

The Consumer Voice in Europe

## **REACH FOR A NON-TOXIC ENVIRONMENT**

BEUC position on the 2017 REACH review



Contact: Pelle Moos - safety@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND

Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • consumers@beuc.eu • www.beuc.eu EC register for interest representatives: identification number 9505781573-45





## Why it matters to consumers

Harmful chemicals are found in many products consumers come in very close, frequent and prolonged contact with. Examples include clothes, kitchen tools, toys, cosmetics, and the list goes on.

The REACH regulation is the EU's primary law to reduce human and environmental exposures to dangerous substances. The European Commission is consulting the public on whether this vital legislative framework performs as intended. BEUC welcomes this exercise as an opportunity to better protect consumers against harmful chemicals as well as to strengthen the consumers' right to know.

#### 10 Years REACH

As the EU's primary chemicals law, REACH plays a fundamental role in the prevention and reduction of chemical risks in Europe and globally. The application of REACH impacts and shapes the capacity of other EU laws, e.g. on cosmetics, biocides or the work environment, to regulate harmful chemicals. As such, it is paramount that REACH achieves its intended objectives.

At 10 years, **REACH** has delivered on some of its promises, especially in relation to an improved understanding of the chemicals industry places on the market. Nevertheless, there are significant shortcomings in how **REACH** is applied as well as a need to further develop the Regulation to ensure better protection of consumers and the environment.

The European Commission will already be familiar with many of these shortcomings, whether from the 2012 REACH review; the European Chemicals Agency's (ECHA) recurrent reporting on the operation of REACH; evaluations and reviews by Member State competent authorities; or from various other sources.

Rather than reiterate these deficiencies, BEUC here wish to highlight how REACH should be developed and its application strengthened to better protect consumers. As a first, overarching point, we however emphasize that **political will on behalf of the Commission and the Member States is a fundamental condition to ensure that REACH delivers its promised objectives**.

European Commission, REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH. 5 February 2013. <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN</a>

<sup>&</sup>lt;sup>2</sup> See *e.g.* ECHA, Report on the Operation of REACH and CLP 2016, June 2016. https://echa.europa.eu/documents/10162/13634/operation\_reach\_clp\_2016\_en.pdf

<sup>&</sup>lt;sup>3</sup> See e.g. KemI, Developing REACH and improving its efficiency – an action plan, 2015. https://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf

See e.g. EEB, A Roadmap to Revitalise REACH, November 2015. <a href="http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/">http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/</a>



#### Enforce the 'no data, no market' principle

Even if REACH has increased available data on chemicals, key information – especially related to exposure – is still missing. ECHA's compliance checks demonstrate beyond dispute that many companies submit registration data of highly deficient quality. ECHA's 2013 REACH Evaluation Report for example states that more than 60% of registrations are incomplete or inadequate. Moreover, since 2008, 64% of dossiers have not been updated. This is unsatisfactory and it hinders the intended effect of REACH that chemical risks should be controlled, eliminated, or justified by their creators.

For this reason, ECHA should be given the tools, backed by a clear political mandate, to reject poor quality registrations. ECHA should likewise cease to assign registration numbers to dossiers that do not fulfil mandatory requirements. This would undoubtedly improve the quality of information in the dossiers. More accurate information in the registration dossiers will in turn lead to better substance and dossier evaluations (see below).

To further improve data availability and quality, we recommend that:

- ✓ The obligation to regularly update registration dossiers, especially on use, exposure and tonnage information, is clarified. As recommended by ECHA, an implementing regulation should be adopted to clarify the criteria triggering an update, including a binding timeframe for regular updates.
- ✓ Stricter information requirements relating to registration of low volume substances (1-10 tonnes) should be introduced. Some 20.000 low volume chemicals are believed to be on the EU market. At present, however, companies are not even required to screen these substances for carcinogenicity, reproductive toxicity, endocrine disruption or PBT properties. Companies registering low volume substances (1-10 tonnes) should be required to submit the same toxicological data and endpoints as for substances in the 10-100 tonnages ban.
- ✓ Notification requirements and basic information (including use) for all substances produced in less than 1 kg should be introduced. This would ensure a better overview of what substances, including novel synthetic nanomaterials, are produced and imported to the EU and where these substances are used.

#### Apply the precautionary principle

Under the old chemicals legislation, a number of decisions were made with reference to the precautionary principle. These decisions balanced the time needed to generate data to inform a decision of 'normal' certainty against the consequences for human health and the environment of that delay in decision-making should the data confirm the concern. Under REACH such an approach has yet to be applied, despite REACH being legally underpinned by the precautionary principle.<sup>8</sup>

<sup>&</sup>lt;sup>5</sup> ECHA, Report on the Operation of REACH and CLP 2016, June 2016. https://echa.europa.eu/documents/10162/13634/operation\_reach\_clp\_2016\_en.pdf

Although ECHA claims to already have the authority to recall registrations, the agency has yet to exercise that authority. Whether REACH in fact does give ECHA such authority is unclear, however.

See ECHA, Report on the Operation of REACH and CLP 2016, June 2016. https://echa.europa.eu/documents/10162/13634/operation reach clp 2016 en.pdf

KemI, Developing REACH and improving its efficiency – an action plan, 2015. https://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf



Quite the contrary, in fact: current REACH processes are moving at a disappointingly, if not glacial pace. Fewer substances are being suggested for restriction than before REACH was in place, while since 2014 few new substances have been added to the Candidate List and Authorisation List.

