



Council of the
European Union

069606/EU XXVI. GP
Eingelangt am 26/06/19

Brussels, 26 June 2019
(OR. en)

10705/19

ENV 662
CHIMIE 92
COMPET 553
IND 198
PHARM 39
AGRI 365
RECH 390
ECOFIN 675
ECO 77
SOC 522
SAN 332
CONSOM 194
MI 546
ENT 160

COVER NOTE

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

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

No. Cion doc.: COM(2019) 264 final

Subject: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT,
THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS Findings of the
Fitness Check of the most relevant chemicals legislation (excluding
REACH) and identified challenges, gaps and weaknesses

Delegations will find attached document COM(2019) 264 final.

Encl.: COM(2019) 264 final



Brussels, 25.6.2019
COM(2019) 264 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE
COMMITTEE OF THE REGIONS**

**Findings of the Fitness Check of the most relevant chemicals legislation (excluding
REACH) and identified challenges, gaps and weaknesses**

{SWD(2019) 199 final}

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses

INTRODUCTION

Reflecting the increasing role that chemicals play in our society and economy and illustrating the continuous commitment to ensuring a high level of protection of human health and the environment, as well as ensuring the free movement of chemicals on the internal market, the EU chemicals legislation has evolved and expanded significantly since the adoption of the first chemicals related directive in the late 1960s. It now regulates both the chemical sector as well as related downstream industries that use chemicals. It covers the full lifecycle of products manufactured in or imported into Europe and the protection of the environment and human health from chemical hazards and risks.

The Commission initiated a Fitness Check of chemicals legislation other than REACH¹ ('the Fitness Check') in 2015², to see whether the legislation was fit for purpose and delivered as intended. This Fitness Check has assessed over 40 pieces of legislation³ that cover a great part of the EU chemicals *acquis*, focusing on the chemical hazard and risk assessment and risk management requirements, procedures and processes in the legislation under its scope. It is part of the European Commission's Regulatory Fitness and Performance programme (REFIT)⁴.

The REACH Regulation⁵, the pharmaceutical⁶, veterinary⁷ and food additives⁸ legislation were excluded from the scope of this Fitness Check.⁹

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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

² http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf

³ See Annex 4 of the Commission's Staff Working Document on the Fitness Check of the most relevant chemicals legislation (excluding REACH) as well as related aspect of legislation applied to downstream industries.

⁴ COM(2012) 746 final

⁵ Except its Annex XIII laying out identification criteria for persistent, bioaccumulative, toxic and very persistent and very bioaccumulative substances. Findings of the second REACH evaluation are presentend in the 'Commission General Report on the operation of REACH and review of certain elements' (COM(2018) 116 final) and its accompanying Staff Working Documents (SWD(2018) 58 final).

⁶ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

⁷ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

The complexity and far-reaching effects of the EU chemicals legislation combined with certain data and evidence gaps made the exercise challenging. Notable efforts were made to collect data and evidence via a number of studies and reports¹⁰. The findings of this Fitness Check have also been informed by a number of consultation activities such as public and targeted stakeholder consultations and two Eurobarometer surveys.¹¹ They were complemented and took into consideration other chemicals related initiatives¹² and the information and data from recently or nearly-completed evaluations¹³.

The assessment provides a comprehensive presentation of how the various pieces of the EU chemicals legislation fit together and what the strengths and weaknesses are. It also takes into account a number of stakeholders' concerns expressed during the consultation activities. Moreover, the evidence and data collected as part of this Fitness Check will set a baseline and will constitute a point of reference for future assessments of the EU chemicals legislation.

This Report presents the main findings and sets the basis for further discussion with stakeholders on how to unlock the full potential of the EU chemicals legislation to deliver a Europe that protects.

1. THE EU CHEMICALS LEGISLATION: 50 YEARS OF CONTINUOUS PROGRESS

The more than 40 pieces of legislation that were assessed for the purposes of this Fitness Check have evolved into a solid framework that reflects 50 years of continuous efforts and progress. These pieces of legislation cover the whole value chain and the full lifecycle, i.e. from the moment chemicals are produced to when they are used and after their release into the environment. Regulated aspects include data gathering, data generation and testing, chemical hazard identification and classification, labelling, risk assessment and risk management.

