



An introduction to safety assessment of the mechanical, physical, flammability and electrical properties of toys as well as hygiene and radioactivity properties

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*The new [Toy Safety Directive 2009/48/EC](#) specifies that manufacturers shall carry out a safety assessment **before** placing a toy on the market, and that this safety assessment shall be part of the technical documentation.*

In the Directive, the safety assessment is defined as an analysis of the possible hazards, associated with the properties of the toy, and an assessment of the potential exposure to such hazards.

The following definitions apply:

- harm: physical injury or any other damage to health, including long term health-effects
- hazard: a potential source of harm
- risk: the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm

Thus, the safety assessment is a kind of risk analysis including chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present. When it comes to chemical risks, the Directive specifies that the risk analysis must include an evaluation of the likelihood of the presence in the toy of prohibited or restricted substances. In addition, the general safety requirement applies, stating that toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way.

The risk analysis for toys can be split up into different hazard-groups:

- mechanical, physical, flammability and electrical hazards, for which standards already exist
- hygienic hazards and hazards linked to radioactivity, for which no toy standards exist at present
- chemical hazards, for which some standards exist

This article does not deal with chemical hazards.

Mechanical, physical, flammability and electrical hazards

For mechanical, physical, flammability and electrical hazards, standards have been developed (EN 71-1, EN 71-2, EN 71-8 and EN 62115) to support the particular safety requirements specified in the Directive. These standards aim, as far as possible, to reduce risks that are not

obvious to the user. When such a standard has been approved by the European Commission, a reference is published in the Official Journal of the European Union. If a toy complies with all applicable requirements in such a referenced standard, it is presumed that it complies also with the particular safety requirements of the Directive.

A **referenced standard** can be considered to be a documented risk analysis made by the standardization body. The aim when drafting the various standards has of course been to cover all hazards (within the scope of the standard) that toys may present and to specify requirements that will minimise risks of injury. The standards also consider the fact that there are cases where all hazards cannot be eliminated by design and that a certain risk of injury therefore remains. One example is the instability of a bicycle, which may lead to a child being injured if it falls over when using the bike.

In such cases, as in the example of the bicycle, the standard can state that residual hazards shall instead be addressed by the use of warnings and/or instructions to the users regarding how the hazards can be avoided or how the potential harm can be minimised (an example would be a warning regarding use of protective equipment when riding a bicycle).

There are a few cases where it has not been possible to define exact methods in the standards for determining whether the toy complies with a particular requirement. In such cases the standard leaves it to the user of the standard to make a subjective assessment. Examples of such cases in EN 71-1 (Mechanical and physical properties) are:

- A visual assessment shall be used to determine if toy material is visually clean and free from infestation
- A toy that fails the test for sharp edges or sharp points shall be assessed to determine whether or not the edge/point presents an unreasonable risk of injury
- Tubes and rigid components in the form of projections shall be assessed to determine if they constitute a puncture hazard (only then do they need to be protected)
- Unless a driving mechanism is assessed to have sufficient power to injure fingers or other parts of the body, it is not covered by certain requirements

Considering the above, it can be concluded that **the main purpose of a safety assessment for mechanical, physical, flammability or electrical hazards is to ascertain that no hazards are present that are not covered by these harmonised standards.** This analysis is particularly important for new, innovative toys (new designs, new materials, new features, etc.) since these may not have been considered when the standards were developed. A historic example which is often used when explaining how innovative toys could suddenly present an unaddressed hazard is toys with magnets. When strong magnets were introduced as a new play value, these toys in some cases proved to be unsafe even though they complied with the standards. This was, however, mainly because the standards did not address the hazard presented by a toy that contained several small and strong magnets. The standard has now been updated but we do not know what types of new innovative toys might be on the market tomorrow. Regardless of which requirements a standard includes or does not include; the general safety requirement of the Directive always applies: toys must be safe!

