Raising standards for consumers

The Consumer Voice in Europe

REGULATORY FITNESS CHECK OF CHEMICALS LEGISLATION EXCEPT REACH – A CONSUMER VIEW

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Why it matters to consumers

Consumers have a right to expect that the products they use do not contain chemicals which could pose a threat to their health and safety. Over the past 50 years, the EU has put in place a broad legislative framework to protect consumers from chemical risks in food, drinking water and consumer products. The European Commission is currently consulting the public on whether this important legislative framework performs as intended or if shortcomings can be identified. ANEC and BEUC are concerned that this exercise could weaken vital legislative provisions that exist to protect consumers, workers and the environment.

Summary

Assessing whether existing EU legislation is fit to protect consumers from harmful chemicals should be at the heart of the fitness check of EU chemicals legislation. This exercise could therefore, in theory, offer an opportunity to address shortcomings in the legislative framework, especially with respect to chemicals in consumer products.

Regrettably, the fitness check suffers from a clear and unequivocal bias towards industry views and interests. As designed by the Commission, the fitness check will fail to produce a balanced, quality assessment of the legislative framework governing chemicals. This holds true in particular for the significant gaps and inadequate chemical provisions in product regulations which need to be addressed as a matter of priority. We therefore strongly caution against using the results of the fitness check to guide decisions on the future course of EU chemicals policy.

The fitness check will fail to provide a sound view of the EU chemicals *acquis*, its implementation and its functioning, which can feed into the Commission's work on a strategy for a non-toxic environment. Instead, the unbalanced focus on regulatory costs will divert attention from a progressive agenda on regulating chemicals of concern in consumer products.

1. Introduction

The European Commission has announced a regulatory fitness check of EU's chemicals and chemicals-related legislation excluding the REACH Regulation. According to the Commission, the "aim of this particular fitness check is to assess whether the current legislative framework for chemicals is fit for purpose and delivers as intended/expected."[1] The results of the fitness check are expected by end of 2017.

As a part of the fitness check, the Commission is consulting stakeholders on the functioning of the legislative framework for chemicals (except REACH).[2] The consultation is meant to inform the Commission Staff Working Document, presenting the results of the fitness check.

Combined with our response to the public consultation (see annex), this joint ANEC and BEUC position paper outlines our view of the Commission fitness check of EU chemicals legislation.

2. The purpose and possible implications of the fitness check are unclear

We regret that the public consultation has been launched before a roadmap for the fitness check is available. According to the Commission's Better Regulation guidelines,[3] stakeholders must be able to give feedback on fitness check roadmaps. Yet, no opportunity has been given to comment on the scope of this fitness check, its methodology and approach as well as the issues it will address.[4]

It is unclear what consequences the fitness check will have for consumer safety

While the Commission on 18 May released a roadmap for the fitness check, it still fails to provide sufficient clarity with respect to the reasons for this exercise and in particular regarding the concrete regulatory consequences that could follow from it. The roadmap thus states that the fitness check "will identify possible further burden reduction actions",[5] but neglects to explain how the Commission might act on them. The Commission in short seems to put the cart before the horse. We therefore ask that the Commission respects its own Better Regulation practices to ensure transparency and predictability for stakeholders.

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1 European Commission, Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. Background document, no date.

2 http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8695&lang=en&title=Consultation-on-the-regulatory-fitness-of-chemicals-legislation-%28excluding-REACH%29

3 http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf

4 The Commission explains that "Roadmaps give a first description of planned Commission initiatives. They describe the problem that the initiative aims to address and possible policy options. They also provide an overview of the different planned stages in the development of the initiative, including consultation of stakeholders and impact assessment work." http://ec.europa.eu/smart-regulation/impact/planned_ia/planned_ia_en.htm

5 European Commission, Roadmap: Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, 18 May 2016. http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

3. As designed, the fitness check will generate biased results

The fitness check should primarily look at identifying shortcomings in the EU legislative frameworks governing chemicals with a view to strengthen consumer protection.

We question, however, whether the fitness check will result in a valid and balanced assessment of the extent to which EU chemicals legislation is fit for purpose. As designed by the Commission, the fitness check suffers from significant flaws and its eventual results should not be used to guide decisions on the future course of EU chemicals policy.

3.1. The scope of the fitness check is too broad

The fitness check considers 45 pieces of legislation from different areas such as worker protection, consumer protection and environmental legislation. However, it is impossible to consider information with sufficient detail with regard to all relevant legislation. Even if the fitness check does not seek an in-depth evaluation of each of these separate and diverse pieces of legislation, we doubt that it can lead to anything but a superficial assessment of the overall functioning of the chemicals framework given the large number of laws operating according to diverse principles and circumstances.

Most of the questions asked in the public consultation are meanwhile formulated at a highly aggregate level such as for instance "to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory?" (Q16) From a consumer perspective, the assessment will however differ significantly from toys over cosmetics to the CLP Regulation. Estimating an average performance level is meaningless and will not provide the Commission with useful information on the actual state of EU chemicals legislation or where improvement would be needed. Unfortunately, both the fitness checks and the public consultation include a number of such ambiguities.

