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Chemicals in Toys Questionnaire

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Introduction and respondent details

Europe Economics is currently carrying out a study for the European Commission Directorate General for Enterprise, investigating the impact of revising Council Directive 88/378/EEC on the Safety of Toys, in particular with regard to the provisions for chemicals. As part of this study, we are seeking the views and opinions of stakeholders across the European Union.

Technological developments in the toys market have raised new issues with respect to the safety of toys, and allied with the experience of the existing Directive on toy safety, a conclusion has been reached to update the safety requirements in Directive 88/378/EEC.

A general impact assessment was carried out on the proposed revision in 2003 and can be found at http://ec.europa.eu.enterprise/toys/index_en.htm.

In addition a specific study on certain chemicals used in toys was carried out in 2006 which investigated the limits of bioavailability in the Annex of the Directive. The results can be found at http://ec.europa.eu/enterprise/toys/index_en.htm.

This current study, launched in March 2007, will explore the impacts of the revision of chemical requirements in the Directive; in particular the three different possible approaches to regulate chemicals in toys in the Directive.

Your answers to this questionnaire will be important for decision makers when deciding which directive on chemical requirements in toys to apply. For an explanation of the policy context please refer to the website of the European Commission Directorate General for Enterprise, http://ec.europa.eu/enterprise/toys/index_en.htm.

Please make sure you answer the questions as accurately as possible. Your answers will be treated in the strictest confidence and individual responses will not be made available to the European Commission.

Question A1

Please complete the following details.

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Question A2

May we contact you for a follow up interview?

Yes (please note that we were already interviewed by Haris Irshad, Consultant at Europe Economics.

Question A3

What is the nature of your business/organisation? (Please choose from below)

		Consumer and health group	
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Consumer and health groups

Question S6.1

Are you aware of any toy products containing ingredients that are likely to trigger allergies, diseases or any other sort of reaction(s)?

Yes

Please find attached a list of our member organisations' publications related to toys and their chemical content.

The Danish Consumer Council carried out different tests (in 2004 and 2006) on toys, which are found in ten different European countries. The test schemes performed were related to volatile organic compounds (VOC), phthalates and the migration of organic compounds. The results showed that many problematic chemicals were contained in and emitted from toys, including substances which are classified as dangerous, may cause cancer, or are known to be dangerous to the environment and/or allergenic. 114 different types of VOCs were found amongst which eight are known to have adverse effects on health and the environment. In one case, the findings of the study lead to actions of the governments. Indeed, cyclohexanone, a substance classified as dangerous, was found to emit from stink blasters¹ in amount of concern. Stinkblasters are figures of which children have to squeeze the head and a funky odor comes out. The migration tests were performed without touching the article. Their placing on the market has been already prohibited notably in Slovakia and Poland (see notifications on the RAPEX system).

The 2006 survey of the Danish Ministry of the Environment on toys and children articles also added to our concern on allergenic fragrances and organic solvents in these products. Fragrances and flavouring additives are more and more often used in toys. These substances are inhaled and in contact with mucous membranes causing irritations, allergies and other health effects. They are also contained in many other products including cosmetic products for children including shampoo, eau de toilette, baby oil, lipstick and perfume mixing set. Under the Cosmetics Directive, it is required that fragrances in children's cosmetic products should be evaluated. The same requirement should apply in the toy sector.

The tests carried out by our Spanish member (OCU) revealed the presence of hazardous substances in high amount. In December 2004, 100 toys available at least in four countries (Belgium, Italy, Spain and Portugal) were tested. Five toys did not meet the chemical requirements of the EN71-3 standard. Fourteen toys did not meet the criteria laid down in Council Directive (1999/815/EC) on phthalates. Three toys failed

¹ <http://www.stinkblasters.com>

the testing for formaldehyde. As an example, phthalates were found in Meccanos, Bath Buddies and children soap. Heavy metals migration was demonstrated in paints and colorants as well as in make up sets for kids and specific toys.

