EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory approach for the free circulation of goods and market surveillance

NOTE TO THE SENIOR OFFICIALS' GROUP FOR STANDARDISATION AND CONFORMITY ASSESSMENT POLICY – MARKET SURVEILLANCE GROUP (SOGS-MSG)

Title:	CERTIF 2010/04 - Risk assessment for market surveillance needs Towards a methodology for assessing risks presented by industrial products placed on the EU market in the framework of Regulation 765/2008		
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Abstract:

The Regulation 765/2008 has reinforced the framework for ensuring market surveillance in the EU, in particular as regards the assessment of and follow-up to be given on products presenting a serious risk. At the EU level, assessment of risk requires a common basis on which assessors may rely. In this context, there is a need to provide general guidelines to be used as a reference when performing control activities.

This paper has the following objectives:

- to report on the current situation at regulatory and normative levels to determine needs; and
- to provide the necessary background for further discussion and development of effective and consistent guidelines for the assessment of risks presented by industrial products.

This paper deals with risk assessment carried out by public authorities of products already manufactured and placed on the EU market or coming from third countries.

Keywords:	Market surveillance, rapid exchange of information system, notification, serious risk, risk assessment, risk management, precautionary principle, market surveillance authorities
References:	Regulation 765/2008; 2001/98/EC Directive (GPSD); RAPEX system; RAPEX Guidelines; Decision 768/2008/EC

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CERTIF 2010/04

RISK ASSESSMENT FOR MARKET SURVEILLANCE NEEDS

Subject: Towards a methodology for assessing risks presented by industrial products placed on the EU market in the framework of Regulation 765/2008

1. OBJECTIVE OF THIS PAPER

By the adoption of the Regulation 765/2008[1] (the Regulation) and the Decision 768/2008[2] (the Decision) the legislator has reinforced the framework for ensuring market surveillance in the EU, in particular as regards the assessment of and follow-up to be given on products presenting a serious risk.

At the EU level assessment of risk requires a common basis on which assessors may rely. In this context, there is a need to provide:

- general guidelines to be used as a reference when performing control activities to avoid diverging results, consequently ensuring legal certainty, transparency, repeatability and objectivity of the controls aiming to identify dangerous products.

- appropriate information concerning the overall best practice, and legislative and normative measures in use for risk assessment purposes.

This paper therefore has the following objectives:

- to report on the current situation at regulatory and normative levels to determine needs; and

[1] Regulation 765/2008/EC setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 – published on OJEU No L 218 of 13.08.2008

[2] Decision 768/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC published on OJEU No L 218 of 13.08.2008

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- to provide the necessary background for further discussion and development of effective and consistent guidelines for the assessment of risks presented by industrial products.

The scope of this paper is to deal with risk assessment carried out by public authorities of products already manufactured and placed on the EU market or coming from third countries, and not:

- the risk assessment carried out by manufacturers for the development of the manufacturing process of a product, or

- the sample testing carried out by manufacturers/economic operators on the products they marketed to comply with the obligations in the Decision.

2. TERMINOLOGY

In the Regulation and the Decision terms such as "risk", "serious risk", "risk assessment" appear several times[3]. However, the legislator has not specified what such terms mean.

A general acceptance of the meaning of key words such as those mentioned above is of fundamental importance for the establishment of common rules, for the proper implementation of such rules and to avoid misunderstandings.

2.1.1. Meanings of "risk", harm" and "hazard"

"Risk" is quite widely defined[4] as a "*Combination of the probability of occurrence of the hazard and the severity of the harm***"** In other words risk means the probable rate of occurrence of a hazard causing harm taken together with the degree of severity of the harm as defined, for example, in the Toys Safety Directive (TSD - Article 3(28)).

- *w*here harm (or injury) is "*the physical injury or damage to the health of the people, or damage to property and environment*"[5] (TSD – Article 3(26)),

- and hazard is "*the potential source of the harm*"[6](TSD – Article 3(27)).

In the RAPEX Guidelines the term "harm" has been replaced by "hazard". For post-market verification it is the potential source (intrinsic properties) of harm/injury that has to be checked in the product.

