Part V: Additional comments

35. In case you have any additional comments with relevance for this public consultation, please insert them here.

1. General criticism on the questionnaire

1.1. Methodological criticism

Most of the questions are asked in a very general way for all pieces of legislation together such as for instance "to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory?" However, the assessment might be different from a consumer perspective for toys than for cosmetics or CLP. Estimating the performance on average is meaningless and does not provide the decision-makers with useful information on where there are areas of satisfaction or where improvement would be needed.

Moreover, we are not specialised in legislation which is not of priority to consumers. However, as a result of the broad nature of most of the questions, we are still indirectly commenting on other areas such as worker protection legislation. As this will be the case for most stakeholders responding to the questionnaire, the results will suffer from a certain unavoidable bias. The information collected through the public consultation will therefore be of little practical value for decision-makers. Most importantly, it will not help guide decision-makers on next steps nor what the practical consequences of this consultation should be.

For many questions there is no free space available for additional information or for clarification of the reply. As it is not possible to put our replies in perspective, the answers may be misunderstood or could even allow the Commission to interpret our response in way contrary to our intent. We therefore provide additional comments on specific questions below.

1.2. The public consultation neglects important questions

The public consultation is meant to help the Commission address questions related to the costs and benefits of EU chemicals legislation. However, whereas the questionnaire devotes extensive attention to possible cost issues, it largely neglects to explore stakeholder views on possible benefits and synergies in the legislative framework governing chemicals.

For example, Q 21, concerning significant costs for companies resulting from requirements in the legislative framework should have been followed by a similar question exploring whether these requirements lead to significant benefits for companies, such as the benefit of avoiding costs associated with business lost due to unacceptable pollution or costs associated with restraints in the reuse or recycling of products or materials subject to certain chemical contamination.

This unbalanced view on regulatory costs will inescapably bias the results of the public consultation and it will therefore be inappropriate to guide decisions on the fitness of EU chemicals legislation.

1.3. The questionnaire employs ambiguous concepts that will distort its results

We regret the questionnaire's use of vague and ill-define concepts. It is for example unclear whether regulatory cost refers to the direct cost incurred by economic operations for meeting their obligations or the indirect costs to society involved as a result of non-compliance leading to enforcement activity, remedial action or a bad test result published in a consumer test magazine forcing corrective action and leading to loss of consumer confidence.

Similarly, the term 'overlap' could be negative, neutral or even have a positive connotation (as when two requirements reinforce each other). If by overlap the public consultation refers to cases when two pieces of legislation regulate the same situation and this results in an inconsistency and/or a duplication in the requirements, the alternative term 'double regulation' should be used.

Unfortunately, the public consultation include a number of such ambiguities which could bias the results as stakeholders may understand the questions differently.

2. Additional comments on specific questions to put our replies in perspective

Reasoning for our replies to Q 10 & 11:

Chronic and very severe diseases such as cancer, cardiovascular diseases, fertility problems, obesity and allergies are increasing in the EU. Many of these diseases may be linked to constant exposure from multiple sources to harmful chemicals. Consumer may be exposed through the products they use and consume everyday such as food, drinking water, textiles, cosmetics and toys but also from construction products which may pollute the indoor air. In addition, there is growing evidence that the environmental background pollution has reached alarmingly high levels leading to chronic consumer exposure with unknown effects in particular for vulnerable groups such as pregnant women, unborn children and infants.

If the EU chemicals legislation were effective, a downward trend towards fewer health problems should be observable. However, bio-monitoring studies show that consumers have worrying levels of chemicals in their blood and tissues suggesting that existing measures targeting harmful chemicals are ineffective and insufficient. More troublesome still, levels of certain chemicals, such as phthalates and bisphenol A (BPA), are even higher in children than in adults even though it is known that kids are very vulnerable in particular in certain stages of their development.

We consider that current legislation is inadequate in multiple ways.

First, the level of protection of existing EU-chemicals related legislation addressing consumer products is most often not ambitious enough. There are numerous examples, where decisions have been delayed and/or have not been set at a sufficiently ambitious level to ensure adequate consumer protection.

For example, the Toy Safety Directive falls short of adequately protecting children and lacks an all-embracing comitology procedure which would allow limits for all kinds of substances and all kinds of toys to be adopted and modified.

The Medical Devices Directive also gives a carte blanche to industry and does not stipulate a single threshold for any chemical substance (covering chemicals just with some nebulous

"essential requirements").