The test performed by our Italian member Altroconsumo gave a special attention to the presence of phthalates. Amongst the 120 toys which were tested, 18 contained phthalates. Non conformity regarding heavy metals (lead and chrome) was also revealed for specific toys.

The Finnish Consumer Agency has carried out various tests on toys (please refer to their website). the followings are few examples: in December 2001, phenol and lead were found in high amount in the painted finish of a wooden train; in December 2004, formaldehyde was found in puzzle pieces and heavy metals were found in high amount in punching bags (lead and cadmium) and robots (lead); in November 2005, phthalates were found in many different products tested.

Heavy metals (arsenic, cadmium, mercury, chromium, lead etc) are environmental toxins to which children are particularly sensitive. In the 1980's, standards have been developed for the migration of heavy metals from toys (88/378 May 1988). There is no upper limit for the total content or migration of heavy metals in toys. The cut-off values are migration limits. This means that estimation is being made about the quantity of the metal which can migrate into an acid solution and a margin of safety of 30-60% is applied. Hereafter only, it is estimated whether or not there is a violation of the migration limits (CEN standard EN71/3, Part 3). The regulation on heavy metals in toys is out-of-date. The total content of heavy metals in toys is sometimes found to be 10 to 100 times higher than the total content of heavy metals in packaging (cf. 1998 packaging Directive). In parallel, the total content of heavy metals in paint for ceilings is 25 times lower than the concentration in finger-paints for children (cf. <http://www.greeninfo.dk>). Heavy metals are known to have health effects as well as negative environmental impacts (including a potential to accumulate in the food chain). Both types of effects should be taken into consideration.

Most of the tests performed on toys have shown that fragrances and other allergenic substances in toys were causing allergies and irritation. The presence of carcinogenic substances (e.g. formaldehyde in puzzles and finger paints) is of concern, as well as this of other substances of very high concern (including CMR² of categories I-III, endocrine disrupters, PBT³, vPvB⁴). Please note that product testing is costly and sometimes hardly feasible for non-for profit organisations. Therefore, our tests must be limited to a certain amount of compounds.

There are several reports available from different organizations showing the existence of different undesirable or dangerous chemicals in toys. Last but not least there are unpublished informal communications from enforcement agencies. We believe that all these reports are just the tip of the iceberg.

Question S6.2

For the identified chemicals, please explain how long it would take for the impact to take effect and which chemicals/ingredients are involved.

² CMR: carcinogenic, mutagenic and toxic for reproduction substances

³ PBT : persistent, bio-accumulative and toxic substances

⁴ vPvB: very persistent and very bio-accumulative substances

For short term biological endpoints, the effects on health are immediate and visible. It is often the case of allergic reactions, skin irritations and irritations of the upper respiratory tract. National consumer organisations may be directly asked by consumers whose children have experienced negative health effects with a toy to help them to get a redress from the manufacturer. They may also be informed directly by manufacturers when products are withdrawn off the market for safety reasons. A regular check of the RAPEX notification system is a useful tool to get information about potential health impacts of toys.

For other more complex biological endpoints, including the hormonal disrupting effects or carcinogenic effects of chemicals, it is very difficult to make the link between the nature and properties of the chemical, the dose, time and pattern of exposure and the adverse health effects. Therefore, despite the fact that our reply to question S6.1 only addresses short term effects, we remain very concerned by the long term potential effects of chemicals in toys and the related lack of information.

Children belong to the most vulnerable populations. Additional particularities need to be taken into account including a higher dermal exposure due to specific behaviour (e.g. playing) and higher breathing rate than adults. A precautionary approach addressing vulnerable populations should be adopted. In our view, substances of very high concern such as carcinogenic should be prohibited in toys.

Question S6.3

Are you aware of any health conditions associated with exposure to the following chemicals?

