



**Ministry of Environment
of Denmark**
Department



**MINISTRY OF INDUSTRY, BUSINESS
AND FINANCIAL AFFAIRS**

NOTE

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Danish comments to public consultation of the revision of the Toy Safety Directive

The Danish Government welcomes the revision of the Toy Safety Directive. It is important that all toys placed on the EU market are safe and compliant with the legislation and that the legislation is up to date with regards to the newest scientific knowledge, new types of toys on the market and new ways of selling toys, e.g. through online marketplaces. Therefore, the revision of the directive is needed and appreciated.

Comments related to the questionnaire

Generic risk approach

The most harmful chemicals, as pointed out in the Chemical Strategy for Sustainability, shall be banned in toys, as CMR substances are banned in toys today. The most harmful chemicals that should be automatically banned in toys include CMR substances, endocrine disrupting substances, substances affecting the immune, neurological or respiratory systems, chemicals toxic to specific organs, substances that can cause an allergic response following skin contact, and PBT's, vPvB's, PMT's and vPvM's. An automatic ban of these substances in toys, must be introduced as soon as possible.

An automatic ban of the most harmful chemicals should be introduced not only in toys, but also in other consumer products. It is essential that products children use (e.g. toys) and products for children (e.g. childcare articles) are handled the same way to ensure a high protection of children. This could be by either broadening the scope of the Toy Safety Directive to toys and products for children or by introducing an identical ban in the REACH Regulation for products for children with the same entry into force as for toys.

To harmonize the generic risk approach, hazard identification of substances shall be performed under the CLP Regulation, and it is important that the CLP Regulation include hazard classes for endocrine disrupting substances for early identification of those hazardous substances. Automatic ban of CMR's, endocrine disrupting substances, substances affecting the immune, neurological or respiratory systems, chemicals toxic to specific organs and substances that can cause an allergic response following skin contact should be introduced in a toy safety directive/regulation. But also automatic ban of substances that are bioaccumulative as

PBT's and vPvB's should be introduced in a toy safety directive/regulation, as these substances can be expected to accumulate in humans as well as in the environment. Automatic ban of PMT and vPvM substances can be introduced in REACH, as the exposure of the environment from these substances from toys will be similar to the exposure from other consumer products.

Derogations to an automatic ban of substances of concern

The Chemical Strategy for Sustainability highlights that the most harmful chemicals are only allowed, if their use is necessary for health, safety or is critical for the functioning of society, and if there are no alternatives that are acceptable from the standpoint of environment and health. Denmark supports that derogation to the automatic ban is introduced, if specific requirements are met. The impacts of the requirements should be assessed and the assessment should include the following:

- Only trace levels of chemicals of concern are allowed as is the case for CMR substances in cosmetic products.
- A scientific committee has assessed the use of the most harmful chemicals as safe under a specific concentration.
- The most harmful chemicals are inaccessible.
- The lack of alternatives.

Denmark is of the opinion that toys, as a product group, is essential for the society. Every single piece of toy can on the other hand not be seen as essential. It is therefore important to set requirements for derogations that makes sure that toy as a product group is not banned due to an automatic ban on the most harmful chemicals, but to set requirements that ensures that toys are safe and to the widest extent do not contain substances of concern. Denmark therefore finds that as a minimum a derogation can only be given for substances of concern, if an assessment of alternatives shows that there are no suitable alternatives and if the use of the chemical has been assessed by a scientific committee and the use is safe under normal and foreseeable conditions.

Setting specific chemical limit values for toys for children of all ages

Denmark strongly supports the possibility to set limit values for chemicals in toys for children of all ages and not just for toys for children under the age of 36 months and to toys intended to be put in the mouth.

There have been several examples on toys for children above 36 months where requirements for chemicals are necessary. An example is preservatives in modeling clay. The preservatives listed in appendix C are skin sensitizers and these preservatives are restricted in toys for children below 36 months, but not in toys for older children as modelling clay, even though they are just as sensitizing for older children.

