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Title:	**EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)**		
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Abstract:

This EU general risk assessment methodology implements Article 20 of Regulation (EC) No 765/2008 and is intended to assist market surveillance authorities when they assess the compliance of **products that are subject to Union harmonization legislation**.

The methodology builds on the RAPEX Guidelines, developed within the framework of the Directive on General Product Safety (GPSD) and extends them in two respects:

1) to make sure that the broader categories of public risk protected under EU harmonization legislation can be taken into account;

2) to reflect the specific legal requirements on harmonised products.

The current document takes into account the comments and the contributions sent by Member States and ADCO Chairs on the previous version between June 2014 and July 2015.

Keywords:	Serious risk; RAPEX notifications; procedure for dealing with products presenting a risk
References:	Articles 20 of Regulation (EC) 765/2008; Model Articles R31 of Decision 768/2008/EC

EU GENERAL RISK ASSESSMENT METHODOLOGY

Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)

Contents

EU GENERAL RISK ASSESSMENT METHODOLOGY

1. Purpose and scope of application of the methodology

This EU general risk assessment methodology **implements Article 20 of Regulation (EC) No 765/2008**. This provision obliges Member States to ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof, in accordance with Article 22. Article 20(2) specifies that the decision whether or not a product represents a serious risk must *'be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence*'. Therefore the **objective of this methodology is to provide guidance to authorities** on when rapid intervention is needed, whether a RAPEX-notification should be made and on which measures to take in relation to the non-conformity of a product (proportionality).

The methodology **builds on the RAPEX Guidelines**, developed within the framework of the Directive on General Product Safety (GPSD)[1] **and extends them** in two respects:

1) to make sure that the broader categories of public risk protected under EU harmonization legislation can be taken into account (see section 2.2 below);

2) to reflect the specific legal requirements on harmonised products (see sections 3.1 and 3.2).

In particular **the risk assessment of a harmonised product does not replace the evaluation of the compliance** of the product with the requirements laid down in EU legislation and the relevant harmonised standards. Product compliance or non-compliance remains the basis on which authorities decide whether corrective action is needed. The risk assessment of a harmonised product complements the product compliance evaluation, as it allows the assessment of how serious the possible consequences of non-compliance could be. It therefore helps to determine the most appropriate type of follow up (rapid intervention, RAPEX notification, proportionate corrective action). More details on possible corrective action depending on the level of risk are given in section 4.

The risk assessment of a harmonised product is inherently linked to the evaluation of its compliance with legal requirements. The application of this methodology does not entitle risk assessors to make abstraction of or freely interpret the applicable legal requirements and standards, which reflect the choice of the EU legislator as to the acceptable level of product risk.

The application of the proposed methodology also adds **transparency** to the authority's decisions. An economic operator may be able to better understand an authority's risk management decision if he is able to understand the risk assessment considerations made by the authority.

This methodology is intended to assist market surveillance authorities when they assess the compliance of **products that are subject to Union harmonization legislation**.

[1] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002,p. 4).

This methodology does not intend to replace **other guidelines that may address specific products** (e.g. chemicals, cosmetics, pharmaceuticals, medical devices, large/complex industrial products) **or users**, or those specifically provided for in legislation. It is strongly recommended to use the specific guidelines, since they are tailor-made. The WELMEC group is developing a methodology for the assessment of the risk due to measuring instruments. The WELMEC methodology is expected to complement the general one with operational guidance in this specific sector (e.g. in relation to the identification of the relevant impacts).

The methodology developed in this paper is **exclusively for the purpose of market surveillance activities**. It should not be used by manufacturers, importers or distributors for the assessment of the risk of the products they intend to make available on the EU market.

There is an important **difference between the use of risk assessment carried out respectively by manufacturers and market surveillance authorities**. Manufactures should make a comprehensive risk assessment as part of the process of assessing the conformity of their products before the placing on the market (or in special cases later when the product is already in the supply chain). Manufacturers' risk assessment has to take into account all relevant product hazards and is the basis for the reduction of risk to acceptable levels when a product is designed or produced. On the other hand, market surveillance authorities have the task of checking the compliance of products already made available and, as explained before, use risk assessment to ascertain whether the conditions of Article 20 of Regulation (EC) No 765/2008 are fulfilled. Furthermore, normally market surveillance authorities carry out a risk assessment targeted at the identified non-compliance.

A quick **overview** and a flow chart on how to prepare a risk assessment pursuant to these guidelines is provided in section 3.

2. Basic principles for a general risk assessment methodology

2.1. Terminology

The following terms[2] are key for the purpose of this methodology:

- **Risk**: combination of the probability of occurrence of a hazard generating harm in a given scenario and the severity of that harm.

- **Harm**: injury or damage to the health of people or damage to property, economic damage to consumers[3], damage to environment, security and other aspects defined in the scope of New Approach Directives.[4]

- **Hazard**: potential source of harm. The hazard, or danger, is intrinsic to the product.

- **Probability of occurrence of that harm**: the likelihood of the harm occurring.

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[2] ISO/IEC Guide 51 Safety aspects – Guidelines for their inclusion in standards and SOGS-MSG WD N 016 of 16.06.2010, point 2.

[3] These can be affected for instance due to the inaccuracy of measurement of a taxi meter, or of a label indicating the wrong level of energy consumption of a domestic appliance.

[4] http://ec.europa.eu/growth/single-market/goods/

- **Risk level:** Degree of risk, which may be 'serious', 'high', 'medium' or 'low'. When different levels of risks in different scenarios have been identified "the risk" of the product is given by the highest risk.

2.2. A generalisation of existing methodologies beyond health and safety

The definition of harm provided above is much broader than injuries and damage to health and safety of people alone. It also includes damage to other public interests covered by EU harmonisation legislation, notably negative economic impact (e.g. unfair transactions, fraud). It is also broader with respect to the possible categories of subjects to be harmed that, depending on the case, may encompass persons (e.g. consumers or workers), animals and (parts of) the environment,

As a result of this definition of harm, the 'risk' of a product may relate to health and safety and/or to other public objectives.

The use of the concept of harm and the subsequent broader concept of risk allows the extension of the basic principles of well-established methodologies for the assessment of product risk in the health and safety area (e.g. RAPEX guidelines methodology, ISO 12100) to the different types of products and public interests covered by EU legislation.

Admittedly these concepts are rather new for categories of products unlikely to endanger people's health . However this approach is consistent with the concept of risk underpinning Regulation (EC) 765/2008[5].

To facilitate the use of this new concept of 'harm' outside the more familiar case of harm to people (i.e. injury), it is suggested to interpret 'harm' as 'negative effect' or 'negative consequence' for, for instance, consumers' economic interests, the environment, security and so on.

2.3. The relevant phases of risk assessment

For the purpose of this methodology, a '**risk assessment'** is the overall process of risk identification, analysis and evaluation[6]:

- Risk identification is the process of finding, recognising and describing risks;
- Risk analysis is the process to understand the nature of the risk and to determine its magnitude , which results from the combination of consequences and their likelihood;
- Risk evaluation is the process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or not.

The following table provides an overview of the risk assessment phases and the specific steps belonging to each phase.

[5] See in particular Article 1(2) and Article 27(3)(a).