The fitness check will not result in a balanced assessment of EU the legislative framework governing chemicals

3.2. The fitness check adopts a biased focus on costs and redundancies

The EU chemicals *acquis* intends to achieve *both* a high level of protection of human health and the environment *and* the proper functioning of the internal market in chemicals. The fitness check therefore needs to devote *equal* attention to assessing whether the legislative framework achieves *both* of these objectives. Nonetheless, the fitness check adopts a narrow focus on identifying regulatory burdens to industry, quantifying costs, and eliminating redundancies.

For example, the public consultation does not aim primarily at assessing whether the current legislative framework is fit for achieving the crucial goal of protecting consumers. In fact, the questions are unfit to identify the serious legislative gaps we – often echoed by national authorities – as consumer organisations have long denounced, especially with respect to consumer products. We further elaborate these criticisms in our response to the public consultation annexed to this paper.

The fitness check must adopt a balanced approach to the costs and benefits of EU chemicals legislation. This should also include a comprehensive review of whether the enforcement of EU chemicals legislation is effective and achieves a high level of protection as the legislation intends. Equal attention needs in this context to be paid to the costs to society of non-compliance with legal requirements, such as for example costs related to disease, productivity loss, increased sick leave, morbidity, health care costs, etc.

We call on the Commission to approach the fitness check as an opportunity to strengthen – not weaken – the legislative framework governing chemicals. Consumer and environmental protection – rather than primarily economic considerations – must be at the heart of this exercise.

4. The fitness check threatens to compromise consumer protection

According to the Commission, the aim of the fitness check is to assess the relevance, coherence, effectiveness, efficiency and added value of the legislative framework for the risk management of chemicals.[6]

The EU should apply a precautionary approach in all consumer relevant chemicals legislation

While the fitness check covers a wide range of diverse laws, only one aspect of the legislative framework, risk management, is singled out for in-depth examination. We strongly object to this narrow focus: as the aim of the fitness check is to assess whether the current legislative framework for chemicals is fit for purpose and delivers as expected, it needs to provide a comprehensive review of the extent to which chemical hazards are identified, communicated *and* addressed in a robust manner.

At the same time, the fitness check aims to examine the "merits and shortcomings" of risk management approaches based on generic risk considerations and specific risk assessments[7] – also known as the distinction between hazard-based and risk-based approaches.[8] Combined with the strong focus on costs to industry – rather than consumer protection – we are concerned that the fitness check will fail to generate a valid assessment of the two risk management approaches adopted in EU chemicals legislation.

Based on the documents released by the Commission to date, including the original tender specifications,[9] the fitness check appears specifically designed to generate evidence to support one particular conclusion: that hazard-based standards are disproportionately burdensome to industry. We reject this premise and instead insist that the fitness check needs to focus on how the EU can strengthen – not weaken – the legislative framework protecting consumers from harmful chemicals.

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6 http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

7 European Commission, Roadmap: Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, 18 May 2016.

8 See *e.g.* *http://chemsec.org/news/news-2016/january-march/1538-hazard-vs-risk-what-is-best-practice-when-assessing-chemicals*

9 European Commission, Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, December 2014.

The EU should apply a precautionary approach in all consumer relevant chemicals legislation. Hazard-based standards allow the EU to ban certain groups of chemicals at once based on their intrinsic properties, such as for instance CMRs in cosmetics or toys. Greater reliance on hazard-based standards would therefore greatly speed up the implementation of legislation meant to protect consumers. We further insist that all relevant chemicals legislation should place the burden of proof on the economic operator, including responsibility for providing sufficient evidence to demonstrate safe use. However, unlike the current prevailing REACH practice the evidence must be independently verified rather than relying on an industry self-assessments. This could be done, for instance, by introducing hazard based exclusions (e.g. for CMRs) with possible derogations or approval systems for (certain) chemicals in consumer products (following the example of colourants, preservatives and UV filters in cosmetics). For both measures evidence should be provided by industry followed by judgements of scientific committees.

All relevant chemicals laws should place the burden of proof for safety on industry

Most risk-based standards by contrast fall short of providing a sufficient level of safety. We know from experience that these methods are slow, expensive and inefficient and that they fail to provide adequate protection of consumers.[10] We therefore reject wider use of such risk management methods in EU chemicals and chemicals-related legislation.

5. The fitness check distracts the EU from needed action on chemicals

Beyond 2018, EU chemicals policy aims to achieve a non-toxic environment that is conducive to public health, innovation and the development of sustainable substitutes.[11] All available evidence however suggests that the EU is falling short of this mark: chronic and severe diseases attributable to chemicals exposure such as cancer, cardiovascular diseases, fertility problems, obesity and allergies are on the rise in the EU. Harmful chemicals are found in many products consumers come in very close, frequent and prolonged contact with, such as clothes, kitchen tools, toys, cosmetics, and the list goes on. Chemical pollutants are further widespread in the air we breathe, the food we eat and the water we drink. A renewed drive to stem the growing toxics exposure is urgently needed if we want to achieve the vision for a non-toxic environment outlined in the EU's 7th Environmental Action Programme.[12]

In this light, the flawed fitness check of EU chemicals legislation diverts political attention and scares resources from a progressive EU agenda on harmful chemicals. The EU chemicals *acquis* is inadequate in multiple ways that requires urgent attention.