Moreover, the Scientific Committee on Health Environment and Emerging Risks (SCHEER) has concluded in an opinion on chemicals in squishy toys (https://ec.europa.eu/health/publications/toxicological-reference-values-certain-organic-chemicals-emitted-squishy-toys-regard-adopting-limit_en) that children younger than 6 years old might bite, chew or suck on the toy with the possibility of a release of substances into saliva due to migration (see appendix 1.1). The current TSD does not cover the oral exposure and possible risk of chemicals in toys for children at 3-6 years old, but only children under the age of 36 months through appendix C. To protect the children of the age of 3-6 years old as much as the smaller children, appendix c should be expanded to cover toys for children up to the age of 6 year.

One way to implement specific chemical limit values could be to introduce one limit value for the specific chemical for children up to 3 years, another for children between 3-6 years and a third limit value for children above 6 years old. In this way, it is possible to consider the realistic exposure scenario and thereby achieve a more safe level for all children.

Labelling obligations of chemicals

We support an introduction of labelling requirement for chemicals in toys that are substances and mixtures and with the possibility to introduce such a requirement for all other toys at a later stage. Labelling requirement would create great value for both consumers, retailers and for authorities:

A Danish survey shows that consumers are concerned about the presence of harmful chemicals in toys. Furthermore, more than half of the consumers see a need for a labelling of chemicals present in toys. One third of the consumers from the survey were looking for information regarding chemicals in toys before buying them, and in many cases, this information was not available.

Experience from a Danish retailer (who has implemented a labelling requirement) and its suppliers show that labelling of chemicals will also be of value for the retailers, as it will lead to greater transparency in relation to the use of chemicals throughout the entire supply chain. Labelling of substances will also make it possible for distributors and importers to set criteria for the content of certain substances and make it relatively easy to check compliance.

Labelling of chemicals on toys will also be of value for authorities, as it will provide valuable information about the use of chemicals in a product group, where this information is not readily available now.

As proposed in this paper under the digital product passport, the information of the content of chemicals could be provided in the digital product passport, and it should be considered, if the information should be on

the product as well. With advantage, possible synergies between these two initiatives could be considered further.

Data security and cyber security for toys

Data and cyber security requirements are important for products to avoid risking that personal information and data are leaked via products or that consumers are exposed to fraud. These challenges are applicable to all internet-connected products. It is not a specific problem for toys alone.

It is therefore advantageous to place rules regarding data and cyber security in more general legislation than to include it in the sector specific legislation for toys and thereby compiling rules for cyber security in RED and rules for data security in GDPR. If specific risks for children's data and cyber security in toys arise and if these are not considered and addressed under any other legislation, then it is our opinion that it is important to include these rules in the revision of the TSD. It is our understanding, that the GDPR covers internet-connected toys and when data processing occur, while RED only covers data containing a radio unit. If there are cyber security or data security risks not covered by these legislations, then it must be included in the revision of the Toy Safety Directive.

Potential psychological risks

The Danish Safety Technology Authority has not received any reports regarding potential psychological risks of toy products, and we are therefore not aware of psychological risk of toys being a widespread problem in Denmark.

We acknowledge that there can be toys and scenarios where toy products can have a negative psychological effect on children, whether the use of the product encourages inappropriate or dangerous behavior or because the toy can be frightening for children in a certain age group.

If rules regarding psychological risks of toys are implemented in the TSD it is important that specific frameworks and guidelines are included so that businesses and market surveillance authorities have a specific starting point for the assessment of such risks. If there is no clear definition then it will be difficult to control for authorities and for companies to be compliant. It is important to acknowledge that there will be a demand for new skills for companies and authorities in order for them to assess the potential psychological risks of toys, and that these skills only are present at a minimal level today. There is therefore a need of clear guidelines for the definition of psychological risks, if these are to be included in the TSD.

Should the directive be converted to a regulation?

It costs resources for authorities to implement changes from the Toy Safety Directive into national law, and it can be advantages to convert the

directive into a regulation, thereby saving national resources. In Denmark, the directive is implemented via the Danish Executive Order, and it is the assessment of the Danish Safety Technology Authority that a conversion from directive to regulation only will have a small amount of influence on the product safety of toys itself. The advantages are therefore in regards to resources and not for the product safety of toys.

Third party verification of toys

Third-party verification/EU-type certificate is rarely seen on toys in Denmark, even on chemicals, where the existing harmonised standards and the chemical requirements in the directive does not cover all hazards that chemicals can cause. Depending on the chemical requirements in a new directive/regulation on toys, it can be considered if third-party verification/EU-type certificates should be more commonly used in cases of chemicals, especially for the emission of chemicals, where no requirements exists. Either there need to be more third-party verification/EU-type certificate of the content/migration/emission of chemicals from toys, or the chemical safety assessment should show that the toy is safe, which is not the experience from the Danish Environmental Protection Agency today.

