

ANNEX

RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS⁽¹⁾

3. *Building a risk assessment step by step*

3.2. **The product hazard**

Hazard is the intrinsic property of the product that may cause an injury to the consumer who uses the product. It can appear in different forms:

- mechanical hazard, such as sharp edges that can cut fingers, or tight openings in which someone can trap their fingers;
- choking hazard, such as from small parts that come loose from a toy, which may be swallowed by a child and make the child choke;
- suffocation hazard, such as from the drawstrings of an anorak hood which may lead to strangulation;
- electrical hazard, such as from live electrical parts that can cause an electric shock;
- heat or fire hazard, such as a heater fan that overheats, catches fire and causes burns;
- thermal hazard, such as the hot outer surface of an oven that can cause a burn;
- chemical hazard, such as a toxic substance that can poison a consumer immediately upon ingestion, or a carcinogenic substance that can cause cancer in the long term. Some chemicals may damage the consumer only after repeated exposure;
- microbiological hazard, such as a bacteriological contamination of cosmetics which may cause a skin infection;
- noise hazard, such as ring tones from toy mobile phones that are much too loud and can damage children's hearing capacity;
- other hazards, such as explosion, implosion, sonic and ultrasonic pressure, fluid pressure, or radiation from laser sources.

For the purpose of these guidelines, hazards have been grouped, linked to the size, shape and surface of a product, to potential, kinetic or electric energy, to extreme temperatures, and others, as shown in table 2. The table is for guidance only, and any risk assessor should adapt the scenario to the product under consideration. Of course not every type of hazard applies to every product.

Nevertheless, table 2 should help risk assessors to look for and identify all possible hazards in consumer products that are being assessed. Where a product has several hazards, each hazard should be taken separately with its own risk assessment and the highest risk identified as 'the risk' of the product. Of course, risks requiring specific risk management measures should also be reported, to ensure that all risks can be reduced.

Note that a single hazard may lead to several injuries in the same scenario. For example, malfunctioning brakes on a motor cycle could cause an accident and result in damage to the driver's head, hands and legs, and could even cause burns if the petrol bursts into flames in the accident. In this case, all injuries would belong to the same injury scenario, and the severity of all injuries together would have to be estimated. Of course, these injuries together are very serious. Several injuries in different scenarios should, however, not be added.

In the daily practice of market surveillance, it may be sufficient to assess the risk from even a single hazard. If the risk from that hazard provides for risk management action, that action can be taken without further ado. Nevertheless, the risk assessor should be sure that the risk identified is (one of) the highest risk(s), to ensure that the risk management action is sufficiently effective. This is always the case when the risk is serious, since this is the highest possible

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risk level proposed in these guidelines. In cases of less than serious risk, however, further risk assessments might be necessary and possibly specific risk management at a later stage. In conclusion, experience with risk assessment in market surveillance practice will limit the number of required risk assessments to a minimum.

Hazard identification by tests and standards

Hazards are often identified and quantified by tests. These tests and how to carry them out may be laid down in European or international product standards. Compliance of a product with a 'harmonised' European standard ('EN ...'), of which the references have been published in the Official Journal, provides presumption of safety (albeit only for the safety characteristics covered by the value(s) or standard(s)). It can be presumed in such cases that the product presents only a minimum risk and a high level of protection with regard to the specific hazard tested.

Nevertheless, there may be instances where presumption of safety is not the case, and in such cases a particularly well-documented risk assessment will have to be prepared, including a call for amendment to the harmonised standard.

On the other hand, if a product fails the test, a risk can normally be assumed, unless the manufacturer can provide evidence that the product is safe.

Products may still present a risk even though they do not cause injuries

Products may not be hazardous but can nevertheless cause a risk, due to not being fit for their intended use. Examples of this can be observed in the area of personal protective equipment or life-saving equipment, such as reflective jackets that car drivers put on after an accident. These jackets are meant to get the attention of oncoming drivers and traffic participants to warn them of the accident, in particular at night. However, they might not be seen if the reflector stripes are too small or do not reflect sufficiently, and do not therefore protect users as they should. These jackets therefore pose a risk even though they are not hazardous in themselves. Another example is a sunscreen product which displays 'high protection' (sun protection factor of 30) on the label but provides only 'low protection' (factor of 6). This can lead to severe sunburn.

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- (1) If you need more information on the Risk Assessment method for harmonised products (both consumer and professional products) in relation to broader categories of public risks protected under EU harmonisation legislation, please refer to Part I, Chapter 5.3.

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