The fitness check diverts political attention and resources from a progressive EU agenda on harmful chemicals

[10] See for example European Environment Agency, Late lessons from early warnings: science, precaution, innovation, 2013.

[11] Decision No 1386/2013/EU of the European Parliament and the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'. http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013D1386&from=EN

[12] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D1386

First, robust chemical provisions are largely non-existent for many consumers products, such as materials in contact with drinking water, products releasing emissions to 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.[13] REACH does not, and will not, compensate for these deficits as 'articles' – particularly imported ones – are barely covered under REACH. Any meaningful strategy for the chemicals area therefore needs a specific approach addressing chemicals in consumer products in sector specific regulation.

Second, current EU chemicals-related legislation regulating consumer products too often fail to set sufficiently ambitious thresholds to ensure adequate protection of consumer health. For example, the Toy Safety Directive falls short of adequately protecting children since endocrine-disrupting chemicals or sensitizers other than allergenic fragrances are not covered, while requirements for CMR substances are not strict enough. At the same time, the Directive lacks a comprehensive comitology procedure which would allow limits for *all* kinds of substances and *all* kinds of toys to be adopted and modified.[14] Strengthening such legislation must be a priority.

Third, enforcement of EU chemical-related legislation at Member State level remains inadequate. The comparative product tests undertaken by our members frequently detect unwanted chemicals in many everyday consumer products. Every year, the EU RAPEX system moreover contains more than 2.000 notifications of dangerous products of which some 20% can be linked to harmful chemicals. However, this figure most likely represents only the tip of the iceberg as the majority of dangerous products are not detected as a result of inefficient and ineffective market surveillance and a lack of clear rules with regard to chemicals in consumer products.

The pace of EU action on harmful chemicals is already scandalously slow. The fitness check should not distract the EU from an ambitious agenda on better protecting consumers

Fourth, hormone-disrupting chemicals (EDCs), combination and low dosage effects of chemicals, nanomaterials, and sensitizers represent risks to consumer safety which are currently not being addressed in a comprehensive manner. For instance, it has now been over two years since the Commission missed the deadline for adopting criteria to identify EDCs, while a compulsory review of the Cosmetics Regulation with respect to these harmful chemicals is more than one year overdue. We thus see a failure to adapt EU legislation to ensure adequate protection of human health and the environment. At the same time, the transition to a circular economy will create new consumer risks where recycled secondary raw materials and reused consumer products incorporate toxic legacy chemicals.[15]

The pace of EU action to address these issues is already scandalously slow – or altogether absent – and the fitness check of EU chemicals legislation should not serve as a distraction from an ambitious agenda on better protecting consumers against harmful chemicals. We are however concerned that under the current Commission many pending decisions are either delay or indefinitely deferred, potentially creating unnecessary and unacceptable

[13] See ANEC, Position Paper. Hazardous chemicals in products - The need for enhanced EU regulations, June 2014, http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

[14] See ANEC and BEUC, EU Subgroup on chemicals in toys fails its mission. Critical review, November 2012. http://www.beuc.eu/publications/2012-00799-01-e.pdf

[15] See CHEMTrust, Circular Economy and Chemicals. Creating a clean and sustainable circle, August 2015, http://www.chemtrust.org.uk/wp-content/uploads/chemtrust-circulareconomy-aug2015.pdf

health risks for consumers. We therefore remind the Commission that safety delayed is safety denied.

END

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Annex ANEC and BEUC response to the consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Purpose and Context of the Consultation

a) The Fitness Check of the most relevant chemicals legislation excluding REACH
The European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) and DG Environment) is conducting a fitness check on chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries.
The scope of this fitness check covers chemical and chemical-related legislation, encompassing legislation governing hazard identification; classification, labelling and packaging; and risk management. This includes chemical-related aspects of worker safety legislation, transport legislation, environmental protection legislation, product legislation, as well as supporting legislation. The full list of legislation covered by the fitness check can be found here.

Please note that the REACH Regulation is not covered by this exercise as it will be the subject of a separate evaluation, and a dedicated public consultation will be organised later this year.

The European Commission (DG GROW) has commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to undertake a supporting study to the preparation of this fitness check (the terms of reference are available online at - http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm). The current open online public consultation is part of the stakeholder consultation and its results will be analysed by the contractors. Please note that the results may also be used in the context of other studies in the chemicals field. The responses will be taken into consideration in the preparation of the Commission Staff Working Document, presenting the results of the fitness check.

