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COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

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Accompanying the document
COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND
SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of
certain elements
Conclusions and Actions
Annex 2

Delegations will find attached document SWD(2018) 58 final - Part 3/7.

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PART 3/7

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE**
**Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions**

Annex 2

{COM(2018) 116 final}

Annex 2: Synopsis report of stakeholder consultation

Consultation activities - introduction and approach

The stakeholder consultation for the REACH (REFIT) evaluation took place between 2014 and 2017¹. As described in the Roadmap of the evaluation², the consultation approach aimed to complement regular consultation on the implementation of REACH through existing channels, ensuring stakeholder engagement and a balanced representation of the relevant interest groups.

In particular, it involved collecting input from a wide range of stakeholders on: (1) the effects, costs and benefits of the implementation of REACH, (2) strengths and weaknesses in the functioning of REACH, as well elements for potential burden reduction (3) stakeholder views on the general approach to the REACH evaluation, identifying potentially missing issues, (4) citizens perception of chemical safety in relation to EU legislation.

As part of the 2017 evaluation of the REACH Regulation a specific public consultation took place to present the approach to the REACH Evaluation 2017 and collect views on any potentially missing elements. Furthermore, views on relevant issues were obtained from Small and Medium Enterprise (SME) through the Europe Enterprise Network.

Stakeholder groups covered by the consultation activities

In line with the consultation strategy, input from a wide range of stakeholders was collected:

- Public authorities, notably competent authorities responsible for the implementation and enforcement authorities in EU Member States
- European Chemicals Agency (ECHA)
- Companies in both the chemicals industry and downstream sectors affected by REACH, focusing in particular on Small and Medium-sized Enterprises (SMEs)
- Industry associations covering both the chemicals industry and downstream sectors
- Workers that manufacture or use chemicals within the chemical industry, downstream sectors or as industrial/professional users
- Trade unions representing the above mentioned workers
- Civil society organisations – NGOs (e.g. environmental, health, animal welfare)
- Consumer associations
- Consumers / citizens
- Third countries' stakeholders defined as above (public authorities, companies etc).
- Other interested groups such as academics/researchers.

¹ The cut-off date is June 2017. Stakeholder contributions received by the Commission after that date could not be taken into account in preparing this document.

² See [Roadmap for the REACH REFIT evaluation published on 18 May 2016](#). One Member State provided feedback on the roadmap for the REACH Evaluation, concerning timing of deliverables and involvement of Member States in the process. The concerns were addressed in the context of the regular meetings of the expert group CARACAL (Competent Authorities for REACH and CLP).

The Commission developed a Stakeholder Consultation Strategy³ providing details on the consultation objectives and activities planned. A 12-week open public consultation was one of the seven consultation tools proposed for the REACH Evaluation. The open public consultation aimed to gather stakeholders' and citizens' views on the general approach to the 2017 REACH Evaluation, strengths and weaknesses of REACH, and any potential missing elements.

Outcome of the consultation activities

1. The open public consultation

The open public consultation ran from 28 October 2016 to 28 January 2017. It was carried out via EU survey, the survey software of the European Commission, and accessible in three languages (English, French and German). The questionnaire⁴ contained 25 questions, including on general information on the respondents (Part I), four compulsory general questions (Part II), 14 optional questions related to the five evaluation criteria, intended for respondents more familiar with REACH (Part IIIa), one extensive question on mechanisms and procedures of the REACH Regulation (Part IIIb) and finally one general open question for respondents' comments. Respondents also had the opportunity to submit position papers. The optional questions (Part III) were geared towards the REACH informed stakeholder.

Participants to the public consultation

Businesses and industry associations have an overly large weight (78% of respondents) in the overall results of the public consultation.

In total, 453 respondents replied to the Open Public Consultation. Most respondents decided to also answer the more specific questions indicative of that they were well-informed stakeholders. The largest group of respondents were businesses (47%) and industry associations (31%), totalling 78% of all respondents. The public sector was represented by 6% of respondents, most of them governments or public authorities and one representing the European Defence Agency, an intergovernmental organisation. NGOs were 4% of the respondents and whereas 6% were individual citizens. However, with 20 NGOs responding this is quite a large representation of the REACH relevant NGOs. Few respondents came from research and education, consumer associations and trade unions (together totalling about 4% too).

Among the 208 businesses who replied, 113 were large companies with 250. SMEs were well represented with 82 respondents. 18 responses came from self-employed/micro enterprises.

Representation throughout the EU and beyond

Except for Bulgaria, Cyprus and Latvia all Member States replied. The two largest groups of respondents came from Germany (32%) and those based in Belgium (20%). A large majority of respondents from Belgium (67%) represent industry associations and organisations that operate at EU level (75%). Other fairly large respondent groups were France, the UK, Austria, Sweden and Italy. 17 respondents came from non-EU countries⁵, making up a fairly large group when compared to the representation of Member States.

³ [Link to the consultation strategy](#)

⁴ [Questionnaires for the open public consultation in relation to the REACH REFIT evaluation](#)

⁵ Thailand (2), Turkey, United States (9), Japan (2), Canada (2).

Most responses came from organisations that operate at global level, followed by those operating at EU level and then at national level.

Respondents from businesses and industry associations were asked to indicate what their field(s) of interest or activity is/are. A large number of respondents (146) mentioned at least one sector in the group of raw materials, metals and wood as their activity and 101 respondents mentioned at least one sector in the group of base chemicals. Other important groups are the transport and mechanical engineering sectors and consumer products.

