13 December 2011

BEST PRACTICE TECHNIQUES IN MARKET SURVEILLANCE

REVISION OF RISK ASSESSMENT CHAPTERS (Chapter 10 + Annex B, C and I)

10 RISK ASSESSMENT

10.1 Introduction

10.1.1 Contents of this chapter

The focus in this chapter is entirely on the risk assessment of specific products in the context of market surveillance. It is based on the RAPEX Guidelines containing a specific method for risk assessment. These Guidelines explain the practical arrangements an authority needs to make in order to do sound risk assessment.

The following parts are dedicated to:

- data collection; what data are needed for an evidence-based risk assessment and how can you get access to them? Data on product use, injury data, test results of products, etc.
- practical recommendations to perform assessments; advantages and disadvantages of different methods.
- reporting risk assessments.

10.1.2 What is risk assessment?

Risk assessment is the process that estimates the risk that a product with dangerous properties poses on people, animals or property. (Note that risk in the context of the GPSD and the RAPEX guidelines focuses on risk posed to people. Other directives, e.g. the low voltage directive have a broader definition that includes “animals and property” as potential victims. Directives that deal with chemical risks often also consider the risk posed on the environment. The broader definition has been adopted in the presentation to make the concept of risk assessment as generally applicable as possible.) The process includes identification of potential hazards associated in particular with the non-compliances against standards or legislation and estimation of the probability that the hazards will lead to an injury.

In general the following equation defines risk:

Risk = Severity x probability

In practice, this equation is difficult to apply as the severity and the probability are seldom well-defined numbers:

- The severity is often given as a verbal qualitative description of an injury caused by a given dangerous property in the product.
- The probability is normally difficult to estimate. Often the market surveillance officer may find it difficult to decide on the most correct order of magnitude.

Risk assessment is carried out for a specific product (that is under investigation by the market surveillance authority) and the output is an estimate of the risk level that can go into the further steps of risk management and communication.

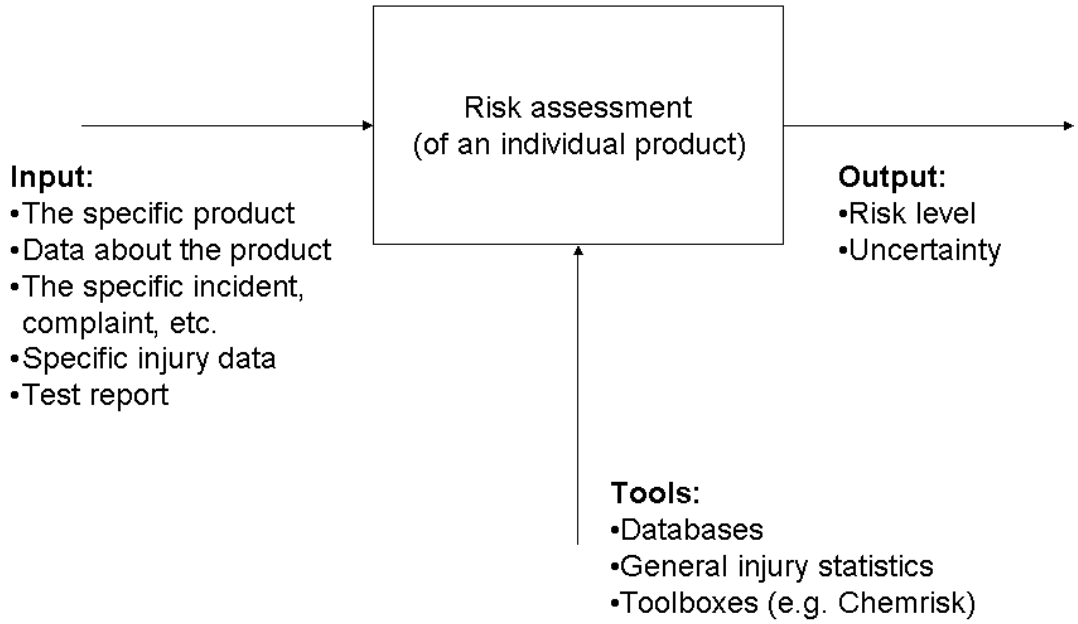

Figure 5 - Input, tools and output from risk assessment of a product

The process uses a number of data for input as indicated in the figure:

- The product itself.
- Data and further information about the product.
- Data about different possible injury scenarios and/or real accidents
- Injury data specific for the case.
- Test reports listing non-compliances that may indicate product hazards

A number of tools are identified in the figure

- Databases with e.g. anthropometric data, statistics on human behaviour, etc.
- General injury statistics

- Toolboxes like for instance the Chemrisks toolbox.

The output from the assessment will be

- The estimated risk level
- The estimated uncertainty in the risk level

10.1.3 Definition of essential terms in risk assessment of consumer products

In order to be sure that different organisations and Member States understand each other's risk assessments, all parties should use the same terminology with the same definitions. Several different frameworks of risk assessment are used, each with its own definitions. Some are common in engineering and accident prevention, in particular the framework adopted by ISO for the safety of machines (ISO 12100); others are common in food and feed, and in chemical safety. The ISO definitions are used in this book, as most RAPEX-notifications deal with mechanical risks. The differences between these two frameworks, including illustrative schemes are described in Annex B – Different frameworks of risk assessment.

Hazard

Source of danger involving the chance of being injured or harmed. A means of quantifying the hazard in a risk assessment is the severity of the possible injury or harm.

Product hazard

Hazard created by the properties of a product.

Risk

Balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time.

Risk assessment

Procedure for identifying and assessing hazards, consisting of three steps:

- identification of the seriousness of a hazard;
- determination of the probability that a consumer will be injured by that hazard;
- combination of the hazard with the probability.

Risk level

Degree of risk, which may be 'serious', 'high', 'medium' and 'low'. When the (highest) level of risk has been identified, the risk assessment is complete.

Risk management

Follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk.

(All definitions according to the RAPEX guidelines [23].)

10.1.4 Why should you use risk assessment?

Risk assessment is a core tool for market surveillance of product safety.

First, every market surveillance authority will have to set priorities for its market surveillance activities, because the number of products on the market is enormous and the resources are limited. The risk associated with a product group will obviously be an important criterion when setting priorities. Priority setting can take place on a strategic level (e.g. long-lasting focus on toys) and on a more tactic level (e.g. a project on wooden jig-saw puzzles for children in a particular year).

Secondly, it is necessary to determine the risk of specific products in the daily control actions. In particular, the effective operation of the system of rapid exchange of information on products presenting a serious risk (RAPEX) requires the authorities to use a fast, fact-based and consistent method of risk assessment.

Risk assessment is also an important tool for product safety work outside the market surveillance authorities. As an example, it should be used by designers, constructors and producers as part of the compliance assessment that ensures that only safe products are placed on the market.

10.1.5 How do you use the result of a risk assessment?

The result of a risk assessment is one important input in the risk management procedure. The purpose of the whole process is to control the risk. Examples of other inputs into risk management include the number of products on the market, the benefit of the product, the effort necessary to lower the risk, etc.

Risk management varies in different sectors, and low risk does not mean that no action is necessary. Technical progress may have lead to a high safety level in certain sectors as defined and agreed upon in harmonised standards.

In general, the level of risks that society accepts is determined by culture, risk perception, technical development, etc.

10.1.6 Risk assessment, conformity assessment or compliance?

Risk assessment should not be confused with compliance to legislation or conformity assessment (please refer to the “Guide to the implementation of directives based on the New Approach and the Global Approach”, also known as the “Blue Guide” [ref]; the figure below aims to clarify the differences):

- The basis of the New Approach is that only products in compliance with legislation or harmonised standards should be placed on the market. Authorities will take measures if products are found not to be in compliance after consultation with the producer). This is referred to as ‘compliance assessment’ in the figure below.
- Conformity assessment is the process by which a producer verifies (or asks a third party to verify) the compliance in principle **before** the product is placed on the market; this verification process continues during production. Conformity assessment implies checking if a given product meets all essential requirements (normally set out in a Directive and specified in harmonised standards). Conformity assessment includes a risk assessment: according to the “Blue Guide”, manufacturers need to carry out risk assessment to determine the essential requirement applicable to the product. Risk assessment is also undertaken during the production stage whenever a non-conformity is revealed.
- Risk assessment implies assessing the risk presented to consumers, animals, or property by a given product. Risk assessment may also be carried out by an authority or a producer when a hazard is found in a product to assist deciding on adequate and proportionate measures. It can be a tool both before and after placing a product on the market.

