Council of the European Union

Brussels, 26 June 2019
(OR. en)

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ADD 3

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	25 June 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2019) 199 final FV3
Subject:	COMMISSION STAFF WORKING DOCUMENT FITNESS CHECK of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries Accompanying the document 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 SWD(2019) 199 final FV3.

Encl.: SWD(2019) 199 final FV3

EUROPEAN
COMMISSION

Brussels, 25.6.2019
SWD(2019) 199 final

PART 3/3

COMMISSION STAFF WORKING DOCUMENT

FITNESS CHECK
of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

Accompanying the document

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

{COM(2019) 264 final}

5 Annex 5 Effectiveness

Section 5 on Effectiveness in the main document analyses the progress made towards achieving the three core objectives of the EU chemicals *acquis*. It looks for evidence of why, whether or how the progress identified is linked (or not) to the EU chemicals policy intervention as well as identifying any unexpected or unintended effects and consequences. Where progress has fallen short of the desired objectives and targets, the factors influencing this are identified and assessed including the feasibility of the objectives and timescales.

Many of the factors that affect the effectiveness of the EU framework of chemicals legislation are also closely linked to the efficiency, coherence, relevance and implementation of the EU chemicals *acquis*. Issues identified in the Effectiveness section are, therefore, sometimes referred to in other sections where they are analysed in more detail.

This Annex provides a more detailed description of the Fitness Check findings regarding effectiveness.

5.1 Evaluation question: to what extent does the EU legislative framework for the risk management of chemicals meet its objectives?

The performance of the EU chemicals legislation is assessed against its three core policy objectives that are shared by nearly all individual pieces of legislation within the scope of this Fitness Check:

- Ensuring a high level of protection of human health from the adverse effects of hazardous chemicals.
- Ensuring a high level of protection of the environment from the adverse effects of hazardous chemicals.
- Supporting the efficient functioning of the internal market for chemicals and enhancing the competitiveness and innovation of EU industry and business.

As the first two objectives are rather different in their nature from the third objective and, therefore, have different sets of performance indicators, they are assessed separately.

5.1.1 The objective of high level of protection of human health and environment

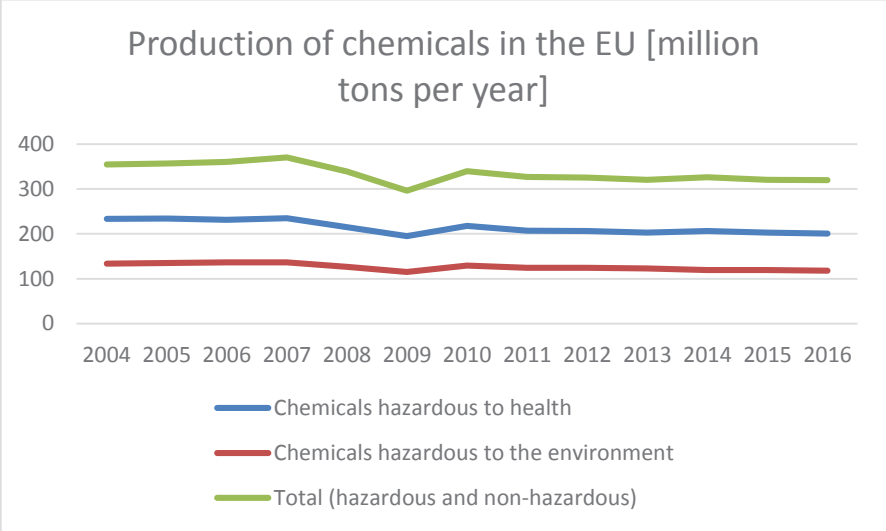
The EU chemicals legislation aims to achieve a high level of protection of human health and the environment by stimulating substitution of hazardous substances by less hazardous chemicals (or alternative non-chemical solutions) and/or by minimising the exposure to hazardous chemicals. The effectiveness of the EU chemicals *acquis* can therefore be measured by analysing the trends in:

- the production and consumption of hazardous substances;
- the human and environmental exposures to hazardous chemicals; and ultimately
- the impacts in the form of the main health and environmental impact parameters associated with exposures to hazardous chemicals, such as trends in the EU incidence rates of certain human diseases, trends in animal population levels, trends in eco-system health/resilience.

A. Production and consumption of hazardous substances

Trends in the production and consumption of hazardous substances, either expressed in absolute terms or relative to overall chemicals production and consumption, are one potential indicator of the substitution of hazardous substances by less hazardous substances. While not shared by all the pieces of legislation within the scope of this Fitness Check, it remains one of the specific goals of the EU chemicals legislation e.g. the Plant Protection Products Regulation and the Biocidal Products Regulation. Eurostat has been producing relevant data sets on this since 2004 for industrial chemicals. The findings of the latest analysis[1] for EU-28 published in December 2017 are:

- The trend in the production of chemicals hazardous to health and environment followed the trend for the overall chemicals production, reaching a peak in 2007, after which there was a significant decline in production during the financial and economic crisis, followed by a strong rebound between 2009 and 2010 and a subsequent more stable phase.
- The share of chemicals hazardous to health and the environment was relatively unchanged over the period 2004–2016. The share of chemicals hazardous to the environment fluctuated between 37% and 39%, while the share of chemicals hazardous to health fell from about 66% in 2004 to 62% in 2016.



[1] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics

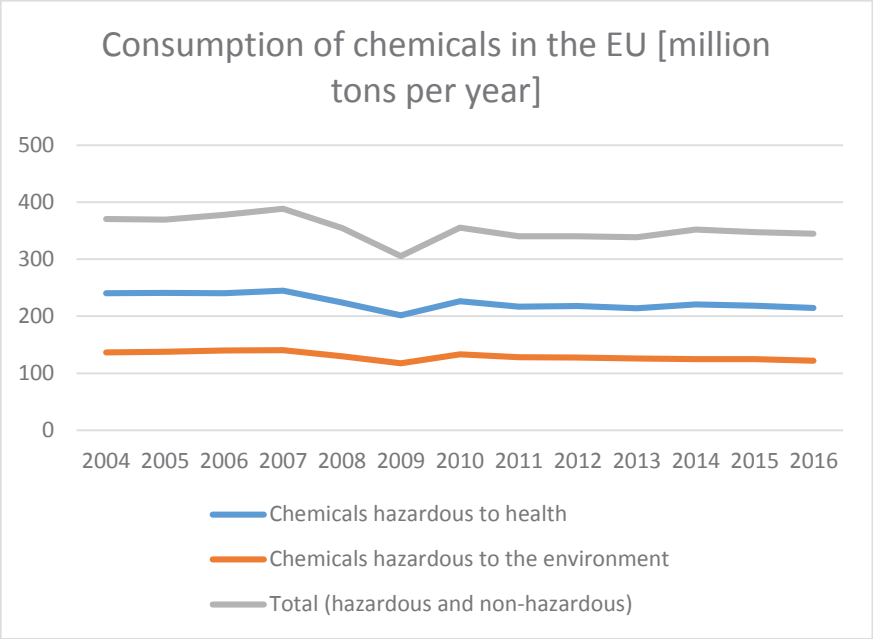


Figure 1 Production and consumption of chemicals, EU-28, 2004-2016. Source: Eurostat (online data codes: env_chmhaz) Note: some chemicals are hazardous to both the environment and human health therefore adding these total together and subtracting the result from the total production or consumption volume to determine the volume of non-hazardous chemicals cannot be done.

Whilst production of chemicals hazardous to the environment fell broadly in line with chemicals production overall, there was variation amongst the five different classes[2] of chemicals.

- The largest overall decrease of 18% in EU-28 production between 2004 and 2016 was recorded for chemicals with the highest level of hazard for the environment (i.e. for chemicals with 'severe chronic environmental hazard and with significant acute environmental hazard').
- The lowest decrease of 4% was for chemicals with moderate chronic environmental hazard (for the period under consideration).