The EU chemicals legislation: state of play

⁸ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

⁹ The pharmaceuticals, veterinary and food additives legislation was excluded from the scope of this Fitness Check because their hazard and risk assessment is based on different considerations (i.e. an assessment of the risk trade-offs between the health benefits of the medical product versus potential undesired side-effects). For example, under the Medicinal Products for Human Use Directive (2001/83/EC) the primary objective is to safeguard public health i.e. treat or prevent disease in human beings, restor, correct or modify physiological functions or make a medical diagnosis.

¹⁰ See Annex 3 of the accompanying Commission's Staff Working Document.

¹¹ See Annex 2 of the accompanying Commission's Staff Working Document

¹² Communication on options to address the interface between chemical, product and waste legislation (COM(2018) 32 final); Communication on the operation of REACH and review of certain elements (COM(2018) 116 final); 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final); 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)

¹³ REFIT Evaluation of the EU legislation on plant protection products and pesticides residues; Fitness Check of Reporting and Monitoring of EU Environment Policy; Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation); the General Food Law Fitness Check; REFIT evaluation of the European Union occupational safety and health Directives. Please refer to Annex 4 Table 3 to see how different sources of information were used for the purposes of this Fitness Check.

The first piece of the EU chemicals legislation, the Dangerous Substances Directive¹⁴, was adopted in 1967 to protect public health, in particular the health of workers handling dangerous substances. Because differences in national provisions in a Europe of Six were hindering trade and, thus, directly affecting the establishment and functioning of the common market, measures were taken to introduce Community-wide provisions on the classification, packaging and labelling of dangerous substances. Since then, the Dangerous Substances Directive has been amended and replaced by the Regulation on Classification, Labelling and Packaging of substances and mixtures¹⁵ (the CLP Regulation), and other pieces of legislation have been progressively adopted to regulate hazardous chemicals in water, waste, fertilizers, pesticides, industrial activities, consumer products and occupational settings. In parallel, the EU engaged in international processes aiming at regulating hazardous chemicals of the highest concern.¹⁶

<i>First-generation EU chemicals legislation</i>				<i>Second generation EU chemicals legislation</i>
1967	1970s	1980s	1990s	2000-2019
Pre-CLP legislation	Detergents	Workers' safety	Vulnerable workers' safety	Recast and repeals of the pre-existing legislation
	Waste	Industrial emissions	General product safety	Codification and framework approach to water and waste
	Water	Toys	Biocides	CLP
	Pre-REACH Directive	Protection of animals used for scientific purposes	Pre-REACH Regulation	REACH
	Cosmetics			
	Fertilizers			
	Pesticide residues			
	Plant protection products			
	Food contact materials			

Improvements to the EU chemicals legislation reflect the need to overcome many global, economic, societal and environmental challenges. These have shaped the ambition of today and have been translated into a series of new objectives that the EU has committed to, such as the United Nations' 2030 Agenda for Sustainable Development¹⁷, or set for itself such as the action plan for the Circular Economy¹⁸ and the strategy for a renewed EU Industrial Policy¹⁹. By doing so, the EU has become a global frontrunner on many aspects. Its chemicals

¹⁴ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

¹⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

¹⁶ For example, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the Basel, Minamata, Rotterdam, and Stockholm Conventions as well as the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)

¹⁷ In particular SDGs 3.9, 6.3, 12.4

¹⁸ COM(2015) 614 final

¹⁹ COM(2017) 479 final

legislation has become a benchmark for the development of chemical risk management rules, at the international level as well as in other countries and regions. Where the EU acts on restricting the use of hazardous chemicals, other countries and regions often follow²⁰.

Different EU policy interventions in the chemicals area demonstrate the EU's commitment to protecting its citizens and the environment and, at the same time, to preserving the internal market which delivers for consumers and where EU business can thrive. EU citizens have much greater confidence in the chemical safety of products manufactured in the EU compared to those imported²¹.

Significant investments have gone into the EU-level risk assessment capacity benefitting directly or indirectly many pieces of legislation within the scope of this Fitness Check. The EU contribution from its general budget to the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) amounted in 2017 to EUR 150 million.²² The EU has also contributed to improving non-animal testing methods by providing more than EUR 650 million since 2000 to research and development²³ and EUR 7 million to the operation of the European Union Reference Laboratory for alternatives to animal testing.²⁴ Different EU funding programmes such as Horizon 2020²⁵, LIFE²⁶ and COSME²⁷ have also supported innovation in the chemicals area, notably on safe and sustainable chemistry.

