



Germany not permitted to deviate from the TSD

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Since the beginning of 2011 there have been discussions and later also legal processes, since Germany chose not to implement some of the chemical requirements laid down in the new Toy Safety Directive. It regarded e.g. the new migration¹ limits for antimony, arsenic and mercury from toy materials. Germany considered that certain limits in the new directive, which came into force July 20, 2013, gave a lower level of protection for children than the limits that applied under the old directive for these substances. The matter was taken to the EU Court of Justice and on July 9, 2015 the final judgment of the European Court of Justice was passed: Germany must implement the limits for antimony, arsenic and mercury that apply under the new Toys Safety Directive and which have been introduced in all other EU countries. The court was of the opinion that Germany had not demonstrated that the old limits would provide a higher level of protection.

Migration limits in the old and new TSD

The amount of certain chemical substances that can be permitted to migrate from toy materials, is specified in the Toy Safety Directive. A supporting standard (EN 71-3) is linked to the directive, and specifies methods for how to measure the migration. Migration is measured by comminuting the material and then placing it in a solution simulating gastric acid. After a specified time, the amounts of chemical substances that have migrated to the solution are measured.

The old directive specified limits for migration of 8 elements from toy materials.

When the new directive was designed, a large piece of scientific was carried out, that led to a new principle for the establishment of migration limits. Simplified one can say that:

- It used the amount of a particular substance that a person can ingest every day, for a lifetime, without having adverse effects. These small amounts are called "tolerable daily intake" (TDI) and are stated as amount per kg body weight.
- It also defined the quantity of toy material a child could theoretically happen to "eat" (every day). The amount was defined for three types of toy materials: Liquid (e.g. soap bubbles), pliable/powder-like materials (e.g. modelling clay/chalk), and scraped-off material (e.g. plastic, metal, or a surface coating of paint). The theoretical ingestible amount is greatest for liquid materials because it is easier for children to accidentally ingest liquid than to ingest a material that must be scraped-off.

¹ Migration means that a chemical substance contained in a material "leaks out", for example when a child puts the material in the mouth and/or ingests parts of it.

- It decided that in a worst-case scenario, not more than 10 % of the TDI should possibly come from toy materials (since children could be exposed to chemicals from other sources too)

Based on these conditions it was estimated, for 19 different substances, how much of the chemical substances that could be permitted to migrate from a certain toy material, without it being harmful to the child (provided that the child "eats" the theoretically possible amount of material each day)².

If one knows that that it is harmless to ingest 1 microgram per kg body weight of a particular substances every day, and that children theoretically can "eat" 100 mg of chalk per day (pliable/powder-like material). You can then calculate that a child of 7,5 kg can be permitted to ingest 7,5 micrograms per day (7,5 kg is the body weight used for all calculations). This means that the material must not leak more than 7,5 micrograms of the substance, from 100 mg chalk. The migration limit is then defined as 7,5 micrograms per 100 mg of material. However, the limit is usually indicated as mg substance per kg material and the migration limit would then be 75 mg/kg. But, since it had been decided to allow only 10 % of the TDI to come from toy materials, the final legal limit would instead be set at 7,5 mg/kg.

For a liquid material, the limit will be 4 times stricter since it is estimated that children can drink 400 mg of liquid material per day, and for scraped-off material, the limit will be 12,5 times higher (less strict) because it is estimated that a child can eat only 8 mg per day of such material.

Since the calculations for the new directive were made for 19 different elements and three types of material (liquid, pliable, scraped-off), a total of 57 limit values were defined. This meant that the number of migration limit values went from 8 in the old directive, to 57 limit values the new directive.

The new directive also introduced the possibility for the EU Commission and the Member States to decide on amendments to the migration limits, if new scientific information became available.

Germany's objection

The old directive did not take into account that the amount a child can ingest of a material, will depend on the properties of the material together with the tolerable daily intake (TDI) for each concerned substance. This meant that the old limits were often "unnecessarily strict" e.g. for scraped-off material. Since the new directive took the material aspect and the most recent TDI:s into account, it meant that for certain chemical substances the limit for scraped-off material was less strict than the "general" limit for that substance, applicable under the old directive. This could be perceived as if the requirements of the new directive had become less strict (but only for a very limited number of combinations of substances/materials).

The fact that some limits were less strict meant that Germany did not want to include the three new migration limits for some specific substances, but instead wanted to keep the old general limits for these substances. They thus retained, for the substances in question, a stricter limit for scraped-off material, but on the other hand they did not impose the stricter limits that would apply to pliable and liquid materials.

² For arsenic, cadmium, chromium (VI), lead, mercury and organic tin, it was decided that the limit values should be set at half of what was considered safe according to scientific criteria.

Legal process

The new Toy Safety Directive was adopted in 2009 and stipulated that all EU member states had to introduce it in their legislation in early 2011 so that it could enter into force 20 July 2011 (the new chemical requirements entered into force July 20, 2013).

Germany, however, in early 2011 requested permission from the European Commission to continue to use the migration limits of the old directive for some substances, and also introduced these limits in a deviating national law.

The European Commission rejected large parts of Germany's request, which caused Germany to sue the European Commission in court in May 2012, still requesting to be permitted to have other limits. In May 2014 a court decision denied Germany the right to have other values for antimony, arsenic and mercury. Germany had originally also demanded to retain the old limit value for lead. Since discussions were ongoing in the EU to lower the limit, the Court decided that Germany could keep the old migration limit for lead until the EU had decided on a new migration limit.

Germany appealed against the decision regarding antimony, arsenic and mercury, but in July 2015 the final verdict came from the EU Court of Justice who said that Germany must impose the limits for antimony, arsenic and mercury that apply under the new Toy Safety Directive and that have been introduced in all other EU countries.

About TIE

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