For more details on the fitness check itself see:
- **Fitness check background document**
- **DG GROW website**
- **DG ENV website**

For more details on the REFIT Programme and public consultations:
- **REFIT Programme**
- **Public consultations**

b) Structure of this questionnaire (pdf version available here)
The questionnaire is available in English, German and French and has five parts:
- **Part I – General Information about respondents (compulsory)**
- **Part II - General Questions for respondents interested in chemicals legislation, but who may not be familiar enough with the existing legislative framework to answer more detailed questions (compulsory)**
- **Part III – Specific Questions which require more extensive knowledge and/or experience of the chemicals and chemicals-related legislation (optional)**
- **Part IV – Specific Questions on the CLP Regulation (optional)**
- **Part V - Additional Comments (optional)**

You may interrupt your session at any time and continue answering at a later stage. Once you have submitted your answers online, you can download a copy of the completed questionnaire.

To facilitate the preparation of your contribution, a pdf version of the questionnaire is available here.

c) Duration of the public consultation

The consultation will last for 12 weeks. Responses to the public consultation must be submitted by Friday 27 May 2016.

Privacy Statement: *The collected personal data and all information related to the above-mentioned public consultation is stored on a computer of the external contractor, acting as processor, who must guarantee data protection and confidentiality as required by Regulation (EC) 45/2001.*

Disclaimer: *This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties. The suggestions contained in this document do not prejudge the form or content of any future proposal by the European Commission.*

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Part I – General Information about Respondents

* 1. Address

Contact name	
Organisation/company	
Country	
Email Address	

2. If you have a Transparency Register ID number, please provide it below.

If your organisation is not registered, you have the opportunity to register now by following this link. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and, as such, will publish it separately.

* 3. Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution.

Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.

- ◯ My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
- ◯ My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication
- ◯ I do not agree that my contribution will be published at all

* 4. We might need to contact you to clarify some of your answers. Please state your preference below:

- ◯ I am available to be contacted
- ◯ I do not want to be contacted

* 5. Please indicate whether you are replying to this questionnaire as:

- ◯ A citizen
- ◯ A business
- ◯ A non-governmental organisation (NGO)
- ◯ A consumer association
- ◯ An industry association
- ◯ A trade union
- ◯ A government or public authority
- ◯ An intergovernmental organisation
- ◯ Academia or a research or educational institute
- ◯ Other

Other (please specify)

6. If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:

- [ ] Agriculture, forestry and fishing (A)
- [ ] Mining and quarrying (B)
- [ ] Manufacture of food products (C10)
- [ ] Manufacture of beverages (C11)
- [ ] Manufacture of tobacco products (C12)
- [ ] Manufacture of textiles (C13)
- [ ] Manufacture of wearing apparel (C14)
- [ ] Manufacture of leather and related products (C15)
- [ ] Manufacture of wood and of products of wood and cork except furniture (C16)
- [ ] Manufacture of paper and paper products (C17)
- [ ] Printing and reproduction of recorded media (C18)
- [ ] Manufacture of coke and refined petroleum products (C19)
- [ ] Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)
- [ ] Manufacture of pesticides and other agrochemical products (C20.2)
- [ ] Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)
- [ ] Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)
- [ ] Manufacture of other chemical products (C20.5)
- [ ] Manufacture of man-made fibres (C20.6)
- [ ] Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)
- [ ] Manufacture of rubber and plastic products (C22)
- [ ] Manufacture of other non-metallic mineral products
- [ ] (C23) Manufacture of basic metals (C24)
- [ ] Manufacture of fabricated metal products, except machinery and equipment (C25)
- [ ] Manufacture of computer, electronic and optical products (C26)
- [ ] Manufacture of electrical equipment (C27)
- [ ] Manufacture of machinery and equipment (C28)
- [ ] Manufacture of motor vehicles, trailers and semi-trailers (C29)
- [ ] Manufacture of other transport equipment (C30)
- [ ] Manufacture of furniture (C31)
- [ ] Manufacture of games and toys (C32.4)
- [ ] Manufacture of medical and dental instruments and supplies (C32.5)
- [ ] Other manufacturing(excluding manufacturing of toys or medical and dental instruments) (C32)
- [ ] Electricity, gas, steam and air conditioning supply (D)
- [ ] Water supply; sewerage; waste management and remediation activities (E)
- [ ] Construction (F)
- [ ] Wholesale and retail trade (G)
- [ ] Transporting and storage (H)
- [ ] Professional, scientific and technical activities
- [ ] (M) Other

Other (please specify)

7. For businesses, please indicate the size of your business:

The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm

- ◯ Self-employed
- ◯ Micro-enterprise (under 10 employees)
- ◯ Small enterprise (under 50 employees)
- ◯ Medium-sized enterprise (under 250 employees)
- ◯ Large company (250 employees or more)

* 8. Please indicate the level at which your organisation is active:

- ◯ Local
- ◯ Regional (e.g. Scandinavia)
- ◯ Global
- ◯ National
- ◯ EU
- ◯ Not applicable