2. AN OVERALL FIT-FOR-PURPOSE FRAMEWORK OF EU CHEMICALS LEGISLATION

This Fitness Check has assessed whether the EU chemicals legislation meets its objectives in terms of risk and hazard assessment and management of hazardous chemicals, and if it does so in a coherent and efficient way. It concludes that, overall, the EU chemicals legislation delivered results as intended and is fit-for-purpose. However, it also identifies a number of important issues and weaknesses that are holding the EU chemicals legislation back from delivering its full potential and which limits its ability to achieve its objectives and to be fit-for-purpose.

The assessment carried out for the purposes of this Fitness Check focused on the chemical hazard and risk assessment and risk management processes specified by the different pieces

²⁰ Study on the cumulative health and environmental benefits of chemicals legislation p. 324

²¹ Special Eurobarometer 456

²² In spite of being out of the scope of this Fitness Check, this figure includes the EU contribution to ECHA for the operation of REACH Regulation as well as that for other pieces of legislation that EFSA is in charge of and which are not covered by this Fitness Check.

²³ Funding came from the 7th as well as the 8th EU Framework Programme for Research and Development, with an annual average of EUR 35 million.

²⁴ This figure includes the REACH Regulation that is not covered by this Fitness Check.

²⁵ See for example European Human Biomonitoring Initiative (HBM4EU). The EU contribution amounts to around EUR 50 million. https://cordis.europa.eu/project/rcn/207219_en.html

²⁶ During the 2014-2016 period LIFE contribution to several projects in chemicals area amounted around EUR 5 million. See for example the following projects: [FLAREX](#), [VERMEER](#), [MATHER](#), [COMBASE](#), [CHEREE](#), [EXTRUCLEAN](#)

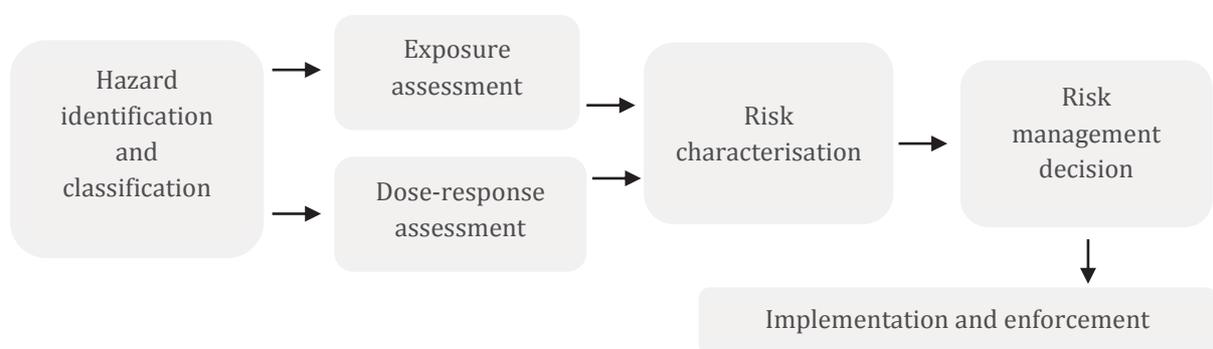
²⁷ A project aiming at facilitating contacts between solutions providers and SMEs interested in substituting chemical substances of potential concern. The second phase of the project was launched in 2019.

of legislation considered. The REACH Regulation, as well as the pharmaceutical, veterinary products, and food additives legislation were excluded from its scope. This presented a number of challenges, particularly in terms of disentangling estimates of costs and benefits as REACH is often an integral part of the policy mix that is responsible for the costs and benefits of reducing the exposure to hazardous chemicals.

The Fitness Check looked at the pieces of legislation directly regulating chemical substances and mixtures as well as those regulating conditions under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, which are manufactured using chemicals (e.g. toys and food contact materials) or the impacts of chemicals in certain environmental compartments (e.g. water and marine).

EU approach to risk assessment and risk management

The human health and environmental risks from the exposure to hazardous chemicals are addressed via hazard and risk assessment procedures prescribed in the EU chemicals legislation. The main steps of the chemicals risk assessment and management process (i.e. decision making and implementation and enforcement) usually involve:



The CLP Regulation is one of the cornerstones of the EU chemicals legislation. It deals with the hazard identification, assessment and classification of chemicals and the communication of those hazards to consumers and workers. For their risk management, several product-specific pieces of legislation refer to the CLP Regulation (e.g. cosmetics, detergents, biocides, plant protection products) using its chemical hazard classification criteria. The CLP is the EU implementation of the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS)²⁸. In addition to the hazard classification under the CLP Regulation, other pieces of legislation may foresee additional hazard categories.