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[3] See Articles 18(2)(a) ; (19)(1),(2) ; 20(1),(2) ; 22(3) ; 23(2) ; 27(3)(a) ; 28(2) ; 29(1),(4),(5) in the Regulation and Articles R2(4), (8), R3((2)(c); R4(2) 2nd paragraph, (6),(7),(9); R5(4),(5); R31(1),(5) in the Decision.

[4] See ISO-IEC Guide 51 – Safety aspect; EN ISO14121-1-2007 – Safety of Machinery; Commission Decision 2010/15/EU RAPEX Guidelines – OJEU L 22 of 26.1.2010 - see par. 2.2.(3); Draft Toys Guidelines.

[5] See ISO-EIC Guide 51

[6] NOTE The term hazard can be qualified in order to define its origin (e.g. mechanical hazard, electrical hazard) or the nature of the potential harm (e.g. electrical shock hazard, cutting hazard, choking hazard, toxic hazard, fire hazard *(See CEN guide 11 clause 3.9 "Hazard")*

The EU legislation does not aim to protect health and safety exclusively, but also other public interests such as protection of the consumer, worker, or the environment, the avoidance of electromagnetic compatibility by limiting disturbances or the correct measurement in legal metrology, etc. These issues must therefore also be considered to be covered by the notion of risk.

2.1.2. Level of risk

The Regulation speaks about "risk". It also refers specifically to the case of "serious risk" (see footnote 3). This means that a distinction should be drawn between a "risk" (non-serious) and a "serious risk".

The identification of the level of a risk is part of a process which, with the support of an appropriate evaluation[7], should lead to determine whether the evaluated risk is either a "non-serious risk" or a "serious risk" i.e. how much the evaluated risk deviates from the requirement or whether the product is in compliance with the permitted risk level since no deviations are admitted (e.g. absolute chemical levels)[8]. The legislative context within which the risk assessment is carried out (harmonised/non harmonised area) will then contribute to determine whether the risk is acceptable or not[9], and hence whether the product is acceptable or not. In general we can say that the acceptable level of risk is notably determined either by the legislation and the harmonised standards which have fixed the safety requirements or by the non harmonised standards or the state of the art.

In addition, the identification of the level of the risk is essential to decide whether corrective measures would be proportionate and adequate to deal with the risk (see Article 18(4)) and whether a RAPEX notification is required in case of a serious risk.

2.1.3. Risk assessment

The reference to risk assessment in the Regulation can be found in Articles 19(1) and 20(2) and in Recital 29.

In accordance with Article 20(2) "*The decision whether or not a product represents a serious risk shall be based* (by NMSAs*) on an* <u>*appropriate risk assessment*</u> *which takes account of the nature of the hazard and the likelihood of its occurrence* (probability). …." The nature of the hazard and the likelihood of its occurrence are the elements on which the definition of risk is based.

According to international definitions, the risk assessment occurs before a product is placed on the market, and results from a scientific and technical evaluation. This is the process whereby the manufacturer controls the concept and verifies the compliance of his product to the regulatory aspects/requirements or to other means before its manufacture

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[7] Decision 768/2008 – Article R31(1) obliges MS to carry out an evaluation in relation to the product concerned covering all the requirements laid down in the applicable EU sectoral legislation where they have sufficient reason to believe that the product presents a risk or where an action have been taken pursuant to Article 20 (serious risk) of the Regulation.

[8] For absolute risk levels the risk assessment methodology should inform further on the conditions for a serious risk

[9] NB a non-conformity does not necessarily imply a risk

in order to ensure that the product finally placed on the market is safe and answers all applicable essential requirements of the relevant EU harmonised legislation, which the conformity assessment procedures should have confirmed.

This therefore implies an improper use of this terminology in the Regulation, meaning that NMSAs in reality carry out limited risk assessment. They most often focus on a limited number of essential requirements or specific hazards and assess if the corresponding risks are acceptable. For a NMSA it is enough to find one unacceptable risk in order to take action against a product. However to remain in line with the Regulation, wording "risk assessment" will be used in this document.