The question is not clear about what is meant by "health conditions". If the question refers to the health effects of the various chemicals, one should refer to the classification list of directive 67/548/EEC and the R-phrases (risk phrases) that are in the related Annex II. For other substances which are not listed in the previous Directive, one must seek for scientific research on a case-by-case basis. We have already highlighted this issue in our previous responses.

Directive 67/548/EEC provides for a classification of dangerous substances. Therefore, the potential effects of classified chemicals are known. Other substances are suspected of having potential effects on health (e.g. endocrine disrupting chemicals) but are not yet classified due to a lack of scientific evidence. The new REACH regulation was adopted to fill in the gap of knowledge on the safety of chemicals and the current toys standards are not stringent enough to properly protect children's health. We therefore do not know yet how many of the chemicals contained in toys will be assessed as dangerous for children's health in the coming years and decades.

(Please refer to our tests for an exhaustive list)

- **Phthalates** are known to cause reproductive abnormalities (endocrine disruption) in laboratory animals, to reduce fertility and be toxic to testicles. They may also induce liver and kidney damage. The current EU legislation on phthalates is very insufficient to protect children's health, notably because it does not address all phthalates and only apply to certain toys (please refer to our position paper for more information). As far as we understand, some Member States have gone further by banning all phthalates in toys (Greece, Austria, Germany, Sweden, and Denmark).
- **Fragrances** are known to frequently cause allergies. They may also cause multiple chemical sensitivity and long term effects. As an example adverse skin effects. They penetrate the skin and are distributed to organs through the blood stream. Inhalation may lead to adverse respiratory and

neurological effects. Ingestion is another important route of exposure because many of the same materials are used as flavors in foods. The number one cause of adverse skin reactions to cosmetics and laundry products is fragrance. A 1998 Danish study found that, after nickel, fragrances were the second most common cause of allergic contact dermatitis (a form of eczema)⁵. The fragrance **D-Limonene** is often used in toys. It is classified as dangerous, may cause sensitisation by skin contact. It is dangerous to the environment as it is very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. It is one of the 26 most allergenic fragrances in cosmetics which should be labelled in the list of ingredients according to the Cosmetics Directive.

- **Formaldehyde** is classified as a human carcinogen by the international agency for research on cancer.
- **Brominated flame retardants**, especially PBDEs, are persistent in the environment and contaminate the food chain, animals, and humans.
- **Toluene**, classified as dangerous. Harmful by inhalation. Possible risk of harm to the unborn child. Danger of serious damage to health by prolonged exposure through inhalation. Vapours may cause drowsiness and dizziness,
- **Cyclohexanone** is classified as dangerous, harmful by inhalation. It is considered to be a substance of potential concern to health,
- **Heavy metals**: lead, chromium, arsenic...Arsenic is the most common cause of acute heavy metal poisoning in adults.

Question S6.4

For each chemical identified, please outline the condition associated with it.

It is not clear what is meant by "condition associated with it". If the question refers to the conditions of use (and misuse), several aspects should be taken into consideration.

The vast majority of toys (and childcare articles) are in contact with the children's skin when handled but also in contact with the mouth and mucous membranes by e.g. inhalation or licking, sucking, biting and chewing behaviours. The contact with mouth is likely to happen for a prolonged period of time, even when the size of the toy is large (e.g. head and other body parts of dolls). For specific chemicals, exposure to very low doses or specific patterns of exposure (e.g. licking and biting versus inhalation) can present a higher risk for children's health. Other routes of exposure should always be considered in addition to the "foreseeable" conditions of use and misuse of toys. Children have higher dermal exposure due to specific behaviour (e.g. playing), have a higher breathing rate than adults, often play next to the floor thereby being exposed to higher amount of chemicals in the air and from dust, and are exposed through specific route (e.g. hand to mouth pattern). As stated earlier, this makes children one of the most vulnerable populations. A precautionary approach should be adopted.

It is also crucial to take into account that children are exposed to a cocktail of chemicals, made of different chemicals from different sources. For example, phthalates are softeners used in toys and many other products, such as computers, floor and wall coverings, furniture, packaging and medical devices. Chemical substances may also interact with each other, giving rise to by-products which may present higher risk for children's health.