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Part II – General Questions

* 9. How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)

**This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.*

***The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.*

	1	2	3	4	5	I don't know
Protecting human health	◯	◯	◯	◯	**5**	◯
Protecting the environment	◯	◯	◯	◯	**5**	◯
Ensuring a well-functioning internal market**	◯	◯	◯	◯	**5**	◯
Stimulating competitiveness and innovation	◯	◯	◯	◯	**5**	◯

* 10. Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

	1	2	3	4	5	I don't know
Protecting human health	○	○	●	○	○	○
Protecting the environment	○	○	●	○	○	○
Ensuring a well-functioning internal market	○	○	●	○	○	○
Stimulating competitiveness and innovation	○	○	●	○	○	○

* 11. If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

	The legislation is unclear	The legislation is not adapted to the issues at stake	The legislation is not effectively implemented	No opinion or not applicable
Protecting human health	☐	☒	☐	☐
Protecting the environment	☐	☒	☐	☐
Ensuring a well-functioning internal market	☐	☒	☐	☐
Stimulating competitiveness and innovation	☐	☐	☐	☒

* 12. To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

	1	2	3	4	5	I don't know
EU-level legislation adds value to national level action	○	○	○	●	○	○

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Part III - Specific Questions

This part contains more detailed questions related to the five evaluation criteria underlying the fitness check: effectiveness, efficiency, relevance, coherence and EU added value

13. For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.

For other stakeholders - Please select the legislation you are familiar with.

- ☐ Classification, labelling and packaging (Regulation No (EC) 1272/2008)
- ☐ Plant protection products (Regulation (EC) No 1107/2009)
- ☐ Biocidal products (Regulation (EU) No 528/2012)
- ☐ REACH, Annex XIII (Regulation (EC) No 1907/2006)
- ☐ Inland transport of dangerous goods (Directive 2008/68/EC)
- ☐ Chemical Agents (Directive 98/24/EC)
- ☐ Asbestos (Directive 2009/148/EC)
- ☐ Carcinogens and mutagens at work (Directive 2004/37/EC)
- ☐ Young people at work (Directive 1994/33/EC)
- ☐ Pregnant workers (Directive 1992/85/EEC)
- ☐ Signs at work (Directive 92/58/EEC)
- ☐ Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
- ☐ Waste framework (Directive 2008/98/EC) and List of Waste
- ☐ Waste shipments (Regulation (EC) No 1013/2006)
- ☐ Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
- ☐ Water Framework (Directive 2000/60/EC)
- ☐ Urban Waste Water (Directive 91/271/EEC)
- ☐ Marine Strategy Framework (Directive 2008/56/EC)
- ☐ Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
- ☐ End of life vehicles (Directive 2000/53/EC)
- ☐ Batteries (Directive 2006/66/EC)
- ☐ Packaging and Packaging Waste (Directive 94/62/EC)
- ☐ Export and import of hazardous chemicals (Regulation No 649/2012)
- ☐ Persistent organic pollutants (Regulation (EC) 850/2004)
- ☐ Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
- ☐ Residues of pesticides (Regulation (EC) No 396/2005)
- ☐ EU Ecolabel (Regulation (EC) 66/2010)
- ☐ Safety of toys (Directive 2009/48/EC)
- ☐ Cosmetic products (Regulation (EC) No 1223/2009)
- ☐ Detergents (Regulation (EC) No 648/2004)
- ☐ Drinking Water (Directive 98/83/EC)
- ☐ Fertilisers (Regulation (EC) No 2003/2003)
- ☐ Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
- ☐ Aerosol dispensers (Directive 75/324/EEC)
- ☐ Explosives (Directive 93/15/EEC)
- ☐ Pressure equipment (Directive 2014/68/EU)
- ☐ Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
- ☐ General Product Safety (Directive 2001/95/EC)
- ☐ Test methods (Regulation (EC) No 440/2008)
- ☐ Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
- ☐ Protection of animals used for scientific purposes (Directive 2010/63/EU)
- ☐ *I am not familiar with any of the pieces of legislation listed above*

ANEC and BEUC

ANEC

BEUC

Other (please specify)

Construction Products Regulation (EU)No 305/2011

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Effectiveness

The following questions explore the extent to which the objectives of the EU legislative framework for chemicals have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

14. In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical.
In your view, do you think EU chemical and chemical-related legislation should, in general:

- ◯ a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)
- ◯ b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted)
- ◯ c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)
- ◯ d. I don't know

If you answered a or b, please explain

> The EU should apply a hazard based approach to all consumer relevant chemicals legislation as this would allow the EU to ban certain groups of chemicals at once based on their harmful properties, such as for instance being CMRs or other categories of chemicals which are of equal concern. This would speed up the adoption and implementation of legislation. Most risk based management methods by contrast falls short to provide a sufficient level of safety and we therefore strongly object to answer "a".

15. In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.

◯ Yes ◯ No ◯ I don't know

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.