Decision-making under REACH is too often hampered by deficiencies in the registration dossiers. This essentially pushes the burden of proof back towards public authorities, challenging them to find the balance between a precautionary approach on the one hand and refraining from measures that could be disproportionate on the other. This becomes apparent in different REACH processes, particularly in the context of restrictions, application for authorisation and substance evaluations.

Problems with limited data can and need to be solved with additional clarifications and/or implementing legislation. Such clarifications should specify what information companies need to deliver (application for authorisation, substance evaluation) and/or the information that is sufficient to impose a restriction or to refuse an authorisation.

To increase speed, reduce the burden on authorities and make the REACH processes more transparent, the Commission and Member States should moreover:

- ✓ Abandon the unnecessary agreement to perform a Risk Management Options Analysis (RMOA) to include a substance on the Candidate List. Since RMOA was introduced as a tool to support decision-making, very few SVHCs have been added to the Candidate List. RMOA thus also hinders the 'right to know' principle since not all SVHCs are added to the Candidate List.
- ✓ Introduce an automated trigger for substances with known CMR, PBT, EDC and other 57f properties (whether classified or not) to be included on the Candidate List. After 2018, if an SVHC on the Candidate List has not been registered, it should immediately be moved to Annex XIV with a sunset date of 18 months to prevent future use. If a substance on Annex XIV has no granted authorisations approved before the sunset date, all uses should be automatically restricted (*i.e.* the substance should be included in Annex XVII). The use of SVHCs in products and articles which children come in contact with should be strictly prohibited.<sup>10</sup>
- ✓ Extend the authorisation requirement to SVHCs present in imported articles. This would close a major gap in current legislation as well as ensure a level playing field for companies operating in the European Economic Area by placing the same strict requirements on domestic articles as on those that are produced abroad.¹¹
- ✓ Make the restriction process less burdensome and extend Article 68.2 to cover all substances fulfilling the SVHC criteria (for example PBT/vPvB, sensitizers, and EDCs).

-

See EEB, A Roadmap to Revitalise REACH, November 2015. <a href="http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/">http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/</a>

See KemI, Increasing children's protection through REACH, January 2014.

See Umweltbundesamt, Enhancement of the REACH requirements for (imported) articles, April 2015. <a href="https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte 41 2015 enhancement of the reach requirements for imported articles 0.pdf">https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte 41 2015 enhancement of the reach requirements for imported articles 0.pdf</a>



#### Strengthen the consumers' right to know

Article 33 of REACH establishes the consumers' right to be informed about substances of very high concern present in products. It is however generally recognised that this mechanism falls short and needs to be strengthened. Research undertaken by BEUC for example found that **consumers experience severe difficulties in accessing information** and that companies rarely have sufficient knowledge of their obligations under REACH.

Clear and readily accessible information about harmful chemicals in articles will facilitate the identification and handling of exposure sources and enable suppliers, distributors and consumers to adopt a preventive approach and choose better alternatives. This would in turn reinforce incentives for industry to phase out the use of hazardous substances. The REACH review therefore needs to strengthen implementation of Article 33. The Commission and Member States should ensure that:

- ✓ **Notification requirements for all SVHCs in articles**, irrespective of tonnage (from 1 kg/year), are introduced and enforced to improve information on the chemicals produced, used and imported in the EU.
- ✓ The scope of Article 33 is extended to cover all substances that meet the SVHC criteria present in articles above 0.1 percent. Manufacturers and importers should be obliged to label articles containing such substances.
- ✓ More and better information is made available on substances used in everyday products so as to encourage manufacturers to substitute ingredients deemed harmful.
- ✓ Increase funding for smartphone applications that allow consumers to submit a right-to-know request directly to the supplier. The Danish Consumer Council for example launched such an app¹⁴ in April 2014 as an innovative tool to simplify and in some cases accelerate communication between consumers and suppliers. We encourage EU leaders to provide funding to NGOs in other countries to replicate this and other innovative tools.
- ✓ **Invest in awareness raising campaigns to educate consumers** so they better understand chemicals' impact on their lives. Guided by this knowledge, EU consumers will become a driving force for substitution and innovation in safer alternatives.

\_

<sup>&</sup>lt;sup>2</sup> ECHA, Report on the Operation of REACH and CLP 2016, June 2016. https://echa.europa.eu/documents/10162/13634/operation\_reach\_clp\_2016\_en.pdf

See BEUC, Consumers, Chemicals, Companies – How much are we told? October 2011. <a href="http://www.beuc.eu/publications/2011-09794-01-e.pdf">http://www.beuc.eu/publications/2011-09794-01-e.pdf</a>

<sup>14</sup> http://tjekkemien.dk/



#### Use the REACH review to achieve the 7EAP commitments

Beyond 2018, EU's chemicals policy aims to achieve a non-toxic environment that is conducive to public health, innovation and the development of sustainable substitutes. <sup>15</sup> 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. 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 7<sup>th</sup> Environmental Action Programme. <sup>16</sup>

As emphasised by the December 2016 Council Conclusions on the sound management of chemicals, <sup>17</sup> the REACH review should focus on how the commitments outlined in the 7EAP can be implemented in and supported through REACH. <sup>18</sup> In particular, the 7EAP commits the EU to

- > take horizontal measures to minimize exposure to endocrine disruptors;
- set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products;
- further develop and implement approaches to address combination effects of chemicals; and
- ensure the safety and sustainable management of nanomaterials and materials with similar properties.

