DMF, an anti-mould chemical substance that is strongly sensitising and can cause severe skin lesions, is not placed or made available on the market. Although the first reports of skin damage implicated imported furniture, primarily leather seats, and leather shoes, the Commission found it judicious to ban DMF from all consumer products, it being reasonably foreseeable that DMF could be used in any product, whether of leather, fabric or other material. Notifications from Member States enforcing the ban throughout 2009 confirmed this comprehensive approach¹³. The Measure also requires that such products are recalled from consumers and that consumers are adequately informed about the risk. The Decision thus harmonised the protective actions expected in all Member States.

Since the Measure is only valid for one year, in accordance with Article 13 of the Directive, it will be prolonged for further periods of one year until a more permanent measure is put in place under EU legislation. The first prolongation was initiated at the end of 2009.

3.3.2 Personal music players

A conference on the risks of hearing loss from personal music players was held in Brussels on 27 January 2009. The conference brought together the European Commission, EU Member States, scientists, standard makers, industry, consumer organisations and other stakeholders to discuss what action should be taken to protect consumers.

Following the conference, a Commission Decision (2009/490/EC) was adopted on 23 June 2009 which defines the safety requirements for personal music players in order to avoid the risk of hearing damage. In particular, the Decision states that, first, exposure to high sound levels shall be limited in order to avoid hearing damage and, second, users shall be provided with adequate warnings and information on the risks of hearing damage.

A mandate to develop new safety standards, based on the safety requirements in the Decision, was subsequently sent to the European Electrical Standardisation Committee (CENELEC) on 28 September 2009. It is expected that the standards will be adopted by the end of 2011.

3.3.3 New rules for magnets in toys

The Commission decision relating to warnings on magnets in toys was not extended because the risk was addressed in the comprehensive revision and the adoption of the new legislation on the safety of toys and in the revised relevant standard (Directive 2009/48/EC)¹⁴

3.3.4 Lighters

Following the adoption in 2008 of specific child safety requirements to be met by European standards for lighters, the European standardisation organisation CEN started its work on the revision of European standard EN 13869-2002: Lighters – Child-resistance for lighters – safety requirements and test methods. Good progress was made but further work is necessary in order to produce a suitable revised standard.

Pending the revision process, the Commission also adopted a follow-up Decision extending, for the third time, the validity of the requirements put in place in 2006, thus prohibiting the sale of non-child resistant and novelty lighters to consumers until 11 March 2010. A further prolongation is planned in 2010.

3.3.5 Ladders

Ladders consistently rank in the "Top-10" list of most dangerous utensils and tools found in the home in Europe. In the area of "Do-It-Yourself", ladders have become the most dangerous consumer product, and were involved in 39% of fractures recorded in the home between 2003 and 2005 in Europe.

Safety requirements should be conceived in such a way as to eliminate the risk already at the design stage. In 1999, the Commission issued a mandate to CEN to revise the relevant European standard on ladders (EN 131) as, in the Commission's view, the standard needed thorough improvement.

A revised version of EN 131 Part 1 has been published along with new EN 131 Parts 3 and 4. These parts deal with definitions, user instructions and hinged ladders. A draft revised version of Part 2, concerning stability requirements, was rejected in 2007.

Given this unsatisfactory outcome, the Commission has been actively working with the Member States and CEN to achieve completion of the mandated work. In 2009, CEN agreed to publish a revised version of EN 131-2 which fulfils some of the requirements of the mandate. At the same time, it was also agreed to set up a dedicated working group whose task would be to identify relevant requirements and adequate tests, in particular for the stability and durability of ladders, in view of completion of the mandate.

3.3.6 Reduced ignition propensity cigarettes

Cigarettes left unattended are a leading cause of fatal fires (the leading cause in some Member States). Work to introduce in the EU reduced ignition propensity (RIP) cigarettes, which rapidly self-extinguish when laid down unattended, has been progressing within the concerned standardisation organisations. The Joint Working Group set up within the International Standardisation Organisation (ISO) met during 2009 and has accelerated its work to deliver the required testing method on time. The European Committee for Standardisation (CEN) is expected to deliver the safety standard by the end of August 2010.

3.3.7 Children's equipment/childcare articles

In December 2009, the Commission adopted the safety requirements for baby bath articles and childproof locks for windows and balcony doors. In October 2009, the Member States adopted the requirements for the safety of 5 products commonly used in the sleep environment of newborns and young children. These requirements are the first step towards submitting the relevant mandates to CEN. All these products are linked to a significant number of accidents, including fatal ones, involving children.