The existence of the harmonised and non harmonised areas must be kept in mind throughout the debate in order to avoid unnecessary duplications or burdens, especially as, objectively, the situations and needs can differ from the harmonised to the non harmonised areas (e.g. absence of specific safety requirements). When harmonised standards are used the product concerned benefits of the presumption of conformity which allows to it an *a priori* conformity to the safety rules and consequently the free circulation. This would not, however, have any influence on the results of the risk assessment which objectives are to detect risks in all cases.

2.1.4. Risk management

The definition of the risk management is also an essential part of the risk assessment. A commonly accepted risk management procedure is crucial to gear consistently the corrective/restrictive measures (bring the product in conformity, ban, withdrawal, recall, etc.) i.e. the implementing measures of the risk assessment. This is therefore the last step of market surveillance controls and also if essential it is not relevant at the current stage of the risk assessment evaluation and will be deepened later.

3. RISK ASSESSMENT OF PRODUCTS ALREADY PLACED ON THE EU MARKET (POST-MARKET SURVEILLANCE)

3.1. Generalities/background

Risk assessment has no explicit textual basis in the Treaty. However, the EU legislation elaborated under Article 114(3) of the EU Treaty takes as a base a high level of protection. The European Court of Justice (ECJ) has developed jurisprudence on this subject in a certain number of cases in relation to the free movement of goods[10] .

In general, the assessment of risk of industrial products for which there is no specific risk assessment methodology is performed by using either the RAPEX Guidelines method alone, or national methodologies alone or the combination of these tools.

3.2. Aim and differences between a pre and a post market risk assessment

The evaluation of a risk presented by a product already manufactured and available on the EU market (post-market control) is different and often more complicated than that which

[10] e.g. Case T-70/99 – Alpharma Inc.

the manufacturer has to perform before initiating the manufacturing process (pre-market control). The detection of a risk or a technical non-compliance of a manufactured product is performed in conditions different from pre-market control, and is sometimes carried out in poorer conditions, i.e. in the absence of relevant technical information (e.g. incomplete/wrong/no technical file or information, evaluation in conflict with economic operators, extrapolations necessary, use of defaults and assumptions, etc.).

The objectives of the two types of risk assessment must therefore be different. The risk assessment carried out by the manufacturer aims to demonstrate that he has designed and manufactured a safe and compliant product in relation to all legislative or normative requirements, whilst the risk assessment carried out for market surveillance purposes is designed to check that the product on the market does not present an unacceptable risk.

Hence, concentrating only on the evaluation of safety aspects, taken in the wide sense of protection of essential public interests, the post-market risk assessment aims to detect only the unacceptable risk(s) and hence determine what corrective/restrictive measures should be taken in relation to the unacceptable product.

3.3. Risk assessment and the harmonised area

For the enforcement of the EU sectoral legislation, the NMSAs have the obligation to ensure that only safe and compliant products are on their market. Within this context, the evaluation of a risk in a specific product should be based on the following:

- The EU legislative requirements which should enable a judgement as to whether a risk exists or not, and which should define the level of acceptable risks for the product.

- The harmonised standards, the references of which have been published in the EU Official Journal, translating the essential safety requirements provided for in the EU legislation into technical specifications.

When EU harmonisation legislation exists (with or without harmonised standards) there should be no room for the application of the precautionary principle, as its very existence constitutes the essential support when a risk assessor has to perform risk evaluation.

4. RISK ASSESSMENT - THE OBLIGATIONS AND NEEDS OF THE REGULATION

4.1. Pre-conditions for a risk assessment

In the framework of Regulation 765/2008, NMSAs have far more specific obligations in order to ensure that only safe and compliant products reach the market and must in particular:

(a) organise proactive or reactive controls on the basis of complaints, accidents, etc. in relation to the overall applicable requirements of the Community harmonisation legislation;

(b) identify products that could present a risk and, in particular, a serious risk either already placed on the EU market or at external borders; and

(c) perform appropriate checks on adequate scale as set out in Article 19(1)[11].

This means that there are different levels of controls, but not all require a (full) risk assessment and when a risk assessment has to be performed this has to be carried out on "the characteristics of the product on an adequate scale" focussing on the highest risk and taking account as far as possible of the available specific regulatory/normative requirements, the technical documentation, etc. (see point 4.3. below).