To achieve these commitments BEUC recommends that

#### **Endocrine disruptors**

• Member States advance their efforts to identify substances with endocrine-disrupting properties and, depending on the outcome, to nominate those substances for the Candidate List. A major obstacle remains the delay in adopting scientific criteria to identify endocrine disruptors within the context of the biocides and pesticides regulations.<sup>19</sup> Although the REACH text does not require criteria to put endocrine disruptors on the Candidate List and make them subject to authorisation, horizontal EDC criteria will make it possible to start identifying such substances systematically compared to the burdensome case-by-case identification today.<sup>20</sup>

http://data.consilium.europa.eu/doc/document/ST-15673-2016-INIT/en/pdf

<sup>9</sup> See BEUC, Hormone-Disrupting Chemicals: When Will The EE Act Against These Everyday Toxicants? July 2016. <a href="http://www.beuc.eu/publications/beuc-x-2016-077">http://www.beuc.eu/publications/beuc-x-2016-077</a> beuc regulation of edcs.pdf

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'. <a href="http://eurlex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013D1386&from=EN">http://eurlex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013D1386&from=EN</a>

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

Government of the Netherlands, REACH Forward. Discussion paper for MS conference, 1 June 2016. https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=0ahUKEwj2ud6L6trRAhVDxxQKHeT8ChwQFggcMAA&url=https%3A%2F%2Fwww.government.nl%2Fbinaries%2Fgovernment%2Fdocuments%2Fpublications%2F2016%2F06%2F03%2Fdiscussion-paper-reachforward%2Fdiscussion-paper-reachforward-version-24-may-final.pdf&usq=AFQjCNH8f2T86R SEVt9t6qA3dZGvuz7w&sig2= 0 8331RCKB66OVD8e-hYA

<sup>&</sup>lt;sup>20</sup> See KemI, Developing REACH and improving its efficiency – an action plan, 2015. https://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf



- Based on the EDC criteria, ECHA and Member State authorities need to assess the endocrine-disrupting potential of all registered substances and, where necessary, pursue appropriate risk management measures. Priority should be given to substances likely to come into contact with the public, particularly with vulnerable populations such as infants, women of childbearing age and pregnant women. The EDC criteria should also play an important role in determining how many and which EDCs become subject to restrictions or authorisation under REACH. EDCs identified as SVHCs should be included on the REACH Authorisation List and phased out without delay. Member States and the Commission likewise need to pursue more restrictions on EDCs in consumer products, especially in imported goods.<sup>21</sup>
- Companies registering chemicals under REACH should be obliged to assess whether a substance is an endocrine disruptor in their chemical safety assessments on the basis of amended standard information requirements. New guidance and methodologies for testing and risk assessment also needs to be developed.<sup>22</sup>
- Unless and until criteria for the classification of endocrine disruptors are incorporated into the CLP Regulation, a separate annex containing criteria for identification of EDCs should be adopted under REACH. This should correspond to the criteria for identification of persistent, bioaccumulative and toxic (PBT) substances contained in Annex XIII.

#### Minimising exposure to hazardous substances, including in articles

- Member States should use their substance evaluation work to target groups of substances (e.g. nonylphenols, bisphenols) and adopt restrictions/authorisations as appropriate to counteract potential regrettable substitutions. Although REACH is primarily focused on the assessment of individual substances, in certain cases, however, groups of substances have already been dealt with jointly in authorisations and restrictions.<sup>23</sup> As part of a comprehensive approach to minimising exposure to hazardous substances REACH thus needs to be developed such that assessment of groups of substances is made easier.
- The regulation of substances in articles needs be significantly improved. 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, tattoo inks, personal protective equipment, furniture, sports and playground surfaces and equipment, car interiors etc.<sup>24</sup> REACH at present does not compensate for these deficits as 'articles' particularly imported ones are barely covered under REACH. Moreover, only restrictions can establish chemical limit values in products. However, the restriction path is laborious and time consuming (see above) and generally precludes generic bans of substances falling in a certain hazard class (e.g. all CMR substances). While Article 68(2) does represent an exception its scope as highlighted above needs to be extended to cover all classified SVHCs as well as other substances with known CMR, PBT, EDC and other 57f properties.