The Toy Safety Directive also specifies that unless a toy fully complies with a referenced standard, it has to undergo an EC-type examination, carried out by a so-called Notified Body. The same applies if the toy presents a hazard which is not covered by the referenced

standard(s). This is why it is essential to ensure that the hazards of a toy are covered in referenced standards. One must also observe that in some cases the Commission has published a reference to the standard together with a restriction. The restriction can state that for a particular clause, the standard does not give presumption of conformity.

When determining if all mechanical, physical, flammability and electrical hazards a toy presents are covered by a referenced standard, the list of hazards presented in the so-called [RAPEX Guidelines](#) can be used for “inspiration” (Part IV, item 5). The table “Hazards, Typical Injury Scenarios And Typical Injuries” presents several hazard groups (e.g. size/shape/surface, kinetic energy, electrical energy) and for each hazard group a number of hazards (product properties) are exemplified together with an injury scenario and also typical injuries (parts of the table has been annexed). The table was not elaborated specifically for toys but still gives good guidance when considering hazards.

Examples of hazards are:

- parts causing entrapment of head/neck, fingers, limbs, feet and hands, for example
- moving parts causing, for example, crushing
- cords causing strangulation
- small parts causing choking
- sheeting or packaging causing suffocation
- edges and projections causing cuts and injuries
- electrical parts causing electric shock
- noise, causing hearing impairment
- flammable parts causing burns

If it turns out that the toy does present a hazard which is not addressed by the relevant referenced standards (EN 71-1, EN 71-2, EN 71-8 and EN 62115) design changes should be made to eliminate the non-covered hazard(s). The alternative is to submit the toy to an EC-type examination.

Hygiene and Radioactivity hazards

No toy safety standards have been developed to support the requirements in the Toy Safety Directive regarding radioactivity and hygiene. The toy must of course fulfil the requirements of the Directive and it is accepted that the manufacturer can ensure compliance with the Directive through the safety assessment procedure.

With regard to **radioactivity**, the Directive requires that toys shall comply with all relevant measures adopted under Chapter III of the [Treaty establishing the European Atomic Community](#).

A simple risk assessment would include ascertaining whether any radioactive materials are present in the toy (have been added to the toy). If the answer is “Yes”, these materials must be removed; if the answer is “No”, the toy is compliant with the Directive.

With regard to **hygiene**, the Directive requires that toys shall meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.

Microbiological contamination can, for example, lead to infection or sickness due to the presence of one or more bacteria, yeasts, mould, fungi, protozoa or their toxins and by-products. The safety assessment should therefore cover the presence of such hazards in cases where the toy contains any natural materials used like nuts, pips, etc. or if any liquids are used. Testing of microbiological activity can be made according to methods described in the [European Pharmacopoeia](#). Also, the notified bodies have adopted a recommendation on "[Microbiological safety of toys containing aqueous media](#)".

Additional requirements regarding hygiene apply to toys intended for children under 3 years. These toys must be possible to clean. In the case of textile toys for children under 3, these shall be washable (except if it contains a mechanism that may be damaged if soaked). A textile toy is a toy which is 100% textile (e.g. a toy with plastic limbs and a textile body is not a textile toy). The safety assessment shall therefore cover such aspects and shall show that such toys fulfil the safety requirements also after having been cleaned/washed in accordance with the manufacturer's instructions. For this purpose, the safety assessment could lead to a conclusion that certain cleaning/washing instructions should be supplied with the toy.

Make further use of the risk analysis

When the risk analysis shows that all the hazards of a toy are covered by the harmonised standards, a manufacturer can decide to reduce the risk further. Even if a toy complies with the standard(s), it may be obvious from the risk assessment that some risks can easily be further reduced, e.g. by design changes. This is an internal decision for manufacturers to take but the manufacturer is entitled to turn to a third party for assistance in the process of assessing whether the safety of the toy can be further improved. When assessing such possibilities, factors such as the age of the intended user (and thus the abilities of the user), the expected and the foreseeable play pattern and the level of adult supervision that can be expected, should be considered.

For further and detailed information on the required safety assessment, consult the European Commission's general guide on Directive 2009/48/EC and the guide on technical documentation under this Directive (which will be published shortly):
http://ec.europa.eu/enterprise/toys/eq_guidance.htm

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