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NOTE

From:	Presidency
To:	Working Party on Technical Harmonisation (Safety of Toys)
Subject:	Proposal for Regulation on the safety of toys : explanations as regards provisions on nitrosamines and nitrosatable substances

European Parliament's justification as regards its position on nitrosamines and nitrosatable substances

The migration limits listed in Point 1 Part A of Appendix have been extended to all toys, components of toys or micro-structurally distinct parts of toys - a change compared to the toy legislation currently in force. The change was made after experts in the subgroup Chemicals, but also in the Expert Group on Toys Safety repeatedly raised the need that children of 36 months and over be equally well protected as those under 36 months. Those calls were later re-confirmed by request from several MS. Older children may also be exposed to chemicals via the skin or via inhalation. In addition, the risk from chemicals is not much different when comparing children under 36 months and older children. As mentioned in the impact assessment accompanying the Commission proposal the bodyweight of children under 36 months was estimated to be 7.5 kg when calculating the migration limits for toxic 'elements' such as arsenic, cadmium or lead. For children of 36 months and over the bodyweight was assumed to be 15 kg. This 2-fold difference is only minor from the toxicological point of view; a notable difference would be 10-fold.

It is not clear why different approach has been used as regards nitrosamines and nitrosatable substances than for the other chemical substances where Commission clearly moved away from differentiation between toys intended for children below or above 36 months.

Updated migration limits for those substances should apply to all toys to ensure that all children are guaranteed the same high level of protection and in order to avoid mislabelling of products to circumvent the migration limit provisions (indicating that a toy is intended for children above 36 months even when it is not the case).

Therefore the EP proposes to keep the limits put forward by the Commission (0,01 mg/kg for nitrosamines and 0,1 mg/kg for nitrosatable substances) but apply them to all toys regardless of the age group targeted. Moreover, EP proposes, as it is the case for other migration limits included in the Appendix, to apply the migration limits for nitrosamines and nitrosatable substances to all toys, components of toys or micro-structurally distinct parts of toys.

Nitrosamines and nitrosatable substances in balloons

Nitrosamines, which are carcinogenic, can be produced during the manufacture of latex if certain compounds (carbamates) are added to accelerate the process. The industry is opposed to extending the migration limits to all toys, as they would also apply to balloons. They claim that it is impossible to attain the proposed limits in the balloon production. However, a 2018 study by the Netherlands Food and Consumer Product Safety Authority states that "alternative accelerators are available, making this risk an avoidable one."

Market inspection of nitrosamines in balloons for the purpose of the same study concluded that:

- 24 out of 58 tested balloons complies with the limit value agreed in the EP mandate (in 16 balloons, no detectable release of nitrosamines or nitrosatable substances was found)

- In addition, 22 balloons comply with the agreed limit for nitrosamines (> 0,01 mg/kg) but not for nitrosatable substances while 5 complies with the limit for nitrosatable substances (>0,1 mg/kg) but not for nitrosamines.

Therefore, compliance does not seem to be a problem and is feasible. In reaction to the above study, the industry claims that the balloons must have been tested immediately after being produced when nitrosamines have not been yet released, as it is a process that takes some time. However, in the introductory part the authors of the study explain the approach taken *"The NVWA sampled 58 types of balloon in total during the period from December 2017 to January 2018. Samples were taken from 35 different brands. They are the brands the most commonly available to the Dutch consumer online and offline (in outlets such as department stores, clothes shops, drug stores and toy shops). Samples were collected from shops, manufacturers, importers and distributors. Balloons were also ordered online from Chinese and Dutch web shops"*.

Even though balloons are labelled as toys for children above 8 years of age, they are largely played with by children of much lower age. Children can ingest nitrosamines by sucking balloons or through hand-to-mouth contact. Research shows that balloons are one of the most common toy items children above the age of 6 months and up to 4 years, put in their mouth.

Nitrosamines and nitrosatable substances in the Council mandate for other products

Council amendment introduces different migration limits for various types of toys. It increases the migration limit for toys destined for children under 36 months (5 times higher for nitrosamines and 10 times higher for nitrosatable substances) as compared to COM proposal. It also substantially increases the migration limits for finger paints, which is a product, aimed at children as of 1 year of age or modelling clay (putty), aimed at children as of 2 years of age (2 times higher for nitrosamines and 10 times higher for nitrosatable substances).