6

<sup>&</sup>lt;sup>21</sup> See BEUC, Hormone-Disrupting Chemicals: When Will The EE Act Against These Everyday Toxicants? July 2016. <a href="http://www.beuc.eu/publications/beuc-x-2016-077">http://www.beuc.eu/publications/beuc-x-2016-077</a> beuc regulation of edcs.pdf

See BEUC, Hormone-Disrupting Chemicals: When Will The EE Act Against These Everyday Toxicants? July 2016. <a href="http://www.beuc.eu/publications/beuc-x-2016-077">http://www.beuc.eu/publications/beuc-x-2016-077</a> beuc regulation of edcs.pdf

See KemI, Developing REACH and improving its efficiency – an action plan, 2015. https://www.kemi.se/global/rapporter/2015/report-2-15-reach.pdf

<sup>&</sup>lt;sup>24</sup> See ANEC, Hazardous chemicals in products - The need for enhanced EU regulations, June 2014. http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf



• The interface between REACH and the General Product Safety Directive (GPSD) must improve. Enforcement of EU consumer and chemicals-related laws remains inadequate. In 2015, 25 per cent of total of notifications to the EU RAPEX system were related to chemical risks.<sup>25</sup> However, as a result of inefficient and ineffective market surveillance activities and a lack of clear rules with regard to chemicals in consumer products, this figure likely represents only the tip of the iceberg. The flow of information between authorities needs to improve. If for example a problematic chemical is identified in REACH this information should be automatically notified to the GPSD authorities who could take immediate action in relation to articles on the market.

#### **Combination effects**

- REACH should require industry to take account of possible combination
  effects in their registration dossiers, for example in the form of an extra
  assessment factor. Testing requirements should further be updated to fully assess
  the impact of total chemicals exposures and of cumulative impacts, corresponding
  to the reality of our exposure.
- In its 2012 Communication on Combination effects of Chemicals,<sup>26</sup> the Commission committed to develop by June 2014 technical guidelines to promote a consistent approach to the assessment of priority mixtures across different EU laws. This has not happened. We urge the Commission to publish as soon as possible guidance documents promoting an integrated and coordinated assessment across all relevant EU laws, including REACH.

#### **Nanomaterials**

• REACH should be revised to adequately regulate nanomaterials. As a first measure, it is paramount that the REACH annexes are updated and guidance documents developed ahead of the 2018 registration deadline.<sup>27</sup> An adaptation of the annexes of REACH alone is however insufficient: a definition of nanomaterials, a provision to ensure that nanomaterials are considered as new substances to be registered independently of any corresponding bulk substances, and lower tonnage thresholds also needs to be introduced.<sup>28</sup> In parallel, a compulsory nano-register needs to be implemented at the EU level to ensure transparency for consumers and traceability of nanomaterials in the supply chain.<sup>29</sup>

**END** 

\_

European Commission, Press release. Protecting European consumers: toys and clothing top the list of dangerous products detected in 2015, Brussels, 25 April 2016. <a href="http://europa.eu/rapid/press-release IP-16-1507">http://europa.eu/rapid/press-release IP-16-1507</a> en.htm

European Commission, Communication from the Commission to the Council. The combination effects of chemicals Chemical mixtures, May 2012. <a href="http://eur-lex.europa.eu/leqalcontent/EN/TXT/PDF/?uri=CELEX:52012DC0252&from=EN">http://eur-lex.europa.eu/leqalcontent/EN/TXT/PDF/?uri=CELEX:52012DC0252&from=EN</a>

See CIEL, ECOS and Oko-Institut, Revision of REACH Annexes for Nanomaterials – Position Paper, September 2015. <a href="http://www.ciel.org/wp-content/uploads/2015/10/Position-Paper-REACH-Annexes-Final.pdf">http://www.ciel.org/wp-content/uploads/2015/10/Position-Paper-REACH-Annexes-Final.pdf</a>

<sup>28</sup> See ANEC, Hazardous chemicals in products - The need for enhanced EU regulations, June 2014. http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

See ANEC and BEUC, Nanotechnology: Small is beautiful but is it safe? June 2009.





This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2014-2020).

The content of this publication represents the views of the author only and it is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

BEUC would like to thank the European Environment and Health Initiative (EEHI) for providing funding for the development of this publication.

# Public Consultation in relation to the REACH REFIT evaluation

Fie	ahla	marked	with	* are	mand	latory
1 10	con	HIGHNEU	VVILII	ale	Hand	iaiui v

### 1) Purpose and Context of the Consultation

#### a) The REACH REFIT evaluation

REACH[1] is the European Regulation for the Registration, Evaluation, Authorisation and Restriction of chemicals (EC) No 1907/2006. It is the main EU law on chemicals, covering substances on their own or in mixtures or in articles for industrial, professional or consumer use[2].

The European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs and DG Environment) is conducting an evaluation of the REACH Regulation as part of the regular reporting obligation to monitor progress in the achievement of the objectives of the Regulation according to Article 117 (4) of REACH. Regular monitoring and reporting provides information to identify needs for adjustment and to propose recommendations to improve the implementation of the Regulation or the need to consider modifications.

This evaluation is part of the Commission's Regulatory Fitness and Performance Programme (REFIT) [3] and will cover the five compulsory evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value, including examining the potential to improve the way in which it delivers on its objectives and the potential for burden reduction and simplification.

The roadmap [4] for the REACH REFIT evaluation outlines the objectives, scope and key evaluation questions to be addressed in the evaluation. Furthermore, the consultation strategy[5] for the REACH REFIT evaluation provides additional details about the consultation objectives, activities and tools planned, including the present open online public consultation.

The objective of the public consultation is to obtain stakeholder views on the general approach to the 2017 REACH REFIT evaluation and to collect stakeholder views on strengths and weaknesses of REACH as well as any potentially missing elements. The responses will be taken into consideration in the preparation of the Commission Staff Working Document, presenting the results of the REACH REFIT evaluation and the Commission general report on the functioning of REACH addressed to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

The current open online public consultation is part of a broader stakeholder consultation strategy which includes also an SME panel circulated through the Europe Enterprise Network. Please note that the results may also be used in the context of other studies in the chemicals field.