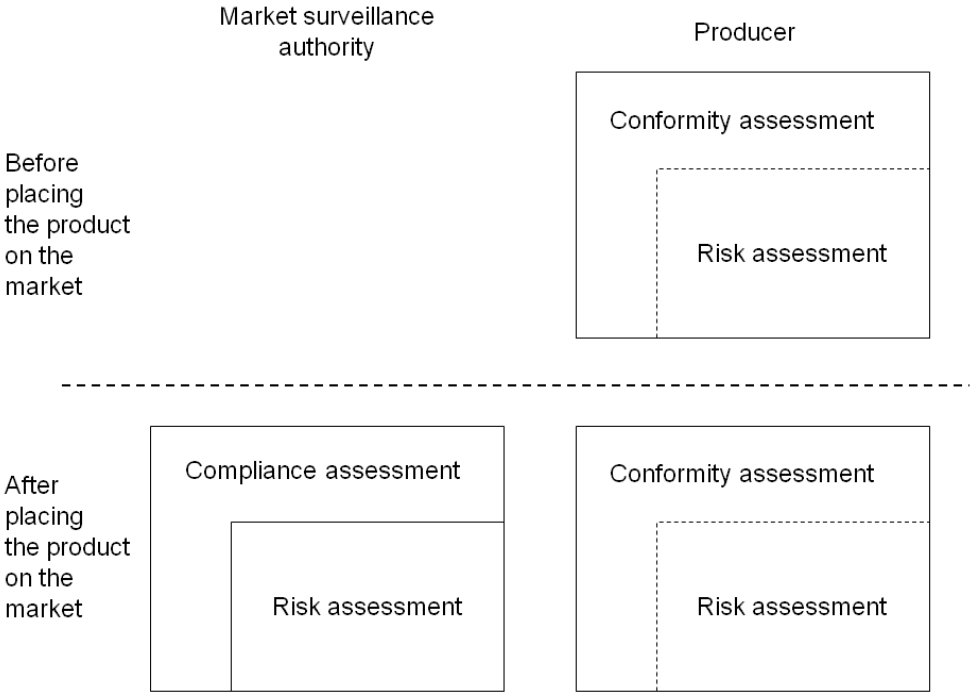

Figure 6 - Relations between conformity assessment, compliance assessment and risk assessment.

This follows the definition of “producer” that is given in the GPSD: A “producer” is to be understood as the manufacturer of the product, the manufacturer's representative, the importer into the EU of the product or other professionals in the supply chain, whose activities may affect the safety properties of a product. (The complete definition is found in the directive 2001/95/EC, article 2, item e.)

As can be seen from the figure, risk assessment is a step in conformity assessment and also plays a role if non-conformity is found. Thus, risk assessment is always carried out even if the user is not explicitly aware of it. Often conformity assessment is done using a harmonised standard. (This will be the case for a lot of products that are covered by New Approach Directives.) A harmonised standard can be expected to lay down all safety requirements, which means that the user can presume that the product conforms to the safety requirements if it complies with the standard. This implies that the risk assessment is taken care of by the standard, i.e. the requirements in the standard set out a safety level that has been assessed to represent a satisfactory level of risk to the consumer. The advantage of standards is that they present very detailed definitions of the requirements given in the directives. This eases the risk assessment for the producer by changing it from an open and broad analysis to a simpler checking of fulfilment of a number of requirements. Nevertheless, it has to be checked in all cases whether the product has features that are not covered by the standard and which may require a risk assessment on their own.

Conformity assessment is carried out by the producer before a product is placed on the market but it will also be a part of the production control that the producer must undertake after the product has been placed on the market. The purpose of the production control conformity assessment is to ensure that all batches of a production stay in conformity. Risk assessment would in general play an insignificant role in this phase of the production unless the producer discovers an unsafe non-conformity with the product. In that case the producer would use risk assessment to decide on the correct (proportionate) voluntary measures to be taken.

Market surveillance authorities may check if a given product (that is on the market) meets all requirements in a directive. This process includes among other things assessing a number of formal requirements as well as a number of safety related requirements. Again the assessment would often be done using a harmonised standard. The major difference to the conformity assessment carried out by the producer is that if the authority finds a non-conformity in the product then the authority would have to carry out a risk assessment (using (one of) the methods from this module) to decide on the risk level associated with the non-conformity. If the producer discovers a non-conformity during the conformity assessment the producer would have to modify the product to bring it in conformity. (If the product was already placed on the market then the producer would furthermore need to make a risk assessment to decide what measure should be taken against products already being on the market.)

It is important to realise that non-conformity does not necessarily imply a risk as is shown in the following two examples.

Example 1: A toy has been found by the market surveillance authorities to have sharp edges. A sharp edge in a toy presents a non-conformity because the toy does not comply with the requirements laid down in EN 71-1. The market surveillance authorities need to do a risk assessment to decide which measure is proportionate to the risk:

- *What is the potential hazard? Most likely it has to do with cutting of fingers but it might be worse depending upon the accessibility of the sharp edge, the sharpness and other geometrical data.*
- *How likely is it that the injury scenario will happen? This will also depend largely upon the accessibility of the edge but also on the exposure to the toy, the numbers it is sold in, the age of the users, etc.*
- *Does this lead to a serious risk or another risk level requiring action?*

Based on the result of the risk assessment and the other elements mentioned in section 10.1.5 above it is decided what to do with the products on the market: Do nothing, inform the consumers, stop the sales, or recall the products from the consumers.
A producer who discovers a sharp edge as part of a quality control programme will have to go through the same analysis to decide on the correct voluntary measure. (He or she might want to adopt more restrictive measures than required by the authority to avoid negative impacts on the brand.)

Example 2: The CE-marking on a toy is 3 mm high. The Toys directive requires a minimum height of 5 mm. Therefore the product does not comply with the directive and it must not be placed on the market. If the producer discovers this non-conformity on a toy that is placed on the market he would carry out the risk analysis. In this case, it will show that there is no immediate injury risk associated with the non-conformity. A producer might therefore choose to change the printing of the CE-marking on future deliveries without taking further action.

10.2 Performing the risk assessment

10.2.1 When do you start a risk assessment?

The starting point for a risk assessment of a specific product can be an incident that happened with a product. A consumer may complain about it, a supplier may report a problem, or the media may signal safety problems. Another possibility is that your own organisation systematically monitors trade, gathers information about certain products on the market and takes samples; in this process, a product may be found that looks unsafe at first sight.

From each starting point the same approach can be followed: find more information about the product, request data from the supplier, possibly perform tests, and start a risk assessment.

The main difference is that in case of an incident or complaint the focus will usually be on one scenario: something has already happened and next step is to analyse whether it is likely to happen again. However, one should distinguish between risk assessment and accident investigation. The purpose of an accident investigation is to find out what happened and to clarify what the injury scenario was. Furthermore it usually includes an assessment of the product in question. The purpose of a risk assessment to decide what level of risk is associated with the hazards in a product. Accident data is used in this analysis to assist defining the injury scenarios and estimate the probabilities but in a general way.

10.2.2 A presentation of the risk assessment process from the data collection to the resulting risk assessment

Risk assessment always focuses on three basic questions [6]:

1) What can go wrong?

2) If it does happen, what are the consequences?

3) How likely is it that it will happen?

In consumer product risk assessment, these questions can be translated to formal steps, using the terms defined in 8.1 (please refer to the figure):

- identification of the hazards, hazardous situations and harmful events (output: One or more injury scenarios);
- characterisation of the hazard and the harm (output: Severity of consequence; measure of damage);
- estimation of the likelihood of the hazardous situations, harmful events and various types of harm (output: Likelihood; level of exposure; probability of injury scenario).

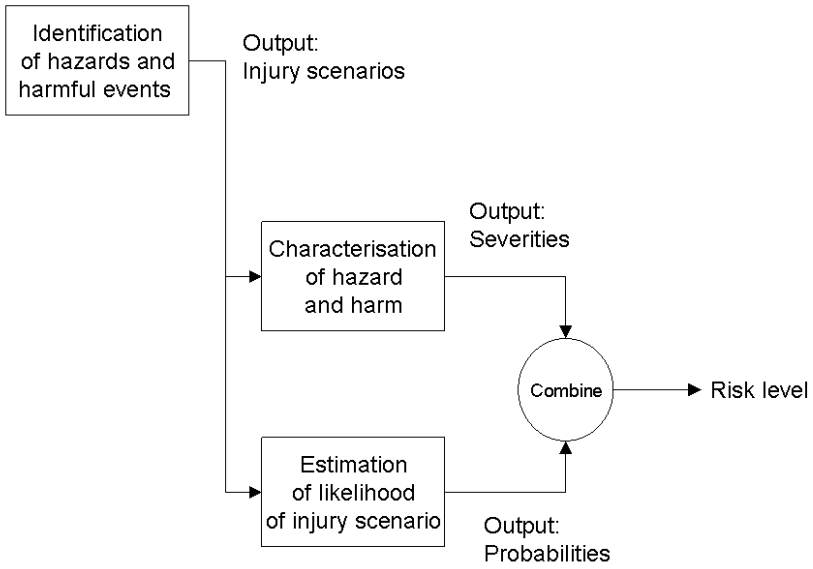

Figure 7 - The steps in risk assessment.

It is important to realise that risk is a combined measure of the likelihood and the severity. For example, all electric household appliances operate on 230 V. One injury scenario would be that the user touches a live wire and gets an electric chock, which can be fatal. However, the producer will normally work to make such a scenario very improbable by insulating the wires and keep all live parts inaccessible behind parts of insulating material. Therefore the probability of the harm and therefore the **risk** of the electrical equipment will be very low.

10.2.3 General procedure

The RAPEX Guidelines [23] constitute a harmonised procedure for supporting decisions on unsafe products. Its main features are:

- define the product under assessment;
- identify the hazard(s) under consideration;
- identify the type of consumer that is concerned;
- describe how the hazard inflicts on the consumer. This will usually result in several injury scenarios per product;
- use the combination of injury type and body part to estimate the severity of each injury scenario (table of examples);
- assess the likelihood each injury scenario by breaking it up into smaller steps that are essential for the injury. Find data on the likelihood of each small step;
- combine severity and probability in a matrix to determine the level of risk.