The ECHA, EFSA and the European Medicines Agency (EMA), and two EU scientific committees²⁹ are responsible for providing the decision makers with scientific advice on hazard and risk assessment. Risk management measures – which can be policy-based and/or technical in nature - are then decided by the Commission in light of the identified hazards and/or risks.

²⁸ http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

²⁹ The Scientific Committee on Consumer Safety (SCCS) , the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) and, previously, the Scientific Committee on Occupational Exposure Limits (SCOEL), whose competences in terms occupational exposure to hazardous chemicals have been transferred since 2019 to the Risk Assessment Committee (RAC) of ECHA.

Depending on the nature and the dimension of hazards and on the exposure situations involved, risk management measures are taken directly based on the identified hazard classification (generic risk consideration) or based on a specific risk assessment. In most cases, the EU chemicals legislation uses a combination of both of these approaches.

The linkages between the different pieces of EU chemicals legislation are generally well-established and functioning reasonably well. The EU legal framework on chemicals is generally designed to make science- and evidence-based decisions. The approach allows it to deliver in an effective, efficient and coherent way. The added value of policy action at the EU level is high and remains relevant.

While the overall regulatory costs of the EU chemicals legislation for the EU industry are estimated to be several billion euro per year, the EU chemicals legislation has also led to significant benefits in terms of avoided health and environmental impacts (e.g. healthcare costs, productivity losses, suffering and premature deaths, remediation costs, and degradation of environmental/eco-system services). The quality and the availability of data needed to perform robust risk assessments and to make sound risk management decisions has improved considerably in recent years. Also, the EU's knowledge base on chemical hazards and risks has become a world-class asset and continues to grow and improve. Much of this reflects the shift of responsibility from EU and Member State authorities to industry for generating the necessary data for hazard and risk assessments and the significant investment of resources in the establishment of recognised and independent EU agencies.

3. IDENTIFIED CHALLENGES, GAPS AND WEAKNESSES

The Fitness Check has identified a number of challenges, gaps and weaknesses. Some of these relate to specific pieces of legislation. However, in line with the broad focus of the Fitness Check, the following sections present only those findings that affect the correct functioning of the legislation from a framework and a more general perspective and that are holding it back from delivering its full potential.

3.1. IMPLEMENTATION AND ENFORCEMENT

The correct functioning of the EU chemicals legislation relies heavily on the availability of the resources of public authorities in charge of its implementation and enforcement. However, cutbacks in, and variations between, the capacity, available resources and expertise of Member States competent authorities are presenting some significant challenges for the implementation and the enforcement of the EU chemicals legislation and its overall effectiveness and efficiency. A number of stakeholders, for instance, have expressed concerns with respect to the pace of the harmonised classification processes in contrast to the processes of self-classification by industry³⁰. Classification enables adequate risk management throughout the EU and also has certain links with the approval process of active substances used in plant protection and biocidal products. The Member States' capacity to prepare harmonised classification dossiers is limited, in particular following the 2008 financial crisis.

³⁰ The CLP Regulation requires industry to 'self-classify' all substances placed on the market irrespective of tonnage. For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMRs) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU in which case the Member States need to agree on the classification of a substance.

Moreover, the workload is unevenly spread between Member States' competent authorities, with just a few Member States carrying the majority of the burden.

Resource constraints at national level affect the capacity to carry out different enforcement activities, such as inspections and other controls including market surveillance activities or reporting. These constraints together with differences in the level of implementation and enforcement from one Member State to another lead to an inconsistent application of the EU law. This can create mistrust amongst Member States, leading to undermining the application of the principle of mutual recognition with ultimately negative consequences on the free movement of goods within the EU.

There is also a considerable lack of information on the level of compliance with the existing EU chemicals legislation, particularly with respect to consumer products. The EU Rapid Alert System for dangerous non-food products (RAPEX) and the Rapid Alert System for Food and Feed (RASFF) are efficient and useful tools for exchange of information and measures taken on products posing a serious risk to health or the environment. However, the risk identified may not be due to a lack of compliance. Moreover, non-compliant products which do not represent a serious risk are not notified through RAPEX or RASFF. Consequently these two alert systems can only provide a partial picture about the overall level of compliance of products placed on the EU market. Moreover, articles imported into the EU, including via online sales³¹, still represent a particular challenge for market surveillance authorities for ensuring both overall consumer protection as well as fair competition.