[6] See ISO 31000:2009, *Risk management – Principles and guidelines* and ISO/IEC 31010:2009, *Risk management – Risk assessment techniques.*

Table 1: Risk assessment phases and corresponding steps

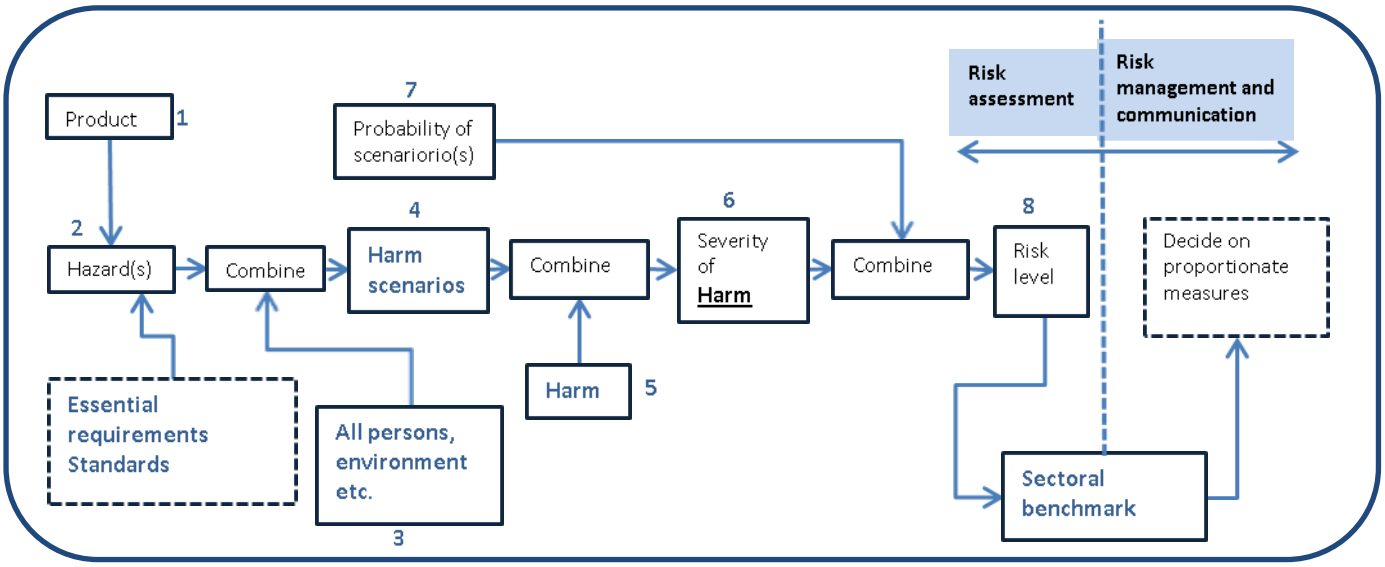
RISK ASSESSMENT PHASES	RISK ASSESSMENT STEPS
a) Risk identification	1. Defining the product; 2. Identifying the hazard(s) 3. Identifying the subject(s) at risk
b) Risk analysis	4. Describing how the hazard may harm the subject; 5. Describing the potential harm
c) Risk evaluation	6. Determining the severity of harm; 7. Determining the probability of harm; 8. Determining the risk level by combining the severity of harm and the probability of that harm occurring in the scenario described.

Risk assessment should be followed up, when the level of risk is not acceptable, by risk management, i.e. the process of identifying, selecting and implementing measures that can be applied to reduce the level of risk. Even though this falls outside the scope of this methodology, section 4 recalls the principles given by Regulation (EC) 765/2008 in terms of restrictive measures.

3. Risk Assessment Process

The proposed risk assessment methodology is summarised in Figure 1:

Figure 1 - Overview of the proposed Methodology



The overview illustrates the step-by-step approach of the method in building up the risk assessment of a product. The process of risk assessment is shown to the left of the vertical dashed line towards the right-hand end of the diagram.

In the area of Union harmonisation legislation risk assessment is inherently linked to the evaluation of compliance of a product with the legal product requirements (see in particular steps 1 and 2).

Each step of the process is described in more detail below.

3.1. Step 1: Defining the Product

The first step in the risk assessment process is to identify the **product**. In the area of EU harmonised legislation this step should go together with identifying the relevant **legal requirements** and other provisions, such as harmonised standards or other means that give presumption of conformity, to the legal requirements.

Union harmonisation legislation covers a wide range of products, hazards and impacts, which both overlap and complement each other (for example the Directives relating to Electromagnetic Compatibility and Pressure Equipment cover phenomena not covered by the Directives relating to Low-voltage Equipment or Machinery). As a result, the general rule is that several pieces of legislation may have to be taken into consideration for the same product, since the making available or putting into service can only take place when the product complies with all applicable provisions and when the conformity assessment has been carried out in accordance with all applicable Union harmonisation legislation.

However, certain Union harmonisation acts exclude from their scope products covered by other acts or incorporate the essential requirements of other acts, which avoids a simultaneous application of redundant requirements. When two or more Union harmonisation acts can cover the same product, hazard or impact, legislation itself may clarify which instrument applies by giving preference to the more specific Union harmonisation act. [7]

3.2. Step 2: Identifying the hazard(s)

Hazard or danger is the property (including aspects of poor performance) of the product that might result in harm.

There may be a considerable number of hazards arising from any given product. The correct identification and estimation of the relevance of these hazards is very much dependent upon the applicable Union harmonisation legislation, which defines the **essential requirements** to be fulfilled by a product to ensure a high level of protection of health and safety or other relevant public interests[8]. They either arise from certain hazards associated with the product (for example physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy), refer to the product or its performance (for

[7] For example the Machinery Directive covers all hazards that come from machinery, including electrical hazards; however, concerning the electrical hazards of machinery, the Machinery Directive is referring to the safety objectives of the Low Voltage Directive, to be applied solely.

[8] A fundamental feature of a large part of Union harmonisation legislation is to limit legislative harmonisation to the essential requirements that are of public interest. These requirements deal with the protection of health and safety of users (usually consumers and workers) but may also cover other fundamental requirements (for example protection of property, scarce resources or the environment).

example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer), or lay down the principal protection objective (for example by means of an illustrative list). Often they are a combination of these.

Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so. The precise technical solution may be provided by a standard or by other technical specifications at the discretion of the manufacturer.

An indicative and non-exhaustive list is set out in Annex 1: "Hazards, Typical Harm Scenarios and Typical Harms". This table is for guidance only and should not be considered as limiting the assessor; the typical harm scenarios should be adapted for specific use when preparing a risk assessment. For chemicals there are specific instructions on how to prepare a risk assessment[9] and therefore they are not dealt with in detail in these guidelines.

The identification of hazards should also build upon the applicable **harmonised standards** used by the manufacturer. The standards also serve as a benchmark for compliance. In exceptional cases, the product might be compliant with the appropriate harmonised standard(s) but would nevertheless present a hazard. In such a case, there might well be a shortcoming in the relevant harmonised standard(s).

For the identification and the assessment of the hazards, authorities should, as far as possible, make use of the information available in the **Declaration of Conformity** and possibly also in the **technical documentation** drafted by the manufacturer. Whilst this might appear to be obvious and straightforward, it is a vital stage in a complete assessment. Indeed, as essential requirements must be complied with as a function of the hazard inherent to a given product, manufacturers must carry out their own risk analysis and determine the essential requirements applicable to the product in question. This analysis has to be documented and included in the technical documentation, unless risk assessment is covered by the harmonised standard. If only part of the harmonised standard is used, then the way risks not covered by it are dealt with should be fully documented.[10]

Furthermore, the required **traceability indications** should be identified, such as the product's name and brand and its serial number.[11] Traceability is particularly important when it comes to managing product risk.

Any labelling information such as the **instructions** and **warnings** accompanying the product are vital to understand the intentions of the manufacturer. Such information may describe limits of use and identify intended users.

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9 REACH Regulation and guidance documents on REACH, see http://echa.europa.eu/. European Chemicals Agency (2008). The Guidance on Information Requirements and Chemical Safety Assessment: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

10 Additional information on the content of the Declaration of Conformity and the technical documentation can be found respectively in sections 4.3 and 4.4 of the Blue Guide.