¹² OJ L 74, 20.3.2009, p. 32–34

¹³ http://ec.europa.eu/consumers/dyna/RAPEX/RAPEX_archives_en.cfm. Search for DMF.

¹⁴ OJ L 170, 30.6.2009, p. 1–37

3.4 International cooperation towards global governance

3.4.1 Bilateral cooperation

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

China

Following the signing in November 2008 of an upgraded Memorandum of Understanding (MoU) between the Commission's Directorate-General for Health and Consumers and the Chinese Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) – the Chinese Ministry responsible for ensuring the safety of exported Chinese consumer products – 2009 saw further strengthening of the collaboration between both partners.

In May, a Chinese product safety expert from AQSIQ started a 3-week internship with the Directorate General for Health and Consumers aimed at learning first-hand about the operation of the consumer product safety framework in Europe. This was followed by visits to France, the Netherlands and the United Kingdom to obtain a better understanding of the market surveillance practice in the Member States.

In June, the annual meeting of the market surveillance/consumer product safety Working Group under the MoU took place in Beijing. The discussions focused on exchanging information on the main developments over the preceding half year and on options for future cooperation for example regarding coordinated surveillance actions. Moreover, a roundtable discussion on the impact of the financial crisis on product safety in China took place, showing that, despite many negative effects, it has resulted in a positive influence on product quality and safety, through consolidation in the industry and more focus on testing and assurance efforts.

In October a Commission delegation visited China to train government officials on the revised risk assessment methodology under the RAPEX system.

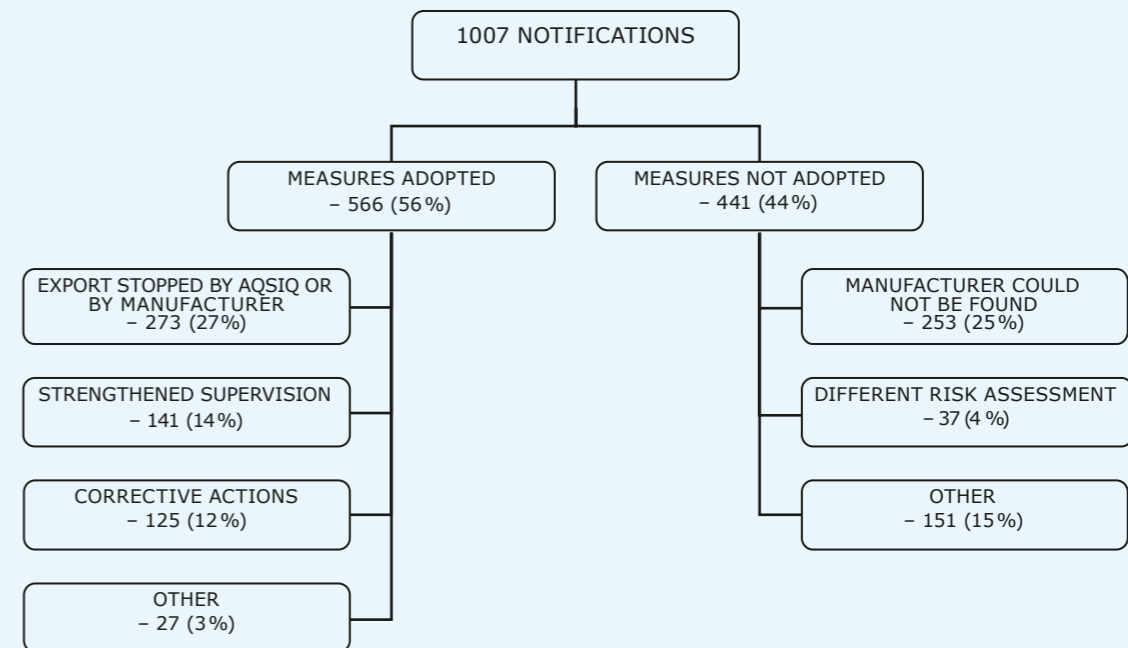
RAPEX-China

AQSIQ has submitted 11 reports to DG SANCO on enforcement actions carried out with regard to RAPEX notifications exchanged via the 'RAPEX-CHINA' system between September 2006 (when the application was established) and August 2009.