Understanding and keeping up-to-date with changes in legal requirements is more challenging for SMEs compared to bigger companies. The level of compliance with the existing rules also depends on the clarity of the rules so that actors understand their legal obligations. The current lack of clarity with respect to how to apply the 'CLP bridging principles method'³² is a case in point. From a Member State and industry association perspective, it can be challenging to reach small companies, and notable differences exist in the level of support that Member States provide to SMEs helping them to understand and comply with the EU chemicals legislation.

3.2. DUPLICATION, BURDENS AND PACE OF PROCEDURES

Currently, scientific advice and risk assessment are provided to the Commission by different agencies and scientific committees. Their areas of intervention and their competencies are

³¹ With regard in particular to online sales, the Commission has recently taken several initiatives involving market surveillance authorities (through the organisation since 2017 of yearly "e-enforcement academies" for improving online surveillance), consumers (with information campaigns on safe online shopping) and online economic operators (involving them in active fulfilment of their obligation thanks to the signature of the ['Product Safety Pledge'](#) with key online sells platforms).

³² The 'bridging principle method' is a method applied when a mixture has not been tested to determine its hazardous properties, but there is sufficient data on similar tested mixtures and individual hazardous ingredients to adequately characterise the hazards of the mixture. In the case of detergents for example this method allows to avoid over-classification which may result from applying the calculation method usually preferred by smaller companies due to cost considerations. The lack of clarity with respect to how to apply the bridging principles hampers the effectiveness of the method and also leads to discrepancies in the interpretation and acceptance of the classification by Member States.

determined in the relevant pieces of legislation. The rules of procedure governing the functioning of the existing committees explicitly recognise the need to ensure good and effective cooperation among them and with the relevant EU agencies. However, the strength of the obligation to seek convergence varies. While the delineation of their tasks and competencies is often clear, there are areas of potential overlap (e.g. toys, detergents or other consumer goods, nanomaterials). This means that the same substance can be assessed by ECHA or by one of the EU scientific committees, depending on which legislation applies, and possibly lead to diverging opinions. The Commission has already started to work on streamlining the hazard/risk assessment by ECHA and EFSA to better ensure the convergence of conclusions. There are additional opportunities for simplifying the current set-up and streamlining the risk assessment processes among all relevant EU assessment bodies. This could make the functioning of the chemicals legislation more efficient (e.g. avoiding duplication of efforts) and more predictable (e.g. reducing the risk of potentially diverging outcomes of hazard/risk assessments at EU level). This could also reduce the need to provide information to multiple interlocutors and ensure that all relevant stakeholders are actively involved.

Some duplication of efforts may also occur in data generation because of the lack of awareness of interested parties of what information is available and where and how the existing data can be used. Problems in data sharing across institutions and legislation are also encountered because of insufficient cooperation but also because of the sometimes too restrictive access and re-use rights. This duplication can generate extra costs, as well as longer-than-necessary timeframes, and, ultimately, negatively affect the level of protection as well as competitiveness and access to the market, in particular for SMEs. These negative impacts risk to be exacerbated in the future given that the wealth of information on substances and their hazardous properties is expected to increase. For example, the shift towards a more circular economy will require tracking substances in articles and waste streams, which will naturally generate more data. At the same time, an increasing amount of information and data is being generated via current and future human and environmental monitoring. A more comprehensive approach across the EU chemicals legislation, including through an open data policy and a better use of smart technologies, could improve the overall efficiency of the EU legal framework for chemicals and contribute to the Commission's commitment towards more transparency³³.

The current substance-by-substance approach³⁴ used in hazard and risk assessment processes is generally effective in identifying the hazards of a specific substance and the risks from the situation in which it is used. Nevertheless, given the high number of substances that need to be assessed and the resources and the time that such an assessment requires, this approach has its limits in terms of the overall efficiency. During the consultation, stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing chemicals with similar hazard, risk or function as a group. This could result in considerable efficiency gains in terms of protecting human health and the environment,

³³ COM/2018/0179 final - 2018/088 (COD)

³⁴ When considering the appropriate risk management for chemicals, a substance can be assessed in an isolated context (substance-specific; risk assessments completed on given substances under given settings) or as part of a substance group, i.e. chemicals with similar properties.

accelerating the pace of the hazard and risk assessment processes and cost savings for industry, because it would avoid replacement of hazardous substances by alternatives that are likely to be banned subsequently. Finding a meaningful way of defining the group of substances remains however an open challenge.