\*\* The consultation will last for 12 weeks. Responses to the public consultation must be submitted by 28 January 2017. \*\*

#### b) Structure of this questionnaire

The questionnaire has four parts and you may choose which parts (or questions) you answer depending on your interest and level of familiarity with the REACH legal text and its implementation:

#### Part I – General Information about respondents (compulsory)

**Part II - General Questions** for respondents interested in REACH, but who may not be familiar enough with the legal text and provisions to answer more detailed questions (compulsory)

**Part III – Specific Questions** which require more in-depth knowledge and experience in dealing with the REACH Regulation (optional)

#### Part IV - Additional Comments

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.

In view of the limited resources for translation as well as the specialised nature of the topic and technical terminology involved in this consultation, the questionnaire is available in English, German and French. Individual replies may be provided in any EU language.

Privacy Statement: The information you provide will be used strictly in accordance with the provisions of Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The content of your contribution and identity will be published on the Internet, unless you ask to remain anonymous.

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.

- [1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) OJ L 396, 30.12.2006
- [2] http://ec.europa.eu/growth/sectors/chemicals/reach/

http://ec.europa.eu/environment/chemicals/reach/reach\_en.htm

- [3] http://ec.europa.eu/smart-regulation/index\_en.htm
- [4] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017\_env\_005\_reach\_refit\_en.pdf
- [5] http://ec.europa.eu/DocsRoom/documents/17785/attachments/1/translations/

## 2) Questionnaire

## Part I – General Information about Respondents (compulsory)

- 1. Please indicate your name or the name of your organisation.
- \* Your name or name of the organisation/company:

BEUC, The European Consumer Organisation

Contact name (for organisations):

Pelle Moos

Transparency Register ID number (for organisations):

(If your organisation is not registered in the transparency register, you have the opportunity to <u>register</u> <u>now</u>. 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.)

9505781573-45

\*Country:

Belgium

Safety@beuc.eu	
the identity of the publication of you	tributions may be published on the Commission's website, with the contributor. Please state your preference with regard to the bur contribution:  gardless the option chosen, your contribution may be subject to a request for
access to document	ts under Regulation 1049/2001 on public access to European Parliament, Council ocuments. In this case the request will be assessed against the conditions set out in in accordance with applicable data protection rules)
· ·	
	ion may be published under the name indicated; I declare that none of it is subject estrictions that prevent publication
•	n may be published but should be kept anonymous; I declare that none of it is byright restrictions that prevent publication
I do not agree	that my contribution will be published at all
your preference	d to contact you to clarify some of your answers. Please state below:  le to be contacted
I do not war	nt to be contacted
* 4. Please indica	ate whether you are replying to this questionnaire as:
A citizen	
A business	
A non-govern	mental organisation
(NGO)	
χ A consumer a  An industry as	
Arrindustry as     A trade union	Sociation
_	or public authority
	nmental organisation
121321011	a research or educational institute
Academia or a	
	private organisation
Third country	private organisation public authority

## \*4.2. Business or industry association - fields of interest or activity(ies) multiple choises possible (the letters in brackets correspond to NACE codes) 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 (please specify)

	2.1. Business or in ease specify	dustry	associatio	on - Fields of	interest or act	tivity(ies	) - Other,
<b>*</b> 4.	3. Business, plea	se indic	ate the siz	ze of your bu	siness: The de	efinition of	small and
	edium-sized enterprise lance sheet of the con	•				al turnove	r or the
	Self-employed						
	Micro-enterprise (u						
	<ul><li>Small enterprise (u</li><li>Medium-sized ente</li></ul>		,	nlovees)			
	Large company (25	. ,					
5. I	Please indicate the	e level a	it which yo	our organisa	tion is active:		
	Local						
	National     Assess several se	untrina (a	a Coordin	ovio)			
	<ul><li>Accross several co</li><li>EU</li></ul>	untries (e	e.g. Scandin	avia)			
	Global						
Pa	rt II – General q	uestio	ns (com	oulsory)			
٦	his part is intended fo	r all respo	ondents inte	rested in REAC	H, including those	e who may	not be
f	amiliar enough with the	e legal te	xt to answer	more detailed	questions.		
թ -	To what extent do	vou thii	nk RFACH	l is achievino	the following	objectiv	res?
•	o what oxioni do	, o a			,	0.0,000	
		1					Do not
		Not	2	3	4	5 Very	know /
		at all	Slightly	Somewhat	Substantially	much	not applicable
		all					аррпсаыс
	*a) Improve	0	0	0	X	0	©
	protection of				^		

consumers

*b) Improve protection of workers	•	•	•	Х	0	•
*c) Improve protection of the environment	•	•	•	Х	0	•
*d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)	•	•	•	•	X	•
*e) Enhance competitiveness and innovation	0	•	•	•	X	•
*f) Promote alternative methods to animal testing for hazard assessment of chemicals	©	©	©	©	•	X

## 7. To what extent do you think REACH is delivering the following results?

1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
-----------------------	---------------	---------------	--------------------	-------------------	---------------------------------------