Table 2.1, Sectoral activity or interest (multiple replies possible)

	Activity in at least one sector in group
raw materials, metals and wood	146
base chemicals	101
consumer products	65
transport and mechanical engineering	64
polymers	43
specialty chemicals	40
consumer chemicals	37
carriers and retailers	33
professional	28
energy	17
agriculture	12
water and waste	8
construction	4

Main outcomes of the public consultation

It should be noted that the overall replies are heavily influenced by respondents from businesses and industry associations due to lower numbers of respondents from other stakeholder groups, an analysis was done to assess if views of some stakeholder groups deviate significantly from the overall results. Where relevant, this is indicated.

Overall Summary of the Open Public Consultation

Industry associations and companies, including SMEs

Industry acknowledges the positive effects of REACH in terms of making information available to ensure safe use of chemicals and they also encourage the Commission and other stakeholders to communicate more strongly about the benefits and the good functioning of REACH in order to build further trust amongst all stakeholders, including the general public.

For industry stakeholders, legal stability and certainty is a key issue as the regulatory framework is an important driver for predictability and thus business decisions. Therefore, they are not in favour of re-opening the enacting terms of the REACH Regulation.

They stress the need to reduce burden and costs by favouring a risk-based approach and to minimise negative impacts in the innovation capacity and competitive position of EU industry vis-à-vis third countries. They also highlight the need to ensure a level playing field by further harmonising enforcement, including at the EU borders.

The coherence between REACH and other legislation, in particular OSH, is another area of concern for industry stakeholders.

SMEs further emphasise the need to reduce burdens and step up efforts to support compliance, in particular in view of the 2018 registration deadline.

Civil society: non-governmental organisations (NGOs) and consumer organisations

For NGOs, REACH has a high potential to deliver a high level of protection of human health and environment and is a model inspiring legislation in other jurisdictions but its potential has not been fully developed after 10 years of implementation.

They raise concerns about the poor quality of data from registration dossiers and about the insufficient information on safe use of chemicals flowing through the supply chain and reaching consumers and adaptation of legal text could be considered. They consider that the mechanisms to address risks through regulatory measures, namely authorisation and restriction, are excessively burdensome and lengthy, leading to slow progress to substitute and phase-out hazardous chemicals. Moreover, the current operation of the authorisation process disfavours innovative companies investing in alternatives to hazardous chemicals.

Such deficiencies result in general principles underlying REACH such as the "no data, no market", the shift in the burden of proof or the precautionary principle not being applied in practice.

Public authorities: Member State, national and regional authorities

Member States in general find that REACH is delivering on its main objectives as it is bringing improvements in the management of chemical risks but they also raise deficiencies related to its implementation. Most Member States express concerns about the quality of data generated by REACH, which is not sufficient for public authorities to conclude on the need for regulatory risk management measures and thus make the shifting of the burden of proof incomplete. They also express concerns about the flow of information in the supply chain, namely about the extended Safety Data Sheets. Some Member States acknowledge that REACH have created costs for industry and that it is more challenging for SMEs to comply with the requirements. In general, Member States do not favour re-opening the enacting terms of the Regulation but propose improvements to close gaps, increase the speed of regulatory measures and minimise the negative impacts on industry.

Trade unions

Trade unions see REACH as a positive development to make companies better informed about the risks posed by chemicals and to improve risk management, also improving the safety of workers using chemicals beyond the chemical industry.

Overall impression

The overall impression from these views is that in general stakeholders believe the REACH legislation is adequate to address most of the different challenges posed to it, but that implementation should be improved.

Overview of the responses to the general and compulsory questions (Part II):

To the question if REACH was reaching its objectives, overall the respondents fairly positive view regarding the improvement of protection of consumers, workers and the environment, as well as promoting alternative methods for animal testing. Respondents believe that REACH is achieving these objectives to some extent. Respondents have more critical views concerning the economic objectives of free circulation of chemicals on the internal market with businesses having an overly large weight in the negative replies as well as on competitiveness and innovation. Figure 1 provides further details.

Figure 2.1: To what extent do you think REACH is achieving the following objectives? (Marker points show average value⁶ of responses (mean) by stakeholder group and across all respondents (total))



Respondents' views on the results of REACH are rather positive regarding some deliverables: overall, the vast majority of respondents think that REACH generates data for hazard/risk management and shifts the burden of proof from public authorities to industry. A slimmer majority agrees that REACH increases information on chemicals for risk management and information exchanged in the supply chain. About half of the respondents agreed that REACH improves development and implementation of risk management measures, promotes the development, use, and acceptability of alternatives to animal testing, and implements the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing.

However, more than half of the respondents believe that REACH fosters innovation slightly or not at all. This question was answered mainly negatively by businesses and industry associations, and answered mainly positively by NGOs. On the dissemination of information on chemicals for the general public there were diverging views between industry associations, which had largely positive views on this result, and businesses which hold largely negative views, with half thinking that this result has been delivered slightly at best.

⁶ See section 5.1.2 for an explanation of the values presented

Overall respondents had a positive view concerning the usefulness of data generated under REACH, almost half of the respondents said that the data was substantially or very useful for adopting the different risk management measures (REACH authorisation, REACH restriction, consumer protection legislation concerning chemicals in articles, environmental legislation, occupational exposure limits in the context of worker protection legislation). Furthermore, NGO respondents were more critical of the usefulness of data for consumer protection legislation and environmental legislation. Also, consumer associations hold a very different view on the usefulness of data for consumer protection legislation: four out of the five consumer associations think that data generated under REACH is only slightly useful for this measure.

Overall, the majority of respondents agree that ECHA has handled the registrations of chemical substances effectively, except for NGO respondents of which almost 50% disagree to this statement. The majority of respondents also agree or strongly agree that ECHA has established a strong and trustful relationship with its stakeholders. However, when it comes to ECHA's work on reducing the impact of REACH on SMEs and to facilitate and innovation-friendly framework, respondents are more critical, with half of the respondents disagreeing and only low shares agreeing to this. However, this critical view is mainly held by businesses and industry associations, while respondents from public authorities, NGOs and trade unions to a large majority agree or strongly agree to these positive effects.