3.3. COMMUNICATION OF HAZARD AND SAFETY INFORMATION

A recent Eurobarometer survey³⁵ found that less than half of the respondents (45%) feel well informed about the potential dangers of the chemicals contained in consumer products. The relatively low level of understanding of certain pictograms, labels and precautionary statements is partly due to the overload of information e.g. too much text or chemical names that consumers are not familiar with printed in multiple languages. In other cases, it can be due to overlaps in legal requirements e.g. between the CLP Regulation, the Detergents Regulation and/or the Cosmetic Products Regulation. This makes it difficult for downstream users and consumers to focus on the essential hazard information. The communication of hazard and safety information to consumers can thus be improved and simplified, including by using digital technologies such as Q-R codes.

At the same time, the lack of some information on consumer goods impacts the consumers' ability to make informed choices. This may be the case regarding the lack of labelling requirements on environmental hazards for cosmetic products. Also, the current approach to allergens lacks coherence with respect to the provision of consumer information and to the assessment of risks to human health. It also creates overlaps in terms of labelling obligations. Improvements in the current approach to allergens could therefore help consumers to be better protected and informed.

The Fitness Check has also identified challenges regarding the Classification and Labelling Inventory held by ECHA, which affect its value as a hazard communication tool. The Inventory contains classification and labelling information for the substances to be placed on the market as notified by manufacturers and importers. However, there are often multiple classifications for the same substance because different notifiers fail to arrive at an agreed entry despite the legal obligation to make every effort to do so and despite ECHA's and the Commission's efforts to provide support to companies. This situation is exacerbated by the lack of a legal basis for ECHA to perform quality checks of the self-classifications and to ensure that the Inventory does not contain any obsolete notifications or errors.

3.4. CONSISTENCY OF RISK MANAGEMENT MEASURES

A potential important gap is the lack of an overarching approach to the protection of vulnerable groups, as highlighted during the consultation activities by several stakeholders representing civil society and NGOs. Reference to vulnerable groups is not systematic across the legislation and risks to these groups are not always addressed in a consistent manner across product/risk/sector specific legislation. Where such legal provisions do exist, risks are taken into consideration on a case-by-case basis with differences in definition and wording used. This could lead to different levels of protection between different pieces of legislation for the same vulnerable group (e.g. children) or for those groups that are particularly sensitive to certain hazardous substances (e.g. unborn children, young infants and adolescents).

³⁵ Special Eurobarometer 468

Some inconsistencies have been identified regarding risk management decisions in the various pieces of legislation as regards endocrine disruptors, substances that are persistent, bio-accumulative, toxic, substances that are very persistent and very bio-accumulative and substances fulfilling the classification criteria for specific target organ toxicity. It is important to ensure consistency across the EU legislation, including for substances of similar concern to substances that are carcinogenic, mutagenic and reprotoxic. The potential added value of introducing new hazard classes in the CLP Regulation (e.g. terrestrial toxicity, neurotoxicity, immunotoxicity, endocrine disruption, persistent bioaccumulative and toxic, very persistent very bioaccumulative) could be explored.

In its recently adopted Communication on endocrine disruptors³⁶ the Commission undertook to launch a cross-sectoral Fitness Check to assess whether the relevant EU legislation on endocrine disruptors is fit for purpose. The Fitness Check will allow an analysis of how the different provisions on and approaches to endocrine disruptors interact, will identify possible gaps, inconsistencies or synergies, and assess their collective impact in terms of costs and benefits for human health and the environment, the competitiveness of EU farmers and industry, and international trade.

In the context of scientific uncertainty and lack of or limited knowledge, the precautionary principle is an important element in helping to ensure the protection of human health and the environment against potential risks, the avoidance of potential costly future impacts and remediation, and the avoidance of disproportionate or unnecessary risk management costs. The Fitness Check highlighted the case of Bisphenol A (BPA) as a positive example of the use of the precautionary principle³⁷. In this case, baby bottles containing BPA were banned from being placed on the market and imported into the EU, to avoid infants' exposure to BPA and possible negative physical and mental consequences. In the public consultation, a number of NGOs, trade unions and some Member State competent authorities still expressed their concerns about the practical application of the precautionary principle considering that it has been applied in very few instances in the chemicals policy area. Its practical application therefore warrants further attention.