11 See Decision 768/2008, Articles R2 and R4

3.3. Step 3: Identifying the subject at risk

As noted above, the scope of the RAPEX guidelines is limited to injury to consumers, whilst Union harmonisation legislation usually aims at protecting a wider range of “subjects”. These “subjects” could include people (consumers as well as workers/ professional users), but they are not limited to that.

These "subjects" are normally the overall public interests covered by the relevant Union harmonisation legislation, such as the protection of the environment, domestic animals or property. Particular attention should be given to “vulnerable subjects".

3.4. Step 4: Describing how the hazard may harm the subject, i.e. the relevant harm scenario

The next step is to combine the hazards and “subjects” at risk and to develop a “Harm Scenario” that describes how the hazard affects the “subject”. E.g. “An electric arc burns a professional user (**subject**) of a powered electric saw (**product**) with un-protected electric conductors (**hazard**) at 230 V AC in a workplace (**circumstances**)". In the case of products that are not necessarily used on their own, but can be further embedded in another product (e.g. radio equipment), the harm scenario will need to be defined in relation to the final product (e.g. crane or other specific type of machinery) otherwise the circumstances of harm and the subjects exposed to it could not be determined. In the case of products subject to the Electro-magnetic Compatibility Directive the relevant harm scenario may need to take into account the consequence of electromagnetic interference of the non-compliant product on the performance of the service (e.g. a safety or security-related service) for which the equipment is used[12].

The description of a harm scenario does not yet take into account any probabilities. Nonetheless it is important to describe the key components of hazard, subject, product and circumstances very thoroughly. This thorough approach and description allows later decisions to be made with greater confidence.

The scenario has to be complete and to contain the shortest or the "critical" path to harm. From experience, it is sufficient to describe a scenario in some 3 to 5 steps.

A major challenge in defining a harm scenario is uncertainty about the relationships between the hazard or danger and the final impact on the subject. The danger could either be happening on a regular basis or could be accidental (e.g. explosion due to a leakage of gas). The likelihood of the impact will also depend on several factors, such as whether the material discharged or emitted could be dispersed or diluted, the probability that people are present and their sensitivity or vulnerability towards what they will be exposed to. More information on how to take into account uncertainty when defining harm scenarios is provided in section 3.8.

For any product there may be scenarios resulting from multiple hazards affecting perhaps more than a single subject. For example, a chemical leak might affect the environment and/or animals and/or persons. The failure of a brake component of a vehicle might have an adverse effect on the professional driver operating the vehicle and also third parties (the public). Each of these

[12] The EMC ADCO is looking into this issue and is expected to provide concrete examples.

events should be described in a scenario of its own, this methodology does not seek to limit the number of scenarios.

3.5. Step 5: Determining the potential harm

This is the step that requires the risk assessor to identify what, and who, is or could be harmed or, in some circumstances, the possible "**loss**" suffered as a consequence of the event.

The RAPEX guidelines provide the assessor with descriptors of "harm" in the form of "typical injury". Whilst these are obviously limited to personal injury, they are useful to the assessor. As mentioned in section 2 above, the concept of harm under this methodology may encompass injury or damage to the health of people or damage to property, economic damage to consumers, damage to environment, security and other aspects defined in the scope of New Approach Directives. In general terms the harm can be represented as the **negative effect or consequence** of product non-compliance.

An indicative and non-exhaustive list of potential harm is set out in Annex 1 "Hazards, typical harm scenarios and typical harms". Whilst many categories of harm could be consistently applied across Directives, it is inevitable that there may be some which are sector specific.

3.6. Step 6: Determining the severity of harm

At this stage of the process, the foreseeable **level of harm to the subject** is to be assessed.

There are two possible approaches. An approach of describing levels of harm for each subject area would have demanded descriptors for each "subject" e.g. levels of harm to persons, which would be different from levels of harm to the environment.

A more efficient method is to use abstract terms, which could be applied to any "subject". This has a significant advantage as it allows flexibility and avoids many layers of description of harm.

Table 2– Abstract levels of severity of harm

Severity descriptors		
		Abstracted
level	**Injury**[13]	**Harm**[14]
4.	Injury or consequence that is, or could be, fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability	Large negative effect[15], irreversible in several aspects, whether or not acute.
3.	Injury or consequence that normally	Significant negative effect only in the

[13] See Rapex-guidelines Part IV, 5 Risk Assessment Guidelines for Consumer Products, Table 3, I introduction.

[14] Harm: see point 3.1.2

[15] If the effect is quantifiable, setting a limit is preferable.

	requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function	longer term, significant effort to reverse by specialist intervention, irreversible without this intervention and effort.
2.	Injury or consequence for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete	Negative effect, reversible within a certain period, specialist intervention is required.
1.	Injury or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible	Negative effect, usually completely reversible within the short term without specialist intervention.

Table 3 shows the equivalence between the abstract terms (right column) and the comparable terms from the RAPEX Guidelines. Specific criteria to determine the size and reversibility/irreversibility of the effect can be developed for different categories of products. For instance the relevant ADCO suggest that in the sector of measuring and non-automatic weighing instruments the appropriate criteria are the average amount of k€ running through per day, the target group, the repeatability of the measurement by the user or consumer and the purpose of the measurement[16].

More information on how to take into account uncertainty when determining severity of harm is provided in section 3.8.

16 See the Impact table of *ICSMS- Risk Classification Tool* developed by the ADCO.

3.7. Step 7: Determining the probability of harm

This is perhaps the most difficult part of an assessment. The RAPEX Guidelines require a quantified figure of probability for each step of the harm scenario. The preferred means is the **use of recognised and reliable probabilities**. For instance, as regards harm to health the determination of the probability could take into account the number of injuries reported in the European Injury Database[17] .

Example: a hammer breaks and the "ejected" part strikes the user's head. The probability of this is estimated at >1/10,000, based on a number of probabilities (probability of hammer breaking 1/10, broken part hits user 1/10, hitting the users head 1/3 and hitting users eye 1/20), the overall probability being derived from a multiplication of the figures.

Whilst this calculation of probabilities is a correct approach, empirical data might not be available in many sectors. In the absence of empirical data **estimates** will be unavoidable.

There are two possibilities to estimate the probability of harm:

- Multiplication of the estimated probabilities of each "step" in the scenario which provides the overall probability of occurrence of the harm (resp. the scenario).
- A single estimated figure for the overall probability.

In many cases, potentially the majority of product risk assessments, it is best practice to estimate the probability of each step.

This estimation is the biggest challenge for the assessor and should be discussed within a group of experts where appropriate and proportionate. A **sensitivity analysis** can help to find out how stable the risk level is following changes of the probabilities. The final outcome of risk assessment is less sensitive to changes in probabilities when the harm that can be caused by a product is very severe (e.g. an accident with large and irreversible effects). More information on how to take into account **uncertainty** when determining probability of harm is provided at the end of section 3.8.

Estimating the probability for each step of the scenario provides **transparency** to the risk assessment. Reasonably estimated probabilities are difficult to refute. In addition a sensitivity analysis, consisting of modifying the probabilities and observing possible changes of the risk level, will increase the confidence in the estimated probabilities if the risk level does not change significantly when probabilities are modified.

Furthermore, if a dispute arises and the assessment is called into question a panel of experts might understand a series of estimated probabilities better than a single probability.
When new and better probability values become available the risk assessment has to be adjusted. This could lead to a change of the *overall* probability and the resulting risk level.

[17] http://ec.europa.eu/health/data_collection/databases/idb/index_en.htm

3.8. Step 8: Determining the risk level by combining the severity of harm and the probability of that harm occurring in the scenario described

The final stage of the assessment process is to combine the severity of harm and the probability of occurrence of the harm in the scenario described.