As regards ECHA's work on facilitating the implementation of the last resort principle concerning animal testing, most respondents are neutral, with NGOs being more critical.

Overview of the responses to the REACH REFIT Evaluation Questions (Part IIIa):

Effectiveness

Overall respondents were positive concerning the implementation of REACH. Chapters that received particularly positive perception are in particular registration, but also data-sharing and avoidance of unnecessary testing, dossier evaluation, and the overall implementation of REACH. Respondents were more critical of substance evaluation, restriction and in particular authorisation.

Consumer associations and NGOs have a much more negative views than most concerning dossier evaluation and restriction, with NGOs in addition being very critical of registration, and consumer associations also being critical of authorisation and the overall REACH implementation. The REACH legal text regarding authorisation is considered as not very clear or predictable by a larger number of respondents. Table 2 summarises the implementation appreciation for the different REACH chapters on average.

Table 2.2: To what extent have the REACH Regulation and its various chapters been implemented successfully?

	5.0	very much
10.a Registration	4.0	substantially

10.b Data-sharing and avoidance of unnecessary testing	3.4	somewhat
10.h Overall implementation of REACH	3.4	
10.d Evaluation – dossier	3.3	
10.e Evaluation – substance	3.2	
10.c Information in the supply chain	3.1	
10.g Restriction	2.9	
10.f Authorisation	2.8	slightly
	2.0	
	1.0	

(sorted by average value of responses (mean)⁷, highest to lowest, on a scale from 1=not at all to 5=very much)

As regards REACH enforcement, replies vary depending on the question. Respondents presented negative views on whether REACH is enforced uniformly across the EU (most negative, with almost 70% replying negative). More positive replies were received on the prioritisation of enforcement activities at EU level via the Forum. Concerning the overall REACH enforcement in the EU REACH enforcement at Member State level and communication of enforcement activities from Member States and the Forum, the overall view is slightly negative.

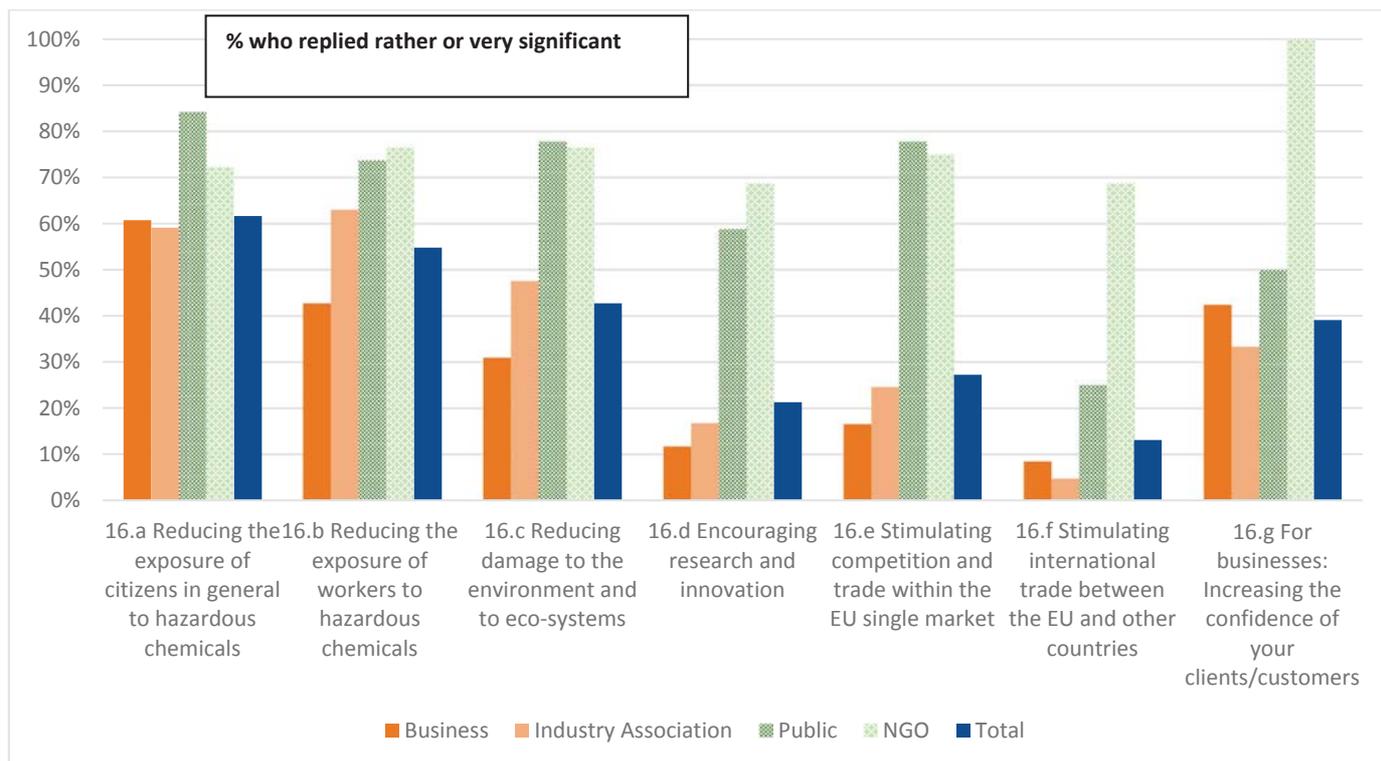
There are consistent differences between stakeholder groups across each of the different aspects of enforcement: NGOs and consumer associations hold much more negative views than other stakeholder groups on the enforcement of all aspects; Businesses also hold more negative views than the average on all aspects. However trade unions, public authorities and – to a slightly lesser extent – industry associations, hold more positive views than the average on all five aspects.