During this period between 2006 and 2009, AQSIQ has investigated and, where necessary, adopted measures in relation to 1 007 RAPEX notifications. Analyses of the received reports show that, on average, AQSIQ investigates 91 RAPEX cases over a three-month period.



Figure 39 – Actions taken by AQSIQ (total figures)



Challenges

Traceability has been the biggest challenge in the operation of the "RAPEX-CHINA" system over these three years. In 253 (25%) out of 1 007 RAPEX cases AQSIQ was not able to find the responsible Chinese companies and thus could not adopt appropriate restrictive measures. The following reasons for such situations stem from the AQSIQ reports: (a) limited resources which do not always allow national authorities to thoroughly investigate this particular aspect of the case, (b) the information about the Chinese companies submitted by the Member States, is incorrect or inaccurate, (c) the Chinese company denies its role in the production or export of a notified product and it does not keep any orders, contracts, invoices or other documents which could prove its involvement, (d) change of address of the responsible Chinese company or bankruptcy, (e) the great complexity of the multiple trade relations of the responsible Chinese authorities.

Reports also show malpractice and negligence of certain European importers. Based on the feedback received from AQSIQ, it can be concluded that some of the dangerous products subject to AQSIQ's investigations were manufactured by Chinese companies according to improper specifications provided by EU importers. Furthermore, in many cases, EU importers have not specified any safety requirements for purchased products, have not requested any tests before shipping products to the EU or have not had products posing risks to consumers approved before shipping them to the EU. These examples show that both the Commission services and the Member States should continue their efforts in informing companies with regard to the obligations of the product safety legislation.

Ongoing and future challenges

United States

In November 2009, the Council authorised the European Commission to open negotiations with the United States of America for an agreement on cooperation and information exchange in the area of consumer product safety. By entering into negotiations with the United States of America the European Commission aims to:

- establish a regular dialogue and co-operation on issues of common interest and formalise the already ongoing informal dialogue with the US Authorities in the product safety area;
- ensure, via cooperation and exchange of information, better protection for consumers both in the European Union and the United States of America.

In 2009, the toy safety working group established between the European Commission and the Consumer Product Safety Commission (CPSC) of the United States of America met three times. The working group provided an important forum to discuss matters common to the US and the EU in the toy safety area and to increase mutual understanding of each other's systems.

Switzerland

On 20 October 2008, the Council of the European Union had authorised the European Commission to enter into negotiations with the Swiss Confederation with a view to achieving greater cooperation and removing technical barriers to trade in the areas of consumers, food safety and health.

In 2009, three negotiation rounds have taken place where both parties discussed the scope of and the necessary criteria for the adoption of the agreement, and negotiations are still pending.

3.4.2 Multilateral cooperation

ICPSC

The International Consumer Product Safety Caucus (ICPSC) is an informal network bringing together governments and regulatory agencies around the world, with the aim of facilitating the exchange of information on consumer product safety issues and strengthening international cooperation in this area. The ICPSC had a productive year culminating in a workshop on product traceability and tracking labels organised in September in Stockholm. With over 70 participants representing a broad range of stakeholder interests, the workshop heard about the regulatory frameworks in place in different jurisdictions, existing solutions offered in the market and explored the requirements for global traceability systems.

OECD Roundtable

The OECD countries have committed to increasing product safety information-sharing across borders. Within this framework the OECD has started drafting a report on enhancing consumer product safety information sharing between public authorities. The report will be available in 2010. The European Commission has been taking active part in this process, including drafting the report.



4.1 The revision of the General Product Safety Directive

The legislative framework set up in 1992 by Directive 92/59/EEC and enhanced in 2004 with the entry into force of a renewed General Product Safety Directive (GPSD) (2001/95/EC) has established over almost two decades a market surveillance system based on the definition of specific roles and responsibilities for all market players – manufacturers and importers, national authorities, the European Commission and consumers. This system integrates the role of European standards for non-harmonised products. However, recurrent product safety alerts, either of global or regional relevance, have made apparent the need for a system which delivers more rapidly, efficiently and consistently throughout the EU and which, at the same time, is flexible enough to adapt to the challenges of globalisation.