The procedure is illustrated in the next figure.

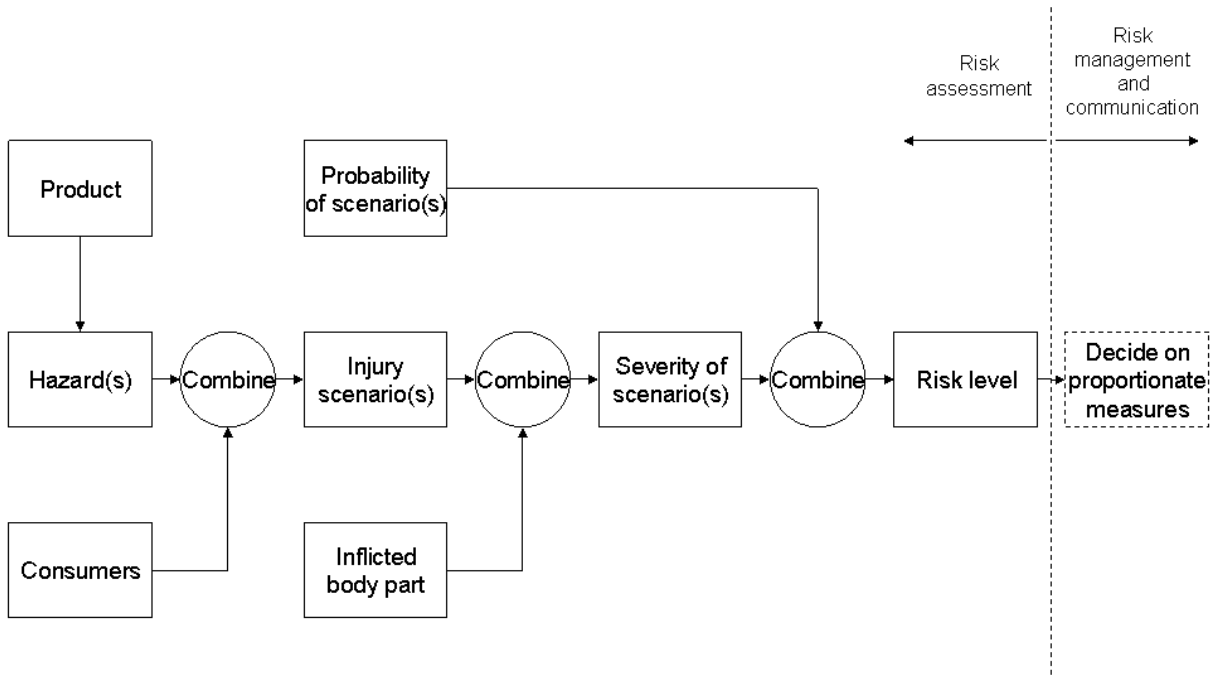

Figure 8 - Overview of the risk assessment procedure. (Please note that what is called "Risk management and communication" in the figure can also be referred to as "Risk Reduction" in other models for risk analysis. Please also see Annex B.)

The output from the risk assessment is an estimate of the risk level. The risk level is one of the inputs to the further risk management process and the decision on proportionate and adequate measures.

The European Commission has developed an IT tool that will guide and support the risk assessor. It is available on the Commission's website [24]. It is used in the following example to illustrate the risk assessment process. Other tools exist and can be used, but the IT tool from the Commission's website is the benchmark if two tools produce different results.

Example: RAPEX notification no. 0125/06 deals with a cross pane hammer with metal handle and black plastic grip. The hammer has three shortcomings:

1. The hammer head is insufficiently fastened on the handle.
2. The plastic grip breaks under normal strain.
3. The plastic grip is insufficiently fastened to the shaft of the hammer.

Figure 9 - RAPEX notification no. 0125/06 deals with a hammer where the handle breaks.

The steps in the risk assessment procedure for this example are as follows:

1. Define the product under assessment

   Cross pane hammer with metal handle and black plastic grip.

   This information is entered in the first two fields in the Risk Assessment Tool. In the 3rd field you can add a more detailed description of the case, the product or other relevant information. Please see figure 9a.

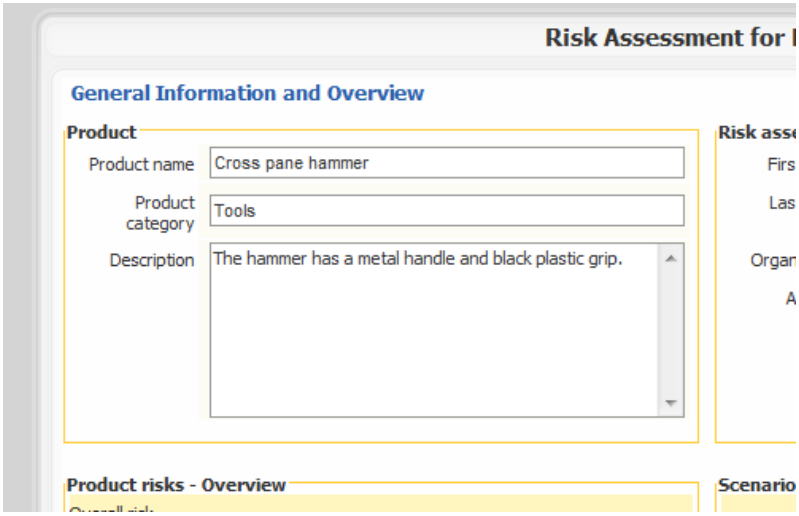

Figure 9a – Fill in product name, product category and any additional description.

2. Identify the type of consumer that is concerned

   The product is normally used by adults.

   Children may want to stand nearby to watch the adult working.

   This information is entered by creating a new scenario (click on the button "Create a scenario") and choosing from the drop box in the field Consumer type. Here "other consumers" has been selected (figure 9b).

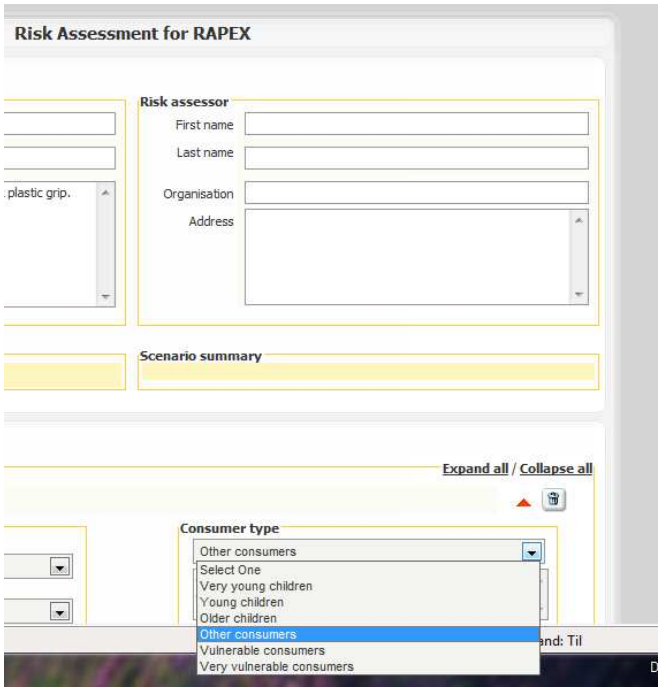

Figure 9b – Select appropriate consumer type.

3. Identify the hazard(s) under consideration

   The plastic grip has insufficient mechanical strength which means that it breaks under normal strain when the user hits a hard surface so that parts fall off and hit the user (only one hazard is considered in this example).

   This is entered in the fields describing the product hazard. First the user must select the hazard group. It is selected from the drop box. Here "Kinetic energy" is selected as the hazard has to do with parts that fly around with dangerously high speed, see figure 9c.

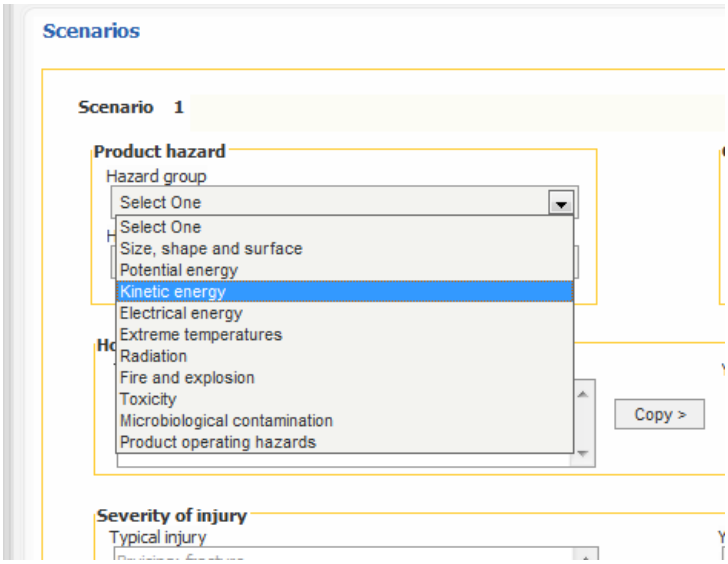

Figure 9c – Select the appropriate hazard group (describing the nature of the hazard).