*a) Generation of data for hazard /risk assessment	0	•	•	х	•	•
*b) Increase in information on chemicals for risk management	0	•	•	Х	0	•
*c) Increase in information exchange in the supply chain	©	•	X	•	0	•
*d) Improvement in development and implementation of risk management measures	©	•	X	•	•	•
*e) Shifting the burden of proof from public authorities to industry	0	•	X	•	•	•
*f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)	•	•	•	X	•	•

*g) Promoting the development, use and acceptability of alternatives to animal testing	•	•	•	•	•	X
*h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing	©	•	•	•	•	X
*i) Dissemination of information on chemicals for the general public	©	©	Х	•	0	•

8. The various processes of REACH (e.g. registration, evaluation) are expected to generate data that can be used by public authorities to adopt adequate risk management measures under REACH or in other EU legislation. To what extent do you think that the data generated are adequate for adopting the following measures?

	1 Not useful at all	2 Slightly useful	3 Somehow useful	4 Substantially useful	5 Very useful	Do not know / not applicable
*a) REACH authorisation	0	0	0	Х	0	•
*b) REACH restriction	0	Х	•	0	0	•
*c) Consumer protection legislation concerning chemicals in articles (e.g. cosmetics, toys, food packaging)	•	X	•	•	•	
*d) Environmental legislation (e. g. Seveso, Industrial Emissions Directive)	©	©	©	X	©	•

*e) Harmonised Classification & Labelling	•	•	х	•	•	•
*f) Occupational Exposure Limits (OEL) in the context of worker protection legislation	•	©	©	X	©	

# 9. To what extent do you agree with the following statements in relation to the European Chemicals Agency (ECHA)?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
*a) ECHA has handled the registrations of chemical substances effectively (i.e. support for registrant, access to IT tools)	•	©	X	•	•	•
*b) ECHA has established a strong and trustful relationship with its stakeholders	•	•	•	X		•

*c) ECHA has contributed to reducing the impact of REACH on SMEs	•	•	•	•	•	X
*d) ECHA's activities and guidance have facilitated an innovation- friendly framework	•	•	•	•	•	X
*e) ECHA has been successful in facilitating the implementation of the last resort principle concerning animal testing.	•	©	©	•	©	X

## Part III - Specific questions that require more experience with REACH

This part contains more detailed questions related to the five evaluation criteria and to REACH procedures.

You may further explain your answers at the end of the consultation.

### Part III. A

### **Effectiveness**

The following questions explore the extent to which the objectives of the REACH Regulation have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

## 10. In your view, to what extent have the REACH Regulation and its various chapters been implemented successfully?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
Registration	0	0	X	0	0	•
Data-sharing and avoidance of unnecessary testing	•	•	•	©	0	X
Information in the supply chain	0	0	X	0	•	0
Evaluation – dossier	0	х	0	•	0	0

Evaluation – substance	0	0	Х	•	•	•
Authorisation	0	х	0	0	0	0
Restriction	Х	0	0	0	0	0
Overall implementation of REACH	0	х	•	•	0	•

# 11. Do you agree that the REACH legal text presents requirements regarding the following chapters in a clear and predictable manner?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
Registration	0	0	0	Х	0	0
Data-sharing and avoidance of unnecessary testing	•	©	0	X	•	•
Information in the supply chain	0	0	0	X	•	0
Evaluation – dossier	0	0	0	Х	0	0
Evaluation – substance	0	0	0	Х	•	0
Authorisation	0	0	0	Х	0	0
Restriction	0	0	0	Х	0	0

# 12. In your view, to what extent are the following elements of REACH working well?

	1 Not well at all	2 Rather not well	3 Neutral	4 Rather well	5 Very well	Do not know / not applicable
Transparency of procedures	0	0	0	0	0	X
Speed with which hazards/risks are identified	Х	•	•	•	0	0
Speed with which identified risks are addressed	Х	0	0	0	0	0
Time to allow duty holders to adapt	0	0	Х	0	0	0
Predictability of the outcomes	0	0	х	0	0	0

# 13. Please identify unintended effects of REACH, indicating whether you consider those to be positive or negative. Please provide evidence to quantify such effects or a qualitative description.

(max. 5.000 characters)

It is an intended goal of REACH to stimulate substitution of harmful chemicals with safer ones. However, the current practice of consistently granting all authorisations, regardless of whether the application meets the requirements laid down in the REACH legal text, results in unintended and negative consequences for those companies that have already made investments in substituting SVHCs. Moreover, granting authorisations when there are alternatives available send an unclear message to companies regarding the legal intention that SVHCs should be substituted when possible.

If an authorisation is granted to an applicant even when competitors use an alternative, all competitors, including the producer of the safer alternative will be disfavoured. This would not happen if the authorisation regime was implemented in line with the intentions of REACH, that is, to grant authorisation only when no alternatives are available and the use has a socioeconomic benefit that outweighs the risk. Therefore it is of great importance that the opinions from ECHA as well as the decisions from the Commission do not disfavour users and producers of alternatives.

# 14. In your view, to what extent are the following elements of REACH enforcement satisfactory?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicable
Overall REACH enforcement in the EU	•	Х	•	•	0	0
REACH enforcement at Member States level	•	Х	•	•	•	©
REACH is enforced uniformly across the EU	х	•	•	•	•	0
Prioritisation of enforcement activities at EU level (by Forum)	•		•			X
Communication on enforcement activities from Member States and Forum	•	•	•	•	•	X

## 14.1. If you answered 3 or less for any of the above, please explain how the relevant aspect of REACH enforcement could be improved.