Efficiency

Reducing the exposure of citizens in general to hazardous chemicals, reducing the exposure of workers to hazardous chemicals and reducing damage to the environment and to eco-systems are considered significant benefits. Negative views among businesses and industry associations prevail concerning the benefits of encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry, stimulating competition and trade within the EU single market and stimulating international trade between the EU and other countries. However, NGOs think also these aspects were significant benefits generated by REACH, as do public authorities. Concerning the benefit for businesses of increasing the confidence of clients/customers in products positive views prevail.

Figure 2.2: How significant are the following benefits generated for society by the REACH Regulation?

⁷ See section 5.1.2 for an explanation of the values presented



Overall, respondents showed balanced views to the question of proportionality of costs on registration and information in the supply chain. Concerning the costs linked to dossier evaluation and substance evaluation, a larger share thinks that costs are not proportionate (around 40%) compared to those holding positive views (20%). For costs related to the chapter on restriction, positive views are slightly more common than negative ones. Regarding costs related to authorisation and to requirements for substances in articles many think that costs are not proportionate. The overall tendency is heavily biased by replies from businesses and industry associations. Public authorities and NGOs think that the costs are substantially proportionate to the benefits regarding all the REACH chapters.

The majority of respondents, mainly businesses, find that there are areas where the REACH Regulation could be simplified to a large extent. There are large differences between the stakeholder groups, with consumer associations, public authorities, NGOs and trade unions believing that the REACH Regulation could be simplified to a minor extent.

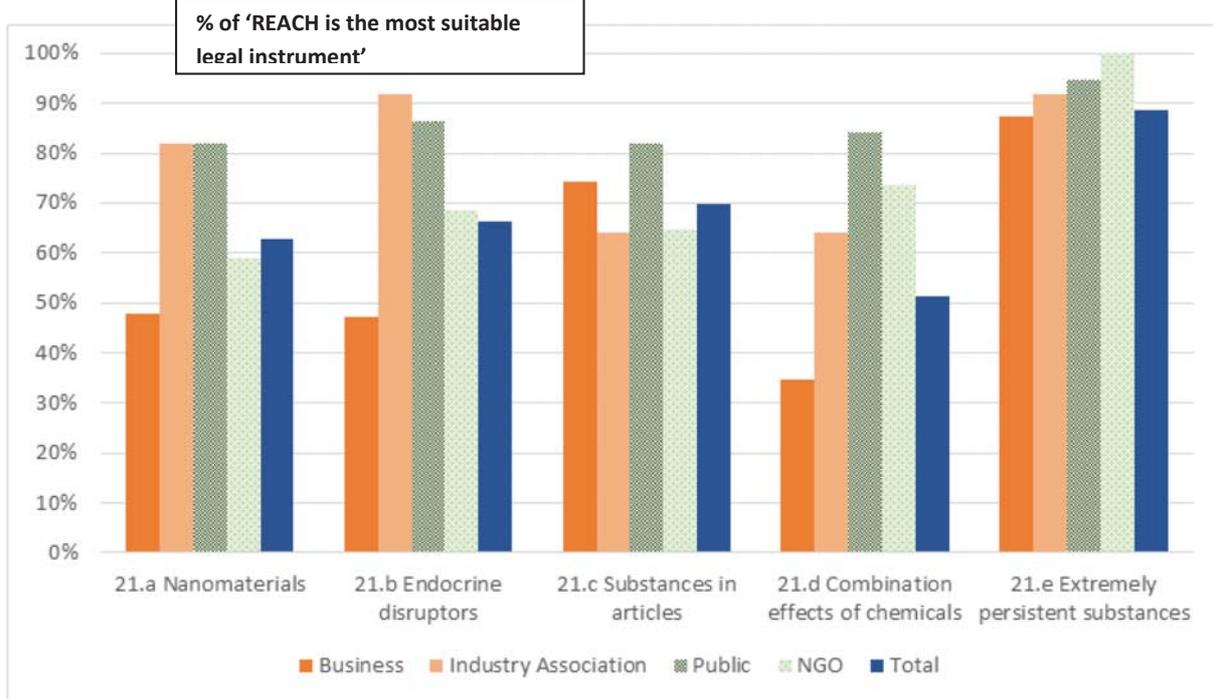
Relevance

Respondents think that the REACH Regulation is relevant for the management of chemicals. Businesses are particularly critical towards the relevance of REACH, whereas NGOS, trade unions and public authorities are particularly positive about it.

For emerging issues most respondents believe that REACH is the most suitable EU legal instrument to address them. The share of these respondents is particularly high concerning the issue of extremely persistent substances and lowest concerning the issue of combination effects of chemicals.

Notably businesses think that REACH should only play a secondary role concerning nanomaterials, endocrine disruptors and combination effects of chemicals. Also some consumer associations and trade unions think REACH should play a secondary role for various emerging issues (further detail in figure 3).

Figure 2.3: How suitable do you consider REACH to be to deal with emerging issues?