Next the user must select the hazard. This is chosen from the drop box with the detailed description of the hazard. Here we choose "Flying parts". See figure 9d.

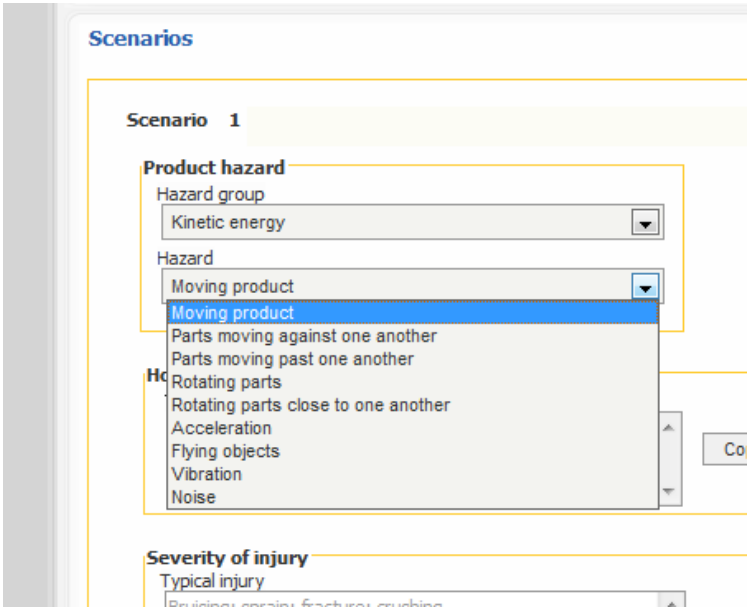

Figure 9d – Select the appropriate hazard for the chosen hazard group.

4. Describe how the hazard causes an injury to the consumer

   The upper part of the hammer bounces back and hits the user's arm. This causes bruising of the arm. (Only one injury scenario is developed in this example.)

   This information is entered in the field "Your injury scenario" as shown in figure 10:

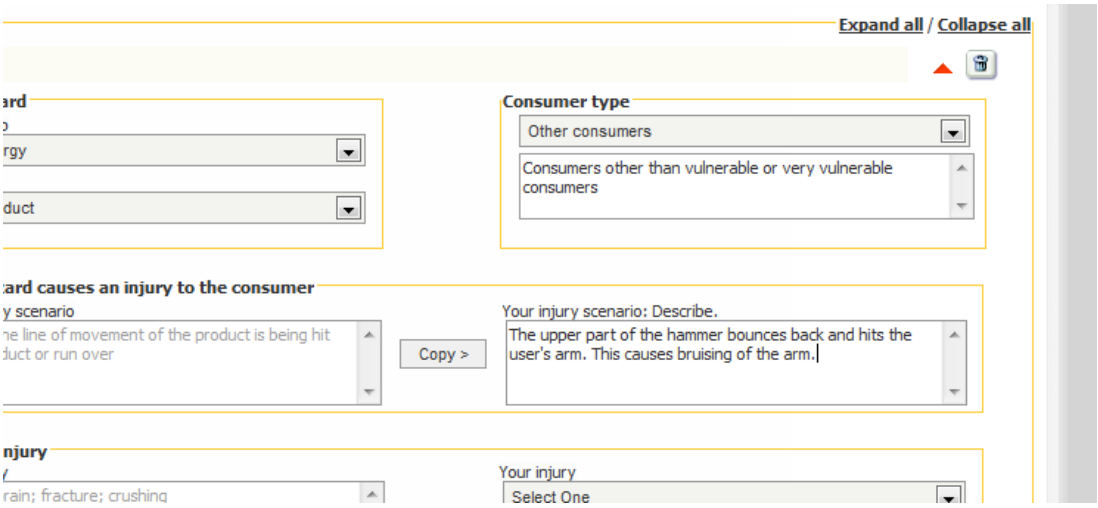

Figure 10 - The injury scenario parties described in the field "Your injury scenario".

5. Use the combination of injury type and body part to estimate the severity of the injury scenario

   This is done in the section "Severity of injury". The severity of the injury “Bruising of arm” is found in two steps. First you select the appropriate nature of the injury in the drop box in the field your injury as shown in figure 11. Here we select "Bruising (abrasion/contusion, swelling, oedema)".

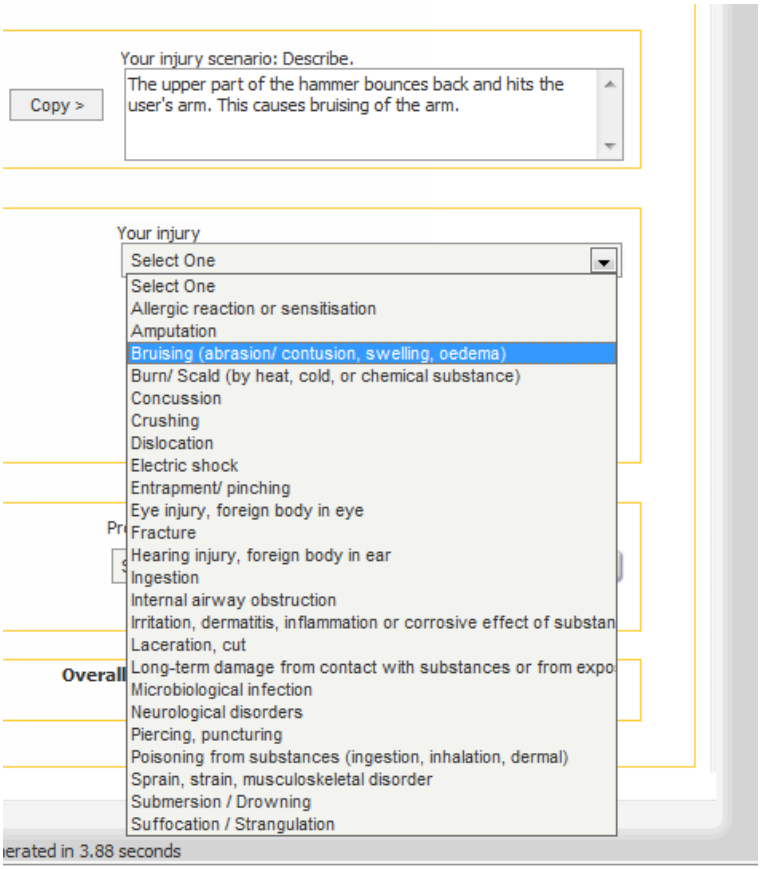

Figure 11 - The nature of the injury is selected in the field "Your injury".

The choice of "Bruising" means that the web tool provides four choices for the severity of the injury as shown in figure 12.

The bruising of the user's arm if hit by the hammer head seems to fit best with the category "< 50 cm2 on body", which translates to a level 1 injury so the first option is chosen.

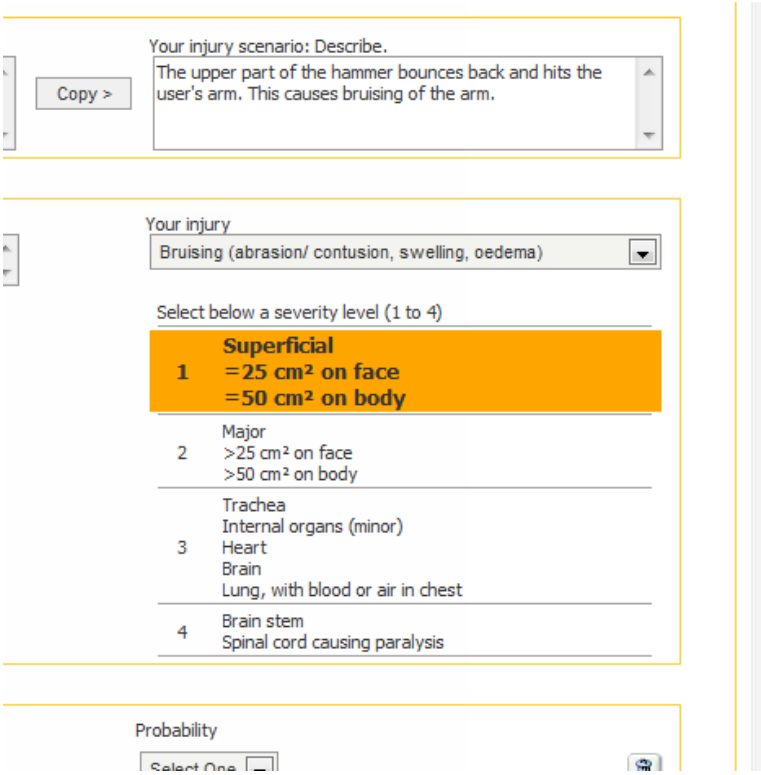

Figure 12 - The severity level is selected among the options offered.

6. Assess the likelihood of each injury scenario by breaking it up into smaller steps that are essential for the injury. Find data on the likelihood of each small step.

   The selected injury scenario is quite simple, as it only breaks up into two steps:

   Step 1: Handle breaking (with an estimated probability of p = 0.5 (50% probability): experts estimated that a large proportion of these products will break during their lifetime. Where possible, test reports should be taken into account to confirm such an estimate).

   Step 2: The upper parts hits the arm (with an estimated probability of p = 0.2 (20% probability): as the handle will usually break while someone is holding it and hits a hard surface, the hammer head will bounce back more or less in the direction of the user, but if the blow with the hammer was not perpendicular to the surface, the hammer head may also miss the arm. See also comment to Step 1).