(max. 5.000 characters)

According to the core REACH principle of "no data, no market", a chemical should only be allowed on the market, once manufacturers and importers prove it is safe by submitting specific information. To date however the quality of registration dossiers remains highly deficient. ECHA's 2013 REACH Evaluation Report for example states that more than 60% of registrations are incomplete or inadequate. Moreover, since 2008, 64% of dossiers have not been updated. This is unsatisfactory and it hinders the intended effect of REACH.

Moreover, it is evident that the soft measures applied by ECHA are ineffective: not only is there a lack of incentives for manufacturers and importers to comply; there are also too many incentives encouraging the opposite, such as the lack of regulatory action and the low chance (5%) that a dossier will be evaluated.

To address this unsatisfactory state of affairs, we recommend that ECHA should refuse or annul registration numbers to companies not providing relevant or insufficient information in their registration dossier. This would undoubtedly lead to a higher quality of information in the dossiers. In addition, the compliance checks rate should be increased beyond the current 5% of registration dossiers. More accurate information in the registration dossiers will in turn lead to better substance and dossier evaluations. It would also facilitate and enable enforcement in all Member states. One of the reasons why enforcement is burdensome for Member States is that relevant data often is missing.

Further, where limit values that restrict chemicals in consumer products are set through REACH (e.g. concerning toys) the RAPEX database shows that there are many cases of compliance.

With regard to consumer products the EU urgently need an EU-harmonised market surveillance system which ensures that 1) Member States dedicate sufficient financial resources, personnel and testing facilities, 2) double testing is avoided and Member States follow-up on tests done in other countries also in their territories, 3) a meaningful number of consumer products is tested in laboratories.

Testing from consumer organisations also demonstrates regularly that some consumer products contain harmful chemicals for which no mandatory limit values have been set through REACH or in sector specific legislation. This lowers the possibilities of Member States to do meaningful enforcement of the General Product Safety legislation and more binding limit values/ bans of harmful chemicals are needed through REACH and/or sector specific legislation.

15.Have you, in th	ne past 5 years, experienced a REACH inspection/control or have your
products been	controlled for REACH compliance? - To be answered only by companies
(REACH dutyh	olders).

Yes
Nο

I don't know

## **Efficiency**

The following questions explore the costs and benefits of implementing the REACH Regulation. 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 trade between EU Member States) and fostering competitiveness and innovation of EU industry (e.g. better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

## 16. In your view, how significant are the following benefits generated for society by the REACH Regulation?

	1 Not significant at all	2 Rather not significant	3 Neutral	4 Rather significant	5 Very significant	Do not know / not applicable
Reducing the exposure of citizens in general to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.			©	©	X	•

Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	•	•	•	•	X	•
Reducing damage to the environment and to eco- systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up contaminated land, etc.			•	•	X	

Encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry by encouraging /supporting a shift towards green, sustainable chemistry and a circular economy					X	
Stimulating competition and trade within the EU single market	•	•	•	•	X	•

Stimulating international trade between the EU and other countries	•	•	•	•	X	•
For businesses: Increasing the confidence of your clients /customers in your products	©	•	•	•	•	•

17. In your view, to what extent are the costs linked to the following REACH chapters (for society, companies, public authorities, etc.) proportionate to the benefits (for society, companies, public authorities, etc.) achieved?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
Registration	0	0	0	•	Х	•
Information in the supply chain (e.g. eSDS - extended Safety Data Sheets)	©	•	©	©	©	X
Evaluation - dossier	0	0	0	•	Х	0
Evaluation - substance	0	0	0	0	Х	0

Authorisation	0	0	0	0	х	0
Restriction	0	0	0	0	х	•
Requirements for substances in articles	0	0	0	0	X	0

# 18. Is the level of the fees and charges paid to ECHA as provided by the Fee Regulation (Commission Regulation (EC) No 340/2008), still adequate?

	Yes	No, it is too high	No, it is too low	I don't know
Fee for registration	0	0	•	X
Fee for authorisation	0	0	0	X
Fee for appeal	0	0	0	X

19. Do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?
Yes to a large extent
X Yes but only to a minor extent
O No
I don't know
If yes, you may provide ideas, preferably substantiated with quantitative evidence or qualitative information, at the end of the questionnaire.
Relevance
The following questions explore the extent to which REACH is consistent with current needs.
20. Do you believe that the REACH Regulation addresses the key issues in relation to the management of chemicals?
X Yes to a large extent
Yes but only to a minor extent
O No
I don't know
If you answered no, you may provide detailed comments at the end of the questionnaire.