[2] Hazardous to the environment chemicals covers the following 5 classes: (1) Significant acute environmental hazard, (2) Chronic environmental hazard, (3) Moderate chronic environmental hazard, (4) Significant chronic environmental hazard, (5) Severe chronic environmental hazard

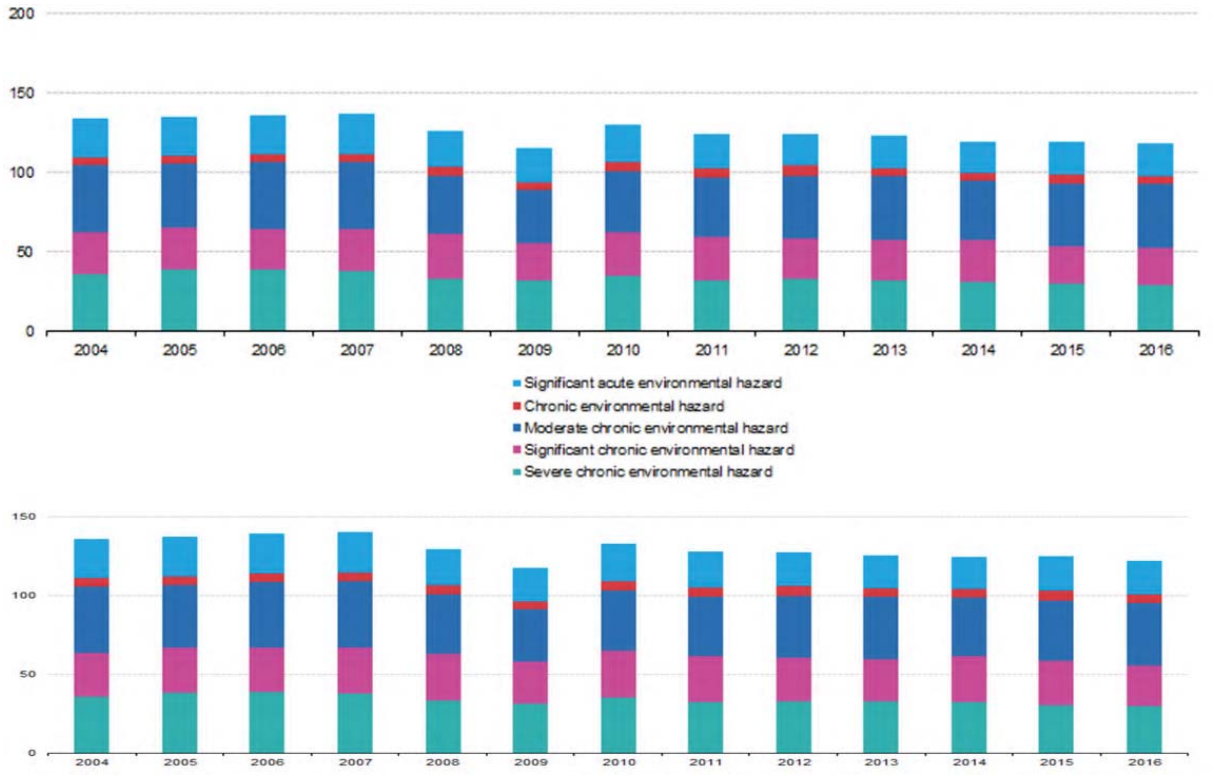


Figure 2 Production (1st diagram) and consumption (2nd diagram) of chemicals hazardous to the environment, EU-28, 2004-2016 (million tonnes). The different classes of chemicals are ranked according to their environmental impact from the most harmful (bottom class) up to the least harmful (top class). Source: Eurostat (online data code: env_chmhaz)

- Production of chemicals[3] that are most hazardous for health (i.e. carcinogenic, mutagenic and toxic for reproduction (CMRs)) fluctuated between 39 million tonnes and 41 million tonnes over the period from 2004 to 2007. Production fell between 2007 and 2008 to stand at 35 million tonnes. This rebounded in 2009 and 2010 back to a level that was similar to that recorded prior to the financial and economic crisis. In part, however, this reflects changes in the underlying categorisations of chemicals used by Eurostat when the CLP Regulation was introduced, although the exact impact of this is not known. From 2010, the level of production of CMRs declined once more to around 33 million tonnes in 2016, the lowest level over the whole period from 2004 to 2016. The relative share of CMRs in total EU-28 chemical production fluctuated between 10% and 12% over the period under consideration.

[3] Hazardous to health covers the following 5 classes: (1) Harmful to health hazard, (2) Toxic health hazard, (3) Very toxic to health hazard, (4) Chronic toxic health hazard, (5) Carcinogenic, mutagenic and reprotixic (CMR) health hazard

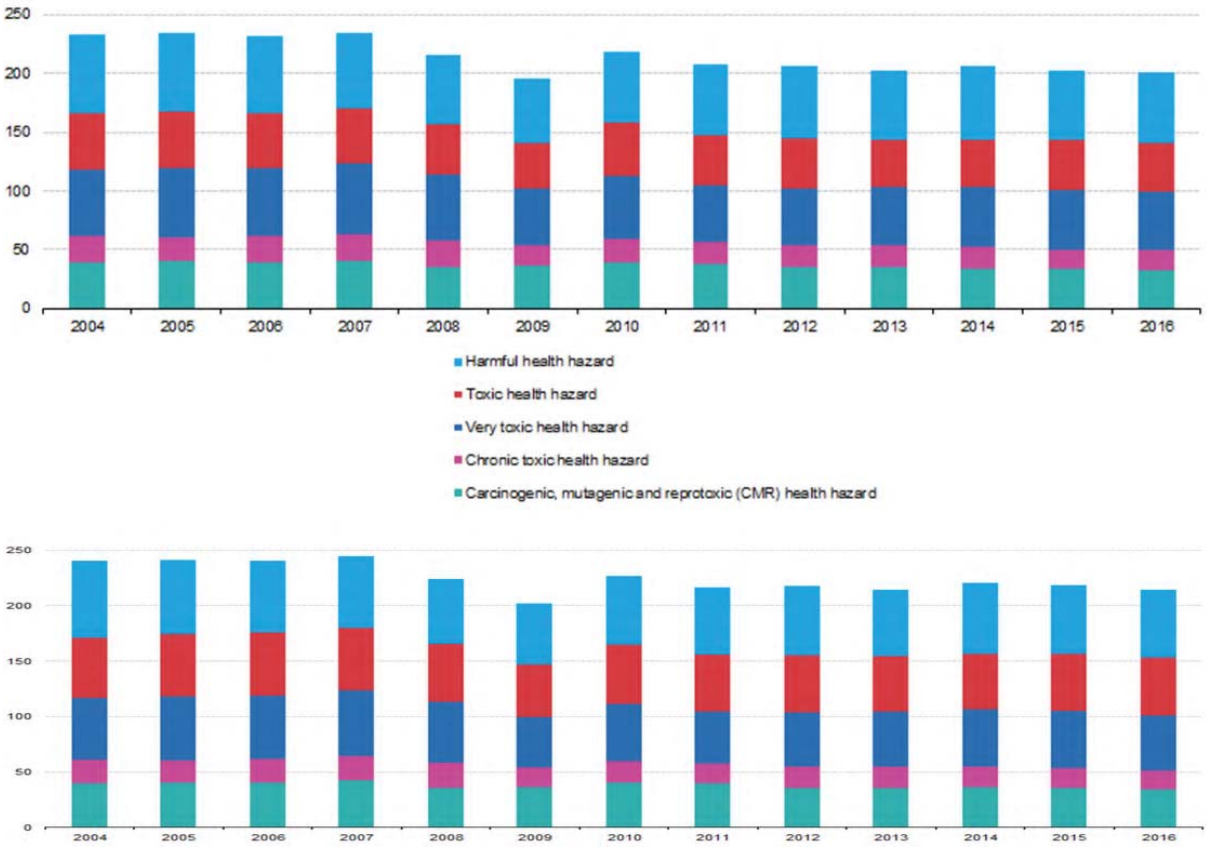


Figure 3 Production (1st diagram) and consumption (2nd diagram) of chemicals hazardous to health, EU-28, 2004-2016 (million tonnes). The different classes of chemicals are ranked according to their human health impact from the most harmful (bottom class) up to the least harmful (top class). Source: Eurostat (online data code: env_chmhaz)

- In general, differences between the consumption and the production of chemicals are small. The consumption is always slightly higher than the production reflecting a net import surplus.

The analysis suggests that substitution of hazardous substances by less hazardous substances has not yet occurred to any notable extent. Essentially, the share of industrial chemicals hazardous to health and the environment in the total chemicals production has remained relatively unchanged over the last decade. This may, in part, reflect the effectiveness of risk management measures in reducing exposures and risks, therefore reducing the incentive to substitute to less hazardous substances.