⁵ Johansen, Andersen et al, "Identification of risk products for fragrance contact allergy: a case-referent study based on patients' histories", American Journal of Contact Dermatitis, 1998.

Question S6.5

With reference to the health conditions identified in the previous question, in your view are the amounts listed below more or less than what is needed to trigger the health conditions you describe? (amounts given are in mg/kg toy material).

List chemicals along side chemical amounts from options, giving the choices or more/less/equal.

Question S6.6

By which method is exposure to these chemicals harmful in toys?

Direct ingestion	Mouthing (sucking/licking)	Skin contact	Inhalation via evaporation	Inhalation via dust/spray	Breaking it	Other
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If other, please specify.

We do consider that there are other specific routes of exposure that should be taken into account. The following routes are of great importance:

- *using a toy and playing with it;*
- *chewing and biting should be part of the mouthing behaviours;*
- *hand to mouth behaviour.*

For all the reasons developed earlier in our contribution, it is hardly feasible to identify (and order) which routes of exposure are the most problematic for children's health.

Chemicals have very different chemical properties which lead to different biological endpoints. Carcinogenic substances and other CMR substances are of great concern at very low doses. Within this category, some are carcinogenic above a certain concentration threshold whereas others present no safe level of exposure. For other chemicals of concern, e.g. persistent, bioaccumulative and reprotoxic, they accumulate in the environment and harm the whole food chain in the long term. Only a precautionary approach can lead to a reduction of children's total exposure to chemicals of high concern.

Question S6.7

For the chemicals and conditions identified, what is the estimated probability that these conditions will occur after exposure (and how long is the necessary exposure)? Please answer in percentage terms.

It is hardly feasible to reply to this question. Chemicals have different properties leading to different potential effects on health and the environment. Safety information is not yet available for the vast majority of chemicals. For some chemicals, the dose makes the risk. For others, very low exposure can lead to irreversible adverse health effects. Children are exposed to a cocktail of chemicals from different sources

and which may interact with each other. Therefore, estimating probabilities of the occurrence of health effects is therefore impossible.

Question S6.8

Are you aware of any of the above chemicals having significant environmental impacts, which may occur during the manufacturing process?

Yes. Many studies have shown that, amongst others, heavy metals, fragrances, PBT and vPvB substances are having environmental impacts.

Health and environmental impacts often go hand in hand. Many substances are known to have an impact on both health and the environment. As an example, is musk ketone, a fragrance used in the formulation of cosmetic products. It is not readily biodegradable, has high potential to bioaccumulate in the environment and its breakdown product is an endocrine disruptor.

Question S6.9

In addition to any environmental impacts, are you aware of any impacts involved in the disposal of the toy?

Yes. Disposal of toys may have impacts on waste and water treatment. As an example, fragrances cannot be removed from wastewater by existing sewage treatments. Synthetic musk compounds are being found in waterways and in aquatic organisms. Many chemicals are bioaccumulative which means that they accumulate in the food chain. There is a lack of research on the implications.

Impact assessment questions

Describe the three options.

Question SI3.1

Would there be any change in the likelihood of adverse health impacts identified previously resulting from the policy change?

In our view, asking this question has no sense.

There is no doubt there will be changes. They will be visible for certain short term biological endpoints (allergies, skin irritations) but not for long term or more complex endpoints (endocrine disrupting or carcinogenic effects). In any case, the changes will hardly measurable and impossible to monitor for long term endpoint.

Today there is no reporting system of adverse effects of toys. There is no efficient post-marketing system, where consumer (and health professionals) awareness of potential adverse effects of toys are elicited. Most of adverse reactions are neither reported nor recorded. The quality of collected data is often poor, mainly due to insufficient involvement of manufacturers, dermatologists, authorities and even affected consumers.

Reducing children's exposure to chemicals should be a priority. It is in line with the precautionary principle.