Today, when companies perform conformity assessments of their toy products, there is only a requirement of third party verification from a notified body, when the products are not tested after harmonized standards or if there are potential risks that the harmonized standards does not take into account. By far, most of toys are today tested after the harmonized standards on the physical/mechanical aspects, and it is relatively rare that toys are verified by third parties before they are brought to market.

There is a number of requirements on how to test toys in the harmonized standards. However, to this day, there are no requirements for the test laboratories that perform these tests after the harmonized standards. This means that there is a potential risk that laboratories without the necessary skills and knowledge are able to test toys that are brought to market afterwards. The Danish Safety Technology Authority therefore believe that there should be requirements for the skills and knowledge of the laboratories that test products by harmonized standards, and that this option will be able to address the issue more effectively than an expansion of third party verifications.

Digital Product Passport

Denmark is in favor of the introduction of a digital product passport (as proposed in the Sustainable Products Initiative) for most products, toys included, and that information about the product will be accessible for

both consumers and authorities in the passport. As such, information concerning e.g. EU-type examination certificates, safety information (including the safety assessment), the content of chemicals for toys etc. disclosed by the responsible company or any notified body would be of value to the enforcement authorities and some of the information would be of interest for consumers.

However, it is important to keep in mind that all the information directed at the consumers should not only be provided digitally. The most important information should be placed and kept on the toys or the packaging of the toy. It should furthermore be considered if a future labelling requirement of chemicals in toys should be given on the physical product or digitally or both.

The Danish Safety Technology Authority's experience is that we in most instances receive the documentation that we request such as conformity assessments and third party test reports when relevant and when requested. Therefore, we cannot conclude that a digital product passport with the relevant and necessary documentation will heighten the compliance of toy products and companies significantly.

However, it is important to note, that the abovementioned compliance to document requests does not exist in the case of online platforms. It is significantly more difficult to obtain the needed and requested documentation from online platforms. A digital passport could make the request for documentation easier for authorities in this instance.

A digital product passport has the potential to further heighten toy safety for children, as it can create a basis of information on which the consumers can decide whether to buy a product or not.

If a general digital product passport is introduced to almost all products across sectors through other legislations, such as the Eco-Design for Sustainable Products Regulation, it would be highly efficient and recommendable to require the documentation for the safety of toy products to be included in the general product passport. This would reduce the amount of resources for market surveillance authorities in the performing product controls when requesting and obtaining documentation. If the right solution is developed, it can potentially also make it easier for companies to provide and display information for consumers and authorities.

The Danish Safety Technology Authority in general encourages streamlined requirements for the digital product passport across all harmonized standards, as it will simplify requirements to the products content to the benefit of as well the consumer, the companies, and the market surveillance authorities.

The market surveillance authorities would benefit from the inclusion of conformity assessments and of documentation of the toy products' safety compliance in the digital product passport. For toys, this documentation typically consists of test reports on the physical/mechanical and chemical tests, where the products are tested after harmonized standards that are published in the Official Journal.

The existing labelling requirements should also be included in the digital product passport. We cannot expect that the consumers always have the necessary means (e.g. smartphone) to access the digital product passport to when buying toy products in a physical store. The Danish Authorities therefore believe that warning labels such as age limits, weight limits, height limits etc., should still physically be placed on the product. It should be considered whether information about chemicals should be given physically on the toy or disclosed in the digital product passport only.

Comments on other issues

Online platforms

Consumer safety should not rely on whether a product is purchased in a physical store or from an online platform. It is important that sellers from third countries who sell from online platforms, does not bypass product safety regulations and requirements for toy products and thereby creating unfair competition for EU businesses and potential risks for consumers. The Danish authorities support the demand for online platforms to assume the same responsibilities as importers, when they facilitate sales from third party countries on the single market.

We do not experience the same issues in obtaining documentation from traditional web shops, where a company sells their products directly to consumers, as companies in general are easily classified as 'manufactures', 'importers' or 'distributors', enabling us to treat them as companies with physical stores.