However, there are also hints of what might be the beginning of a positive substitution trend. The largest overall decrease in EU-28 production between 2004 and 2016 was recorded for chemicals with severe chronic environmental hazard and for chemicals with significant acute environmental hazard (as the production volume was reduced by about 18 % for both classes over the period under consideration). This may indicate that the substitution for these groups to less hazardous chemicals has started to happen (while it does not seem to be the case yet for chemicals hazardous to health). It should be noted, however, that where substitution is referenced in existing pieces of the EU chemicals legislation, it does not provide any qualitative or quantitative basis against which to assess the pace of substitution per se. Also, the currently available statistics do not allow to link changes in the share of chemicals

hazardous to health and the environment to the EU intervention. In order to do so, more in-depth analysis would be required.

When drawing conclusions from this analysis, one should be aware of its limitations. The results are developed on the basis of the Classification and Labelling Inventory (CLI), covering harmonised classification under the CLP Regulation but also self-classifications. New harmonised classifications and re-classifications are on-going. Furthermore, the 'consumption' of chemicals that are contained in articles imported into the EU is not captured in the data presented above.

Respondents to the open public consultation[4] were asked to assign a score of between 1 (no contribution) to 5 (large contribution) to the role of the EU legislative framework in reducing the use of hazardous chemicals and/or substitution with safer alternatives. Scores assigned show considerable variation among the four groups. The weighted scores show that it is Group 2 Industry association/business and 3 Public authority (with weighted scores of 3.4 and 3.5, respectively) that consider the EU chemicals framework to have made the largest contribution to a reduction in number or use of hazardous chemicals and/or an increase in substitution to safer alternatives. Citizens (Group 1) and NGOs and others (Group 5) were less positive with weighted scores of 2.9 and 3.0 respectively.

B. Human and environmental exposures to hazardous chemicals

There is clear evidence that, where targeted EU policy and regulatory actions have been taken, human and environmental exposures to a number of well-known hazardous chemicals have been successfully reduced and, in many cases, minimised. As one example, consumer exposure to lead e.g. in petrol, paints, toys, drinking water, etc., has been reduced by an estimated 89% in the EU between 1990 and 2011, following a variety of risk management measures implemented by Member States, at least in part due to EU legislation.[5] This has resulted in a sustained and significant reduction, on average, in measured levels of lead in blood[6] (see Figure 4 below).

[4] Question 23

[5] CuBA Study p. 373

[6] Ibidem p. 78

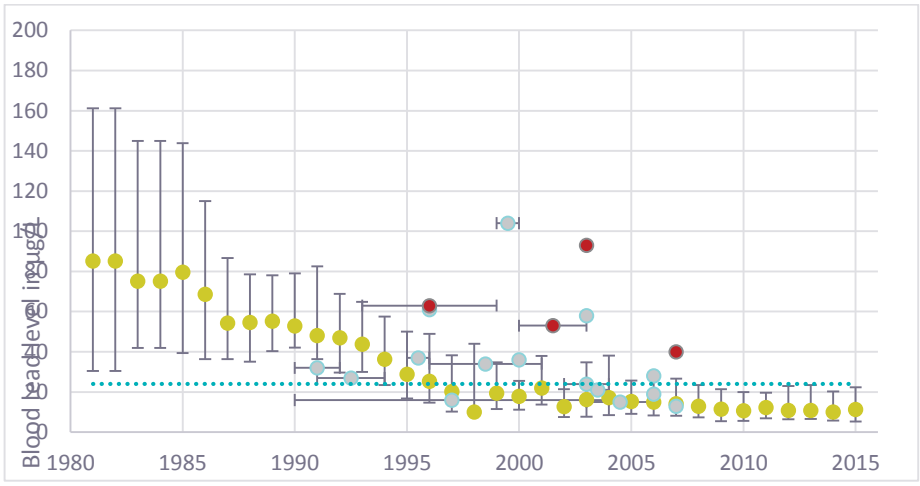


Figure 4 Medians (green dots) and 5th to 95th interval of the distribution of lead levels in the blood of German students from 1981 to 2015, along with levels of lead in blood of children from various European cohorts included in the WHO ENHIS database in grey (no known large lead pollution sources) and red (in the vicinity of known lead pollution sources). Dotted line represents the threshold implied by the WHO IQ loss model.[7]

Another example is emissions of volatile organic compounds (VOCs), which contribute to a host of adverse health effects, including hypertension and chronic obstructive pulmonary diseases (COPD). Following EU and Member States policy interventions, emissions fell by approximately 37% in the EU between 2000 and 2012.[8]

From the environmental perspective, similar outcomes have been achieved in the EU between 1990 and 2011 for a number of heavy metals such as mercury (66% emissions reduction), cadmium (64% emission reduction) and arsenic (78% emissions reduction) over similar timeframes[9] (see Figure 5). Reductions in the concentration of a number of other hazardous chemicals in the environment such as tributyltin, polychlorinated biphenyls (PCBs), dioxins, dichlorodiphenyltrichloroethane (DDT), have also been achieved following EU policy intervention.

[7] Ibidem p. 75

[8] Ibidem p. 90

[9] Ibidem p. 89

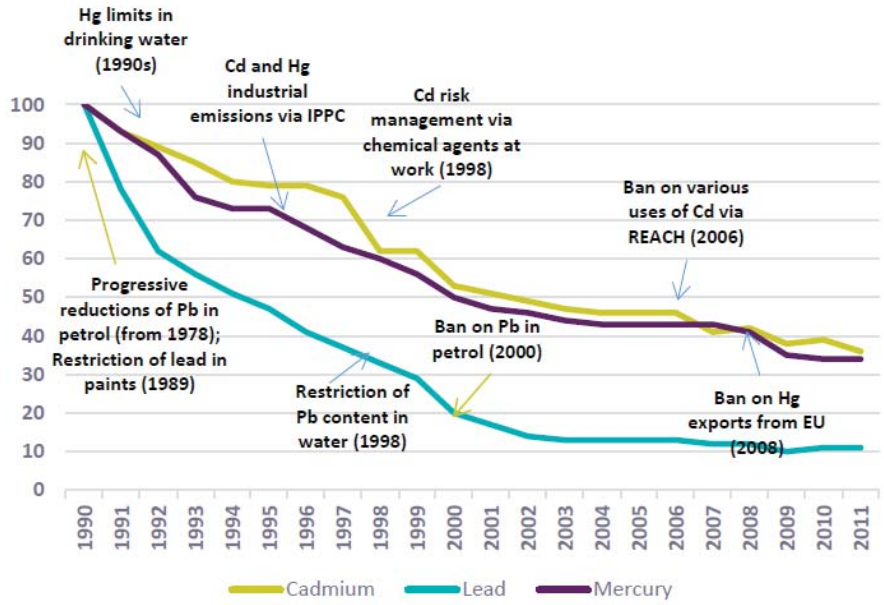


Figure 5 Mercury, Cadmium and Lead emissions (indexed, 1990-2011) alongside selected regulatory action

There are, however, a number of on-going exposure situations that give cause for concern and which point to some shortcomings in meeting the objectives of protecting human health and the environment. These reflect both new, emerging issues, as well as existing ones that require further attention in terms of exposure reduction and control.

Based on current evidence[10], some of the most notable human health related on-going exposure issues in the EU are:

- **Exposures to carcinogenic substances at the workplace:** the European Agency for Safety and Health at Work (EU-OSHA) estimated in 2017 that cancer is the main cause of work-related deaths with 106,307 fatal cases per year in the EU-28[11]. There are many cases of occupational cancers due to past exposures. Setting EU-wide occupational exposure limits (OELs) for a number of substances has helped reduce these exposures. However, regarding substances for which OELs have not been set there are on-going exposure issues. For example, it is estimated that the recent proposal to introduce EU-wide OELs for beryllium, cadmium, arsenic, formaldehyde and 4,4'-Methylenebis(2-chloroaniline) (MOCA) when adopted, in the longer term would prevent over 22 000 cases of work-related ill-health (cancers and non-cancers).[12]
- **Exposures to neurotoxic substances:** whilst the estimates are uncertain, in the EU, some 30 000 disability adjusted life years (DALYs)[13] related to neurodevelopmental

[10] Ibidem, Part A: Protecting Human Health

[11] EU OSH (2017): What are the main work-related illnesses and injuries resulting in death and in DALY: https://visualisation.osha.europa.eu/osh-costs

[12] COM(2018) 171 final

[13] A Disability Adjusted Life Year (DALY) is a method of quantifying the burden of disease. One DALY can be equated to one lost year of "healthy" life. The sum of DALYs across the population - the burden of disease – measures the gap between current health status and an ideal health situation.

disease may be the result of chemicals exposure (and irrespective of a person's genetic predisposition/sensitivity), with some 250 000 DALYs for both chemicals exposure combined with underlying genetic predisposition. This is based on a 'top down' assessment of impacts of pervasive neurodevelopmental disorders from the World Health Organisation (WHO) and an estimate that 3% is due to environmental exposure to chemicals such as lead and other environmental pollutants.