The proposed methodology achieves this by using the related RAPEX matrix.
The **severity** of harm is identified on the horizontal axis. The **probability of the occurrence of the harm (or the scenario)** is identified on the vertical axis. The intersection then determines the level of risk.

The risk level "serious" is consistent with Article 20 of Regulation 765/2008/EC. The other three levels can assist Market Surveillance Authorities to determine which measures are proportionate to a certain level of risk (as required in Article R31 of Decision 768/2008). If necessary, these levels might be adapted to specific conditions within a sector. The four levels of severity of harm tie in with the abstract terms explained in 3.7 above.

When different harm scenarios have been identified for a product "the risk" of the product corresponds to the highest risk level determined in all scenarios.

Figure 4 – Risk level from the combination of severity of harm and probability

Combination of severity of harm and probability to risk level

Probability of occurrence of the harm scenario (during the foreseeable lifetime of the product)		Severity of harm 1	2	3	4
High ▼	> 50 %	High risk	Serious risk	Serious risk	Serious risk
	> 1/10	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/100	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/1.000	Low risk	High risk	Serious risk	Serious risk
	> 1/10.000	Low risk	Medium risk	High risk	Serious risk
	> 1/100.000	Low risk	Low risk	Medium risk	High risk
	> 1/1.000.000	Low risk	Low risk	Low risk	Medium risk
Low	> 1/10.000.000	Low risk	Low risk	Low risk	Low risk

A practical suggestion to help risk assessors understand and use this table is to try and reverse the process from past practice to the table. Each inspector/ADCO member will surely recognise past situations where measures were taken concerning a product presenting a serious risk, such as a public warning or a product recall, to prevent irreversible harm / negative effect on a given subject. Of course it must be kept in mind to what extent arguments from risk management are used for taking measures. Analysis of such past situations may help to see how the serious risk level is related to the serious risk level in the table above.

3.9. Uncertainty concerning risk assessment

The conclusion on the risk level is highly dependent on the assumptions made in previous steps. Thus, possible **uncertainty about** those **assumptions** needs to be addressed in the market surveillance risk assessment methodology. “Uncertainty” is sometimes called “strength of knowledge”, expressing confidence in the risk assessment carried out. Section 5.4.3 of ISO 31000 describes standard principles of risk analysis and states that: "*The confidence in the determination of the level of risk and its sensitivity to preconditions and assumptions should be considered in the analysis, and communicated effectively to decision makers and, as appropriate, to other stakeholders. Factors such as divergence of opinion among experts, uncertainty, availability, quality, quantity and ongoing relevance of information, or limitations on modelling should be stated and can be highlighted.*"

Three different kinds of uncertainly within risk assessment can be identified from Figure 1 in the “EU general Risk assessment methodology for products” in relation to the following steps:

- Step 4: Uncertainty in the correctness and completeness of the harm scenarios taken into account during the risk assessment
- Step 6: Uncertainty in the correctness and completeness of the severity of the harm : this is for instance a real issue in chemical safety of machinery where injuries and health damage caused by chemicals often only become manifest after many years have passed
- Step 7: Uncertainty in the correctness and completeness of the probability of the scenarios. For instance, assessing the fail rate of a single component within machinery is time consuming, but assessing the fail rate of an assembly of many components within complex machinery is very complicated and time consuming.

A simple way of taking into account these separate kinds of uncertainty could be to clearly **mention the level of uncertainty** of those risks in the risk matrix. A ‘low’ uncertainty would relate to a risk that is well known and has been encountered many times and there is sufficient information available to enable it to be fully understood and evaluated. ‘High’ uncertainty would apply to a risk about which there is very little information or knowledge available.

Figure 5 – Assessment of uncertainty about risk level

Combination of severity of harm and probability to risk level

Probability of occurrence of the harm scenario (during the foreseeable lifetime of the product)		Severity of harm			
		1	2	3	4
High ▼	> 50 %	High risk	Serious risk	Serious risk	Serious risk
	> 1/10	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/100	Medium risk	Serious risk	Serious risk	Serious risk
	> 1/1.000	Low risk	High risk	Serious risk	Serious risk
	> 1/10.000	Low risk	Medium risk	Serious risk	Serious risk
	> 1/100.000	Low risk	Low risk	Medium risk	High risk
	> 1/1.000.000	Low risk	Low risk	Low risk	Medium risk
Low	> 1/10.000.000	Low risk	Low risk	Low risk	Low risk

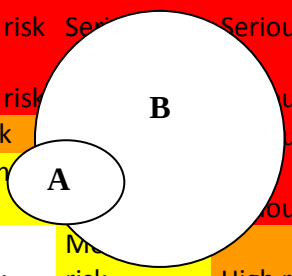


Figure 5 pictures the conclusions of two risk assessments with different degrees of uncertainly. Bubble A illustrates the assessment of a product presenting a hazard which is well understood

(e.g. in terms of types of harm scenarios likely to occur), so that the probabilities and potential consequences are well known. The level of uncertainty can then be considered as 'Low'. By contrast, Bubble B illustrates the situation of a new product with less well understood conditions of use and less clear possible harm scenarios. In this case the level of uncertainty can be rated as 'High'.

For instance in the case of an agricultural fold-up boom sprayer which is found to be defective, the uncertainty of the risk will depend on what exactly is defective. If the machine is compliant apart from the boom fold-up height being too high, the main risk is contact with overhead electric lines. The minimum clearance of these is known in a Member States, subject to some variance. Uncertainty in this case might be relatively small and the situation could be similar to bubble A. If however the defect is in the spraying system resulting in overspray the uncertainty could be more complex and depend for instance on the type of chemicals used, its location of use, wind direction and the toxicity of the possible chemicals being used. This will give a significant level of uncertainty as illustrated in Bubble B.

The uncertainty is expected to be reduced as more information becomes available. An illustrative example is the handling of the Ayafjallajokull volcano ash cloud in aviation. At the beginning, when there was little knowledge about the potential consequences of the ash cloud, there were strong restrictions on aviation. However, as more information became available, the uncertainty became smaller, and some restrictions could be lifted.

4. From risk to action[18]

Following the risk assessment, market surveillance authorities are expected to take action to deal with risks that are not acceptable. Deciding on the proportionate action is part of the risk management process, not of risk assessment.

In deciding the most appropriate action, market surveillance authorities are requested to take into account the provisions set out in Regulation (EC) No 765/2008.

In particular, **when products present a serious risk,** Article 20 of Regulation (EC) No 765/2008 provides specific indications as to the timing of the follow up, the type of measures applicable and the means to inform the Commission and the other Member States.

As to the timing of the follow up, Article 20 indicates that "rapid intervention" is necessary. Article 21 also suggests that, in view of the need to act urgently, the authorities may postpone the consultation of the relevant economic operator to a stage subsequent to the adoption of any necessary restrictive measures.

As to the *measures* applicable when products present a serious risk, Article 20 states that authorities should ensure the relevant products are recalled, withdrawn or that their being made available on the market is prohibited. Furthermore, according to Article 19, if they deem it necessary, authorities may destroy or otherwise render inoperable products presenting a serious risk.

[18] The mandate for the RATF was to advise on a risk assessment methodology in relation to Regulation 765/2008 objectives, without an explicit instruction on advice beyond the assessment process. The group agreed that there should be some reference on the process of taking action based on an assessment.

As the means to *inform the Commission and other Member States,* Article 20 states this should be done via the RAPEX rapid alert system according to the criteria laid down in Article 22.