4.2. The risk assessment legal framework

Article 16(2) of the Regulation puts "risk assessment" at the centre of market surveillance controls, thus making it the core element for the achievement of the market surveillance objectives.

Risk assessment is thus required under Article 19:

- for checks of product safety aspects - "… *When doing so* (e.g. appropriate checks) *they* (the NMSAs) *shall take account of established principles of risk assessments, complaints and other information.*"(Article 19(1))

and then under Article 20:

- to decide whether a product presents a serious risk or not - "…*the decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment..."* (Article 20 (2)).

The conditions to be taken into account are specified in Recital (29): "*Risk assessment should take all relevant data into account, including, where available, data on risks that have materialised with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks.*"

4.3. Scope of application of risk assessment under 765/2008

Article 15 stipulates that the market surveillance framework applies to products covered by Community harmonisation legislation i.e. to industrial products covered by EU sectoral legislation. Therefore, the Regulation applies to EU sectoral legislation in relation to their:

- Product scope, i.e. the range of products covered (e.g. machinery, toys, lifts, etc.)
- User scope, i.e. to whom the products are specifically intended (e.g. children for toys),
- Public interest scope, i.e. all public interests mentioned in the EU Treaty (Article 36) e.g. the protection of health and safety, the health and safety of workplace, consumer protection, but also animals, plants, environment, property and security.

In addition, in order to avoid confusion, it is necessary to note that the EU sectoral legislation, in particular that under the "New Approach" principles, fixes for a large

[11] Article 19(1) : NMSA shall perform appropriate checks on the characteristics of products on adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks .." . For more information on checks see WP SOGS-MSG N008 or CERTIF 2009-006.

category of products the general framework and the essential safety requirements in relation to which the manufacturer has to manufacture his products.

This means that often elements such as vulnerable people (e.g. children, elderly, etc.), or risks caused to bystanders, or potential long-term adverse effects due for example to exposure to dangerous products, etc. are not specifically mentioned. These elements are nevertheless covered by the legislation.

However, for the sake of clarity, it should be underlined that the above situation does not exempt the manufacturer from organising the manufacturing process taking into account the overall foreseeable conditions that could affect the product and the precautionary principle rules which continue to apply.

4.4. Specific legal provisions

The Regulation, over and above the obligation to carry out risk assessments, and in order to complete the controls on the market and make them more effective, obliges NMSAs, even before any measures are taken, to:

- require economic operators to make such documentation and information available (Article 19(1) 2nd paragraph);
- take account of test reports or certificates issued by an accredited conformity assessment body (Article 19(1) 3rd paragraph);
- cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by themselves (Article 19(2) 2nd paragraph).

4.5. Products coming from third countries

For products coming from third countries the same principles apply, as for products already placed on the EU market, i.e. the same types of controls to check if a product presents a serious risk or not should be carried out, including, in appropriate cases, the risk assessment.

5. RAPEX GUIDELINES

The RAPEX Guidelines have been tailored to reply to the requirements of Articles 11 and 12 of the GPSD i.e. for normal and serious risks in the non harmonised fields. On 16 December 2009 the Commission adopted new RAPEX Guidelines. These guidelines are divided into two parts: management and risk assessment.

Article 22 of Regulation 765/2008 refers to the GPSD as regards the use of RAPEX, which shall therefore be the system to be used for notifications to be sent under the Regulation. In these conditions, and on the basis that it was developed fundamentally to cope for non harmonised products, it should therefore be examined to what extent and in what conditions the RAPEX Guidelines risk assessment methodology should/can be extended and/or adapted to the needs of the Regulation.

What the RAPEX Guidelines currently cover

The RAPEX guide is meant for consumer products as defined in Article 2(a) of the GPSD, i.e. products that are intended for consumer use or are likely to be used by consumers. The GPSD is aimed at ensuring that consumer products placed on the EU market are safe, and establishes a general framework to protect the health and safety of consumers. Contrary to harmonisation legislation, it does not set specific safety requirements against which it is possible to measure either safety or risk. The RAPEX guidelines have therefore been developed to cover this situation.