- **Exposures to chemicals linked to cardiovascular and respiratory (CVR) disease:** despite the successful reduction of exposures to lead by some 89% over the last two decades, on-going exposures of EU citizens still account for an estimated 45 000 premature deaths per annum and just over 1 million DALYs related to heart attacks and strokes. Respiratory diseases (primarily obstructive chronic pulmonary disease (COPD) and asthma) account for just over 50 000 deaths per year and some 2.3 million DALYs. Of this, asthma accounts for 10 000 deaths and approximately 1 million DALYs.
- **Exposures to endocrine disruptors (EDs):** the costs of on-going exposures to EDs in the EU-28 have been estimated in a few studies[14] [15] [16] [17] [18] to amount to hundreds of billion euros per year with an estimated median annual cost of EUR 163 billion per year[19] - a significant proportion of which relates to lost productivity and earning potential, being a cost for both society and industry. EDs are considered in these studies as probably responsible for IQ loss and associated intellectual disability, autism, attention deficit hyperactivity disorder, genital malformation, fibroids, childhood obesity, adult obesity, adult diabetes, male infertility and mortality associated with reduced testosterone levels[20]. The above mentioned studies and their conclusions have received some criticism in the past[21] [22] [23] because of the hypothesis

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[14] Olsson, I-M., et al. 2014. The cost of inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Copenhagen: Nordisk Ministerråd. Retrieved from http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf

[15] Legler, J., et al.2015. Obesity, diabetes, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism. 100(4):1278-1288. DOI http://dx.doi.org/10.1210/jc.2014-4326

[16] Bellanger, M., Demeneix, B., Grandjean, P., Zoeller, R. T., & Trasande, L. 2015. Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism. 100(4):1256-1266. DOI http://dx.doi.org/10.1210/jc.2014-4324

[17] Trasande, L., et al. 2015. Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, Journal of Clinical Endocrinology and Metabolism. 100(4):1245-1255. DOI http://dx.doi.org/10.1210/jc.2014-4324

[18] Hauser, R., et al. 2015. Male reproductive disorders, diseases, and costs of exposure to endocrine-disrupting chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism.100(4):1267-1277. DOI http://dx.doi.org/10.1210/jc.2014-4325

[19] Study on the cumulative health and environmental benefits of chemicals legislation

[20] CuBA Study p. 16 and p. 134 and onwards

[21] Gregory G Bond, Daniel R Dietrich, Journal of Epidemiology and Community Health, 2017, Further thoughts on limitations, uncertainties and competing interpretations regarding chemical exposures and diabeteshttp://jech.bmj.com/content/71/9/943

on which they were based and the attribution challenge (e.g. that EDs are responsible to cause several diseases for a certain minimal percent factor of probability).

Some of the more notable environment related on-going exposure issues[24] in the EU are:

- **Presence of hazardous substances in land:** EU regulatory action has contributed to the remediation of known contaminated sites as well as to prevention of creating new contaminated sites through stringent industrial and major accident policies as well as substance-specific actions. Hazardous substances in land have the potential to cause harm to people, species and/or significant pollution of surface waters or groundwater. The most common contaminants affecting soils in Europe include heavy metals and mineral oils (contributing around 60% of contaminated sites), polyaromatic hydrocarbons (PAHs), PCBs, dioxins, phenols, asbestos and pesticides. Many Member States however still lack comprehensive inventories on contaminated sites and details on the pollutants present which renders challenging the identification of all contaminated sites requiring an action and estimating the full extent of local soil and groundwater contamination.
- **Hazardous chemical exposures affecting the quality of surface and groundwater[25]:**

  - for surface waters, good chemical status is defined by limits (environmental quality standards (EQS)) on the concentration of certain pollutants (i.e. priority substances) found across the EU. 38 % of surface water bodies are in good chemical status, while 46 % have not achieved good chemical status and for 16 % their status is unknown. In many Member States, relatively few substances are responsible for failure to achieve good chemical status. Mercury causes failure in a large number of water bodies. If the widespread pollution by ubiquitous priority substances (pBDEs, PAHs, mercury) is omitted, the proportion of water bodies in good chemical status increases to 81 %, with 3 % that have not achieved good status and 16 % whose status is unknown. The main reasons for failure to achieve good status are atmospheric deposition and discharges from urban waste water treatment plants.
  - Since the publication of the first river basin management plans (RBMPs), Member States have made progress in tackling priority substances, leading to a reduction in the number of water bodies failing to meet standards for substances such as priority metals (cadmium, lead and nickel) and pesticides.
  - More recent concerns, for example newly identified harmful substances such as polybrominated diphenyl ethers or fluoranthener, or issues such as toxicity of mixtures of chemicals, are not reflected in the current list of priority substances

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[22] Hermann M. Bolt, Archives of Toxicology, 2017, The current debate on cost burden by human exposure to endocrine disrupting chemicals, https://link.springer.com/article/10.1007/s00204-017-2014-x

[23] European Commission Impact Assessment Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation: https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

[24] CuBA Study, Part B Environmental Protection

[25] EEA Report 'European Waters- Assessment of status and pressures 2018 (July 2018) p. 47

(the list was established in 2008) and therefore not yet reported by Member States. While these standards are to be met only by 2021, some Member States e.g. Sweden, Luxembourg and Netherlands, have started already to implement these. Experience thus gathered seems to indicate the new standards will be difficult to achieve.[26]

- **Hazardous chemical exposures with implications for eco-system health/resilience:**

  - Much has been done in the EU to ensure that particularly problematic pesticides are identified and banned or restricted. For example, EFSA recently confirmed that most uses of neonicotinoid pesticides such as clothianidin, imidacloprid and thiamethoxam represent a risk to wild bees and honeybees[27]. As a result, the EU Commission has restricted the use of these three pesticides to permanent greenhouses only[28].
  - Total sales of pesticides across the EU as a whole stayed constant between 2011 and 2015 (there was an insignificant increase of 0.2 %). After a small decline from 2011 to 2013, sales increased again in 2014 to just under 400 000 tonnes and came back to the 2011 level in 2015. The EU demand for pesticides has therefore remained nearly stable. While exposure to pesticides cannot be directly equated with pesticide sales, which is why the indicator tells us little about the absolute magnitude of the specific risks, these figures could however indicate that the risks of pesticides to humans and the environment have remained constant.[29]
  - Chemical pollution coupled and sometimes exacerbated by habitat degradation, lack of feed sources, etc., impacts terrestrial organisms.

Respondents to the open public consultation[30] from industry and companies as well as those representing public authorities were overall the most positive about the extent to which the EU legislative framework sufficiently addresses emerging areas of concern while civil society representatives and citizens assigned the lowest scores.

C. Human health and environmental impact evidence and indicators

The trends in the main health and environmental impact parameters that are known, or strongly suspected, to be associated with exposures to hazardous chemicals (e.g. trends in the incidence rates of certain cancers, reproductive diseases, sperm count and quality and trends in animal populations and eco-system health/resilience) are important to consider when examining the effectiveness of EU chemicals policy. However, using human health and environmental adverse effects as direct and reliable indicators of chemicals policy performance needs to be treated with caution because of the attribution challenge: many of the

[26] EEA Report 'European Waters- Assessment of status and pressures 2018 (July 2018) p. 47

[27] https://www.efsa.europa.eu/en/press/news/180228

[28] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

[29] Environmental indicator report 2017 – In support to the monitoring of the 7th Environment Action Programme, EEA report No21/2017, European Environment Agency

[30] Question 24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern?

observed health and environmental adverse effects may derive from multiple causes (life-style, genetics, habitat destruction/degradation, etc.) and it is difficult to determine to what extent exposure to hazardous chemicals contributes to the observed adverse effects. Complicating things further is the fact that observable adverse effects in human health and the environment often do not materialise immediately after exposure. For example, the latency between exposure to carcinogens and the development of cancer can often be as much as 20 years or more.