Neither the Regulation, nor this methodology, intend to suggest that authorities should not follow up non-compliant products presenting a level of risk considered as lower than 'serious'. On the contrary, according to Article 16 (2) of Regulation (EC) No 765/2008, market surveillance authorities shall ensure that products covered by Union harmonisation legislation which are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in by legislation are withdrawn or their being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly. There is therefore a general obligation to act against non-compliant products, regardless of the level of risk implied.

On the other hand by comparing Article 16(2) and Article 20 it is argued, for **products that do not present a serious risk**, that authorities are not subject to the additional requirement of ensuring a 'rapid intervention'. As to measures available, the regulation refers to all possible restrictions of the marketing of products including their prohibition or withdrawal[19]. Informing the Commission and the other Member States is also expressly required for products that do not present a serious risk, however Member States in this case are not obliged to use the RAPEX system.

It can also happen that, at the end of the risk assessment process, the **product is not found to present a risk, however** certain **formal non-compliance** with Union harmonisation legislation may be identified (for example when the conformity marking has been affixed in violation of the applicable Union act; the conformity marking has not been affixed; the EC declaration of conformity has not been drawn up; the EC declaration of conformity has not been drawn up correctly; or the technical documentation is either not available or not complete). In this case, according to model Article R34 of Decision N. 768/2008 (and the corresponding provisions in aligned harmonisation directives), proportionate action consists in requesting the economic operator to correct the formal non-compliance. If the formal non-compliance persists, the market surveillance authority concerned should nevertheless take appropriate measures to restrict or prohibit the product being made available on the market, or ensure that it is recalled or withdrawn from the market.

[19] The Regulation is not more specific as to the measures to be taken depending on the risk. During consultation on this methodology, a Member State explained that it takes the following approach, which can be considered as an example of gradation of authorities' measures according to the seriousness of the product risk in question:

- In case of product compliance or only insignificant risk: no measure;
- In case of low risk: remark letter to distributor/importer/manufacturer;
- In case of medium risk: sale bans, withdrawals;
- In case of serious risk: withdrawals, recalls.

Annex 1. Hazards, Typical Harm Scenarios and Typical Harm

Table 1 provides a non-exhaustive list of hazards, possible harm scenarios and harm related to products falling under specific directives. In particular:

- for machinery products the table reports hazards based on EN ISO 12100 - Safety of machinery - General principles for design - Risk assessment and risk reduction
- for low voltage products the table reports hazards based on CENELEC Guide 32 – Guidelines for Safety related Risk Assessment and Risk reduction for Low Voltage Equipment (Edition , 2014-07)

Please note that these risks/professional products are not covered by the current Rapex Guidelines.

This table is for guidance only; the proposed typical harm scenarios should be adapted or new ones should be developed when preparing a risk assessment. Depending on the nature of hazard, other specific tools could be applied further (see for instance. Part IV – Risk Assessment Guidelines for Consumer Products - of the Commission Decision of 16 December 2009; ECHA Guidance on Information Requirements and Chemical Safety Assessment, Environmental Impact Assessment Guidance on risk assessment at work, etc.).

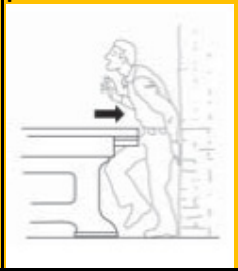
The current version of the table does not contain information on all relevant sectors/legislative areas. The information in the table will then need to be progressively complemented with additional information collected on the basis of specific examples of application of the new methodology. Practical experience on some test cases is particularly needed for products presenting a risk of economic harm, such as an energy-using product (e.g. washing machine) consuming more energy than declared on the mandatory label; or a medical device that does not damage a person's health but nevertheless performs below the required level.

Table 2 provides examples of environmental risk covered by Regulation (EC) 765/2008.

Table 1: Hazards under Machinery, Low Voltage, Personal Protective Equipment, Eco-design, Energy Labelling, Measuring Instruments and Non-Automatic-Weighting and Pressure Equipment Directives.

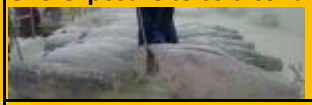
Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
Mechanical, electrical, biological, chemical, ergonomic hazards under Machinery Directive	**Acceleration, deceleration**	**Person increases/decreases speed of the machine.** 	**Injuries (being run over)**
	Gravity	**Person is working with the bulk material which is solidified.** 	**Injuries (crushing, collapse, falling, slumping, wedging)** **Suffocation** **Entrapment**
	Height from the ground	**Falling, slipping, tripping of person from elevation hazards (for example: fall from an unprotected side or edge which is 1.8 m or more above the lower level is not protected from falling by the use of a guard rail system, safety net system, or personal fall arrest system).** 	**Injuries (falls)**
	Cutting parts	**A person cuts wood during renovations on a housing complex.** 	**Cuts**

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Shape and/or superficial finishing of accessible parts of the machine (sharp edges, angular parts)	Person is in contact with rough surfaces. Person is in contact with sharp edges and corners, protruding parts. Person is involved in handling sheet or strip metal. During work at presses, where small pieces of metal with sharp edges are handled frequently, a person is in contact with machinery blades, cutters or tools. 	Injuries Cuts
	Rough, slippery surface	Person falls backwards on a wet/dry contaminated floor. 	Injuries
	Moving elements	Drawing-in into the moving parts of the machinery and difficulty to access control devices to stop the machine (for example: the risk of being dawned into the moving parts of machinery that requires material infeed). Person is near moving parts. Person is exposed to ejection of parts. Trapping between moving parts. Friction between moving parts or inappropriate maintenance/use of pressure vessels. 	Injuries (crushing, impact, shearing, impact, friction/abrasion, drawing-in, severing) Entrapment

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Approach of a moving element to a fixed part	Person is entrapped between moving element and a fixed part. 	Injuries (crushing, impact) Entrapment
	Rotating elements	Machine part/functions are not safeguarded while person is using the machine. Person is in contact with rotating open ends which are inadequately guarded. 	Injuries (severing, entanglement)
	Falling objects	The multi-purpose machine is not fitted with FOPS (Falling Object Protective Structure), therefore when handling objects, there is a risk of crushing (eg. the spine of the operator) if hit by a falling object. Machinery (such as small tractors) without roll-over protection structures (ROPS) could affect persons (operators). Free movement of parts or material (falling, rolling, sliding, tipping, flying off, swinging, collapsing) which may result in a person being hit. Person is underneath the load which falls. 	Injuries (crushing, impact)

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		Tractors without roll-over protection structures (ROPS), power take-off (PTO) shafts, chainsaws, augers, motorbikes and machinery with unguarded moving parts could affect farm animals.	Injuries to animals Health risk/other: fatal accident
		Base material, fasteners or other impacted elements, or splinters from the machinery intended for the hard marking of materials by imprinting or captive bolt pistols for the stunning of animals break and hit parts of the body of the animal.	Injuries to animals
	Kinetic energy	Falling or ejection of objects on person or properties. 	Injuries Damage to properties
	Instability of the machine and/or parts of the machine (Machinery Directive, Recreational Crafts Directive)	Person loses stability on the unstable machine. 	Cuts Entrapment
	Elastic elements	Break-up during operation. 	Injuries (crushing)

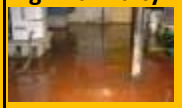
Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	High pressure; stored energy; vacuum (pneumatic, hydraulic equipment)	Presence of fluids under pressure (compressed air, steam, liquids). 	Suffocation
	Electrical hazards (arc; electromagnetic phenomena; electrostatic phenomena; live parts; not enough distance to live parts under high voltage; overload; parts which have become live under fault conditions; short-circuit; thermal radiation)	Person is in contact with electric energy. Metal parts of the machine are in electrical continuity with the cutting wheel, therefore the output shaft can come in contact with live electrical wire and can electrocute the user through the metal parts in the grasping surface. 	Electric shock Fire
		Person is exposed to live electrical parts.	Electric shock Burns
		The insulation of the electronic LED driver is not sufficient and the clearance/creepage distances between the primary and secondary circuits are not sufficient.	Electric shock
		Inappropriate electrical installation, insulation, control; inappropriate use of electrical portable tools.	Electric shock