Especially in terms of *toys sold online through online marketplaces* by traders established outside the EU, the non-compliance with the TSD is very high – and the issue is that the current legislation has no effective measures to place the liability for the non-compliance on an economic operator.

It is an issue, that online platforms cannot easily be placed into these categories defined by current regulations. This means that we cannot effectively hold online platforms accountable for their products' compliance to product safety, and we find it difficult to obtain requested documentation.

It is important that online platforms can be held accountable to the same degree that traditional importers are when they act according to this role. Online platforms must make sure that their products are compliant with the rules and requirements in the TSD and other relevant legislation for toy products, when no other relevant economic operator is available.

We had expected that the Digital Services Act amending Directive 2000/31 (the e-Commerce Directive) would close this legal loophole by introducing that a liability on an economic operator in the EU existed in all cases. This would create a level playing field for all economic operators making products available on the market, it would enable and facilitate enforcement by the market surveillance authorities in cases of non-compliance and it would raise the level of protection for consumers in the EU. However, the regulation does not introduce such a liability and that the measures actually introduced are not sufficient to battle the issues of non-compliant toys sold on online marketplaces. For instance, it remains to solve the issue of illegal products constantly reappearing online though they have already at least once been removed.

We believe that any natural or legal person established outside EU that makes a toy available on the market, should always appoint a person established in the EU that is responsible for the compliance of the product – and that the online marketplace shall be responsible for the compliance of the product, if no such person has been appointed. This way the online marketplace would hold a liability corresponding to its importer-like role in the product distribution chain. Furthermore, we suggest that for online marketplaces established outside the EU, the legal representative that is to be appointed according to the DSA, should be liable for the non-compliance with obligations under this regulation, i.e. if the online marketplace does not live up to its responsibility.

Another thing is the increasing emergence of so-called “pop-up” companies, i.e. companies that are only in business for a short while, usually in order to benefit from the access to the market without having to face possible legal consequences of non-compliance. This issue of these cases of “voluntary bankruptcy” is of more horizontal character, but still we believe that it is an issue that should be held in mind when revising the chemicals legislation, including the TSD. A possible way forward could be introducing a liability rule, similar to the one proposed in regards to online marketplaces, that ensures that the responsibility for the compliance of a product can always be placed on a *solvent* economic operator established in the EU.

Finally, on a more general level we note that enforcement measures should promote smooth interplay of knowledge and procedures between customs authorities and market surveillance authorities. Under the

REACH Regulation it is being proposed to embed the Authorised Economic Operator and to develop an EU-wide TARIC list of high-risk products. Similar measures could with benefit be considered under the revision of the TSD in coordination with DG TAUX. Furthermore, it is important that control procedures are the same regardless of the “Port of entry” which is chosen in a specific case, so that an economic operator cannot benefit from choosing one port of entry instead of the other.

Combined exposure of chemicals – introduction of a Mixture Assessment Factor

During the course of a day, a child typically uses a wide range of toys and other products. Hence, the probability of exposure to substances with the same mechanism of action from various products is substantial. Currently, specific chemical limit values for toys are evaluated as substance-by-substance, when specific chemical limit values are established.

Thereby the exposure from other substances with the same mechanism of action are not taken into account. To ensure that children are consistently protected, and there are no risk for children’s safety, the combined exposure should be included in the evaluation and safety assessment. One possible method for doing this is by introducing a Mixture Assessment Factor (MAF). A MAF addressing co-exposure from unknown unintentional mixtures should be introduced as soon as possible.

We have commented in the targeted survey launched by the consultants providing input to the Commissions planned impact assessment with support for introducing a single MAF addressing both human health and the environment with a factor of 10 for all registered substances. It is long overdue to address the issues with combination effects of chemicals and the need for action was announced more than 10 years ago in both Council Conclusions (17820/09) and in a message from the Commission to the Council and Parliament (COM(2012) 252 final).

Chemical safety assessments and requirements for toy safety assessors

According to the current TSD, manufacturers must prepare a safety assessment, including a chemical safety assessment, as part of the technical documentation. It is mandatory to perform a safety assessments for all toys and the assessments shall cover all relevant aspects to ensure the safety of human health.