The Commission has therefore announced its intention to review the GPSD with the aim to:

- align its provisions with the New Legislative Framework¹⁵ to secure smooth coordination between the general and sector-specific product safety rules,
- allow the market surveillance framework to live up to the speed of technological development and emergence of new risks,
- ensure proper enforcement of product safety rules.

4.2 Traceability

Traceability serves to identify economic operators in the entire supply chain for consumer products. With this information, corrective measures, such as product withdrawals and recalls, can be effectively put in place. Traceability has steadily grown in importance due to the integration and globalisation of markets and global sourcing of products. As the journey from the factory floor to the store shelf often spans the globe, ensuring traceability throughout the whole supply chain has become more challenging.

The GPSD contains general obligations for producers to provide traceability information on the product or its packaging. Nevertheless, it is up to the Member States to adopt concrete measures to implement such obligations. The number of notifications in which the product is untraceable has decreased significantly in comparison with previous years. However, there is still room for improvement, as products that pose a serious risk and whose country of origin is unknown still account for 7% of all RAPEX notifications and those where the brand/clear product identification is missing 14%.

The statistics under the RAPEX-China system have also made it clear that problems with traceability – not being able to trace the manufacturer of the product – are a major reason why the Chinese authorities cannot take corrective actions or stop dangerous goods at source. The activity reports received from AQSIQ indicate that, in almost half of the cases investigated, the lack of corrective measures was due to the fact that they could not trace the Chinese companies responsible for manufacturing or exporting the notified dangerous products into the EU.

Decision 768/2008/EC, which entered into force on 1 January 2010, requires the indication of the name and address of the manufacturer – and, in the case of imported products, both the importer and the manufacturer – as a general principle

¹⁵ Regulation (EC) No 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008 and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82–128

More details about the RAPEX system

for Community harmonisation legislation. Within the context of its revision, it is considered whether the GPSD should simply incorporate the same traceability requirements or what solution should be chosen.

Finally, following the successful international ICPC workshop on product traceability (see Chapter 3.4.2) and tracking labels organised in September 2009 in Stockholm, further work needs to be undertaken to drive international alignment of existing global traceability systems.

4.3 RAPEX operation: extension of RAPEX to new products and risks under the New Legislative Framework

This 2009 report is the last annual report in which the operation of the RAPEX system is limited to consumer products and risks to consumer health and safety. As of 1 January 2010, following the entry into force of Regulation (EC) No 765/2008 on the market surveillance framework for marketing of products¹⁶ (the "Regulation"), the scope of the RAPEX system is being extended to certain non-consumer products and also risks other than the risk to health and safety of consumers (risks to health and safety at workplace, environmental risks, security risks).

4.4 GRAS – new IT system

In 2010, the first version of a new IT application for the RAPEX system (called 'GRAS-RAPEX') should be handed over to national market surveillance authorities. 'GRAS-RAPEX' will replace the current RAPEX application called 'REIS', which has been in use since 2004.

In 2009, the project was given new impetus due to a change in the project management and the arrival of a new team of developers. Work concentrated mostly on the proper integration into the system of the new notification and reaction forms (introduced by the new RAPEX guidelines) and on the migration of RAPEX data from 'REIS' to 'GRAS-RAPEX'.

It is expected that 'GRAS-RAPEX', due to new functions and new applied solutions, will allow a greater number of authorities to cooperate with RAPEX and will facilitate and speed up the daily work of the national authorities and the Commission services with regard to RAPEX notifications.



4.5 Cooperation with customs authorities

With more and more products coming into the EU's internal market from third countries, it is becoming increasingly important to undertake surveillance activities at our external borders. This will require ever closer involvement of, and cooperation with, customs authorities, who are the gatekeepers of the internal market. Next to ongoing work on providing customs officials with practical guidance on how to address product safety concerns with incoming consignments, more effort will need to be made over the coming years to link existing information systems and to streamline risk analysis. Only by developing an effective network of surveillance authorities in Europe will it be possible to rise to the challenge of protecting European consumers in a global market place.

4.6 Improved monitoring of product safety enforcement in the EU

As mentioned in Chapter 3.1.2.3, improving the monitoring of product safety enforcement in the EU is a priority for the Commission. Already in 2009, the indicators collected were more reliable, indicating some strengths and weaknesses in the system. The data collected in 2008 and 2009 will become increasingly relevant when matched to similar information gathered during the coming years, which means that the project should continue on a yearly basis, allowing for the possibility to draw up a more accurate picture of how Member States are allocating resources and how efficient safety enforcement is, to the benefit of the European consumers and economic operators.