   Probability factors can be determined in many ways, e.g. based on test data, based on accident statistics, selected from the PROSAFE databases with probability factors, etc.

   The steps and their probability are entered in the fields under "Probability of an injury" as shown in figure 13. This scenario has 2 steps so one extra step has to be added by use of the button "Add a Step to Injury".

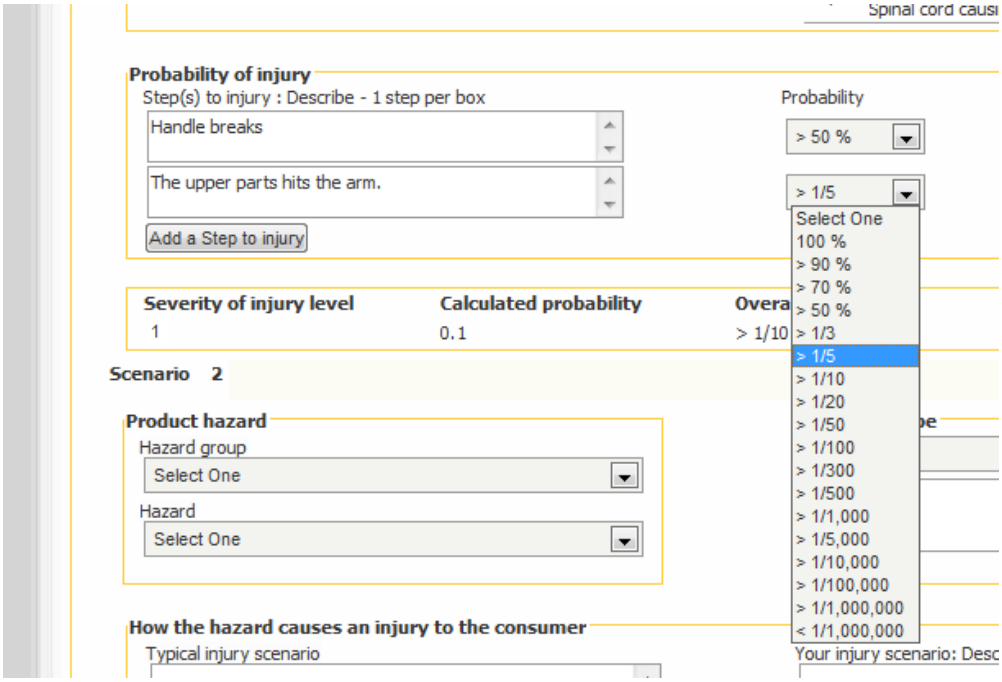

Figure 13 - The steps and the probabilities of the steps in the injury scenario are entered under "Probability of the injury".

7. Combine severity and probability to determine the level of risk.

   The resulting probability is calculated by the programme and compared to a scale with indicative statistical values. The resulting overall probability is combined with the severity of the injury and the resulting risk of the scenario is found. The programme displays the result in the bottom line of the scenario as shown in figure 14.

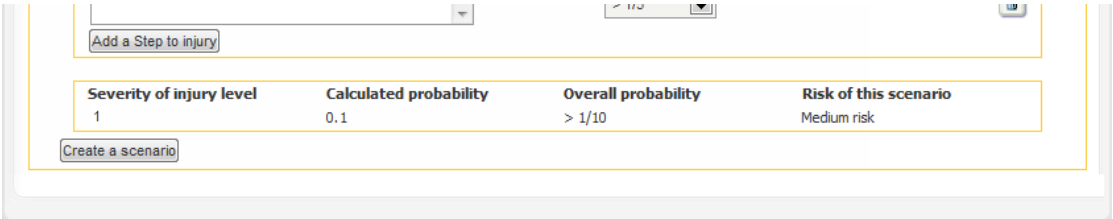

Figure 14 - The result of the risk assessment.

In this case the probabilities of each step in the injury scenario are multiplied to give >0.1. (Note that the programme only indicates the calculated probability as "0,1" even though it would be more correct to say ">0.1" as the result arises from multiplying the sub-probabilities ">50%" and ">1/5".)

This translates to an overall probability of ">1/10" as indicated.

The severity of the injury was level 1 (step 5).

The combination of “>1/10” and level 1 gives “medium risk” as can be seen in figure 15.

The combining of the severity and the probability is based on the table from the RAPEX guidelines [23]. The table is shown in figure 15.

Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		1	2	3	4
	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1,000	L	H	S	S
	> 1/10,000	L	M	H	S
	> 1/100,000	L	L	M	H
	> 1/1,000,000	L	L	L	M
	< 1/1,000,000	L	L	L	L

S –	Serious risk
H –	High risk
M –	Medium risk
L –	Low risk

Figure 15 - The matrix that is used for combining severity and probability

The above procedure considers a product that is unsafe in itself, e.g. a toy with small parts that can be swallowed, an electrical appliance that can cause fire or electric shock, a product with sharp edges, etc. The procedure can however also be used to assess the risk caused by protective equipment, i.e. products or equipment that is intended to protect the user against some risk even though such products are seldom unsafe in themselves. Such non-compliant products lead to a dangerous situation because the user relies on their protective properties and changes his behaviour accordingly. Many users will for instance not use a chain saw without protective trousers, glasses and helmet because they consider the risk for being injured too high. If they wear non-compliant protective trousers they will believe they are well protected and use the chain saw without further considerations.

When assessing the risks with such (non-compliant) products, the risk assessor should develop scenarios that presume that the user employs the protective equipment thereby exposing himself to a dangerous situation without knowing.

10.2.4 Getting the necessary data for the risk assessment

In the beginning of 10.2.2, the three questions that are relevant in risk assessment were presented. If an evidence-based risk assessment is to be carried out, data is needed for every question. The below text provides some suggestions for the type of data and how to access them.

What can go wrong?

A first impression of actual product use can be obtained from the instructions for use, but this includes only the use as intended by the producer. In order to get a more realistic picture, you could start with questions such as: will children or elderly people have access to this product and are they likely to use it for its purpose? How may a person be using a product in view of product functions and user goals? If there is a detailed description of an (almost-) accident this will obviously provide additional ideas of the use. In addition, it may be feasible to perform product use studies with the product, or information about such studies may be available in the scientific literature. It might also be relevant to search for information in databases with accident statistics such as the European injury database, IDB. (The public part of this database can be accessed on the website https://webgate.ec.europa.eu/idbpa/.). A useful overview of questions that may help in finding relevant injury scenarios can be found on the EuroSafe website: http://www.eurosafe.eu.com; look under *Knowledge base* and then *Risk assessment.*

The answer to the question should be a list of injury scenarios. Often a product has several hazards that should all be analysed (unless it is immediately obvious that some of the hazards have very little risk associated with them). You will also normally find that one specific hazard may result in several likely injury scenarios. Again, one should analyse all scenarios unless it is obvious that some scenarios end up in an acceptable risk. However, one should be careful because it is usually complicated to anticipate the outcome of a scenario without doing the complete analysis.

Example: The cross pane hammer from the previous example (RAPEX notification no. 0125/06). Analysing the product and its shortcomings will produce a number of possible injury scenarios, e.g.:

- *The hammer head breaks when a person uses the hammer and hits a hard surface. Parts of the head fly off and hit the user's eye.*
- *The hammer head breaks when a person uses the hammer and hits a hard surface. Large parts of the head fly off and hit the user's head.*
- *The hammer head breaks when a person uses the hammer and hits a hard surface. Parts of the head fly off and hit the user's hand, foot or other body part*
- *The handle of the hammer slides off the shaft when a person swings the hammer. The upper part of the hammer flies off and hits the head of a nearby person (perhaps a child).*
- *The handle of the hammer slides off the shaft when a person swings the hammer. The upper part of the hammer flies off and hits the body of the user or a nearby person (perhaps a child).*
- *The handle of the hammer breaks when a person uses the hammer and hits a hard surface. The upper part of the hammer bounces back and hits the user's arm.*

Note that it is not immediately obvious which of these scenarios will lead to the highest risk.. If a part of the hammer hits the user in the eye (the first scenario), the result might be blindness on that eye. This is in general considered to be a more serious injury than getting a scar in the face, which might be the outcome of the second scenario. If, however, the probability of getting hit in the eye is sufficiently much lower than the probability of getting hit in the face, then the second scenario would turn out to have the highest risk level.

If it does happen, what are the consequences?

It is essential to evaluate the final outcome of each scenario that has been identified. This requires qualitative data such as the type of injury that may result from a mechanism, and quantitative data such as the severity, medical treatment need, etc. Preferably, a detailed injury mechanism should be given.

The result should be that the injury scenario is linked to one of the four levels of severity in the RAPEX guidelines.

How likely is it that it will happen?

The probability that a given hazard will lead to an injury is often very difficult to estimate. In case of a reported injury, reality show that it is possible, but could it happen again? Some Member States have a system for collecting accident and injury data; the authorities of those Members States should use these data wherever possible. However, you should take into account that the data rarely relate to the exact type, brand and model of product that you are interested in for your risk assessment. They usually refer to a complete class of products. Nevertheless, injury data may support the conclusion that a particular scenario is quite likely with this type of product.

