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"Safety Assessment" of Toys - a Requirement?

According to the Toy Safety Directive, manufacturers must carry out a safety assessment of their toys before they are placed on the market.

Law Requirements

Article 18 of the Toy Safety Directive states: "Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards".

In other words, before placing a toy on the market, toy manufacturers need to carry out a risk analysis of the existing hazards that their toys may present, together with an assessment of the potential exposure to such hazards.

Annex IV to the Toy Safety Directive also states that the safety assessment should be part of the manufacturer's technical documentation. This means that the safety assessment is to be documented and manufacturers shall be able to present it to authorities upon request.

What's its purpose?

The purpose of the safety assessment is, of course, that only safe toys are put on the market. The safety assessment can, however, bring other benefits such as:

- it is a good tool for determining which tests are relevant and it can therefore help eliminating unnecessary testing costs,
- it can lead to the identification of improvement opportunities beyond what is required by law,
- it can help verifying that the tools used (e.g. standards) ensure that the toy is compliant with the general and particular requirements of the Toy Safety Directive.

Is there any guidance?

The Commission's Guidance Document on the application of the Toy Safety Directive provides detailed information on the safety assessment of:

- Mechanical, physical and electrical hazards as well as flammability. These are areas for which there are standards with requirements that support the Directive's requirements (EN 71-1, EN 71-2, EN 71-8, EN 71-14 and EN 62115)
- Hygienic properties and radioactivity. These are areas for which there are currently no standards but where the safety assessment is considered to be a way of demonstrating that toys are in compliance with the requirements of the Directive



– Chemical hazards. This is an area where there are certain standards (such as EN 71-3, 71-4, 71-5, 71-7, 71-12 and 71-13) that support the Directive's requirements. However, where standards are missing for other chemical hazards, the safety assessment is considered to be an alternative way of demonstrating that toys comply with the requirements of the Directive

Aren't the standards sufficient?

Making a safety assessment is not the same as "just" testing the compliance with one or more standards. Also and as mentioned, there aren't always standards available covering all aspects

The safety assessment is about:

- Identifying the intended and foreseeable use of the toy, taking into account the age group the toy is intended for.
- Identifying the hazards that the toy can present to the users.
- Identifying which standards are currently available.
- Determining whether the requirements in the standards cover the hazards that the toy can present.

In order to identify the hazards that a toy may present one can, in addition to the standards, use one's experience, consumers' complaints, the Rapid Alert System for dangerous non-food products, industry associations' newsletters, EU Commission guidance documents, etc.

Overall, the safety assessment assumes that you have a good knowledge of the toys you manufacture, of how they can be used, how to assess their risks, the legal requirements that apply to them, etc.

How "good" should the safety assessment be?

The Toy Safety Directive does not specify in detail what a safety assessment should look like - the text only states that it should be carried out and documented. However, the better the safety assessment, the less likely that the toys put on the market can cause harm to children and/or be non-compliant. Therefore, one can claim that it is in the interest of the manufacturer to have the best possible process for the safety assessment.

When is an update required?

The safety assessment must be carried out before the toy is placed on the market and updates are not required without reason. However, in the following cases an update should be made:

- Changes in the toy design or of the raw materials used for its manufacturing
- Changes to the legal framework or to safety standards
- Consumers' complaints indicating the existence of potential risks
- Justified recalls of similar toys

The update should include a validation if/how the new information affects the previous safety assessment.



Mechanical, physical, electrical and flammability hazards

Standards are indeed of great help when it comes to mechanical, physical and electrical hazards as well as flammability. The safety assessment in those cases is relatively simple because there are well-established standards. However, it is important to be especially careful when introducing new play features and novelty properties to toys. Standards are in the majority of cases based on knowledge of today's toys but not on tomorrow's. For example, there were no specific requirements for magnets in the relevant standard when strong magnets began to be used in toys. Today, we know that strong magnets can be dangerous if a child swallows two or more and the standard has been therefore updated with the new requirements. This example shows that a safety assessment can lead to the identification of a hazard that was not previously covered by a standard.

Hygienic hazards and radioactivity

Hygienic hazards include the risk of microbial contamination of water-based materials or natural materials such as kernels, peas, etc. It can also be about the possibility of cleaning or washing toys intended for children under three years old (the cleaning option is a requirement in the Toy Safety Directive). It is difficult to give examples of dangers related to radioactivity, but it could for instance be about materials coming from areas contaminated with radioactivity.

Determining whether microbial growth can occur or not in water-based or natural materials often requires laboratory tests. The body for cooperation between the notified bodies under the Toy Safety Directive, has recommended certain tests in a document available on the European Commission's website (see link at the bottom of the article).

Similarly, the notified bodies group has agreed on testing methods that can be used to ensure that a textile toy for children under three years can be washed without the level of safety being lowered such that it fails limits in safety standards.

Chemical safety

A safety assessment of the chemical hazards is aimed at evaluating the likelihood of the presence in the toy of substances prohibited or restricted under the Toy Safety Directive or other applicable regulations. However, other chemical hazards should also be taken into account, for example, if there is knowledge of the presence of chemical substances for which restrictions are planned but not yet introduced, as well as knowledge of substances on the candidate list (see link at the bottom of the article for more information).

It is important to have as much knowledge as possible about the chemicals used during the toy production. The less information one has, the greater the risk that one is not in control of chemical hazards. An optimal situation for a comprehensive chemical safety assessment could be when:

- There is a Bill of Materials (BOM) which contains only approved and traceable materials (i.e. the trade names are known)
- There is a Bill of Substances ((BOS) which is available for all the materials
- All substances in the BOS have been evaluated and it has been found that they:
 - o Do not exceed the total/migration limits set in laws/standards



- Do not contain any inherent hazards to which the user may be exposed
- No changes are made to BOM / BOS without new materials/substances being evaluated/approved
- There is a safety data sheet available for the chemicals used in production (when required by REACH)
- Test reports can be clearly linked to the materials/components used

Very few manufacturers find themselves in this "optimal situation" but everyone should strive in that direction.

More information

On the European Commission's website one can find the documents mentioned in the article:

http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm<https://www.echa.europa.eu/sv/candidate-list-table>