¹⁶ Regulation (EC) No 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30

5.1 Objective

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

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

5.2 The legal basis of RAPEX

The Directive on general product safety 2001/95/EC (GPSD)¹⁷ provides the legal framework for RAPEX. In addition, in 2010 the Commission introduced the new RAPEX Guidelines (new Decision 2010/15/EU¹⁸), which aim to facilitate the effective and consistent application of the provisions of the GPSD related to the notification procedure¹⁹.

The GPSD is available at:
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT>
 The RAPEX Guidelines are available at:
[http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418R\(01\):EN:HTML](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0418R(01):EN:HTML)

The RAPEX system is used to exchange information on dangerous, non-food, consumer products, including those covered by "sectoral" Directives (e.g. toys, cosmetics, electrical appliances, personal protective equipment, machinery, motor vehicles), which pose risks to the health and safety of consumers.

However, some of these "sectoral" Directives foresee a notification procedure known as the "Safeguard Clause", but its aim – to check the grounds for national measures which seek to restrict the free movement of products – differs from the RAPEX objectives. The RAPEX system allows for a rapid exchange of information on dangerous products in order to protect the health and safety of consumers.

Sectoral legislation relevant to consumer protection includes:

- Toys Directive 88/378/EEC (revised Directive in 2009)
- 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

¹⁷ OJ L 11, 15.1.2002, p. 4.

¹⁸ OJ L 151, 30.04.2004, p. 83.

¹⁹ For more information on the new RAPEX Guidelines please see Chapter 3.1.1

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. They are available at: http://ec.europa.eu/consumers/safety/RAPEX/key_docs_en.htm

5.3 When is RAPEX used?

5.3.1 RAPEX Notifications

According to the GPSD, the national authorities of Member States notify the European Commission, via the RAPEX system, of those measures taken to prevent or restrict the marketing or use of consumer products posing a serious risk to the health and safety of consumers and which may be available in at least two European countries. This obligation is laid down in Article 12 of the GPSD (see box).

What products are concerned by measures notified?

RAPEX is dedicated only to non-food consumer products, which are defined as:

- products which are intended for consumers;
- products which, even if not intended for consumers, are accessible to them (for example, a machine tool, originally intended for professional use, but which can be purchased in a shop by a consumer).

RAPEX covers consumer products that are purchased by consumers, as well as products provided to consumers in the context of a service, or products that are in the premises of the service providers and involve an active use by the consumer (for example, hairdryers in hotels and sunbeds, if operated almost exclusively by the consumer).

The most frequently notified consumer 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 consumer products. Certain products such as food, feed, medical devices and pharmaceuticals are excluded from the scope of RAPEX because information about such products is exchanged through specific alert systems established at European level. For example, the Rapid Alert System for Food and Feed (RASFF) is used to exchange information about dangerous food and feed.

What measures can be taken?

Member States notify through RAPEX dangerous consumer products that were subject to both measures ordered by national authorities and/or actions taken 'voluntarily' by producers and distributors. The most common measures are sales bans, withdrawals of dangerous products from the market and recalls of dangerous products from consumers.



What is a serious risk?

Products notified through the RAPEX system have to pose a "serious risk" to the health and safety of consumers. A "serious risk" is defined by the GPSD as one which requires rapid intervention by the public authorities, and includes risks of which the effects are not immediate. The national authorities are obliged to assess the risks posed by a product they intend to notify (using the risk assessment method provided in the RAPEX Guidelines), since only those products which pose a "serious risk" are required to be notified through RAPEX.

What is the cross-border effect?

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

5.3.2 Other types of information exchanged

The RAPEX system is also used for the exchange of other information about dangerous products available in Member States, as well as the adopted preventive or restrictive measures taken.

For example, Member States submit to the Commission through the RAPEX system information on measures ordered by the national authorities in relation to products that present only a moderate risk for consumers. These notifications come under Article 11 of the GPSD.

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

Information exchanged through RAPEX

RAPEX notifications

- **Notification under Article 12:** 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:** notifications of measures ordered by the national authorities in relation to products presenting a moderate risk.
- **Notifications 'for information':** notifications of measures ordered by the national authorities, or actions taken 'voluntarily' by producers or distributors in relation to dangerous products, disseminated for information purposes only due to insufficient product identification.