The EU's current system of evaluating and managing chemicals hazards is outdated and not in line with the latest scientific findings in particular with regard to mixture toxicity, hormone-disrupting chemicals and nanomaterials. We are very disappointed that 1) there has been no concrete follow-up to the Commission's Communication on mixture toxicity from 2012, that 2) despite legal requirements to define scientific criteria for endocrine disrupters the Commission has still not set such criteria and focuses on the economic impact rather than societal benefits in its current impact assessment and that 3) the EU is reluctant and late in regulating nanomaterials despite such materials being used in a large and growing number of consumer products.

16. In your view, to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

	1	2	3	4	5	I don't know
Transparency of procedures	○	**2**	○	○	○	○
Speed with which hazards/risks are identified	○	**2**	○	○	○	○
Speed with which identified risks are addressed	**1**	○	○	○	○	○
Time to allow duty holders to adapt	○	○	○	○	○	**X**
Predictability of the outcomes	○	**2**	○	○	○	○
Stability of the legal framework	○	○	**3**	○	○	○
Clarity of the legal texts	○	○	**3**	○	○	○
Guidance documents and implementation support	○	**2**	○	○	○	○
Effective implementation and enforcement across Member States	○	**2**	○	○	○	○
Consistent implementation and enforcement across Member States	○	**2**	○	○	○	○
Public awareness and outreach	○	**2**	○	○	○	○
International collaboration and harmonisation	○	**2**	○	○	○	○

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

Speed of hazard identification and management: Timelines for hormone disrupters and nanomaterials are unacceptably slow. The Commission let various legal deadlines pass without taking satisfactory action on hormone disrupters for biocides, pesticides, cosmetics, waste water and is not taking sufficient action to address hormone disrupters in other consumer products.

Despite having published a recommendation for a definition for the term "nanomaterial" in 2011, this has never consistently been implemented in sector specific legislation such as food and cosmetics.

The implementation of the General Product Safety Directive with regard to chemicals provisions has slowed down since the current Commission took office: despite an

agreement in the GPSD Committee to address tattoo-inks, the Commission blocks progress. In addition, the European Commission refuses to address chemical issues adequately in the development of safety requirements and related standardisation requests (e.g. of consumer products are candles and children's shoes).

The overhaul of the EU's General Product Safety Directive and Market Surveillance system is unacceptably slow: the Commission started to discuss a revision in 2010, but published only 3 years later a legislative package which is blocked already for the last 3 years in Council related to a political question (country of origin labelling) which is irrelevant for product safety. Therefore also enforcement and consistency of enforcement are insufficient.

The points above are also the reason why outcomes are partly unpredictable for consumers: political and industry interests are placed regularly above societal interests in the area of chemicals management.

While "stability" of the legal framework is beneficial in some cases, there is also a risk that the regulatory framework will become outdated and prevent progress.

Clarity of the legal texts: Definitions and requirements are often not used consistently across legislation, e.g. nanodefinition & requirements for EDCs.

With regard to TTIP & chemicals, we are not reassured that the EU will do its best to keep the safety level of the EU at its highest possible level. The transparency of these negotiations is also unacceptable as too little is known about the negotiations in general and the US demands in particular.

17. In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

	1	2	3	4	5	I don't know
Hazard identification criteria			3			
Risk assessment and characterisation			3			
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)		2				
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)						X
Risk management measures restricting or banning the use of chemicals	1					
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	1					

If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.

Communication: ECHA, some Member States (e.g. NL) and some consumer organisations have undertaken a lot of efforts to familiarise consumers with the new

CLP pictograms. However, the new pictograms as such are partly less clear and not familiar to consumers and more efforts are needed.

Hazard categories for PBTs and vPvB have not been defined in the CLP Regulation. In addition, criteria for endocrine disrupting chemicals are overdue.

To conduct a (sophisticated) risk assessment according to the established guidelines is often an impossible task in view of lacking data and the enormous resources needed for this.

Risk management: See also answers to Q 14-16.

18. Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?

◯ Yes ◯ No ◯ I don't know

If you answered no, please explain your answer

All peer reviewed and published scientific literature should be taken into account. Studies done under good laboratory practice (GLP) certification should not be considered to be of higher value compared to well-conducted and well-reported studies, which are not done in GLP certified laboratories. Conformity to GLP does not necessarily mean intelligent study design nor compliance with state-of-the-art science. Some EU agencies such as EFSA tend to ignore non-GLP studies in their risk assessment without looking into their content even though they could contribute to an appropriate assessment based on a weight of evidence approach

Efficiency

The following questions explore the costs and benefits of implementing the EU legislative framework for chemicals. The legislation was designed to deliver benefits in terms of protection of human health and the environment, better functioning of the EU internal market (e.g. facilitating exports and imports between EU member states) and fostering competitiveness and innovation (e.g. better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

19. In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)

- [ ] Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.
- [ ] Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.
- [ ] Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.
- [ ] Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy
- [ ] Stimulating competition and trade within the EU single market
- [ ] Stimulating international trade between the EU and other countries
- [ ] I don't know