Question SI3.2

If we choose option 1 (fully-risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

See our general response below.

Question SI3.3

If we choose option 2 (combined hazard/risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

In our view, asking this question has no sense.

Question SI3.4

If we choose option 3 (hazard/risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

In our view, asking this question has no sense.

Question SI3.5

Are you aware of any of the identified chemicals as having significant environmental impacts, which may occur during the manufacturing process? If yes, please explain.

Yes. Many studies have shown that, amongst others, heavy metals, fragrances, PBT and vPvB substances are having environmental impacts.

Question SI3.6

In your opinion, which of the three proposed options is the most appropriate one?

Option 1	
Option 2	
Option 3	

In our view, even the fully-risk based approach (option 3) is not stringent enough to protect children's health. We believe that a positive list of chemicals which can be used in toys should be elaborated.

CMR substances of categories I, II and III should simply be prohibited in toys. There is no reason to make an analogy with the Cosmetics Directive when referring to allergenic substances and not doing it when it relates to CMR substances of class I-III. In addition, toys should not contained the following substances:

- *fragrances and all allergenic substances;*

- endocrine disrupting chemicals (including all phthalates) whatever the age of the child and if the toy can be placed in mouth;
- heavy metals;
- PBT and vPvB.

PBT and vPvB are bioaccumulative substances. Multiple exposures to low levels of these substances add up in the long term and build up in the human body. Their capacity to bioaccumulate in fatty tissue and biomagnify up the food chain, in combination with their persistence and toxicity, make these chemicals of high concern to children's (and human) health and the environment. They are being found up and down the food chain, in sediments, wild animals, and women's milk, human serum and adipose tissue. There is no safe dose associated with these chemicals.

The ban of all substances listed above should be part of the essential safety requirements of toys. More importantly, no exemptions should be applied to the prohibition of CMR I-III, endocrine disrupting chemicals and other chemicals of very high concern. Toys which require these substances for their functioning should simply not be allowed on the market.

Children are exposed to a cocktail of chemicals in their everyday life. Therefore the most problematic chemicals have simply not their place in toys. A hazard based approach is the only approach which will protect children from exposure to problematic chemicals. A risk-based approach is a resource intensive approach which would take decades (e.g. REACH is though to provide with information on less than 25% of chemicals which are used on the EU market in a very long time). Research is already available to demonstrate that children are exposed to a number of problematic chemicals including CMR substances.

Question S13.7

Are there any further comments you wish to add?

The revision of the toy safety directive should be in line with the precautionary principle. Chemicals of very high concern should be prohibited in toys. In addition, the exposure to other potentially dangerous chemicals should be minimised taking into account other sources of exposure and the particular vulnerability of children. As a general rule, the acceptable limit of a chemical in toys should correspond to 10% of the Tolerable Daily Intake (TDI) value. Only chemicals for which sufficient toxicological and ecotoxicological data are available and which have been fully assessed should be used in toys. This principle of using only approved and evaluated chemicals should apply particularly for toys for children under three years of age. An approval system could be envisaged.

In addition to the possible analogies with the cosmetics directive (e.g. allergenic substances and CMR), analogies with the legislation on food contact materials could be envisaged. However, the migration test to which this legislation relates would need to be adapted to the dynamic criteria of the migration of chemicals from toys.

Environmental requirements should be incorporated in the toy safety legislation. It would be in line with the general community policy to reduce environmental impacts of products and with the developments in the field of integrated product policy. This goes towards a limitation of the chemical contents of products.

A full chemical content declaration in the technical file would be useful.