In the approach of the RAPEX Guidelines, each scenario is broken up into smaller steps that are essential for the injury. Several considerations have to be made:

1. Product characteristics.
   How likely is it that the hazard or shortcoming will occur during the lifetime of the product? (Example: What force is required for the hammer to break, and how does this compare to the forces that may occur when using the hammer? Do all products share the same characteristics, or is there a distribution of test outcomes?)
   If the product has been tested according to a (harmonised) standard, the results may help the process. The threshold values in the standard define the benchmark that the product must meet to be presumed safe so the test result (and the magnitude of the deviance from the threshold value) will tell something the probability that accidents will happen. (Example: The standard EN 71-1 prescribes that a small part must withstand a pull of 90 N to be securely attached to the toy. If a small part becomes detached at a pull of 10 N, it is far below the threshold value from the standard. Therefore it is quite likely that a child can detach the part, so the probability gets close to 100 %.)
   Some standards prescribe that a number of items must be tested to pass the test. Non-compliance will in these cases mean that a share of such a test batch doesn't meet the requirement in the standard. An estimate for the probability will be the proportion of non-conforming products relative to the total test batch. (Example: 50 lighters are tested. 5 fail. The probability is estimated to 10 %.)

2. Exposure to the hazard.
   How likely is it that people will actually be exposed to the hazard, again during the lifetime of the product? (Example: How likely is it that someone will be hit by pieces of the hammer head flying off?) Does exposure depend on specific behaviour or is it sufficient if the victim is near?

3. Injury mechanism.
   How likely is it that the injury occurs given that the product fails? (Example: How likely is it that the broken part of the hammer hitting the user will cause the injury?)
   In the example with the breaking hammer, the probability that an object that hits an eye actually causes an eye injury will depend upon the energy and shape of the object, and information on this probability could be available in the medical literature.

It will be clear that data to estimate the probability of each step may come from different sources: *product tests* can be performed to get information about the critical product characteristics; *product use studies and ergonomics research* may provide information about frequency of actions, forces used, etc. To help market surveillance authorities, PROSAFE has established a database with examples of probability factors that can serve as inspiration with probabilities are determined for the specific case.

When building the scenarios and estimating the probabilities it may be helpful to recall the underlying principles as illustrated in the figure below. In principle, one should draw up an event tree as indicated in the figure. Each step in the tree must list all possible outcomes so that the complete tree would describe all possible events and consequences of the particular product. That is, in principle one should on the extreme right have listed all the outcomes that would be the result of placing the entire population of the specific product (or batch of products) on the market. Each scenario will be associated with a probability.

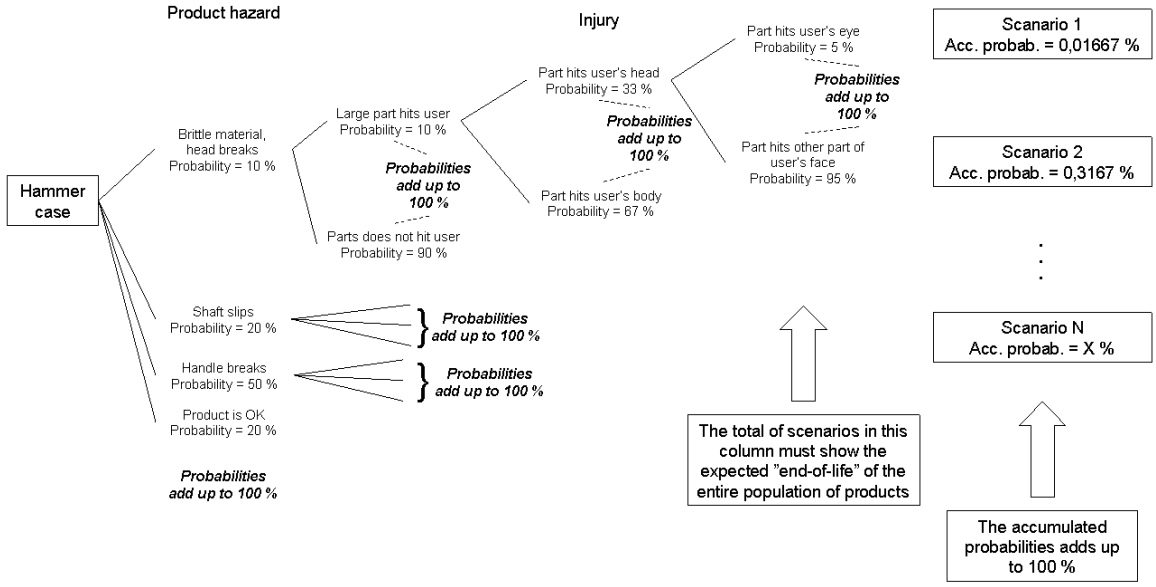

Figure 17 - The principle behind calculating the probabilities is that the sum of the probabilities for each event adds up to 100 %.

The result of this should be that the injury scenario is linked to one of the eight levels of probability in the RAPEX guidelines.

The entire process appears at first sight to be rather complicated but is still realistic. Risk assessment is more comprehensive than conformity assessment and it is found to be important to make the outcome as objective and correct as possible. Therefore, it seems necessary to spend the effort to gather the background data. An authority should however observe that the time to carry out a risk assessment would decrease as experience with using the method is built up and as examples of “standard risk assessments” are collected.

The risk assessor should be aware that the risk assessment method is neither perfect nor as scientific as it may suggest, but it is a plausible approach to assessing the risk of a product.

Is the risk assessment realistic?

The risk assessor should end all risk assessments by doing a final "reality check". This could for instance be done by use of accident statistics, the manufacturer's complaints register or other data from the manufacturer and the purpose would be to check that the overall probability of the total risk assessment seems valid. The risk assessor could for instance calculate the likely number of accidents per year if the probability was true.

Example: An electrical appliance has a non-compliant plug that will cause an electric shock to the user when then user grabs the plug to pull it out of the AC mains. The risk assessor has estimated the probability for a fatal electric shock to be 1/5. The manufacturer informs that the product is a bestseller that is sold in tens of thousands every year. If the probability and the number of items sold were correct, it would mean that the authority would see thousands of fatalities every year from that product alone. This is most likely not the case so the probability or the injury scenario has to be reviewed.

When reviewing the risk assessment – probably with the help from the manufacturer or the importer – it is worth keeping in mind that market surveillance people tend to be "worst case thinkers" whereas manufacturers tend to be too optimistic.

10.2.5 Sensitivity analysis

The estimate of the probability is often based on a number of assumptions and not only on exact numbers. Often it is difficult to make a more precise estimate than an indication of the order of magnitude. Therefore, it is also important to state the level of uncertainty on each of the factors in 10.2.2 because the influence of such uncertainty should be analysed in a sensitivity analysis. Also the uncertainty in the severity of injury should be included in such an analysis.

The purpose of the sensitivity analysis is to clarify how sensitive the result of the risk assessment is to variations in the estimated probabilities or in the severities.

A very practical way of doing the sensitivity analysis is to calculate how much higher or lower the probability should be to change the risk level. Then you evaluate if such a change in probability is realistic.

Another approach is to repeat the risk assessment as in 10.2.2 using the highest probabilities that one could estimate for each step (worst case approach). The resulting risk level will then be the highest level found in this assessment.

If it is the same as the originally estimated level, then the uncertainties on the probabilities or severities do not have an impact on the result (which of course is the ideal case).

If the highest possible risk level is higher than the originally estimated level, one has to go back into the risk assessment to see if anything can be done to improve the estimates of any of the individual factors. If this is not possible, one should at least note that one of the injury scenarios might have a more severe outcome than estimated. This should be taken into account when drawing the conclusion of the whole risk assessment. If for instance the analysis has revealed several injury scenarios each with a moderate risk and the sensitivity analysis has shown that most of the injury scenarios could result in serious risk when the uncertainty is taken into account, then the most correct conclusion of the whole case might be that the product carries a serious risk.

An alternative is to try to improve the estimates of the probabilities by consulting more experts. If the uncertainties on one or more of the probability factors (or on the outcome) is high, it is a clear sign that the risk assessor should consult more experts or undertake more testing (if feasible) to obtain better estimates of the uncertainties or an improved understanding of the scenario leading from the hazard to the injury. The authority could also ask the manufacturer to analyse and comment the risk assessment.

10.2.6 Reporting a risk assessment result

The result from the risk assessment must be reported to ensure that the considerations are registered and that they can be used in the proper context. (Normally risk assessment is done as part of a market surveillance case or perhaps even an investigation of an accident.) If the report has a suitable form, the market surveillance officer might be able to use it with little modification in the communication with the producer. On the other hand it is important that it has an appearance so that it can be produced in a court case should that be requested.

To ensure proper reporting it is recommended to use a reporting form that is simple, easy to use and that does not require the user to fill in unnecessary information. The advantage of using a form is also that it assures that all necessary information is included.

A risk assessment report should as a minimum include the following headings:

1. Identification of product and case, description of the context.
   In most market surveillance cases most (or all) of this information is given if a reference is made to the case identification that the authority uses (e.g. a case number).

2. Description of the hazards.
   This could be a list with (verbal) description of the identified hazards in the product. The hazards are sometimes identified from a test report with non-compliances.