20. In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)

- [ ] Costs for authorities at EU level
- [ ] Costs for authorities at national level
- [ ] Costs for small and medium sized enterprises
- [ ] Costs for large enterprises
- [ ] Costs for consumers
- [ ] Costs for society in general
- [ ] I don't know

21. In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?

- [ ] Classification requirements for substances and mixtures
- [ ] Chemical labelling and packaging requirements
- [ ] Risk management measures under the different legislation
- [ ] Understanding and keeping up-to-date with changes in legal requirements
- [ ] Other (please specify)
- [ ] Training staff to ensure compliance with legal
- [ ] requirements Inspections and administrative requirements
- [ ] We do not view the business costs of meeting EU chemicals legislation to be significant
- [ ] I don't know

Questions 20 and 21 should also look into which significant costs are created for companies because of an absence of adequate chemicals management. (See also our comments to question 20 under additional comments.) These costs include both direct and indirect costs for human health, the environment and society related to the exposure to and dispersion of chemicals, such as: costs related to human diseases resulting in e.g. productivity loss, increased sick leave, morbidity, health care costs etc.; costs related to the degradation of natural resources (e.g. water supplies); or costs arising as a result of a need for remediation, restoration and compensation as well as business loss due to unacceptable pollution or other financial risks in case of liability claims. Moreover, as society bears many of these costs (e.g. increased health care costs) fewer public resources are available to fund and support research in safer chemicals, potentially placing the EU chemicals industry at competitive disadvantage with its international competitors. For the consumer, inadequate chemicals provisions could result in lower disposable income (either as a direct consequence of health damages or through the need for private health insurance), thus depressing private consumption and demand for the industry's products. Absence of adequate chemicals provisions also contributes to diminished consumer trust in the chemicals industry, potentially resulting in significant intangible or reputational costs and an eventual business loss. Finally, the European industry can only survive when the bar is raised - it will not be competitive on a cost basis. Absence of adequate chemical provisions in the EU can therefore also contribute to competitive disadvantage for the European industry (favouring industries outside the EU) as the industry faces fewer incentives to invest in safer alternatives and, as a consequence, the industry risks losing global market shares.

22. Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?

○ Yes ○ No ○ I don't know

If you answered yes, please indicate what these are.

Given that chemical provisions - particularly for consumer products - are widely absent it is difficult for us to identify excessive costs for market surveillance.

However, the current market surveillance system is ineffective and inefficient and the EU must urgently unblock the product safety and market surveillance package to create a EU-based and more harmonised system which equips market surveillance authorities with better financial and human resources.

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Relevance

The following questions explore the extent to which the EU legislative framework for chemicals is consistent with current needs.

23. To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

	1	2	3	4	5	I don't know
Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	○	○	● 3	○	○	○

24. To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

	1	2	3	4	5	I don't know
Novel areas of concern sufficiently addressed by framework	● 1	○	○	○	○	○

Please comment

Mixture toxicity, hormone disrupters, non-monotonic dose response relationships and nanomaterials are not sufficiently addressed based on the advances in science.

Scientific research also demonstrated that numerous chronic diseases which are linked to environmental exposure to chemicals are increasing constantly such as cancer, cardiovascular problems, allergies, obesity, fertility problems and autism which shows that the EU approach to chemicals management is insufficient.

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Coherence

This section explores whether the chemical-related provisions in the various pieces of legislation within the scope of this fitness check are consistent with each other, whether they are complementary or if there are significant gaps, overlaps and inconsistencies that stand in the way of their effective implementation.

25. Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
The EU chemicals legislation framework contains gaps and missing links	○	○	○	○	5
The EU chemicals legislation framework has overlaps	○	2	○	○	○
The EU chemicals legislation framework is internally inconsistent	○	○	○	4	○

26. Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

Gaps or missing links: See comments on EDCs, nano and cocktail effect. Chemicals in textiles need to be regulated

In the food contact materials regulation EC/10/2011 only plastics are comprehensively regulated even though with significant gaps related to colorants, solvents or printing inks. EU rules for more materials are urgently needed. Moreover, the provisions for plastics need to be improved.

In directive 93/42/EEC there are no clear limit values for the content of chemicals in medical devices which is a severe shortcoming for consumer safety as patients are in particular vulnerable.

The toy safety directive 2009/48 lacks appropriate level of protection as the CLP values are not suitable to set safe levels for chemical use in toys and as not all relevant chemicals have been regulated with specific limit values. As a consequence, market surveillance authorities have not enough clarity which toys should be taken off the market despite the fact that they are harmful to children.

Moreover many consumer articles lack almost completely regulatory provisions for chemicals (child care articles, tattoo inks, packaging, construction products, clothing, furniture, floor coverings, sports equipment, car interiors…)

The drinking water directive needs to be enhanced to improve chemical safety of water supply materials.