# 21. How suitable do you consider REACH to be to deal with the following emerging issues?

	REACH is the most suitable EU legal instrument to address the issue	REACH should only play a secondary role and the issues should be addressed by specific legislation	REACH is not a suitable instrument and should not address the issue at all	Do not know / Not applicable
Nanomaterials	©	Х	0	•
Endocrine disruptors	0	Х	0	0
Substances in articles	0	Х	0	•
Combination effects of chemicals	Х	0	0	•
Extremely persistent substances	Х	0	0	•

## Coherence

## 22. Please tell us to what extent you agree or disagree with the following statements:

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
The different chapters (e.g. registration, authorisation, restriction,) in REACH are applied in a coherent manner (e.g. there are no contradictions, inconsistencies)	©	X		©	•	•
The different chapters in REACH (e.g. registration, authorisation, restriction,) are applied in a coherent manner (e.g. there are no contradictions, inconsistencies, they are complementary) in relation to other EU legislation (e.g. worker protection legislation, consumer protection legislation, environmental legislation)		X				

The implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH	•	X	•	©	•	•
The implementation of the SVHC Roadmap, including the RMOA, contributes to coherent implementation of REACH in relation to other EU legislation (e.g. there are no contradictions, inconsistencies, they are complementary)	©	X	•	©	•	•

## 22.1. If you disagree with one or more of the statements above, where do you consider coherence should be enhanced?

(max. 5.000 characters)

Since Risk Management Option Analysis (RMOA) was introduced very few substances have been added to the REACH Candidate List: in the last two years, only 24 substances have been included. This is equivalent to 12 substances per year, compared to 29 substances included in 2010, 28 in 2011 and 67 in 2012 (See EEB, A Roadmap to revitalize REACH).

The process for including substances of very high concern in the Candidate List should be swift, but has instead become overly costly and burdensome for Member States through the introduction of the RMOA.

Further, and in conflict with the intentions of REACH, the RMOA introduces risk as a first step in the process of hazard identification of SVHCs. By front-loading the process with demands for use and exposure information that legally belongs only to the prioritisation step, the RMOA process is dissuading Member States from preparing dossiers. RMOA requires accurate data of use that in many cases is non-existing in the dossiers, which means a proper RMOA cannot be performed.

Finally, RMOAs not only hamper the substitution goal and undermines the precautionary principle, but also deny EU consumers their 'right to know'. SVHC identification thus serves an important function independent from the authorisation procedure.

RMOA should therefore in short not become a mandatory requirement under REACH.

### **EU Added Value**

23. To what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (1= no value, 5= a very high value)

	1	2	3	4	5	Do not know / not applicable
Registration	0	0	0	0	X	0
Data-sharing and avoidance of unnecessary testing	0	0	0	•	X	0
Information in the supply chain	0	0	0	•	Х	•
Evaluation – dossier	0	0	0	0	Х	0
Evaluation – substance	0	0	0	0	Х	0

Authorisation	0	0	0	0	Х	0
Restriction	0	0	0	0	х	0

## Part III. B

# 24. In your view, how satisfactory are the following mechanisms and procedures of the REACH Regulation?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicable
Awareness raising for duty holders on key obligations and deadlines	•	•	•	©	•	X
Support for preparation of registration dossiers	•	•	0	•	•	X
Participation in Substance Information Exchange Fora (SIEFs) – data sharing	©	•	•	•	•	X

Dossier submission - IT tools	•	•	•	0	•	Х
Communication of information along the supply chain	•	Х	•	•	•	•
eSDS - extended Safety Data Sheets	•	•	•	•	•	X
Notification of SVHCs in articles	Х	0	0	0	0	0
Information concerning presence of SVHCs in articles	х	•	•	0	•	•
Assessment of testing proposals	0	0	0	0	0	Х

Dossier compliance check	•	Х	0	0	0	0
Enforcement /follow-up of compliance check decisions	0	х	0	0	0	0
Substance evaluation activities by Member States	•	0	х	•	•	•
Identification of relevant SVHCs for the candidate list	•	Х	•	0	•	•
RMOA (Risk Management Option Analysis) process	Х	•	0	•	•	•
Prioritisation of SVHCs for authorisation	0	0	X	0	0	0

Amendments to the list of substances subject to authorisation	Х	•	•	•	•	•
Substitution of SVHCs	•	0	•	Х	0	0
Support for applicants for authorisation	•	0	•	0	•	X
Assessment of applications for authorisation by ECHA	Х	•	•	•	•	•
ECHA public consultations (e. g. in restriction or authorisation)	•	•	•	•	•	X

Consideration of the availability and feasibility of alternatives	Х	•	•	•	•	•
Decision making by Commission on applications for authorisation	X		•	•	•	
Preparation of Annex XV dossiers to propose new restrictions	©	X	•	•	•	•
Assessment of proposals for new restriction	•	Х	•	0	0	•
Decision making by Commission on new restrictions	Х	•	•	•	•	•

Exemptions for R&D activities	0	•	•	0	0	Х
Reduction of fees for SMEs	•	•	0	0	•	Х
Guidance by ECHA	0	•	0	•	•	х
Guidance by national authorities	•	•	•	•	•	х
Guidance by industry associations	•	•	•	0	0	Х
Support provided by Helpdesks	•	•	•	0	0	Х
Operation of the Board of Appeal	0	0	0	0	0	Х
Inspections by enforcement authorities	•	•	•	•	•	X

25.	If you have any additional comments relevant to this public consultation, ple	ase
	insert them here. You may also upload position pap	ers.

(max. 5.000 characters)

See attached BEUC position on the 2017 REACH review

Please upload your additional document(s) (one by one, any format)

26. Are you interested in being contacted in the context of the ongoing study on the impact of authorisation?

X Yes

O No