The available evidence regarding the trends in the main health and environmental impact parameters points to a mixed picture. Some clear improvements have been achieved, for example, in the reduction of cancers related to workplace exposure to a number of targeted carcinogens which has resulted in the estimated prevention of 1 million new cancer cases in the EU over the last 20 years partly through the implementation of the occupation safety and health (OSH) legislation[31]. However, a number of other trends suggest there is still cause for concern, for example:

- The health burdens resulting from most cancers continue to rise in the EU (except for lung cancer) (see Figure 6 for trends for breast cancer). For many cancers, the contributing role of chemical exposures is not yet well understood and defined while at the same time suspected to be a contributing factor. As a result, it is often unclear which specific chemical exposures should be targeted by regulation, in an attempt to eliminate preventable disease causes.

[31] Carcinogens and Mutagens at Work Directive (2004/37/EC).

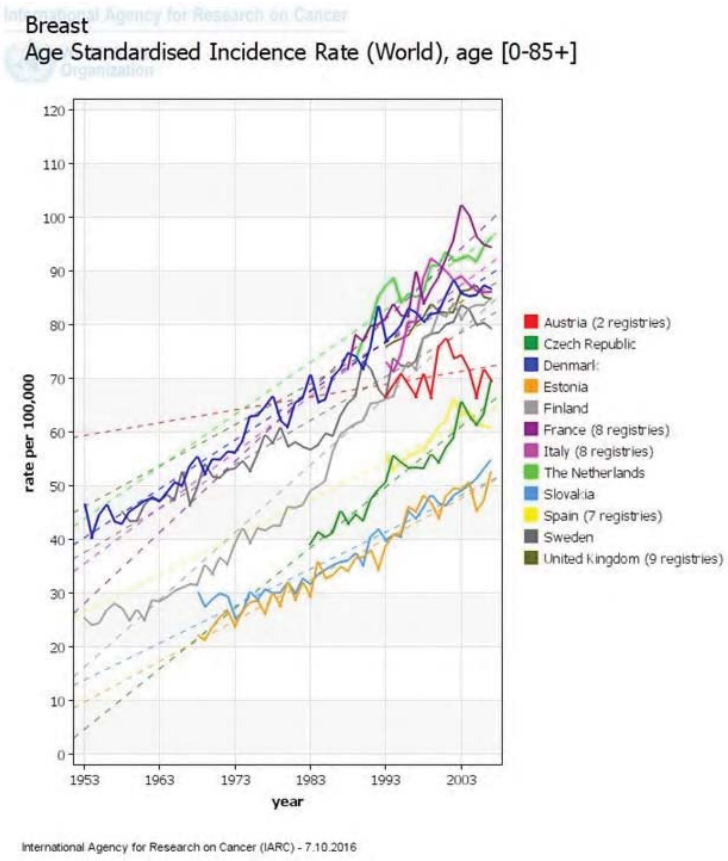

Figure 6 Age-standardised incidence rate trends for breast cancer in several European countries[32]

- The same is true for neurodevelopment and reproductive health. While both male and female fertility rates are decreasing in Europe[33] [34] and while some neurodevelopmental disorders (e.g. autism) increase[35] there is no data on how many of these cases are attributable to exposure to hazardous chemicals. However, it is likely that hazardous chemicals play a role in these adverse health outcomes.[36] Substance categories of concern include certain phthalates, dioxins, perfluorinated chemicals, analgesics, etc. These issues are more generally linked to the need to obtain better information about the spectrum of chemicals with relevance to human exposures and diseases. Achieving this includes improvments regarding data requirements, toxicological testing and screening methods, human biomonitoring as well as better predictive and prioritisation approaches.

[32] CuBA Study, p. 47 Figure 4.2

[33] Temporal trends in sperm count: a systematic review and meta-regression analysis, Hagai Levine et al, Human Reproduction Update, pp1-14, 2017.

[34] Male reproductive disorders and fertility trends: influences of environment and genetic susceptibility Skakkebaek NE, Rajpert-De Meyts E, Buck Louis GM, Toppari J, Andersson AM, Eisenberg ML, Jensen TK, Jorgensen N, Swan SH, Sapra KJ et al. Physiol Rev 2016;96:55–97.

[35] CuBA Study, p. 60

[36] CuBA Study p. 326-328

In the area of environment, the trends also point to a mixed picture:

- Improvements in water quality[37] in some areas may have contributed to some recovery of aquatic ecosystems[38] and the restriction on the use of tributyltin (TBT) as an antifoulant in marine paints has resulted in the recovery of mollusc populations in many ports and coastal areas in Europe[39] (see Figure 7).

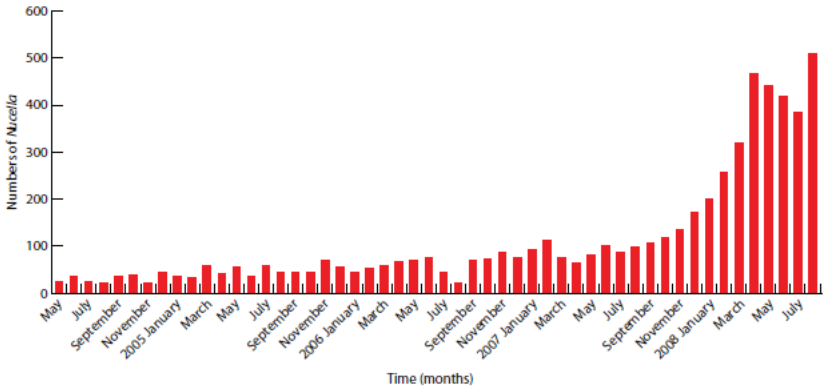

Figure 2.29. The numbers of dog whelks (*N. lapillus*) recorded from a single location (Mewsbrook Groyne at Littlehampton on the southeastern coast of England) every month from May 2004 to August 2008 coinciding with the period immediately after TBT was banned globally as a ship anti-foulant (Morton, 2009). During the study period, the size of the population of *N. lapillus* grew from ~25 individuals to >500, i.e., a 20-fold increase. (Figure redrawn from Morton, (2009); Used with publisher's permission)

Figure 7 Recovery of mollusc populations after the restriction on use of tributyltin (TBT) in marine paints

- Major declines (as high as 50-75%) in the populations of a number of animal species in the EU have been observed over the past 3-4 decades including pollinators, other flying insects[40] (see Figure 8), amphibians, and birds. Europe's wild bee population is in decline with nearly one in ten species facing the threat of extinction and more than a quarter of bumblebee species being currently at risk of dying out[41]. The populations of over 20% of bird species in the EU are in significant decline[42] [43], with the largest declines (46% between 1990 and 2014) for common farmland birds. The causes of these declines requires further research but are likely to be multifaceted including exposure to hazardous chemicals, changes in agricultural practices, habitat degradation, climate change, etc.

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[37] CuBA Study, p185

[38] https://www.eea.europa.eu/publications/state-of-water, p32

[39] CuBA Study, p204

[40] Hallmann CA, Sorg M, Jongejans E, Siepel H, Hofland N, Schwan H, et al. (2017) More than 75 percent decline over 27 years in total flying insect biomass in protected areas. PLoS ONE 12 (10): e0185809

[41] CuBA Study, p. 387

[42] Inger, R., Gregory, R., Duffy, J. P., *et al*. (2014). Common European birds are declining rapidly while less abundant species' numbers are rising *Ecology Letters*, DOI:10.1111/ele.12387

[43] The State of Nature in the EU, Reporting under the EU Habitats and Birds Directives 2007–2012 European Union, 2015

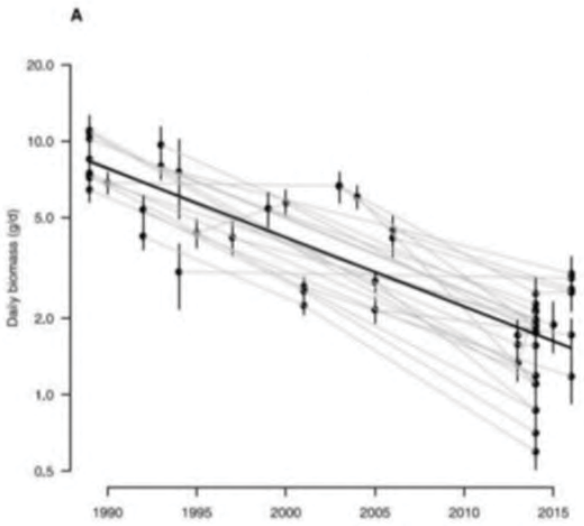

Figure 8 Temporal distribution of insect biomass at selected locations in Germany. Daily biomass across 26 locations in multiple years

The current approach and indicators used in monitoring and assessing human health and environmental impacts could benefit from being more holistic. For instance, such more holistic impact assessments could feed into exposure indicators (e.g. passive sampling, representative mixtures, human biomonitoring) as well as impact indicators (e.g. (eco)epidemiology, effect based methods as proposed in the Water Framework Directive).