3.5. RISK ASSESSMENT, KNOWLEDGE GAPS AND CHALLENGES IN KEEPING UP WITH SCIENCE

The proper functioning of the EU chemicals legislation and its capacity to respond to future challenges depends, amongst other things, on the ability of the EU and Member States to make their decisions based on robust and relevant up-to-date data. Enormous efforts have been made at the EU and Member State level to ensure that the necessary data to take effective chemical risk management decisions is available, comparable and of good quality. Likewise, the scientific understanding of how hazardous chemicals impact human health and the environment has improved significantly over the last two decades. The current EU knowledge base on chemicals – including their properties, data on eco-toxicity of chemicals

³⁶ COM(2018) 734 final

³⁷ http://europa.eu/rapid/press-release_IP-11-664_en.htm; Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials; applicable as of 6 September 2018

and on chemical uses and exposures – is unique in the world and is, in many instances, made available also to governments, industries and stakeholders beyond the EU.

Nevertheless, important knowledge gaps still remain, in particular regarding exposure to hazardous chemicals, their use and their impacts on humans and the environment, including on biodiversity and ecosystems' resilience. Similar concerns exist regarding new and emerging chemical risks. The role of hazardous chemicals in the complex interaction with other environmental stressors and their actual contribution to the effects seen in the environment are not fully understood. This means that the current regulatory framework, including test and assessment methods, typically cannot focus on these long term, large scale and complex environmental effects. EU research and innovation funding remain therefore paramount to overall improve human and environmental monitoring and to close these knowledge gaps. Information thus gathered could also feed into an EU-level early warning system for identifying new, emerging chemical risks.

Information on exposure to hazardous chemicals is necessary to develop exposure scenarios with regard to the intended, normal, reasonable and/or foreseeable use of a product or foreseeable/predictable situation. The evidence shows that industry and public authorities may not always be aware of all the uses of certain hazardous chemicals that have a broad range of applications in a myriad of different consumer products. Moreover, there is only limited information available about the overall volumes of hazardous chemicals emitted/released into the environment. These two elements combined can affect their capacity to develop realistic, acceptable and robust exposure scenarios and as a consequence to identify the most appropriate risk management measures.

Authorities in charge of hazard and risk assessment are not always aware of all the potentially relevant or the latest information and data necessary for decision-making process. In this regard, peer-reviewed studies are an important complement provided that they are reliable and properly documented, in particular for the identification of, and reaction to, early warning signals. Tools that bring together and monitor recent and useful scientific publications and ensure that authorities are well aware of what is available are however lacking. Moreover, there are still barriers to the use and acceptance of alternative (non-animal) test methods³⁸ for regulatory purposes, partially linked to gaps in the available test guidelines.

Risk assessment processes implemented within the EU chemicals legislation are not expressly designed to identify and assess potential human health and environmental risks of different hazardous chemicals acting in combination (also known as the 'combination effect' or 'cocktail effect'). The Commission noted³⁹ back in 2012 that the then "current EU legislation does not provide for a comprehensive and integrated assessment", and announced a number of follow-up actions to remedy this. Since then, progress has been made with regard to knowledge building and the development of risk assessment methodologies in the context of plant protection products⁴⁰ and in the broader context of the food chain⁴¹.

³⁸ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes amongst other promotes the development, validation and implementation of alternative (non-animal) test methods.

³⁹ COM/2012/0252 final

⁴⁰ <https://www.efsa.europa.eu/en/press/news/130712> ; <https://www.efsa.europa.eu/en/press/news/180626>

Nevertheless, a workable methodological framework for all chemicals has not been agreed upon. Requirements to ensure the risk assessment of combination effects exist only in some pieces of legislation (e.g. in the area of pesticides) while other relevant pieces of legislation do not contain legal provisions that cater for such an assessment.

Lack of knowledge about substances in articles is increasingly concerning as the EU is in the process of shifting towards a more circular economy. While steps have been taken regarding traceability of hazardous chemicals in waste and recycled material streams⁴², the shift towards a more circular economy will require that, instead of looking at the potential risks posed by hazardous chemicals during one and unique ‘life’ based on a linear ‘take-make-dispose’ approach, the risk assessment may need to take into account the potential of such hazardous chemicals to re-enter the loop via recycling. The way hazard and risk assessments are carried out may need to be adapted accordingly, given the increasing consumer awareness and demand for sustainable and more circular products.