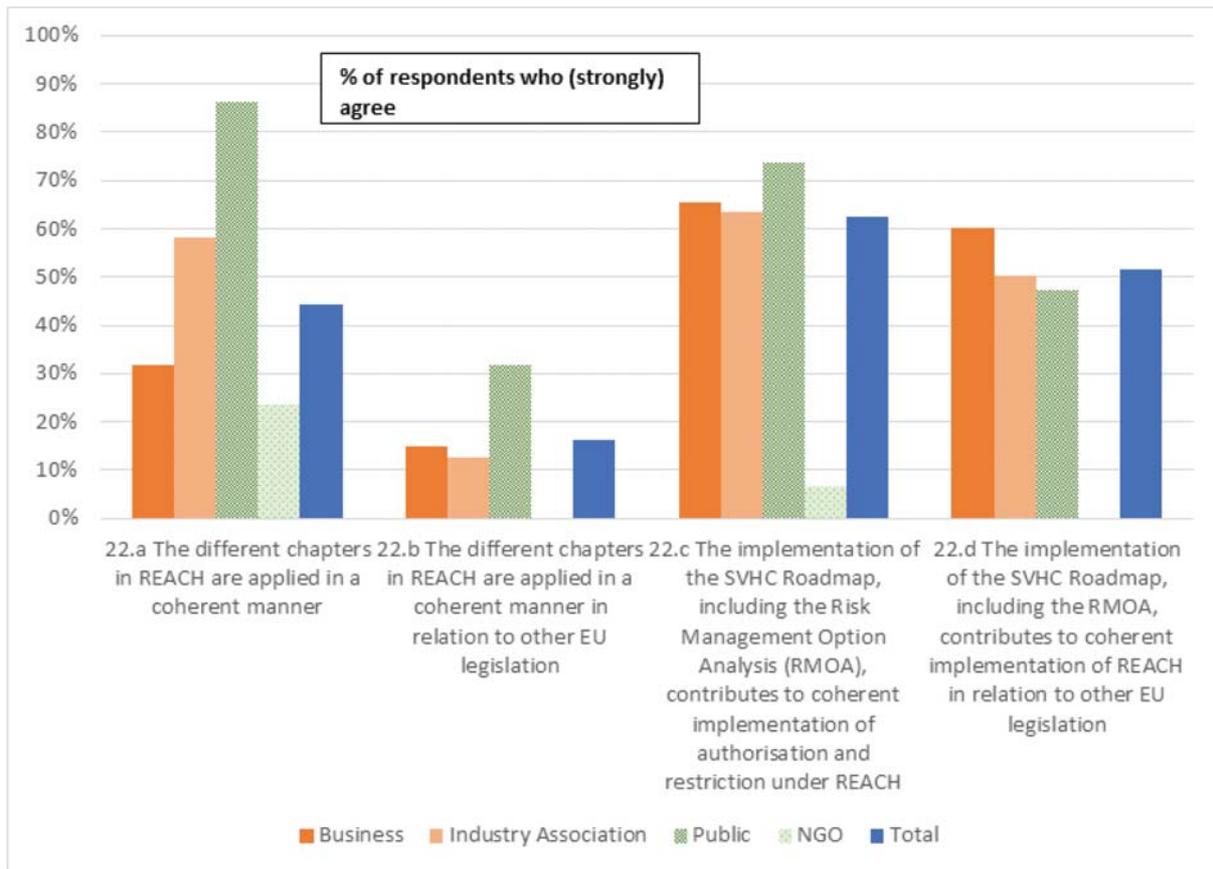


Coherence

Overall views were largely positive on the coherent implementation of authorisation and restriction under REACH' via implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA) also in relation to other EU legislation. Views were more divided regarding if the different chapters of REACH are applied in a coherent manner and the respondents were largely negative concerning the coherence of the application of the different chapters in REACH in relation to other EU legislation (see figure 4 for further details).

Business respondents have a more critical view than industry associations on the coherence of the REACH chapters. Consumer associations and NGOs oppose more strongly than the other stakeholders and all four consumer associations strongly disagree that the different chapters in REACH are applied in a coherent manner with other EU legislation.

Figure 2.4, Coherence: Please tell us to what extent you agree or disagree with the following statements?



EU added Value

Overall, respondents think REACH has significant EU added value. It should be noted that respondents from businesses, academic institutions and individual citizens in particular hold more negative views than all other groups regarding the EU added value. Consumer associations, NGOs and industry associations have a particularly positive view concerning the EU added value.

Summary of the responses to the REACH REFIT Evaluation Open Questions and Position Papers (Part IIIb):

Respondents had the opportunity to submit position papers in addition to the open questions. These papers and responses were systematically summarised via categorisation. Main messages provided by the different categories of stakeholders are summarised below. The stakeholder groups ‘business’ and ‘industry association’ have been commonly addressed as ‘industry respondents’ or ‘industry representatives’.

The legal text should not be changed, adaptation through guidance should be sufficient

According to industry respondents, problems with the operation of the REACH Regulation are mostly due to implementation of rather than the legal text, and can be resolved by developing more guidance, rules of practice or templates.

According to some stakeholders, REACH has effectively increased knowledge on chemical substances, communication in the supply chain and has encouraged substitution of SVHC

A number of respondents, mostly industry associations and businesses, stated that REACH performed well in improving the knowledge on chemical substances, increasing the transfer of information through the supply chain and encouraging safe use of chemicals in companies, and supporting the phasing out of hazardous substances from the market. A very small number of industry respondents stated that the REACH Regulation had benefits for the free circulation of chemicals in the single market.

According to industry respondents REACH had negative effects on the competitiveness and innovation of the EU industry

Industry respondents were generally rather negative on the performance of REACH concerning competitiveness and innovation. According to them, compliance costs and risk management measures (e.g. authorisation and restriction) have led to some extent to the relocation of activities outside the EU and the withdrawal of substances from the market, especially those produced in low volumes, forcing market concentration and causing disruption in the supply chains of certain products. Reducing business uncertainty caused by the placing of a substance on the Candidate List has often been mentioned as a necessity to reduce negative impacts on competitiveness.

A large number of respondents also argued that, because they do not have to apply for authorisation, but can export products containing SVHC in the single market, non-EU producers have a competitive advantage, which harms the competitiveness of the EU industry. Respondents also argued that compliance costs had a negative impact on innovation, since, in companies, resources normally dedicated to research and the development of new products have been focused on compliance and substitution.