5.1.2 Internal market, competitiveness and innovation

The EU chemicals legislation aims to ensure the efficient functioning of the internal market and to enhance competitiveness and innovation. The effectiveness of the EU chemicals legislation in achieving these objectives can therefore be measured by analysing:

- trends in the development of intra-EU sales of chemicals compared to domestic sales;
- trends in the EU export of chemicals and global market share;
- the role that the legislation plays in boosting the competitiveness of the EU chemicals industry and innovation

A. Internal market

The free circulation of chemicals within the internal market through harmonisation and reduction of the barriers for intra-EU trade is one of the main objectives of most of the pieces of the EU chemicals legislation within the scope of this Fitness Check.

The EU chemicals legislation has been instrumental in creating harmonised standards and requirements e.g. product labelling, communication of chemical hazard and risk information, concentration/migration/emission limits, authorisations, restrictions, bans, etc. Over the years, many pieces of chemicals legislation that were previously Directives have been turned into Regulations because of Member State and industry demands for improved harmonisation at the EU level. For example, the CLP Regulation (repealing the Dangerous Substances Directive and the Dangerous Preparations Directive) provides the basis for consistently identifying properties of concern, with this information then used in hazard communication to workers, downstream users and consumers of chemicals. The CLP is broadly considered by industry, Member State authorities and civil society stakeholders to be a more easily applied

system than the previous Directives, with this contributing towards the efficient functioning of the single market. Similar stories can be told for cosmetics, detergents, fertilisers, etc., where EU product specific chemicals legislation has been enacted.

Europe has a large and integrated market of over 500 million consumers and with chemicals sales (within the EU and worldwide) worth EUR 507 billion in 2016[44]. A first finding is that the internal market seems to have been strengthened for chemicals, as shown by the shift from domestic production to intra-EU trade[45]:

- More than 50% of all EU chemical sales in 2016 were intra-EU 'exports' (EU companies selling in the EU single market rather than only in their home country market[46].
- There has been a continuous increase of the share of the intra-EU trade of chemicals in the total sold production of chemicals from 43% in 2006 to 55% in 2016. Removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007 have strengthened this development. Intra-EU sales increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 – a 28 % increase during the last 10 years.
- At the same time, domestic (home country market) sales have dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016. This is an indication that, as a result of a functioning internal market, domestic sales have been replaced by intra-EU sales.

As most rules affecting the safe management of chemicals in the EU have been harmonised over the past decades, it is difficult to speculate about the dimension of the internal market benefits compared to a hypothetical scenario of 28 different sets of chemicals legislation at the national level that would likely have arisen in the absence of harmonised EU rules. An indication of the dimension of those benefits, however, can be drawn from the conclusions of a recent study on the harmonisation of information requirements for poison centres[47]. Those requirements are currently still set at national level. Harmonising those requirements to one single set of requirements alone is assessed to result in an estimated EUR 890 million of annual cost savings for industry in the EU.

Nevertheless, there are areas where divergences persist at Member States level, in particular on emerging and controversial issues where national rules are set ahead of EU legislation (e.g. on restrictions of Bisphenol A in France) or where EU rules are implemented and interpreted in a different way. Although such divergences are in principle undesirable in terms of further development of internal market and harmonisation, they may be necessary to accommodate

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[44] CEFIC Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017

[45] The intra-EU sales 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, CEFIC, 2017

[46] Ibidem

[47] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation);
http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations

strongly diverging national preferences or simply occur shortly after the entry into force of new legal rules for an adaptation period.

An example of such divergences in interpretation is the application of calculation rules and bridging principles for the classification of chemical mixtures. In addition to potentially inaccurate estimates of the hazardousness of mixtures, this may also result in differences in classification and labelling between Member States, the need to relabel products and different legal consequences of classification. Rules based on specific risk assessments may be interpreted and applied differently from Member State to Member State and may even diverge within one Member State, depending on companies and regional enforcement authorities. Moreover, there are significant variations in approaches to, and levels of, enforcement, which works against the achievement of the single market and the establishment of a level playing field for companies[48].

With regards to downstream users, chemicals legislation is helping to ensure that they have better and more comparable information e.g. through the harmonisation of chemical hazard labels and risk communication which allows for the improved management and use of chemicals.

Under a number of pieces of the EU chemicals legislation Member States are not required to report information on enforcement or information provided is of poor quality. This will be reviewed, for example, in line with the commitments in "Actions to streamline Environmental Reporting[49]" as follow up to the Fitness Check of monitoring and reporting of environmental policy.

The majority of stakeholders are clearly in favour of EU-level harmonisation of chemicals legislation. The open public consultation found that this was ranked as very important by citizens and industry. Industry and national authorities considered chemicals legislation to be generally effective in meeting the internal market objective, while citizens considered it to be moderately effective[50]. Citizens, authorities and NGOs generally considered that the weakness in delivery came from legislation not being adapted to issues at stake; whilst industry felt that lack of consistent enforcement was an issue.

B. Innovation

The beginnings of a possible positive trend can be observed concerning substitution to less hazardous or non-chemical solutions[51] for substances hazardous to the environment. In many cases, hazard classification under the CLP alone, for example, is an incentive for substitution as it triggers a number of legal obligations, including labelling and communication to downstream users as well as consumers. Indeed, increasing consumer awareness of the health risks associated with certain hazard classifications (most notably carcinogens) is a powerful

[48] More information on implementation, monitoring and enforcement is available in the 1st FC Study, Annex II, chapter 12 and Annex IV chapter 8, p. 156 ff. However, presentation of quantified information remains problematic, as clearly divergent terminology is applied, e.g. in tables 12-4 and 12-5 of Annex II, p. 198-199.

[49] COM (2017) 312

[50] 1st FC Study, Annex II table 7-13, p. 103, and Annex IV table 3-4, p. 64.

[51] The 1st FC Study Annex IV p. 55

trigger for substitution in the supply chain.[52] In other cases, risk management measures (such as bans and restrictions) triggered by a certain hazard classification provide such incentives[53].

Innovation and substitution are encouraged by many pieces of legislation acting in concert and supported by drivers, such as consumer demands, market circumstances and initiatives e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme[54]. Overall impacts of chemicals legislation on innovation are, however, more complex, as described in the REACH Evaluation[55]. As no specific indicators exist for assessing these and many other factors play a role e.g. intention to develop new applications in order to conquer new markets, it is currently not possible to know whether the EU chemicals legislation has been a major trigger of, or a barrier to, innovation.

The innovation objective may be undermined if alternatives result in similar or even worse risks than the hazardous substance replaced ('regrettable substitution')[56]. The risk of regrettable substitution is one of the disadvantages of risk management measures based on specific risk considerations, because producers do not get any guidance on what properties to avoid in newly developed chemicals.[57] One way to avoid regrettable substitution is to promote grouping approach of substances[58], when they are assessed, or when risk management measures are defined, and to promote the use of generic risk assessment approaches[59].

The effect of chemicals legislation on innovation is viewed very differently among stakeholders. While only 10% of industry respondents identified innovation as a benefit of chemicals legislation, 27% of citizens, 41% of authorities and 70% of NGOs saw innovation as a benefit. Citizens, industry and NGOs consider chemicals legislation to be moderately effective in stimulating competitiveness and innovation, while authorities consider chemicals legislation to be mostly effective in meeting this objective.

In general, stakeholders consider that chemicals legislation is important in triggering innovation towards less hazardous substances and other, non-chemical solutions. For example, 8 out of 14 of the Member States who responded to the targeted consultation carried as a part of this Fitness Check believed that the chemicals legislative framework has had a positive impact on the promotion of access to and use of substances/products with a more favourable hazard or risk profile.