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Thermal hazards (explosion; flame; objects or materials with a high or low temperature; radiation from heat sources; hot surfaces of machines)	Heat stress at work. 	Health risk/other: • burns • dehydration
		Overexposure to cold conditions or extreme cold. 	Health risk/other: • discomfort • frostbite
		Machine creates a fire and destroys surrounding installations and buildings.	Fire (damage to property)
		Explosions occurs when the combustion of certain concentrations of flammable substances such as gases, vapours, mists or dust in air is triggered by an ignition source of sufficient energy. The damage caused by explosions to property is due to the violent emission of flames, thermal radiation, pressure waves, flying debris and hazardous substances.	Fire (damage to property) Other: explosion
		Person touches hot surface of machine. 	Burns Injuries

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Noise hazards (cavitation phenomena; exhausting system; gas leaking at high speed; manufacturing process (stamping, cutting, etc.); moving parts; scraping surfaces; unbalanced rotating parts; whistling pneumatics; worn parts)	Person is exposed to noise, ultrasounds. Person works in a noisy manufacturing process. 	Health risk/other: • discomfort • loss of awareness • loss of balance • permanent hearing loss • stress • tinnitus • tiredness
		Machinery produces noise pollution to farm animals.	Damage to animals' hearing
	Vibration hazards (cavitation phenomena; misalignment of moving parts; mobile equipment; scraping surfaces; unbalanced rotating parts; vibrating equipment; worn parts)	Long periods of sitting and vibration for commercial drivers.  Person is exposed to mechanical vibrations.	Health risk/other: • discomfort • low-back morbidity • neurological disorder • osteo-articular disorder • trauma of the spine • vascular disorder
		Person works with the vibrating equipment. 	Health risk/other: • osteo-articular disorder • vascular disorder
	Radiation hazards (ionizing radiation source; low frequency electromagnetic radiation; optical radiation (infrared, visible and ultraviolet), including laser; radio frequency electromagnetic radiation)	Person is exposed to electromagnetic radiation. 	Burns Damage to sight Health risk/other: • damage to skin • effects on reproductive capability • mutation • headache, insomnia
		Person is exposed to laser beam. 	Burns Damage to eyes Health risk/other: damage to skin

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Material/ substance hazards (aerosol; biological and microbiological (viral or bacterial) agent; combustible; explosive; fibre; flammable; fluid; fume; gas; mist; Oxidizer)	Exposures to bacteria, viruses, fungi (mould). Handling and resulting in unintentional exposure to micro-organisms, exo- and endo-toxins. Inadvertent exposure to micro-organisms (e.g. legionella dispersed from wet cooling towers). Presence of allergens. Person is working/living at brownfield site (real property, the expansion, redevelopment or reuse). Contaminants may be present in surface soil, buildings or containers (drums, underground tanks), subsurface soil, and groundwater aquifers. Contaminants: petroleum hydrocarbons, lead, construction debris (lead paint or asbestos containing materials), polychlorinated biphenyls (PCBs), treated wood (creosote, cadmium/chromium/arsenic), industrial chemicals, and diesel fuel. Exposure to air pollutants (benzene, which is found in gasoline; perchloroethylene, which is emitted from some dry cleaning facilities; and methylene chloride, which is used as a solvent and paint stripper by a number of industries; dioxin, asbestos, toluene, and metals such as cadmium, mercury, chromium, and lead compounds). Exposure to asbestos. 	Suffocation Fire Chemical Microbiological Health risk/other: • difficult breathing • cancer • corrosion • effects on reproductive capability • infection • mutation • sensitization
		Milk vats located in confined space contain unsafe atmospheres.	Chemical (poisoning) Suffocation

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		Materials used to constitute the machinery, the environment of the machinery or ancillary substances used with the machinery intended for use with foodstuff or products concerned for animal consumption are the source of hazardous contamination of the foodstuffs products and are therefore dangerous for domestic animals.	Chemical harm (poisoning) to animals
		Person is exposed to dust (emissions).	Damage to sight Health risk/other: breathing difficulties
		Person is exposed to fumes.	Microbiological Chemical Health risk/other: • breathing difficulties • irritation
	Ergonomic hazards (access; design or location of indicators and visual displays units; design, location or identification of control devices; effort; flicker, dazzling, shadow, stroboscopic effect; local lighting; mental overload/underload; repetitive activity;)	Employment of bad ergonomic design and increase of repeated strenuous movements or lifts.  Inappropriate design of the work station which does not suit the person.	Health risk/other: • discomfort • fatigue • musculoskeletal disorder • stress
		Awkward and static postures and prolonged sitting or standing. 	Health risk/other: • discomfort • fatigue • musculoskeletal disorder
	Visibility	Person loses direct visibility of the working area.	Injuries

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Hazards associated with the environment in which the machine is used (dust and fog; electromagnetic disturbance; lightning; moisture; pollution; snow; temperature; water; wind; lack of oxygen)	Person does not have enough ventilation, lack of fresh outdoor air or contaminated air being brought into the building.  Poor upkeep of ventilation, heating and air-conditioning systems. Dampness and moisture damage due to leaks, flooding or high humidity.  Occupant activities, such as construction or remodelling. Indoor and outdoor contaminated air.  Person does not have enough light for this/her working need or too much light for the working needs (glare) or improper contrast or poorly distributed light or flicker. Person is exposed to aromatic solvents and metals including lead, arsenic, and mercury. Chemicals derived from furniture (formaldehyde, resins etc.). Chemicals derived from printing equipment.	Injuries Suffocation Chemical
	Machinery mobility	Security defects in vehicles.	Injuries

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		The lower panel may detach from the refrigeration unit on the truck while driving. The panel could fall on the road and lead to an accident. 	Injuries
		If devices fitted to the machinery which, for operational purposes, are deployed outside the normal clearance zone are not secured in a safe position before travel movements of the machinery or of the vehicle on which it is mounted, they may hit bridges, tunnels, overhead electricity lines etc. Such collisions can cause substantial damage to property.	Other: damage to property
Electrical, mechanical and others hazards under LVD Directive	Electrical hazards (leakage current; energy supply; stored charges; arcs; electric shock; burns.)	Current leakage occurs at aging part of electrical wire. While connecting electrical the wires person touches aging part.	Electrical shock/ injuries due to current through human body
		While electrical motor is in operation, electrostatic discharge spark and spark splashes on combustible substances	Burn/death of person Burn of motor, damage to property
	Mechanical hazards (instability, break-down during operation, falling or ejected objects; inadequate surfaces, edges or corners; moving parts, especially where there may be variations in the rotational speed of parts; vibration; improper fitting of parts)	While cleaning equipment worker touches sharp edge of the equipment While using a drilling machine, equipment falls due to strong vibration	Cuts in hands Injuries