However, substitution is considered as an important driver for innovation by NGOs

Several environmental NGOs stated, on the contrary, that there is evidence that regulation or the anticipation of regulation efficiently drives innovation and help to bring new products to the market. Some NGOs added that substitution can also have economic benefits for companies, which will be saving on the handling of hazardous chemicals.

According to industry respondents, REACH should be simplified, administrative burdens and costs should be reduced

According to industry respondents, compliance costs and administrative burden have been generally much higher compared to what had been anticipated by duty holders. Most of their comments relate to the registration process, particularly to the preparation and update of registration dossiers, the management of consortia, data collection, testing and data sharing, fees of ECHA, etc. but also to applications for authorisation and substitution. Respondents also frequently stated that SMEs are more affected than large companies and need specific support to comply with the REACH Regulation.

The quality of registration dossiers still needs to be improved

Many respondents from all categories of respondents indicated that the quality of registration dossiers was still not satisfactory, with different perspectives: for industry respondents, all registrants should be treated equally and free-riders punished, for other respondents, the good functioning and objectives of REACH are hindered by the poor quality of some dossiers. This is why NGOs and consumer associations who participated to the consultation, emphasised the need to implement with more severity the 'no data, no market' principle and to refuse to grant or withdraw their registration number to non-compliant dossiers.

Reduction in animal testing could be greater

Respondents from almost all stakeholder groups agreed that the principle of ‘animal testing as a last resort’ is not yet fully implemented. Respondents explain this problem by strict information requirements coupled with a low acceptance of alternative methods.

According to downstream users, extended Safety Data Sheets should be simplified and reflect better conditions of use

Numerous downstream users (or associations of downstream users) stated that the extended safety data sheets they received were too lengthy and technical to be useful for their needs. Many respondents, therefore, called for uniform templates to be used. Respondents also criticised that the exposure scenarios are often not reflecting reality. Some respondents added that, in general, the quality of safety data sheets is poor.

According to industry respondents, information requirements on SVHC in articles should remain manageable for companies

Numerous industry representatives expressed concern over the European Court of Justice ruling on applying the 0.1% threshold for notifying SVHCs in articles, which concluded that the obligation to notify applies to each article included as a component of a complex article. In many position papers, industry representatives called for more guidance on the requirements concerning articles under REACH.

However, according to other respondents, information on SVHC in article should be improved and better communicated

A mix of stakeholder types stressed the importance of improving, and for some respondents extending, the information on substances in articles communicated in the supply chain to enable consumers to make conscious choices, to support companies who invest in substituting hazardous chemicals by safer alternatives, and to improve traceability of recycled materials. Several respondents mentioned that information on SVHC in articles communicated through the supply chain did not reach the recycling industry, which creates problems for fulfilling obligations applying to recycled materials. Stakeholders of several types, including industry and NGOs, stressed the importance of extending the Article 33 requirements to imported articles. Some respondents also proposed to extend the provision of Article 56 on authorisation to articles.

Enforcement efforts at national level need to be increased and harmonised

Respondents generally argued that enforcement at national level needed to be significantly harmonised, both in term of level of activity and interpretation of the rules, industry respondents emphasising that the lack of harmonisation leads to an uneven playing fields for EU companies, other respondents, especially NGOs, that it generally puts at risk the achievement of better health and environmental protection in the EU. In particular, increased controls of imported goods at EU borders are deemed necessary by a significant number of respondents.

Industry respondents favour a risk-based approach to risk management measures

The question of applying a risk-based or hazard-based approach to risk management measures profoundly divided respondents to the consultation. According to industry respondents, data on exposure and socio-economic considerations should be considered much earlier in the

process, to reduce the time between the identification of a substance as an SVHC and the adoption of the risk management measures, avoid unnecessary measures and eventually increase the legal certainty for duty holders. Industry respondents are therefore very much in favour of integrating the RMOA as a compulsory step in the regulatory process.

Non-industry respondents defend and wish to strengthen the current hazard-based approach

Non-industry respondents, in particular environmental NGOs, argued, on the contrary, that the inclusion of substances on the Candidate List should remain an independent step, exclusively hazard-based, to ensure that all potentially hazardous substances are identified according to the objectives of the SVHC Roadmap. They blamed the slowing down of SVHC listing and identification of PBT /vPvB substances, and called for abandoning or at least not give more importance to the RMOA, accused of the burden of proof to authorities.

According to industry respondents, the authorisation procedure should be simplified and more targeted

Industry respondents called for a simplification of the procedure to apply for authorisation, in particular for low volumes or substances used in legacy spare parts, and supported the ongoing initiative from the European Commission on that matter. According to many industry respondents, the inclusion of substances in Annex XIV does not take enough into account that some substances cannot be substituted. These respondents generally argued for better considering other risk management measures before authorisation, in particular restrictions, which have the benefits of prohibiting the most hazardous use of a substance while preserving critical uses of the substance for certain products. Many respondents also called for longer review periods to achieve substitution of substances used in products requiring long development and testing periods or with a very long life-span.

According to other respondents, authorisations should not be granted when alternatives are available

Other respondents, and in particular NGOs, consumer associations, and some public authorities, argued that the practice of granting all authorisations, even when alternatives exist, was disadvantaging companies who have invested in safer alternatives and not incentivising enough the substitution of hazardous substances. They supported a more thorough assessment of alternatives in socio-economic analyses, not only taking into account the applicant's perspective but 'all relevant aspects', including the impact of the authorisation on alternative producers, as required by Article 60(5). In addition, NGOs and consumer associations called for addressing groups of substances rather than individual substances in SVHC listing to avoid regrettable substitution.