The Packaging Directive contains just one limit for heavy metals (lead, cadmium, mercury and hexavalent chromium) ignoring all other substances.

The RoHS Directive does not include limits for many substances identified in various studies (notably by Ökoinstitut and the Austrian UBA).

Second, the level of protection and the internal market are not functioning because of missing legislation addressing consumer products at EU level.

Adequate chemical provisions are (almost) non-existent for many products consumers come into contact with, such as non-plastics food contact materials, materials in contact with drinking water, products releasing emissions to the indoor air, clothing and other consumer textiles, child use and care articles, other articles for children, tattoo inks, personal protective equipment, furniture, sports and playground surfaces and equipment, car interiors etc.

It should be noted that the absence of legislation in several areas has been subject of strong critique by interested parties including industry (e.g. food contact materials, materials in contact with drinking water). REACH does not, and will not, compensate for these deficits as a result of its severe deficits, e.g. because articles – particularly imported ones - are barely covered.

Third, the EU legislative framework is not in line with the latest findings of modern toxicology which should be applied to hazard identification and management. The EU does not take into account the combination effect of chemicals even though it is known that exposure to a “chemical cocktail” can be much more harmful than what could be expected when looking into the safety of chemicals based on a substance by substance approach.

The EU also fails to take into account recent findings related to endocrine disrupters which show that the basic assumption of Paracelsus “the dose makes the poison” is not always true. Certain chemicals show “non-monotonic dose responses” which means that a smaller dose can have a much higher detrimental impact than a higher exposure if the exposure takes place at a very unfortunate moment of human development (e.g. depending on the stage of the embryonic development). EU chemicals legislation needs to be adapted to take these issues into account.

Fourth, the EU fails to address areas of concern with adequate measures such as the management of nanomaterials and of hormone-disrupting chemicals as well as sensitizers and other chemicals of similar concern. For instance, it has now been over two years since the Commission missed the deadlines for adopting criteria to identify Endocrine Disrupting Chemicals (EDCs): the Biocides Products Regulation and the Plant Protection Product Regulation require the Commission to adopt scientific criteria for identifying EDCs by 13 and 14 December 2013 respectively. Earlier this year, on 11 January 2016, the Commission missed a third deadline failing to take action on EDCs in cosmetics, as required under the Cosmetics Regulation. We thus see a failure to adapt EU legislation to the issues at stake with regard to protecting human health and the environment that needs to be urgently addressed.

Fifth, the legislation has also not been effective as it is not properly enforced at Member State level. The EU RAPEX system contains every year more than 2.000 notifications of dangerous

products of which about 20% can be linked to exposure to harmful chemicals. However, this is only the tip of the iceberg as most likely the majority of dangerous products are not even detected because of inefficient and ineffective market surveillance and a lack of clear rules with regard to chemicals in consumer products.

Reasoning for our reply to Q 12:

Action at EU-level has a high added value because it makes sure that certain rules will be mandatory for the whole internal market. But further action is needed to better protect EU consumers against harmful chemicals. Under the current Commission in particular a lot of pending decisions are however not taken, potentially creating unnecessary and unacceptable health risks for consumers. We therefore remind the Commission that safety delayed is safety denied. For the areas of inaction, see also our response to Q. 10 & 11 above.

In the absence of adequate EU action, it must always remain possible for concerned Member States to go beyond the minimum requirements in EU legislation. Member States who wish to offer a higher level of protection to their citizens should not need to go to court and be forced to lower the level of ambition at national level as has been the case for Germany who insisted that better protection of children from chemicals in toys was needed.

Reasoning for our reply to Q 20:

The most significant costs for European society in general are linked to health and environmental damage resulting from insufficient chemicals regulation and enforcement.

For example, an economic analysis has found that endocrine disrupting chemicals likely cost the EU countries billions of euro a year in healthcare expenses and lost earnings. A series of peer-reviewed studies published in March 2015 in the Endocrine Society's Journal of Clinical Endocrinology and Metabolism estimate €157 billion (1.23% of European GDP) of costs to EU society can be attributed to hormone disrupting chemical exposure. This was a conservative calculation, but real costs could be as high as €270 billion, or 2% of GDP. The Endocrine Society points out that the biggest costs related to IQ detriment and intellectual disabilities caused by chemical exposure of the unborn child, primarily through pesticides containing organophosphates. Adult obesity linked to exposure to phthalates generated the second-highest costs. These studies are additional evidence of the urgent need for EU action.