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[52] 1st FC Study, Annex IV, p. 56

[53] Ibidem

[54] https://www.subsport.eu/

[55] REACH Evaluation SWD, chapter 6.1.1.3.3, p. 51 ff.

[56] 1st FC Study, Annex III, p. 45

[57] 1st FC Study, Annex IV, p. 111.

[58] 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.

[59] 1st FC Study, Annex IV, section 4.3, p. 76 ff.

C. Competitiveness

The EU chemicals legislation can improve competitiveness by strengthening the internal market (see above) and by promoting innovation (see above). On the other hand, it can reduce competitiveness compared to other regions of the world by increasing costs for the sector in such a way that competition inside or outside the EU is on an uneven basis i.e. if imports are treated differently to domestic production.

The use of chemicals continues to increase. From 1950 until 2000, chemicals production globally expanded 60-fold by tonnage. Global chemicals sales increased from EUR 1 029 billion in 1996 to EUR 3 360 billion in 2016).

The chemical manufacturing industry is the fifth largest in the EU, accounting for 7% of the EU's industrial production. With annual EU chemicals sales of EUR 507 billion[60], the sector compromises over 28 000 companies and it directly employs around 1.2 million people as well as generating estimated additional 3.6 million indirect jobs. SMEs account for around 96% of the companies in the sector, approximately one third of the direct employment and one third of the sector's value-added.[61] The EU chemicals sector generated a value-added of approximately EUR 115 billion[62] in 2014 representing about 0.8% of EU GDP. In 2016, extra-EU chemicals exports amounted to EUR 146.2 billion and extra-EU imports reached EUR 99 billion (the EU chemicals trade surplus outside the EU being valued at EUR 47.2).[63] In 2017, there was an increase in both exports and imports compared to 2016 (+ 6.5% and + 8.3%).[64]

In terms of international competitiveness, the EU chemical industry in 2016 represented 15.1% of the global market, behind China (39.6%) but ahead of the United States (14.2%)[65]. Although the European share of global sales has decreased (32.5% in 1996) the EU chemicals industry remains internationally competitive as evidenced by the trade surplus of 2016. The decrease in the share of global sales is mainly due to relative growth in other parts of the world, such as China and India, served by their own domestic production. Other potential reasons given for this are high energy prices, currency appreciation, high labour costs, regulatory and tax burdens. Yet the EU remains the largest chemicals exporting region in the world. The main competitive advantage of the EU chemical industry is the high level of technological development, skilled workforce and strong research base.

Over 100 000 chemical substances are present on the EU market today, with some 35 000 chemicals marketed in volumes above 1 tonne per year. Moreover, the number of known

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[60] CEFIC Facts and Figures Report, CEFIC, 2017, p. 5

[61] The intra-EU sales 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, CEFIC, 2017

[62] Eurostat 2014 figure for NACE 20

[63] CEFIC Facts and Figures Report, CEFIC, 2017, p.15

[64] Monthly summary of the Chemicals Trends Report; Cefic; 20 April 2018

[65] Ibidem

chemicals continues to grow. The CAS Registry[66], which already lists over 129 million unique organic and inorganic chemical substances, is reportedly updated with 15 000 new substances every day[67].

It is also interesting to note that several countries in competitor regions (e.g. China, South Korea, and India) consider the EU framework of chemicals legislation to be an important benchmark and are in the process of introducing or aligning their existing legislation to the EU model and standards for chemicals risk assessment and management (mainly REACH).

Citizens, industry and NGOs consider chemicals legislation to be moderately effective in stimulating competitiveness and innovation, while authorities consider chemicals legislation to be mostly effective in meeting this objective[68]. Despite differences in implementation of the UN Global Harmonised System (GHS) building blocks worldwide, numerous industry stakeholders believe that the GHS (implemented via the CLP Regulation) has helped to reduce technical barriers to international trade within the EU and externally[69]. Nevertheless, industry remains concerned that stricter measures in the EU vis-à-vis the main competitor regions of North America and Asia affect the competitiveness of the EU chemicals industry. Industry stakeholders worry that differences in approaches to risk management on a global scale could make the EU export market less competitive.

It should be noted that, in principle, any competitiveness impact is mitigated by the fact that companies, whether they export from the EU or import in the EU, face the reciprocal legal rules e.g. a non-EU company willing to place its products on the EU market need to ensure that these are compliant with the EU rules and vice versa when an EU company wants to export its products. Enforcement of EU rules vis-à-vis imported products remains however an issue.

5.2 Evaluation question: what factors affect (either positively or negatively) the correct functioning of the EU legislative framework for the hazard identification and risk management of chemicals? What are the consequences or effects that were not originally planned for?

An effective framework of chemicals legislation ensures the timely and sound identification of chemical hazards and risks, the appropriate control of human and environmental exposures to hazardous chemicals and, for hazardous chemicals where the exposures cannot be reliably controlled, a progressive shift towards the use of less hazardous chemicals (substitution) including non-chemical solutions.

The basic steps of the risk management procedures and processes applied to chemicals within the EU framework of chemicals legislation are:

- hazard identification (based on toxicity tests and other relevant information);
- dose (concentration) – response (effect) assessment;

[66] CAS Registry Numbers (often referred to as CAS RN® or CAS Numbers) are universally used to provide a unique, unmistakable identifier for chemical substances.

[67] https://www.cas.org/content/chemical-substances#how (accessed 30.03.2017)

[68] 1st FC Study, Annex II, Table 7-13, p. 103

[69] 1st FC Study, Annex II, p. 186.

- exposure assessment – exposure scenarios for relevant uses of the chemical (based on models and measurements of the occurrence of the chemical);
- risk characterisation; and
- risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

The correct functioning of each of these risk management steps can be affected by one or more key performance factors, including:

- Whether the necessary scientific knowledge (including recognised and accepted test methodologies for hazard identification) and data/information (e.g. on chemical uses and exposure scenarios) are available, are used appropriately and can be shared between different risk assessment regimes to ensure the coherence of findings and to avoid duplication of effort.
- Whether and how the hazard identification and risk assessment process is triggered.
- Whether the overall 'speed' of the hazard identification and classification and risk assessment processes can handle the quantity of existing and newly designed hazardous chemicals placed on the market. This is not simply a question of efficiency but, fundamentally, of effectiveness. If the framework fails to identify and address the hazards and risks of chemicals in a timely manner, its effectiveness is reduced. This also requires further discussion on how to better prioritise and in which areas and/or for which substances such prioritisation would be necessary.
- Whether the necessary competences and resources are available at EU and Member State level to ensure robust and timely hazard identification/assessment/classification, risk assessment and risk management decision-making.
- Whether the use of generic risk considerations (GRC) and specific risk assessment (SRA) based approaches is appropriate and balanced.
- Whether the desired transition to non-animal test methods is happening and is effective.
- These different factors can affect the performance of one or more of the risk management steps outlined above. For example, poor quality or missing data affects the ability to correctly identify and classify hazards, to determine reliable exposure scenarios, and, therefore, to arrive at a robust risk assessment. The assessment of the effectiveness of the framework of EU chemicals legislation has, therefore, been structured and presented according to these factors.

5.2.1 Data, knowledge and information

Scientific understanding and the availability of good-quality, reliable data underpin the effective functioning of the EU chemicals legislation. It includes, among other things, knowledge and information on chemical properties, data on eco-toxicity of chemicals and on chemical uses and exposures to chemicals (including occurrence in, and release from, articles (consumer products)).

A. State of science / state of scientific understanding

The scientific understanding of how chemicals interact with living organisms including the adverse effects that can be caused, the dose response relationships, and the real exposures levels has improved considerably over the last two decades in the EU. Support via the Commission's research framework programmes and the Life Plus initiatives has contributed significantly to the recent progress.

Although knowledge gaps are progressively being closed, the understanding of mechanisms and pathways of how chemicals interact with organisms (i.e. the Adverse Outcome Pathways (AOP)[70] of chemicals) is still far from complete. An understanding of AOPs improves the ability to predict chemical toxicity, avoid animal testing, and make better informed regulatory decisions.