3. Description of injury scenarios and sensitivity.
   Each injury scenario should describe the injury type and location, the severity of the injury, the probability of the injury, the resulting probability of the total scenario and the risk level. Often it will also be relevant to describe the sensitivity of the scenario, i.e. the impact on the risk level when the input probabilities vary.

4. Conclusion
   The conclusion should present the overall assessment of the product, e.g. “serious risk” (requiring rapid action).
   The conclusion should be drawn up to reflect as transparently as possible how the resulting overall risk level is derived from the estimated levels in the table.

The web tool that has been developed by the European Commission [24] allows the user to print a report with the resulting risk assessment. The report from the tool has been used for the reporting of the model risk assessments in Annex C.

10.2.7 Quality assurance

One of the drawbacks of the risk assessment method is that it includes a lot of estimation and individual judgements. The aim of the method is to support the market surveillance officer as far as possible by replacing estimation by looking up values in a table and by forcing the estimates to be as transparent as possible. Still there is a risk for subjective judgements in the method.

The best way to handle this is by doing the risk assessment in pairs or groups where all participants in common carry out the risk assessment. To prepare the risk assessment it is recommended that all participants do individual risk assessments before the common assessment.

This might be difficult to achieve in practice. Often the authority would look for ways that take less time and are less resource demanding. Two methods are described here:

– The lowest recommendable level of quality assurance is to have one market surveillance officer to do the risk assessment and have another person to check the report afterwards. The second person should co-sign the risk assessment report or should file a note on the case with his or her comments to the report.
– In projects where many similar products are investigated, it might be possible to do the risk assessment of the first product in common in a group and use this as a base for the assessments of the other products. Again, it is recommendable to have another person to check all the final risk assessments.

10.3 Pitfalls that may occur in practice and advice to avoid them

This chapter addresses a number of practical problems that the EMARS Risk Assessment team has seen when performing the analysis for specific cases and suggests approaches to avoid these pitfalls.

10.3.1 Must I perform a risk assessment every time?

Often the risks are so obvious that it seems superfluous to do a risk assessment using the method from 10.2 If the user can touch live parts in an electrical appliance, then “everybody” immediately knows that it is dangerous, so why bother about the paperwork?

It is considered best practice always to carry out a risk assessment.

Firstly, non-conformities to harmonised standards are not sufficient for market surveillance authorities to take measures unless they make the product dangerous. The producer is not obliged to follow a harmonised standard and therefore non-compliance with such a standard may not necessarily mean non-conformity with the (safety) requirements of the directives. Therefore, the legal argument behind a measure against non-conformity must describe the associated risk.

Secondly, market surveillance cases end up in court now and then because the producer or importer may decide to challenge the opinion of the market surveillance authority. In such cases, the authority will have a stronger case if it can refer to a risk assessment that was carried out and documented when the proportionate risk management measure was decided.

Of course, many types of shortcomings are generally agreed to be dangerous (e.g. small parts in toys, accessible live parts in electrical appliances, etc.) and many market surveillance inspectors would feel it unnecessary to go through the complete procedure repeatedly for the same type of shortcomings. An alternative would be to develop a list of "standard risk assessments" for those common shortcomings, which the inspector could refer to. Such a "standard risk assessment" could also include a standard phrase that could go into the legal letter to the producer.

10.3.2 Serious injury = serious risk?

If an injury scenario leads to a serious injury, you might expect (or want?) to arrive at a serious risk.

As shown in 10.1.5 this will not necessarily be the case. Risk also depends on the probability of the scenario. If the scenario is virtually impossible then serious injuries might still lead to a moderate or even low risk.

10.3.3 Risk due to a product hazard versus risk due to inadequate functioning

A special case is the risk assessment of products that are supposed to have a kind of protective function, for example personal protective equipment, socket protectors, or fire extinguishers. These products do not necessarily have shortcomings that are dangerous in themselves (e.g. sharp edges where the user can get cut). Therefore the primary hazard is not a property of the product. Rather, the risks are associated with a failing or insufficient protective function.

The approach to risk assessment is not fundamentally different, but you will need to include injury scenarios in which the product does not provide the required protection (e.g. the fire extinguisher doesn't work). This means that the person is exposed to the hazard that the equipment was supposed to protect from.

10.3.4 Small probability but many products

Some products may have shortcomings that can cause serious injuries but the associated probability is very low. Then, a risk assessment will reveal that the risk level is low or acceptable, which may seem unacceptable. If the product is sold in very large numbers then the exposure for society as a whole would be high. This would imply that serious accidents might happen at regular intervals. If furthermore it is easy to make the product safer, the market surveillance authority would have a problem explaining its inactivity based on the low or acceptable risk level.

Such observations should be noted in the report and taken into account in the risk management phase, when the authority decides which measures would be appropriate to deal with the risk. But the risk assessment and the resulting risk level should not be modified. The problem lies in the society's perception of a given risk, which may be different from the objective result of the risk assessment. (In general, people will not accept fatalities related to

any consumer product – even though they live with several dozens of traffic fatalities per million per year.) One solution is to separate perception of risk from risk assessment and deal with the perception of the risk under risk communication and management (i.e. when deciding on adequate and proportionate measures). It could also prove helpful to check the total exposure of the product to the population.

Example: Milk was sold in a milk carton, which was closed with a lid that was small enough to fit into the small parts cylinder (defined in EN 71-1). Even though the risk level was estimated as very low, the producer and the authorities decided to take action by printing a warning on the milk carton.

10.3.5 How to avoid that the number of scenarios explodes?

A major question is what can go wrong. In the RAPEX Guidelines this is implemented by developing an overview of scenarios that can happen with the product. If you make enough assumptions, you may end up with a long list of scenarios that could happen. For example, in a risk analysis of a chain saw you may assume that the user is standing on a stepladder; and also that the person may be wearing unsuitable shoes and standing on a stepladder. Where do you stop?

Every extra step you add in a scenario will lead to another factor in the likelihood that is less than 100%. The most likely scenarios will be those that 1) lead to the injury that you have chosen for the scenario and 2) present the shortest way to the injury. More complicated scenarios may normally be disregarded, unless they lead to new types of injury.

10.3.6 Vulnerable groups

In the first version of the risk assessment method used for justifying RAPEX notifications, (very) vulnerable groups were given much attention. The matrix that was used to decide on the risk level contained specific columns for vulnerable and very vulnerable groups (defined as children, elderly, people with handicaps, etc.). The result of this approach was that even quite low risks could be labelled as unacceptable if the product could come into the hands of young children.

The RAPEX Guidelines [23] do not feature such a special place for vulnerable people, but it is still *possible and desirable* to pay specific attention to them.

How can that be done?

- first, take into account any (very) vulnerable groups when describing scenarios;
- second, analyse if (very) vulnerable people could suffer more serious injuries in those scenarios, or whether the probability of any step in the scenario will be influenced by the vulnerability. Use this information for determining the risk level.

Example: A small part can be broken of a whistle. An injury scenario is that the user breaks off this part while he or she is blowing the whistle and gets into the user's mouth. From here, two developments are possible:

1. *If the user is an adult then he or she would most likely spit out the part and nothing will happen.*
2. *If the user is a small child (i.e. a very vulnerable person), it is more likely that the child will swallow the part. This means that there is a risk that it ends up in the lungs, which in general is considered to be a serious injury.*

In this example the injury scenario worsens dramatically because the probability increases and the injury becomes much more serious. Both affect the risk level.

10.3.7 Subjectivity

If a single expert does an assessment, his or her personal experience may influence the estimation of injury severity and likelihood. The table of injury levels is intended to achieve more consistency and standardisation in this estimation.

To avoid subjectivity:

– use quantitative measures and data;

– work with colleagues from the start or have them review the result.

10.3.8 Non-compliance to a standard means risk?

A shortcoming that is commonly found in RAPEX notifications is that no risk assessment is reported, but just a list of non-compliances to harmonised standards. The market surveillance officer might find the faults so obvious or well-known that it seems superfluous to describe the risk. Risk assessments are probably carried out sometimes to back up the notification or in reaction to it, but this information is not available in the public domain.

As explained in 10.1.3, the pure fact that a product does not comply with a standard is not sufficient to decide on the level of risk. The risk level depends upon the exact requirement and possibly also on how much the measured value deviates from the requirement. A risk assessment is necessary to decide the risk level (which in turn is necessary to decide if a RAPEX notification is at all required). The risk assessment could however be fairly short if the hazard and the injury is well-known. Alternatively existing risk assessments of such well-known hazards could be re-used to quickly decide on measures (this is the basis for so-called failure code lists).

Example: Electrical lamps must meet the requirements of the Low Voltage Directive. The detailed safety requirements are given by standards in the EN 60598 series. One requirement is that the user must not be able to touch live conductors.
If it is possible to touch live conductors in a specific lamp, a sufficient risk assessment would be: "It is likely that a user can touch live wires thus risking a fatal electrical shock."

10.3.9 Products causing damage to property

The risk assessment method in the RAPEX guidelines works on the assumption that products cause injuries to people. This is however not necessarily the case. If the product is a candle light, then the most likely scenarios have to do with candles putting fire to property.

One approach to handling this is to write injury scenarios that imply that a person is injured (e.g. gets burns, is poisoned by the smoke, dies, etc.). An example of such a scenario could be "Candle puts fire to a curtain, which ignites the room. A person is asleep and does not wake up. The person dies from smoke poisoning."