Coherence of REACH with other legislation, especially the OSH legislation, needs to be improved

A large number of industry respondents stressed the need for better coherence between REACH and the OSH legislation, and, in particular, the confusion created by the application of both OELs developed under the OSH legislation and DNELs developed under REACH. Some suggested harmonising OELs and DNELs and aligning methodologies used by SCOEL and RAC, to avoid the co-existence of multiple and different values. Others proposed to prioritize OELs over DNELs at the workplace. These respondents also defended the use of the RMOA as a tool to assess which regulation is the most appropriate to address the hazard early in the process and avoid the duplication of risk management measures. The great majority of

this respondents suggested that EU OSH legislation should be prioritized under RMOAs. The other main coherence issues identified concerned the relation between REACH and RoHS, the EU water legislation, or the waste legislation.

REACH should enable the development of the circular economy

The relation between REACH and the objectives of the circular economy received a lot of comments in several questions of the questionnaire. A number of industry respondents indicated as a potential unintended effect the possibility that REACH prevents the development of the recycling sector by including recycled materials in the scope of risk management measures and called for the implementation of a ‘repair as produced’ principle for recycled materials. Other respondents on the contrary mentioned that REACH should enable the development of the circular economy by ensuring that articles do not contain hazardous substances and that the lifecycle of the product is clean. This should be supported, as mentioned above, by the transfer of sound information on substances in articles, through the whole supply chain, including recyclers.

REACH is the relevant instrument for addressing emerging risks, but information requirements should be strengthened to properly manage these risks, according to some respondents

Most respondents considered that REACH is the suitable instrument to address emerging issues, such as nanomaterials, endocrine disruptor, or combined exposure. However, certain respondents, mainly NGOs, consumer associations, and public authorities, indicated that, among other issues, information and testing requirements should be amended to take better account of the specific risks and properties of nanomaterials and endocrine disruptors or to take account of possible combination effects in their registration dossiers.

Overall impression

The overall impression from these views is that in general all stakeholders believe the REACH legislation is adequate to address most of the different challenges posed to it, but that implementation should be improved.

Stakeholders generally acknowledge the positive effects of REACH so far but they all see considerable room for improvement in different areas. Most stakeholders, mainly industry, have indicated that at this stage, they do not favour reopening the enacting terms of the REACH Regulation but rather improve the implementation through changes in the Annexes, development of guidance and more cooperation between stakeholders and institutions.

Industry stakeholders stress the need to reduce burden and costs to minimise negative impacts in the innovation capacity and competitive position of EU industry. For NGOs, the full potential of REACH to deliver benefits for human health and the environment has not been developed.

Stakeholders do share appreciation for addressing chemical risks at EU level rather than at national level. Most stakeholders also encourage the Commission, ECHA and Member States to communicate more strongly about the benefits and the good functioning of REACH. This will help building further trust amongst all stakeholders, including the general public.

2. Other consultation activities

The implementation of REACH is subject to extensive consultation with the stakeholders involved through existing discussion fora and through public consultation on specific matters.

The implementation of REACH is steered through targeted consultation that takes place in the context of the expert group CARACAL, which meets regularly (three times/year) to discuss matters related to the implementation of REACH. The group is composed of experts from Competent Authorities nominated by Member States as well as observers representing industry associations, trade unions, civil society organisations and third countries. The regular meetings of CARACAL have been used to report progress in the implementation of the recommendations resulting from the REACH review 2013 and has been used to disseminate information regularly concerning the preparation of the REACH report 2017 as well as to collect the views of the stakeholders on the development of this work. Agendas, minutes and documents from CARACAL are publicly available.

In addition, dedicated consultation activities planned in the context of the REACH REFIT evaluation included the following:

- Targeted consultations to gather specific evidence through questionnaires, interviews or case studies in the context of thematic studies⁸
- An SME specific consultation (SME panel) carried out through the Europe Enterprise Network (EEN) between November 2016 and January 2017⁹,
- A Eurobarometer survey carried out between in the 28 Member States of the European Union between 26 November and 5 December 2016¹⁰.

Another important source of information was the Member States and ECHA reports¹¹, as well as the documents related to the "REACH forward" conference organised by the Dutch presidency on 1 June 2016, which then informed the Environment Council on 19 December 2016.

Furthermore, public consultations are regularly conducted by the ECHA in the context of the preparatory work for the implementation of regulatory action such as listing substances in the candidate list, prioritising substances to be subject to the authorisation regime, examination of proposals for restrictions and applications for authorisation for substances included in Annex XIV. Evidence available from public consultations made by ECHA has been used where appropriate (e.g. evidence on the socio-economic impacts and benefits expected from restrictions). (<http://echa.europa.eu>)

2.1 The Eurobarometer survey

28,157 face-to-face interviews were conducted with the aim to understand EU citizens' awareness and perceptions of chemical products, including comparisons (where appropriate) with similar surveys conducted in 2012 and 2010. This survey was carried out in 28 EU Member States. Some 27 929 EU citizens from different social and demographic categories were interviewed face-to-face at home and in their native language according to the methodology established for Commission's Eurobarometer surveys. Two-thirds of citizens are

⁸ Annex 3 provides a detailed account of the thematic studies carried out for this review, including the consultation tools

⁹ Link to the results of the SME panel

¹⁰ [Link to the Eurobarometer survey on chemical safety](#)

¹¹ Further details about information sources used is extensively described in section 5 and Annex 3 of this SWD.

concerned about exposure to chemicals, and less than half feel well informed about the potential dangers of chemicals. Citizens consider that product safety has improved over the last 10-15 years and they consider products manufactured in the EU safer than those imported from outside the EU, although three in ten say that none of the products are safe. Two-thirds of citizens believe that retailers provide information, upon request, on the presence of particularly hazardous chemicals in products. In addition, half of respondents say that the current level of regulation and standards in the EU are not high enough to protect human health and the environment and should be increased¹². The results of the Eurobarometer survey were published on 8 June 2017.