This methodology is based on the following main parts i.e. description of the product and its hazards, identification of the potential consumers, description of the injury scenario, determination of the severity of the injury, determination of the probability of the injury and determination of the level of the risk. At the end of this process the risk assessors have to communicate the level of risk. Risk managers are then to take the appropriate action(s).

Section 3 of the guide describes in detail what points have to be taken into account i.e. the product to check, the hazard(s) that the product could present, the potential consumer(s) and what questions have to be asked when preparing a risk assessment (e.g. Will age and usage change the type or the extent of the hazard?, How long is the time to product failure?, What is the product's lifetime, including shelf life?, How long is the product used in practice by the consumer before it becomes waste?, etc.)

Section 5 provides a brief description of how to prepare a risk assessment and a schematic flow of how to build it (see Annex I).

In addition table 4 provides guidance on the combination of the severity of injury and the probabilities of its occurrence although the number of injury scenarios remains of the responsibility of the risk assessor who will take account of the various factors to be considered for the specific case (see annex II). The meaning of the most important terms in use in the current RAPEX Guidelines such as hazard, risk, risk assessment, product hazard, etc. are set out in Annex II.

6. TOWARDS A COMPREHENSIVE RISK ASSESSMENT GUIDELINES

The objectives of the Regulation are wider than those covered by the GPSD. Moreover, the Regulation covers the harmonised area and as such includes all the objectives covered by the sectoral Community legislation. This also means that the requirements in the Regulation in relation to risk assessment are to be taken within the overall context where NMSAs are obliged under such sectoral legislation to carry out post-market risk assessments.

6.1. Main elements to be included

Taking account of the analysis above and to be in line with the Regulation's requirements, the current RAPEX risk assessment guidelines should be extended to cover:

- the determination of the scope in relation to the applicable legislation including the Regulation. This is essential since the sector-specific legislation (and related harmonised standards) provides the level of safety or the public interest protection expected from the relevant product. Where EU legislation (and harmonised standards)

is in place, this provides the common basis for the evaluation of the risks associated with a product.

- the overall objectives of the Regulation which implies that risks other than health and safety for consumers are also taken into consideration for example risks to the environment or to the health and safety at work place .

- the inclusion of the relevant provisions concerning the evaluation of a risk and in particular those concerning cooperation with relevant economic operators, and the use of available technical documentation, test reports and certificates.

6.2. Precautionary principle

The EU sectoral legislation which aims to give the overall framework (essential and non essential requirements) for the manufacturing of a product cannot adequately reflect all the relevant public interests at the same time. The precautionary principle aims to prevent potentially dangerous effects on the environment, on human, animal or plant health that are not covered by the EU legislation.

The fact that it is difficult or impossible to carry out a comprehensive risk assessment should not prevent the NMSAs from taking preventive/risk management measures in case of uncertainty (precautionary principle). In other words, the precautionary principle should be applied in situations where the available scientific evidence is too uncertain or incomplete to allow an accurate risk assessment.

The Regulation does not make clear reference to the precautionary principle as does other EU legislation[12]. However, this principle, which aims at preventing potentially dangerous effects on the environment, on human, animal or plant health will always be applied (see the Commission Communication on the precautionary principle (COM (2000) 1)[13].)

When action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review,* in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

In other words the measures taken should counterbalance in a reasonable manner the absence of a risk assessment or of an incomplete risk assessment, and give a similar result.

[12] See e.g. GPSD – Art.8 or Directive 2009/48/EC on toys – Art. 39

[13] http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

6.3. Main open questions

The fundamental question on risk assessment methodology is therefore to determine whether and to what extent the methodology set out in the new RAPEX guidelines is applicable as such or should be adapted to cover the needs of Regulation.

In this context, in addition to the regulatory requirements discussed above, the following non-exhaustive questions should be taken into consideration:

- Is it technically possible to have a single methodology for the assessment of a risk both for harmonised and non-harmonised products?
- Should it be possible to elaborate a wide risk assessment methodology covering all risks including e.g. chemicals, cosmetics, etc. in absence of dedicated methodologies?
- How far could the evaluation of risks such as those concerning the protection of the environment or the protection of workers be covered by the same methodology? If not, are there suitable alternative methodologies already available or what approach should be followed?
- To what extent a method focussing on potential users and in particular on vulnerable groups (e.g. children, elderly) is feasible /desirable in the harmonised area when the related products are intended for use by these groups ?
- How evaluate the potential long-term adverse effects due for example to exposure to dangerous chemicals?
- How do the risk assessment results ensure legal certainty?
- How can the repeatability of a risk assessment be ensured?