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	Other hazards (Explosion; Hazards arising from electric, magnetic, and electromagnetic fields, other ionizing and non-ionizing radiation; Electric, magnetic or electromagnetic disturbances; Optical radiation ; Fire; Temperature; Acoustic noise; Biological and chemical effects; Emissions, production and/or use of hazardous substances (e.g. gases, liquids, dusts, mists, vapour ; Unattended operation; Connection to and interruption from power supply ; Combination of equipment; Implosion; Hygiene conditions; Ergonomics)		
Inappropriate protection of products, covered by Personal protective equipment, at workplace (PPE Directive)	Inappropriate respiratory protection	The self-contained breathing device has limited air supply limits work duration, therefore formation of carbon monoxide/carbon can occur. It may impair movement in confined spaces (like tunnels, tanks, access shafts, rail tank cars storage bins etc.).	Injuries (slips, fall) Chemical (poisoning) Health risk/other: unconsciousness
		The positive-pressure supplied-air respirator is used in oxygen-deficient atmospheres, but it is not equipped with an emergency egress unit such as an escape-only self-contained breathing apparatus that can provide immediate emergency respiratory protection in case of air-line failure.	Health risk/other: • impaired thinking and attention • poor judgement • faulty coordination • impaired respiration • inability to move • loss of consciousness • convulsions • fatal accident

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		The air-purifying respirator has limited duration of protection. It may be hard to estimate safe operating time in field conditions. It protects against specific chemicals and up to specific concentrations.	Chemical (poisoning) Health risk/other: Dermatitis, skin irritation
		The usage of the entry-and-escape self-contained breathing device (open-circuit self-contained breathing device) for more than 60 min.	Chemical (poisoning) Health risk/other: fatal accident
		The closed-circuit self-contained breathing device is operated at very cold temperatures, therefore scrubber efficiency may be reduced and CO2 breakthrough may occur. Units retain the heat normally exchanged in exhalation and generate heat in the CO2 scrubbing operations, adding to the danger of heat stress.	Health risk/other: • rapid breathing • fatigue • vomiting • coma • fatal accident
		The escape-only self-contained breathing device, which is approved for escape purposes only, is used for entry.	Health risk/other: • rapid breathing • fatigue • vomiting • coma • fatal accident
	Inappropriate emergency equipment	The fully-encapsulating suit (one-piece garment; Boots and gloves may be integral, attached and replaceable, or separate) is worn in conjunction with a closed-circuit self-contained breathing apparatus. The person may be encapsulated in a microclimate, due to an increase in thermal resistance and decrease in vapour permeability.	Health risk/other: heat stress

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		The non-encapsulating suit (jacket, hood, pants, or bib overalls, and one-piece coveralls) does not have gas-tight protection. Exposure to dangerous and toxic chemicals.	Burns Health risk/other: • irritation of the skin • Blistering • tissue fatal accident • infection
		Flotation gear (life jackets or work vests) is not worn underneath chemical protective clothing to prevent flotation gear degradation by chemicals. Damage to the material may be slight or as severe as complete deterioration. The reaction may cause the material to shrink or swell, become brittle or very soft, or completely change its chemical and physical structure. Changes such as these may enhance or restrict permeation or allow penetration by the contaminant.	Health risk/other: skin damage (irritation, dermatitis, sensitization)
	Inappropriate emergency equipment against high temperature environments, low temperature environment and radiation environment	There is excessive heat transmission by radiation and excessive heat transmission by flame while wearing firefighter's protective clothing (gloves, helmet, running or bunker coat, running or bunker pants and boots).	Burns
		Flame/fire retardant coveralls add bulk and may exacerbate heat stress problems and impair mobility.	Injuries Health risk/other: heat stress
		Cooling garment (jackets or vests) pose ice storage and recharge problems.	Health risk/other: heat stress
		The person is exposed to radiation and not evacuated immediately by wearing inappropriate radiation contamination protective suit.	Burns
	Inappropriate insulation in high-tension work	Blast and fragmentation suit (blast and fragmentation vests and clothing, bomb blankets, and bomb carriers) does not provide for hearing protection.	Damage to hearing
	Inappropriate protection of head, face, eyes, ears	Safety helmet does not protect the head from blows.	Injuries
		Safety helmet liner does not properly insulate against cold.	Health risk/other: heat stress

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		Hood does not protect against chemical splashes, particulates, and rain.	Burns (acid burn)
		Protective hair covering does not protect against chemical contamination of hair.	Injuries
		Face shield does not have sufficient protection against chemical splashes.	Damage to sight Chemical
		Splash hood does not have sufficient protection against chemical splashes.	Damage to sight Chemical
		Protective safety glasses do not offer sufficient protection to eyes against large particles and projectiles.	Damage to sight
		Goggles do not offer sufficient protection against vaporized chemicals, splashes, large particles.	Damage to sight
		Sweat bands do not offer sufficient protection against sweat-induced eye irritation and vision impairment.	Damage to sight
		Ear plugs and muffs do not offer sufficient protection against physiological damage and psychological disturbance.	Damage to hearing
		Radio headset with throat microphone does not offer sufficient hearing protection while enabling communication.	Damage to hearing
	Inappropriate protection against mechanical, chemical and electrical risks	Gloves and sleeves do not offer sufficient protection to hands and arms from chemical and/or electrical contact.	Electric shock Injuries Chemical Health risk/other: • abrasions • lesions • fatal accident
		Over gloves do not provide supplemental protection to the wearer and do not protect more expensive undergarments from abrasions, tears, and contamination.	
		Disposable gloves do not offer sufficient protection against contamination.	

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		Safety boots are not constructed of chemical-resistant material, therefore they do not protect feet from contact with chemicals.	
		Safety boots are not constructed with some steel materials (e.g., toes, shanks, insoles), therefore they do not protect feet from compression, crushing, or puncture by falling, moving, or sharp objects. Safety boots are not constructed from nonconductive, spark resistant materials or coatings, therefore they do not protect the wearer against electrical hazards and prevent ignition of combustible gases or vapours.	Injuries (crush, fall) Electric shock Health risk/other: fatal accident
		Disposable shoe or boot does not offer sufficient protection against contamination. They do not protect feet from contact with chemicals.	Injuries Chemical
		Aprons, leggings, and sleeve protectors (fully sleeved and gloved apron; separate coverings for arms and legs) are used when there is a high probability of total body contact with contaminants.	Health risk/other: irritation, rash, redness or discoloration, dermatitis.
		Proximity garment (approach suit: one- or two-piece over garment with boot covers, gloves and hood of aluminized nylon or cotton fabric) impairs person's mobility, vision and communication.	Injuries
	Unsuitability of accessories	In the event of an emergency or equipment failure knife does not allow a person in a fully encapsulating suit to cut his or her way out of the suit.	Injuries
		Flashlight or lantern does not enhance visibility in buildings, enclosed spaces, and the dark.	Injuries
		Personal dosimeter does not accurately measure person's exposure to ionizing radiation and to certain chemicals.	Chemical

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		Personal locator beacon does not operate correctly, therefore it cannot enable emergency personnel to locate victim.	Injuries
		Two-way radio does not operate correctly, therefore field persons cannot communicate with personnel in the support zone.	Injuries/fatal accident
	Inappropriate protection against falls from a height	Person slips and falls while working at heights or falls off boat etc. because of deficient lanyards, mobile fall arresters, karabiners, energy absorbers, connectors or anchor points.	Injuries (falls) Drowning Health risk/other: fatal accident
		Person slips and falls during mountaineering, rock climbing, speleology, etc. because of deficient harnesses, thigh straps, belts, or lifeline.	Injuries (fall) Drowning Health risk/other: fatal accident
		Safety belts, harnesses, and lifeline are not constructed of spark-free hardware and chemical-resistant materials, therefore personnel working in elevated areas or entering confined areas, could fall. Impact caused by falling or projecting objects and collision of parts of the body with an obstacle.	Injuries (fall) Health risk/other: fatal accidents