5.4 How does RAPEX work?

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

5.4.1 Role and obligations of national authorities

Each Member State has designated competent market surveillance authorities and granted them with 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 consumer products placed on the market, to test them in laboratories and – in cases where these products pose risks to consumers – order producers and distributors to stop their sale, withdraw them from the market and/or recall them from consumers.

In addition, each country participating in the system has also established a single national RAPEX Contact Point, which coordinates the operation of the RAPEX system at national level.

When the national authorities or a producer/distributor take measures which prevent or restrict the marketing or use of a consumer product posing serious risks to the health and safety of consumers, the RAPEX Contact Point submits to the Commission – using a standard notification form – information about the product and details regarding:

- 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.



AQSIQ	General Administration for Quality Supervision, Inspection and Quarantine of the People's Republic of China
Article 11 notification	Notification of measures or actions taken for products presenting a moderate risk
Article 12 notification	Notification of measures or actions taken for products presenting a serious risk
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 are not members of the European Union, namely Norway, Iceland and Liechtenstein
EU-27	All EU countries
'For information only' notification	Notification of measures or actions taken which the Commission disseminated to the National Contact Points for information only because they do not fall under the scope of Article 12 or Article 11 of the GPSD
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. stopping of sales, informing consumers, withdrawal from the market, recall from consumers) on the business' own initiative, without the intervention of a public authority

National contact details

National RAPEX Contact Points

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

Product safety information for consumers per country

Austria

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

Belgium

www.economie.fgov.be

Bulgaria

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

Cyprus

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

Czech Republic

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

Denmark

Informationscenter for miljø og sundhed www.miljoeogsundhed.dk/default.aspx?node=281
 The Danish Consumer Council www.forbrugerradet.dk/english/

Estonia

Consumer Protection Board www.tka.riik.ee

Finland

Safety Technology Authority (Tukes) www.tukes.fi

France

www.minefi.gouv.fr/DGCCRF

Germany

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

Greece

www.efpolis.gr

Hungary

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



Iceland

Neytendastofu/Consumer Agency www.neytendastofa.is

Ireland

National Consumer Agency www.consumerconnect.ie – e-mail: ask@consumerconnect.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 Handel und Transport (Office of Trade and Transport) www.aht.llv.li

Lithuania

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

Luxembourg

www.ilnas.lu

Malta

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

Netherlands

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

Norway

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

Poland

www.uokik.gov.pl

Portugal

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

Romania

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

Slovakia

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

Slovenia

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

Spain

Instituto Nacional del Consumo www.consumo-inc.es/Seguridad/home.htm

Sweden

Swedish Consumer Agency www.konsumentverket.se

United Kingdom

www.bis.gov.uk

European Commission**RAPEX:**

<http://ec.europa.eu/RAPEX>

Business application:

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

EU Commission, Directorate-General for Health and Consumers:

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

EU Commission, Directorate for Consumer Affairs:

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

EU Commissioner for Consumer Affairs, Mr John Dalli:

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

(Former) EU Commissioner for Consumer Affairs (2007–2009), Ms Meglena Kuneva:

http://ec.europa.eu/commission_barroso/kuneva/index_en.htm

EU Commission, Directorate-General for Enterprise and Industry – “New Approach” Sectoral

Directives: http://ec.europa.eu/enterprise/sectors_en.htm

EU Commission, Directorate-General for Taxation and Customs Union:

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

Specific products**Lighters:**

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

Toys:

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

Dimethyl fumarate (DMF):

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

Personal music players:

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

Consumer product safety regulation/enforcement agencies**CPSC (US Consumer Product Safety Commission):**

<http://www.cpsc.gov/>

AQSIQ (China Administration for Quality Supervision, Inspection and Quarantine):

<http://english.aqsiq.gov.cn/>

Health Canada:

<http://www.hc-sc.gc.ca/>

NITE (Japan, National Institute of Technology and Evaluation):

<http://www.nite.go.jp/index-e.html>

The Commission's RAPEX Team

KATS (Korean Agency for Technology & Standards):
<http://www.ats.go.kr/english/>

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

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

International consumer safety organisations

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

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

Market surveillance

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

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

ICSMS:
<http://www.icsms.org/icsms/App/index.jsp>

Standardisation

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

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

CENELEC:
<http://www.cenelec.eu/Cenelec/Homepage.htm>

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

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