As given from the article (art. 18), the manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical (...) hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Experience has shown that the chemical safety assessments, that has been requested, quite often are unavailable or deficient to a varying degree. It is the overall experience that an analysis of the chemical hazards has not

been done, and that the manufacturer uncritically analyse after the standard EN 71-3. Therefore, toys are generally not assessed for the chemical hazards that the specific toy might possess as is the goal of the chemical safety assessment. As a result of this, any assessment of the potential exposure to the hazards has not been done either.

It is also the overall experience that guidance and instruction from the authority in the attempt to correct the evidently huge issue of deficient or lacking safety assessments are scarcely fruitful. Any attempt of correction of the safety assessment performed by the manufacturer often result in the fact that the corrected safety assessment cannot be accepted either.

In dialogue with the Danish Toy Industry, it is made clear that the guidance document on technical documentation is not sufficient as a guiding tool, and the industry in general has not sufficient knowledge on how the safety assessments with regards to the chemical aspects should be performed.

Therefore, we strongly recommend to make it more clear how the safety assessment for the chemical aspects should be carried out. Firstly, it should be specified in the regulation that the assessment of chemicals should take into account the general toxicological profile of the ingredients, their chemical structure and their level of exposure. Secondly, a generic template should be developed as the one implemented in the Cosmetics Regulation, Annex I. As a minimum of obligations and requirements that should be considered included in the template are the following elements:

Unique number to identify the toy.

- Information on manufacturer and/or importer.
- Bill of materials (BOM); List of raw materials, intermediates and components used to manufacture the final toy, stating the quantities used.
- Bill of substances (BOS); List of chemical substances in each material and where the chemical is in the product, stating the substance CAS numbers and the concentrations in which the substances are present.
- Safety Data Sheet (SDS); Safety data sheets for chemicals used in the manufacturing process if required under REACH Regulation.
- Test reports when relevant; Results of chemical analyses documenting that the toy complies with relevant regulation, but also name and address of the laboratory performing the test.
- Hazard characterization of the substances listed in BOS.
- Exposure scenario that includes all routes of exposure to all the chemicals in the toy.
- Risk assessment carried out in accordance to updated EU-guidance.

To support the template in a new toy directive/regulation, a new guidance document should be developed. The Danish authority has in collaboration with the Danish Toy Industry made a guidance document to support the industry in how to carry out the chemical safety assessment, but also how the importer and distributors could prepare the dialogue with the suppliers. This is available in both Danish and English and it (or a shorter version) could be used as an supporting guidance document. Besides the definition, template and guidance on chemical safety assessments of toys, we also recommend that the new TSD is setting minimum requirements for the safety assessors and their qualifications. To carry out a chemical safety assessment, it is crucial that the assessment is carried out by a person in possession of the necessary qualifications. It necessary, but also appropriate, to require, that the chemical safety assessment shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy or toxicology, chemistry and theoretical and practical knowledge on chemical risk assessment.

Transitional periods for new chemical requirements

The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01) states that "The placing on the market is the most decisive point in time concerning the application of the Union harmonised legislation" and that "Compliant products once they have been placed on the market may subsequently be made available along the delivery chain without additional considerations, even in case of revisions to the applicable legislation or the relevant harmonised standards, unless otherwise specified in the legislation." This guidance text applies unless otherwise specified in the product legislation concerned.

Today, when new requirements for chemicals in toys are introduced, there is no specification of whether and how long toys containing the banned chemicals can be made available on the market. This means that the principle above applies, i.e. that a toy containing banned chemical substances can be made available on the EU market for many years, if the toy at the time of the placing on the market was compliant with the legislation.

This creates an unnecessary exposure for children of chemicals that might be harmful. Furthermore, in practice, this state of law is also almost impossible to enforce by the market surveillance authorities, since any enforcement measure in this regard requires information on exactly when the product was made available on the market for the first time i.e. the time of the placing on the market in order to determine which legislation applied at that time. When performing market surveillance activities such as the power to carry out unannounced on-site inspections and physical checks of products cf. article 14 (4), litra d in Regulation 2019/1020 , the

information on the time of the placing on the market is rarely available to the market surveillance authorities.

To overcome the issues above, we suggest that transitional periods for the making available on the market of toys containing banned chemicals are being inserted in a directive/regulation. Such transitional periods are used under other product legislations, e.g. the Cosmetics Regulation, and are known to be workable for both industry and market surveillance authorities. The length of the transitional period can vary depending on the availability of alternatives.