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
Consumption of energy-related products covered by implementing acts under Directive 2009/125/EC and/or delegated acts under Directive 2010/30/EU	High energy use	Consumer or professional user buys a less energy-efficient or environmentally friendly product, because of lack of information or wrong information or because the product does not meet the minimum requirements to be allowed on the market. Some examples: Consumer or professional user buys an inefficient refrigerator. She/he consumes more electricity than needed and wanted and spends more money on energy bills. She/he does not contribute to efficient measures to reduce emissions of greenhouse gases. Consumer or professional user buys non-compliant lighting. She/he consumes more electricity than needed and wanted and spends more money on energy bills. She/he could be exposed to high mercury content, which is toxic. Consumer or professional user buys an inefficient space heater. She/he consumes more energy than needed and wanted and spends more money on utility bills. Consumer buys or professional user an inefficient dishwasher which uses more energy and water than needed and wanted. She/he spends more money on energy and water bills and does not contribute to efficient measures to reduce emissions of greenhouse gases and to reduce pressure on water supply.	• High bills for energy and other resources during use (social and economic impact). • High greenhouse gas emissions and other environmental impacts (environmental impact). • Reduced energy security (social and economic impact).
Measurement with the support of products covered by the Measuring Instruments and Non-Automatic-Weighting Directives	Incorrect measurement (Inaccurate registration of the quantity of consumption or use)	Water meter incorrectly measures, memorises and displays the volume at metering conditions of water passing through the measurement transducer.	• Unfair transaction, Fraud (higher / lower bills for amount of goods purchased) • No trust in the metrology system by the user of the instrument
		Gas meter incorrectly measures, memorises and displays the quantity of fuel gas (volume or mass) that has passed it.	

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		An active electrical energy meter incorrectly measures the active electrical energy consumed in a circuit.	
		A heat meter incorrectly measures the heat which, in a heat exchange circuit, is given up by a liquid called the heat-conveying liquid.	
		Measuring systems for continuous and dynamic measurement of quantities of liquids other than water connected to the calculator which measures incorrectly certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.	
		Automatic weighing instrument incorrectly determines the mass of a product without the intervention of an operator and follows a predetermined programme of automatic processes characteristic of the instrument.	
		Taxi meter incorrectly measures duration, calculates distance on the basis of a signal delivered by the distance signal generator.	

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		A Weighing instrument for determination of mass for making up medicines on prescription in a pharmacy must conform to the harmonised EU law. Should this not be the case an instrument that incorrectly measures pharmaceutical application can lead to incorrect dosage of the medicine with all the consequences that may have including the patient dying.	**Health and safety: diseases, death**
Hazard group	**Hazard (product property)** [20]	**Typical harm scenario**	**Typical harm/Potential consequences/ Negative effect**
Pressure or related hazards under Pressure Equipment Directive: **Potential** **energy**	**Low mechanical stability**	**Vessel tips because of poor support:** - **a person on top of the vessel falls from height or** - **a person and/or subject near the vessel is hit by vessel or in another manner negatively affected**	**Bruising; dislocation; sprain; fracture, concussion; crushing**
	Low mechanical strength	**Vessel collapses / bursts because of overloading /overpressure / overheating:** - **person or subject is negatively affected; e.g. hit by the flying object,** - **pressurised / hot / toxic fluid is suddenly released; person in the vicinity is hit**	**Bruising; dislocation; fracture, concussion; crushing; burns; acute poisoning; irritation, dermatitis**

[20] The product is either not designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions or the problem is caused by poor design, manufacture, equipment and/or incorrect operation and/or imperfect instructions for use.

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
	High position of user / operator	Person on the vessel loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture, concussion; crushing
Extreme temperatures	Hot / cold surfaces	Person does not recognise the hot / cold surface and touches it; the person sustains burns / frostbite	Burn
	Hot fluids	Person can open a vessel under pressure: - person in the vicinity is hit, - person breathes in the hot gases and suffers lung burn	Scald, lung burn
Fire and explosion	Ignition sources	Vessel itself or parts of it represent ignition sources and cause a fire (e.g. hot surface) : - a person is injured by flames - a person is hit by the blast wave	Burn, scald, poisoning, bruising, dislocation, sprain, fracture, concussion, crushing, eye or hearing injury, foreign body in eye or ear
	Overheating	Vessel overheats; fire, explosion (s.a. low mechanical strength)	
Product operating hazards	Unhealthy posture	Design causes unhealthy posture of person when operating the vessel (e.g. while filling or emptying the vessel)	Strain; musculoskeletal disorder
	Anatomical unsuitability	Design is not adapted to human anatomy, which makes it difficult or impossible: - to operate, check or clean the vessel and / or - to rescue a person (e.g. no or to less / small man	Various injuries

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm/Potential consequences/ Negative effect
		holes)	
	Insufficient warning instructions, signs and symbols	User / operator does not notice warning instructions signs and/or does not understand symbols	Various injuries
	Insufficient warning signals	User does not see or hear warning signal (optical or audio), causing dangerous operation	Various injuries

Table 2: Examples of environmental risk is covered by Regulation (EC) 765/2008.

In the cases illustrated by the table, the correct level of the risk needs to be established on the basis of the limits values provided in specific EU legislation.

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm
Environment (REACH Regulation, POP Regulation – persistent organic pollutants, RoHS Directive, The Paints Directive, Regulation on substances that deplete the ozone layer etc.)	**Chemical pollution**	**The plastic bag of a toy contains short chain chlorinated paraffins in a concentration of 20 000 mg/kg (2% by weight). The limit is 1% according to the Commission Regulation 519/2012 on persistent organic pollutants (POP Regulation).**	**Environmental pollution (toxic to aquatic organisms and carcinogenic to rats and mice)**
		The packaging made of PVC contains up to 1 600 mg/kg of cadmium. The restricted limit is 100 mg/kg according to REACH Regulation.	**Soil and water pollution (cadmium uptake by plants; potential danger to animals that are dependent upon the plants for survival; earthworms and other essential soil organisms die at very low concentration). When cadmium concentrations in soils are high they can influence soil processes of microorganisms and threat the whole soil ecosystem.**
		The solders of toy remote control contain up to 54% of lead. The limit is 0.1% according to Commission Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive).	**Water and soil contamination (water and soil organisms)**
		The car refinishing product contains up to 548 g/l of VOC (volatile organic compounds). The limit is 420 g/l according to the Paints Directive 2004/42/EC.	**Environmental pollution (VOC content of car refinishing products give rise to significant emissions of VOCs into the air, which contribute to the local and trans boundary formation of photochemical oxidants in the boundary layer of the atmosphere).**

Hazard group	Hazard (product property)	Typical harm scenario	Typical harm
		The fireworks contain POP hexachlorobenzene in a quantity of 2 500 mg/kg. POPs Regulation (Regulation 850/2004/EC on persistent organic pollutants) prohibits the production, placing on the market or use of hexachlorobenzene for any purpose, whether on its own as a substance, as a preparation or as a constituent of an article.	Environmental pollution (Soil and water contamination)
		The bathroom cleaner contains 1 % of nonylphenol ethoxylate The limit is 0.1% according to REACH Regulation.	Environmental pollution (aquatic organisms, birds)
		The soft ice machine contains the controlled substance R22 as a refrigerant which is forbidden according to Regulation 1005/2009 on substances that deplete the ozone layer.	Environmental pollution (highly ozone-depleting; global warning potential)
		Content of the oil retention in ammonium nitrate fertilizers is 5.7%, which is above the maximum threshold after taking into account the measurement uncertainty according to Regulation 2003/2003 relating to fertilizers.	Detonation (Detonation is a extremely rapid exothermic chemical process where combustion is driven by the energy shock wave produced by the reaction).
Environment (Recreational Crafts Directive – RCD)	Mechanical/systems failure	• Accidental discharge of fuel or any product capable of producing sheen upon the water. • Propulsion engines do not meet RCD requirements for emissions. • Unintentional discharge of trash caused by wind or seas.	Environmental pollution