7. CONCLUSIONS

The current methodology set out in the RAPEX guidelines for risk assessment should constitute the starting point of reflexions on the needs of the Regulation in the light of the of the preoccupations set out in this paper.

Member States are invited to examine their current rules and practices in this area and to present comments and suggestions.

The Commission could envisage setting up an *ad hoc* Task-Force on this issue under SOGS-MSG, in order to accelerate progress on this issue.

ANNEX I

Extract from RAPEX Guidelines - Risk assessment part (Section 5)

5. HOW TO PREPARE A RISK ASSESSMENT – IN BRIEF

(1) Describe the product and its hazard.

Describe the product unambiguously. Does the hazard concern the entire product or only a (separable) part of the product?

Is there only one hazard within the product? Are there several hazards? See table 2 for guidance.

Identify the standard(s) or legislation applicable to the product.

(2) Identify the type of consumer you want to include in your injury scenario with the hazardous product.

Start with the intended user and the intended use of the product for your first injury scenario. Take other consumers (See table 1) and uses for further scenarios.

(3) Describe an injury scenario in which the product hazard(s) you have selected causes an injury(ies) or adverse health effect(s) to the consumer you selected.

Describe the steps to the injury(ies) clearly and concisely, without exaggerating the details ('shortest path to injury', 'critical path to injury'). If there are several concurrent injuries in your scenario, include them all in that same scenario.

When you describe the injury scenario, consider the frequency and duration of use, hazard recognition by the consumer, whether the consumer is vulnerable (in particular children), protective equipment, the consumer's behaviour in the case of an accident, the consumer's cultural background, and other factors that you consider important for the risk assessment.

See section 3.3 and table 2 for guidance.

(4) Determine the severity of the injury.

Determine the level of severity (1 to 4) of the injury to the consumer. If the consumer suffers from several injuries in your injury scenario, estimate the severity of all those injuries together.

See table 3 for guidance.

(5) Determine the probability of the injury scenario.

Assign a probability to each step of your injury scenario. Multiply the probabilities to calculate the overall probability of your injury scenario.

See left-hand side of table 4 for guidance.

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(6) Determine the risk level.

Combine the severity of the injury and the overall probability of the injury scenario and check the risk level in table 4.

(7) Check whether the risk level is plausible.

If the risk level does not seem plausible, or if you are uncertain about the severity of injury(ies) or about the probability(ies), move them one level up and down and recalculate the risk. This 'sensitivity analysis' will show you whether the risk changes when your input changes.

If the risk level remains the same, you can be quite confident of your risk assessment. If it changes easily, you may want to err on the safe side and take the higher risk level as 'the risk' of the consumer product.

You could also discuss the plausibility of the risk level with experienced colleagues.

(8) Develop several injury scenarios to identify the highest risk of the product.

If your first injury scenario identifies a risk level below the highest risk level set out in these guidelines, and if you think that the product may pose a higher risk than the one identified,

- select other consumers (including vulnerable consumers, in particular children);
- identify other uses (including reasonably foreseeable uses),

in order to determine which injury scenario puts the product at its highest risk.

The highest risk is normally 'the risk' of the product that allows the most effective risk management measures. In specific cases, a particular hazard may lead to a less-than-highest risk and require specific risk management measures. This has to be taken duly into account.

As a rule of thumb, injury scenarios may lead to the highest risk level set out in these guidelines where:

- the injury(ies) considered are at least at levels 3 or 4;
- the overall probability of an injury scenario is at least > 1/100.