Approaches summary

- 1.1 The following questions seek responses to three possible options for revising the Toy Safety Directive.
- 1.2 The options are (1) Fully risk-based approach, (2) Combined hazard / risk-based approach, and (3) Hazard / risk-based approach.
- 1.3 Within the three options, there are some common features. These are summarised as follows:
- 1.4 Manufacturers shall ensure that toys are so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed of or which they contain, when the toys are used as specified in Article 5 (2) of the Toy Safety Directive.
- 1.5 Toys shall in all cases comply with relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and preparations. Toys that are themselves substances or preparations must comply also with Directives 67/548/EEC and 1999/45/EC relating to the classification, packaging and labelling of dangerous substances and dangerous preparations.
- 1.6 Cosmetic toys, such as play cosmetics for dolls, shall also comply with directive 76/768/EEC.
- 1.7 For the protection of children's health, the following migration limits, from toys or components of toys that are accessible to children during use, shall not be exceeded (all units in mg/kg toy material): aluminium (5625 mg/kg), antimony (45 mg/kg), arsenic (7.5 mg/kg), barium (4500 mg/kg), boron (1200 mg/kg), cadmium (3.8 mg/kg), chromium (37.5 mg/kg), chromium (VI) (0.04 mg/kg), cobalt (10.5 mg/kg), copper (622.5 mg/kg), lead (27 mg/kg), manganese (1200 mg/kg), mercury (15 mg/kg), nickel (75 mg/kg), selenium (37.5 mg/kg), silver (37.5 mg/kg), strontium (4500 mg/kg), tin (15000 mg/kg), organic tin (1.9), zinc (3750 mg/kg).
- 1.8 The differences are as follows

Option 1: Fully risk-based approach

- 1.9 Toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children when toys are used as specified in Article 5 (1) shall not contain allergenic fragrances that appear on the list of substances in Annex II of Directive 76/768/EEC. In addition, toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children during use as specified in Article 5 (2) shall list if added, as such, at

concentrations exceeding 0.01 % by weight, the allergenic fragrances that appear on the list of substances in Annex III, Part 1 of Directive 76/768/EEC.

- 1.10 The Fully risk-based approach will also require a detailed description of the design and manufacture, including the safety data sheets on chemicals used to be obtained from chemical suppliers.

Option 2: Combined hazard / risk-based approach

- 1.11 Toys shall not contain substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2 (CMR) according to Directive 67/548/EEC unless the incorporation of that substance has been authorised in accordance with the procedure foreseen in Article [57 to 61] of Regulation [...] (REACH). However, the presence of traces of those substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to paragraph 1.
- 1.12 Toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children when toys are used as specified in Article 5 (1) shall not contain substances that meet the criteria for classification as respiratory allergens and skin contact allergens according to Directive 76/768/EEC.
- 1.13 In addition, toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children during use as specified in Article 5 (2) shall list if added, as such, at concentrations exceeding 0.01 % by weight, the allergenic fragrances that appear on the list of substances in Annex III, Part 1 of Directive 76/768/EEC.
- 1.14 The combined hazard/risk-based approach will also require a detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers.

Option 3: Hazard / risk-based approach

- 1.15 The use in toys of the following substances shall be prohibited: a) substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3 (CMR) according to Directive 67/548/EEC, (b) substances such as those having endocrine disrupting properties or and which are identified as causing serious and irreversible effects to humans which are equivalent to those of substances listed in point (a). However, the substances referred to in the first subparagraph can be used under the following conditions: (a) the substance is essential to the functioning of the toy; (b) there are no alternative substances available with intrinsic hazard properties of a lower order of toxicity than the referred to in the first subparagraph; (c) the manufacturer has

demonstrated that the substance is not released in amounts that are detectable by a validated method when the toy is used as specified in Article 5 (2); and (d) the substance has been evaluated by the Scientific Committee on Health and Environmental Risks found acceptable to be used in toys by a decision taken by the Commission in accordance with the procedure laid down in Article X [Comitology procedure]. The presence of traces of substances referred to in subparagraph 1 shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to paragraph 1.

- 1.16 Hazard/risk-based approach will also include a detailed description of the design and manufacture, including substances contained in the toy as well as the amount of the individual substances and the relevant Safety data sheets on chemicals to be obtained from chemical suppliers.