3.6. GLOBAL COMPETITIVENESS, INNOVATION AND SUSTAINABILITY

The EU chemicals legislation has been instrumental in ensuring free circulation of substances, mixtures and articles through harmonisation of standards and requirements. To a large degree, there is a level playing field in Europe, and chemicals legislation has strengthened the internal market and enhanced the competitiveness of EU industry as reflected in the growth in intra-EU trade⁴³. The EU chemicals industry remains internationally competitive although the European share of global sales has decreased⁴⁴. Globalisation, a strong growth in the production of chemicals in other parts of the world and rapid technological change are the main challenges for the EU chemicals industry. Significant efforts will be needed by all interested parties at all levels and most importantly by industry itself to maintain and reinforce Europe's industrial leadership⁴⁵. The main assets of the EU chemicals industry are a high level of technological development, a skilled and talented workforce and a world-class science base. These assets, combined with the EU's global leadership on many sustainability⁴⁶ and chemicals related aspects⁴⁷, provide a solid basis for tackling these challenges.

The internal market is another asset that the EU and Member States authorities as well as the EU industry can build upon. Digitisation, IT tools and other novel and smart technologies offer many opportunities. The uptake of smart technologies can offer better communication of chemical hazard and safety information to consumers as already explained above. Reaping

⁴¹ <https://www.efsa.europa.eu/en/consultations/call/161024a>

⁴² COM(2019) 190 final

⁴³ The intra-EU sales of chemicals increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 (+28%). Domestic sales (sales in the home country) dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016 (-56%). Extra-EU exports increased from EUR 102 billion in 2006 to EUR 146.2 billion in 2016 (+43%). Source: CEFIC Facts and Figures Report, 2017

⁴⁴ Ibidem

⁴⁵ COM/2017/0479 final

⁴⁶ Reflection Paper ‘Towards a Sustainable Europe by 2030’ 30 January 2019

⁴⁷ The United Nations Strategic Approach to Chemicals Management (SAICM); <http://www.saicm.org>

the benefits of the digital age also means potential burden reduction for SMEs, improving the enforcement and compliance including via the real-time use of data and monitoring, as well as reinforcing cooperation between competent authorities, including customs and market surveillance authorities⁴⁸.

The available data on production and consumption of hazardous chemicals⁴⁹ shows that the share of industrial chemicals hazardous to health and the environment in the total chemicals production has remained relatively unchanged. No legislation-specific information is available to assess the pace of substitution of hazardous substances. Statistics do not allow to directly link changes in the share of chemicals hazardous to health and the environment to the EU intervention. Nevertheless, the evidence gathered seems to indicate that the EU chemicals legislation has the potential to act as a driver of innovation, in particular with regard to the achievement of the UN Sustainable Development Goals. Europe has already started to implement and to deliver many of its commitments regarding the shift towards a more circular economy⁵⁰. Additional support to the development of smart, innovative, and sustainable chemicals and to encourage 'green chemistry'⁵¹ will be critical to ensure sustainability as well as the competitiveness of the EU chemicals industry for the future.

CONCLUSIONS

The purpose of this Fitness Check was to take a step back and to look at what the EU has achieved in the area of chemicals management and how it performs. We have come a long way and this Fitness Check has found that, overall, the EU framework of chemicals legislation is fit for purpose and delivers a high level of protection of people and the environment in balance with the needs of an efficiently functioning internal market and of a competitive and innovative chemicals industry.

It has also found a number of areas where there is scope for further improvement, simplification and burden reduction or that warrant attention.

As explained in the Introduction of this Report, the Fitness Check is a further step in the reflection process on the EU chemicals legislation. It is intended to provide a common understanding of the challenges and to invite all interested parties to get involved.

The Commission invites the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions to discuss these findings and to bring their own contribution to the debate.

The findings of this Fitness Check will help ensure that any improvements and refinements to be made in the chemicals policy area are well-founded and well-focused. It is particularly important that the different pieces of the EU chemicals legislation, including those not assessed in this Fitness Check, such as REACH, continue to consistently deliver a high level

⁴⁸ In line with the Commission communication 'The Goods Package: Reinforcing trust in the single market' (COM(2017/0787 final)

⁴⁹ http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics

⁵⁰ COM(2019) 190 final

⁵¹ Green chemistry is the utilisation of a set of principles that reduces or eliminates the use or generation of hazardous substances in the design, manufacture and application of chemical products. Definition by Anastas and Warner (1998).

of protection of human health and the environment and to ensure the efficient functioning of the internal market while contributing to the overall objective of enhancing competitiveness and innovation.