Similarly existing legislation has serious gaps in addressing products that emit hazardous substances in the indoor air should be tackled. Please also refer to ANEC position paper 'Hazardous chemicals in products - The need for enhanced EU regulations'

Overlaps

A study to assess overlaps in EU chemicals legislation carried out by Milieu ltd. for the European Commission in the context of the 2012 REACH review (http://ec.europa.eu/environment/chemicals/reach/studies/study8_review_2012_en.htm) could not identify many instances of double regulation. The study conclusion states: “Overall, REACH’s various in-built mechanisms for avoiding overlap seem to work well. Moreover, the large number of synergies identified between REACH and the various sector-specific legislative acts also demonstrates a high level of coherence. Nonetheless, some instances of double regulation have been identified where legislative changes or – in some cases – guidance could lead to greater legal certainty and reduced confusion on the part of duty holder.”

Inconsistencies

Definitions for nano and requirements on EDCs

27. Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

When considering the above gaps regarding water supply materials and products leading to indoor emissions, the Construction Products Regulation should also be considered. This does not set performance requirements - so (construction) products producing indoor emissions or these are - in theory - subject of the GPSD.

Today, water supply materials are covered by the Construction Products Regulation. The Construction Products Regulation does not set performance requirements and therefore there are no specific provisions on chemical safety for water supply materials. As a consequence, consumers might be exposed to harmful chemicals in drinking water through chemicals which are leaking from the distribution pipes. To ensure better chemicals safety, we propose to urgently set specific requirements under the drinking water directive.

Moreover, the Construction Products Regulation does not take adequate measures to effectively control indoor air pollution stemming from construction products. Today, potential measures could only be taken in case consumer health and safety is at risk because of harmful emissions into the indoor air through the General Product Safety Directive (GPSD). However, as the GPSD does usually not stipulate limits for chemicals in products either, consumers are left without adequate protection from harmful indoor air pollution. We believe that neither the Construction Products Regulation nor the GPSD would be the adequate legal instrument to set requirements for indoor air quality. However, we urge the Commission to develop an adequate regulatory framework specifically with regard to controlling emissions to the indoor air coming from different sources including from construction products and other consumer products present in consumers' homes.

Part IV: Specific questions on the CLP Regulation

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation') governs the identification and classification of the health, environmental and physical hazards of chemicals, as well as the communication of these hazards to workers and consumers.

28. CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

	1	2	3	4	5	I don't know
To what extent are CLP labels effective in communicating hazards to workers?	○	○	○	○	○	X
To what extent are CLP labels effective in communicating hazards to consumers?	○	2	○	○	○	○

29. Do the hazard classes in the CLP Regulation cover all relevant hazards?

	Yes	No	I don't know
Environmental		No	○
Physical	○	○	X ○
Human health		No	○

Please list any hazard classes that are not covered

The EU should adopt a classification and labelling system for hormone-disrupting chemicals and also include a hazard class for PBTs and vPvBs - or similar - covering persistent substances.

30. How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)

	1	2	3	4	5	No experience
Guidance documents	○	2	○	○	○	○
Helpdesks	○	○	○	○	○	X
Industry association guidance and materials	1 ○	○	○	○	○	○
Other (training, conferences, etc.)	○	○	○	○	○	X

Please add further details as necessary

On important issues, the EU never compiled guidance documents. For instance, the definition for nanomaterials in cosmetics contains unclear terms such as "insoluable" and "bio-accumulative". A guidance to clarify manufacturers labelling obligations has never been published leading to uncertainty. Industry association guidelines are of no use. On the contrary, these documents often seek to interpret legislation in the most unambitious manner (such as for instance labelling "nano" in the ingredients list of food.

31. To what extent is CLP enforced in a harmonised manner across Member States?

- ◯ Enforcement is harmonised across all Member States
- ◯ Enforcement is not harmonised across most Member States
- ◯ Enforcement is harmonised across most Member States
- ◯ I don't know

Please add further details as necessary

32. To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)

	1	2	3	4	5	I don't know
Ease of implementation for duty holders	◯	◯	◯	◯	◯	X
Appropriateness of classification criteria and methods for substances	◯	2	◯	◯	◯	◯
Appropriateness of classification criteria and methods for mixtures	◯	2	◯	◯	◯	◯
International harmonisation through the Globally Harmonised System (GHS)	◯	◯	◯	◯	◯	X

If you answered 1, 2 or 3 and would like to provide further information, please explain your answer

See answer to Q 29.

33. CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?

- ◯ Transition period is sufficient
- ◯ Transtion period is too long
- ◯ Transition period is too short
- ◯ I don't know or have no opinion

Please elaborate if you answered that the transition period is too short or too long.

34. To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)

	1	2	3	4	5	I don't know
Transparency of the procedures	○	○	○	○	○	○
Involvement of stakeholders	○	○	○	○	○	○
Quality of scientific data and related information	○	○	○	○	○	○
Speed of the procedure	○	○	○	○	○	○

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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.

Please forward any position papers to the following email address: *enquiries@rpaltd.co.uk*

Thank you for your cooperation.