The probability of this kind of scenarios can be checked with data from fire statistics. The scenarios include the probability that someone dies in case of a house fire. This probability can be estimated: dividing the number of victims by the number of fires. This estimate takes into account the probability of escaping in time.

Another approach to handling this is to categorise the fire (according to the extent and the resulting damage) in categories that fit with the scale from the RAPEX guidelines, for example:

Severity level	Description of fire
4	A whole building or several rooms are destroyed by the fire.
3	One room is destroyed by the fire or several rooms are affected e.g. by smoke.
2	Few pieces of furniture or curtains are destroyed or one room is affected e.g. by smoke or burn marks.
1	Few pieces of furniture are affected e.g. by smoke or burn marks.

Example of how severity levels can be adapted to incidents that don't involve people. The example concerns fires

Similar categorisations can be developed for damages to other kinds of property or injuries to animals.

10.4 Alternative methods

Several practical tools have been developed for performing risk assessment. A report compiled on behalf of the EU Commission lists six formal methods that were used recently in Europe , but probably more methods exist that had not been formally published (including the use of expert panels). The report further distinguishes between qualitative, semi-quantitative and quantitative methods. For example, a method that makes use of a nomograph is classified as semi-quantitative.

The EMARS Risk Assessment team has tried three methods for various cases to get an idea of the strengths and weaknesses:

- The first version of the risk assessment method used for justifying RAPEX notifications as developed in 2003 for the European Commission as modified and presented in 10.4.1
- The Nomograph method (see 10.4.2).
- The RAPEX procedure [23] (see 10.4.3).

10.4.1 The first version of the risk assessment method used for justifying RAPEX notifications

The first version of the risk assessment method used for justifying RAPEX notifications uses the red-yellow-green matrix that all market surveillance authorities should be familiar with:

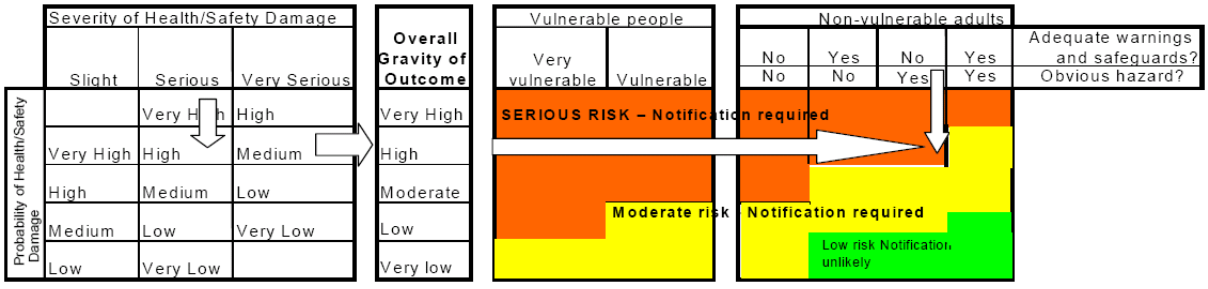

Figure 18 - The matrix from the first version of the risk assessment method used for justifying RAPEX notifications.

A couple of problems have been identified with this method [5]. The primary problem being that the method quite often yields the result "serious risk". This has led to modifications of the method. The method was found to provide less transparency in the background of the results and less diversified (and realistic) results. Finally the homogeneity in different experts' assessments of the same hazard seems to be lower than compared to the RAPEX procedure (chapter 10.4.3 and [23]).

10.4.2 The nomograph method

The Nomograph method uses maximum potential injury (6 levels), probability of hazard occurrence (6 levels) and hazard recognition (5 levels) to make an initial (individual, or single product) risk assessment; this can be combined with the availability of the product (from Rare to Widespread) to arrive at the final (collective, or market) risk assessment. The risk estimation is made using a graph.

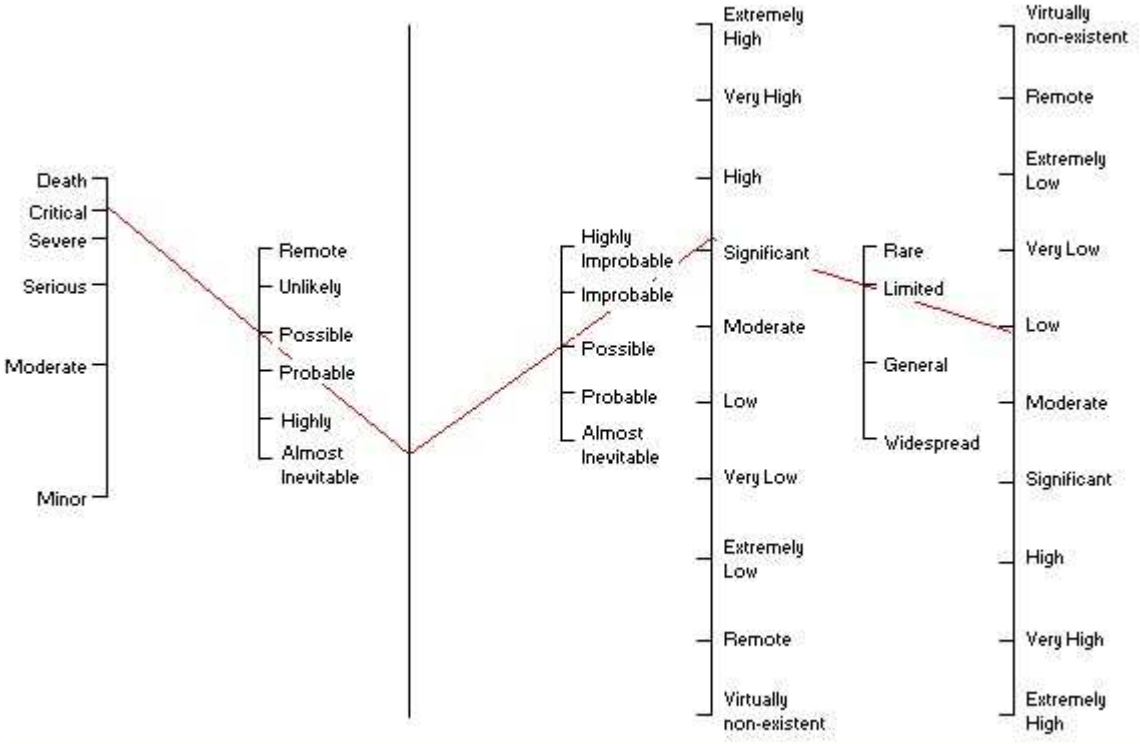

Figure 19 - The nomograph that is used for risk assessment in the nomograph method.

The nomograph method gave a wide range of outcomes in each of the cases and also large variation between experts.

In the RAPEX system, hazard occurrence and hazard recognition can both be included in the injury scenarios. The RAPEX guidelines are found to provide more guidance on selecting the injury level and the probability factors.

10.4.3 The method from the RAPEX guidelines

The method in the RAPEX guidelines is currently the most suitable tool for decisions about unsafe products. Its main features are highlighted above. The method was developed from the one described in chapter 10.4.1 by the Working Group for the Improvement of the Risk Assessment Guidelines WG IRAG (Working Group for the Improvement of the Risk Assessment Guidelines).

The basic instrument in the method is still a matrix but further guidance has been added to facilitate the choice of probabilities and severity of injury. Furthermore, risk for vulnerable consumers is dealt with in a different way: vulnerable consumers have to be taken into account when setting up the injury scenarios.

The method provides guidance on when to issue RAPEX notifications and serves as the preferred method when justifying RAPEX cases.

The method is described in detail in [23].

10.4.4 Why one common method?

Risk assessment can be done in numerous ways but the recommendation is to use the method from the RAPEX guidelines as the standard method for risk assessment in general in Europe.

The advantage of having one harmonised, commonly used method is that it introduces a common language to describe the phenomena associated with risk assessments. This means that problems can be more efficiently discussed and solved among experts in risk assessment. It also increases transparency so that it becomes more obvious why a specific product has been evaluated the way it has and so that differences can be tracked back to obvious reasons (like e.g. differences in the climate in which the product is used).

Furthermore, the method from the RAPEX guidelines is seen to decrease subjectivity as subjective judgements are replaced to the largest possible extent by factors that can be found in tables. As experience with this method grows, more and more exposure factors will be estimated and reported; these factors should be made accessible somehow to further assist in making risk assessments.

The method is harmonised, but it is not mandatory. Other methods can be applied if it can be justified that they giver better, more reliable results. This could be the case for specific sectors, where other (and more complex) risk assessment tools exist. An example would be the FMEA method that is used to assess the risks associated with machinery; another example is the modelling and calculation of exposure to chemical substances emitted or migrating from consumer products.

10.5 Examples with model assessments

Six examples of risk assessments have been developed and are included in Annex C.

They cover the following type of products:

- A toy with small parts as an example of a product covered by a harmonised standard;
- Hammers as an example of an assessment that is initialised because of a sample by a Member State;
- A rubber luggage strap as an example of an assessment that is initialised by an accident with a product;
- A cord extension set as an example of an electrical product.
- Socket protectors as an example of an assessment of protective products;
- A candle as an example of a product that is not covered by a standard;
- Bathing mattresses as an example dealing with a chemical hazard;

All examples are presented using the reporting form provided by the web tool available from the Commission's website [24].