2.2 The SME panel

The SME specific consultation carried out through the Europe Enterprise Network (EEN) received 181 replies. The main strength of the consultation is the wide coverage in terms of company size (see figure 5), sector of activity and role under REACH (figure 6). Its main limitation is the geographical coverage, as respondents concentrated in few Member States (Italy 22%, France 14%, Germany 12%, Poland, Belgium, Greece, Cyprus and Latvia around 7- 9% each) and for more than half of the Member almost no responses were obtained.

Figure 2.5: Respondents by size of business

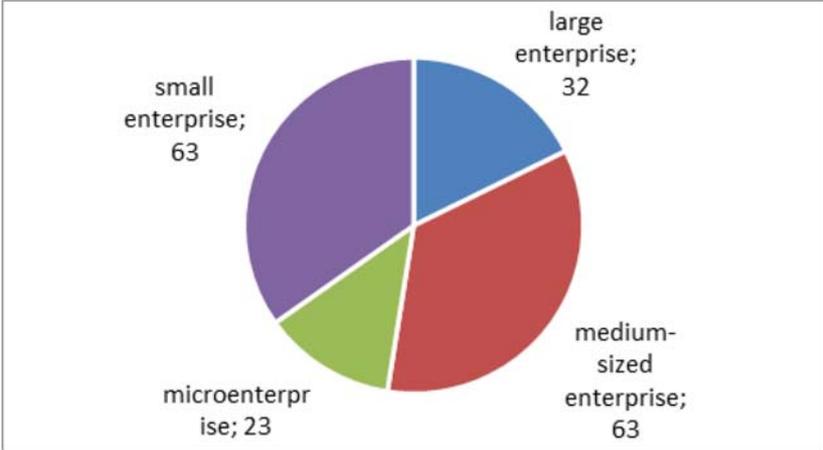
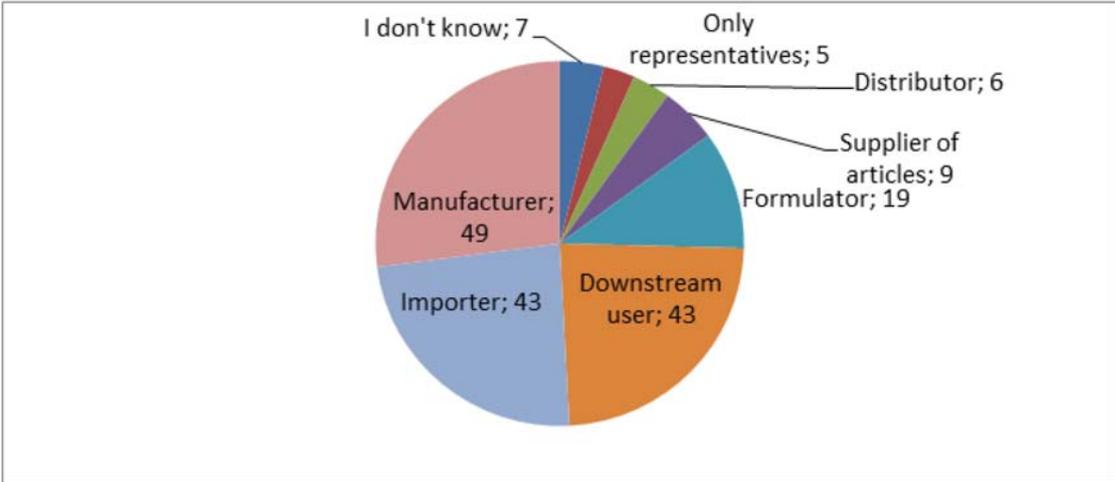


Figure 2.6: Respondents by role under REACH



¹² See section 7 of the main report on Relevance for further details

The SME panel consisted of a specific questionnaire tackling SME related issues in relation to the information sources, existing support mechanisms, effects of REACH and their relation with authorities.

According to the responses received, respondents expressed a wide variation in the satisfaction with the sources of information available on REACH. The main sources of information used by companies are suppliers, helpdesks and guidance provided by ECHA or industry associations.

Companies replies on the effects of REACH suggest that companies were generally not able to pass costs increases on to customers, although there was a wide variation in the cost impact, with registration and testing as well as substitution of SVHCs being the main cost factors indicated by the companies. The replies also indicate that the main challenges are the complexity of the Regulation, the obligation to communicate information in the supply chain as well as the access to data, and the company replies suggest that these requirements have a significant impact on companies, regardless of their type, size or sector. When looking at differences based on the role under REACH, distributors, importers, only representatives and suppliers of articles generally score these challenges higher than other stakeholders.

Regarding company size, micro-enterprises generally consider the challenges to be bigger compared to larger companies. Regarding the differences between the sectors, the respondents perceive the challenges as more or less equally important. The main opportunities and benefits of REACH appear in relation to the reduction of workers risks and environmental risks, as well as the substitution of hazardous substances. The effects on R&D activities of the respondents seem to be limited.

As regards the experience when contacting public authorities in relation to REACH a rather positive feedback was provided on the replies obtained from national helpdesks in terms of content and time needed to get a reply.

A final open question in the SME panel allowed respondents to provide additional comments or suggestions for reducing any burdens while keeping the main objectives of REACH. The most frequent comment was that REACH creates administrative burden and market distortions in favour of larger companies or third country producers. Respondents also demanded more guidance and training tailored for the needs of SMEs, including support by authorities.

2.3 Targeted consultation

Targeted consultations were carried out through questionnaires and interviews in the context of thematic studies¹³ used for this evaluation.

The stakeholders provided their input on:

- Structure and magnitude of costs expected or resulting from REACH.
- Views on the factors affecting the implementation of REACH as well as its effects.
- Identification and analysis of relevant case studies.

¹³ Annex 3 provides a detailed account of the thematic studies carried out for this review, including the consultation tools