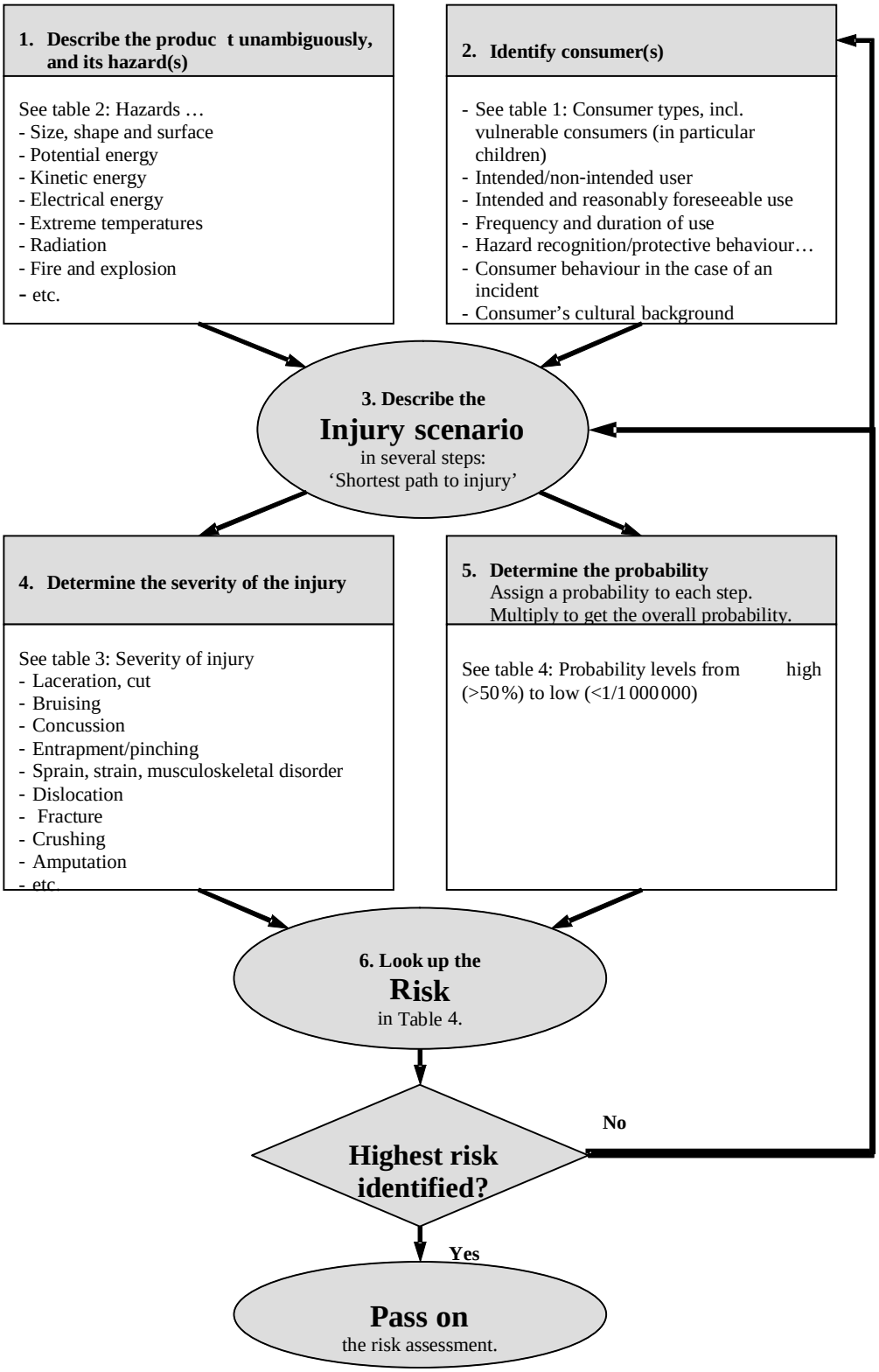
See table 4 for guidance.

(9) Document and pass on your risk assessment.

Be transparent and also set out all the uncertainties that you encountered when making your risk assessment.

Examples for reporting risk assessments are provided in section 6 of these guidelines.

Schematic flow of risk assessment



ANNEX II

Extract from RAPEX Guidelines - risk assessment part

Table 4. Risk Level From The Combination Of The Severity Of Injury And Probability

Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		1	2	3	4
High	> 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
Low	< 1/1 000 000	L	L	L	L

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

Glossary of terms

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.

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