As regards exposure data, there continue to be significant gaps in our knowledge of which chemicals and their combinations, and at what concentrations, human and the environment are being exposed to. To address the issue for humans, the EU Commission has funded the European Human Biomonitoring Initiative (HBM4EU[71]). However, a similar holistic initiative for animals, plants and eco-systems is currently lacking[72] [73]. Further, the screening of 'unknowns' (i.e. sampling and testing designed to detect unsuspected hazardous chemicals) in humans and the environment is missing. Chemical monitoring, whether in humans or the environmental species, is a powerful tool to assess aggregated exposure to hazardous chemicals and their mixtures from various sources. It helps assess the effectiveness of regulatory risk control and measures and compliance activities as well as identify as yet undetected risks. However, chemical monitoring is not a suitable tool for predictive (ex-ante) risk assessment, as the monitoring detects exposures that have already happened. Therefore, to complete the knowledge base on exposure additional information would be needed regarding the use, presence of hazardous chemicals as well as the frequency with which people and workers come into contact with these in their daily lives.

B. Data quality

Much has been done under the EU chemicals *acquis* to improve the quality, reliability and reproducibility of hazard and risk assessment studies and data. Quality standards are prescribed for how hazard and risk analysis is to be conducted, including the testing methodologies. Toxicity studies submitted by producers or importers need to be performed

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[70] http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[71] https://www.hbm4eu.eu/

[72] However the monitoring of emerging pollutants is carried out since 2011 by the Network of reference laboratories for monitoring emerging environmental pollutants (NORMAN Association) together with the Commission to support the Common Implementation Strategy of the Water Framework Directive. More information is available at https://ec.europa.eu/jrc/en/publication/norman-interlaboratory-study-ils-passive-sampling-emerging-pollutants

[73] SOLUTIONS is a project funded by the EU aiming at searching for new and improved tools, models, and methods to support decisions in environmental and water policies. The overall goal of the project is to produce consistent solutions for the large number of legacy, present and future emerging chemicals posing a risk to European water bodies with respect to ecosystems and human health. More information available at https://www.solutions-project.eu/project/#article-24

according to validated test guidelines (as far as such guidelines exist for specific endpoints), such as those adopted by the Organization for Economic Co-operation and Development (OECD), the US Environmental Protection Agency (US EPA), and the European and Mediterranean Plant Protection Organization (EPPO). In addition, the laboratories where chemical hazard and risk assessment studies are performed must comply with the requirements stipulated within the system for Good Laboratory Practices (GLP), which was introduced to ensure integrity and quality of the laboratory studies. The existence of these requirements has helped make data more reproducible, reliable and trustworthy. In addition, it has helped to achieve the mutual acceptance of data across jurisdictions and thus reduce costs for industry as well as the number of animals used in testing.

Beyond the reproducibility of data, there are only certain pieces of chemicals legislation where the quality and completeness are being systematically checked by public authorities; primarily where approval/authorisation is needed before the substance/product can be placed on the market (e.g. plant protection products, biocidal products).

The majority of respondents to the open public consultation[74] from Group 2 Industry association/business (63% or 111) and from Group 3 Public authority (51% (18)) replied that they did think the quality requirements were appropriate. The most common response from Group 1 Citizens was 'don't know' at 48% (13), followed by 'yes' at 41% (11). For Group 4 NGOs and others, though, the most common response was 'no' at 44% (21) with 31% (15) saying 'yes' and 25% saying 'don't know'. Views on the extent to which GLP is considered to be important for ensuring reliability of information were, however, diverging and somewhat contradictory.

C. Data/information use

The EU chemicals legislation allows, and in some cases requires, both industry and regulatory authorities to consider 'all available information' (including peer-reviewed studies published by academic researchers) when performing and reporting on hazard or risk assessments.

A number of stakeholders, however, expressed concern that potentially relevant and useful peer-reviewed scientific studies and data were being ignored or overlooked during regulatory hazard and risk assessments because they are not GLP-compliant. Examples of highly debated cases, where the reliability (i.e. inherent quality) and relevance of peer-reviewed studies have been contentious include assessments of the brominated flame retardant decaBDE, bisphenol A, and the herbicides atrazine and glyphosate. In addition, industry and NGO stakeholders raised concerns that different EU agencies (e.g. ECHA and EFSA) have different expectations and quality acceptance criteria for data used under different legislation, with some more conservative than others in their approach to the uptake of potentially relevant non-GLP data or data not produced according to internationally accepted standardised protocol.

There are two issues with the uptake of peer-reviewed scientific studies in the regulatory hazard and risk assessments.[75] First, scientific peer-reviewed studies are often not adequately documented which results in difficulty assessing their reliability. In part, this arises from a lack of awareness by scientists (and scientific journal publishers) of the EU regulatory

[74] Question 18: Do you consider the quality requirements aimed at ensuring the reliability and reproducibility of safety data for chemical to be appropriate?

[75] FC+ Study p. 45-47

assessment and data quality criteria when publishing their results. Several recommendations have been made by academic researchers, consultancies and governmental representatives to ensure sufficient reliability and reporting of peer-reviewed studies[76]. However, progress has been slow so far. The second issue is that the current weight-of-evidence[77] practice tends to give a higher weight to a study performed according to standardised protocols and GLP as opposed to a scientific peer-reviewed study that has not been performed according to standardised protocol and GLP, even if the peer-reviewed study is very well documented. This warrants some attention and action because the peer-reviewed studies may use test designs, test species and test endpoints that are more sensitive and relevant than those used in standardised studies and can, therefore, be an important complement to the standardised studies.

It remains a challenge for EU and Member State authorities to check whether 'all available data' has been used in the development and submission of industry performed risk assessments. However, the recent Commission proposal to improve transparency and public trust in scientific studies on food safety takes steps forward to address this in the area of food-related legislation by creating a common European register of industry-commissioned studies[78].

D. Data access and sharing

Data sharing between different legal clusters and, therefore, between Member States competent authorities, the Commission services and EU agencies is an important factor that influences the effectiveness of the EU chemicals legislation.

As the information used in risk assessments is held in a variety of databases across the EU with no centralised access point, part of this issue relates to awareness of what data is available where. For chemical occurrence data generated as a result of chemical monitoring activities, this has recently started to be addressed by the Information Platform for Chemical Monitoring data (IPCHEM[79]). IPCHEM provides a single access point to chemical occurrence data held by all Commission services and EU Agencies and also by Member States and scientists and could become an important information source provided that IPCHEM continues to be populated with the data. For hazard data, the problem continues to exist.

Another part of the issue is having full access to data which, in some cases, has not been possible due to intellectual property rights, legal concerns or existing agreements between the

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[76] Ågerstrand, M., Sobek, A., Lilja, K. *et al.* (2017). An academic researcher's guide to increased impact on regulatory assessment of chemicals. *Environmental Science: Processes & Impacts*. 19: 644-655. DOI: 10.1039/C7EM00075H.

[77] The weight of evidence approach involves the use of a combination of information from several independent sources to give sufficient evidence to fulfil an information requirement. This approach is beneficial when (i) the information from a single piece of evidence alone is not sufficient to fulfil an information requirement and/or (ii) individual studies provide different or conflicting conclusions. The weight given to the available evidence depends on factors such as the quality of the data, consistency of results, nature and severity of effects, and relevance of the information. The weight of evidence approach requires use of scientific judgment and, therefore, it is essential that it's use is underpinned by adequate and reliable documentation

[78] http://europa.eu/rapid/press-release_IP-18-2941_en.htm

[79] https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html#intro

EU agencies and Member States.[80] For example, the chemical occurrence data being collected by EFSA under the EU food legislation or by European Environmental Agency (EEA) for its 'State of the Environment' reporting cannot be re-used for other purposes or by another entity, at least not without specific agreement from the individual sources. Issues with access to REACH registration data have created obstacles for the hazardous chemical prioritisation exercise under the Water Framework Directive, but the situation is improving. A wide range of stakeholders expressed a need for further action to improve access to and sharing of data between regulatory frameworks.

Awareness of, and readily available access to knowledge and to scientific peer-reviewed data is another important aspect. Searching for, and getting access to, peer-reviewed studies is resource demanding and therefore, they are not used to the extent that they could be in regulatory assessments[81] [82]. A proposal was made to develop a tool that provides a single point of reference to identify, to access and to retrieve relevant scientific studies in order to enhance accessibility of peer-reviewed data to policy makers and to industry stakeholders.

E. Hazard data/information requirements

Data/information requirements are legal obligations placed on manufacturers or importers to generate and make available relevant hazard/exposure/risk assessment information to the authorities (and, in some cases, to other parties along the supply chain). Setting the data/information requirements requires a carefully balanced trade-off between protection of human health and the environment on one side and burden on economic operators on the other side.

Information requirements vary considerably between the different pieces of the EU chemicals legislation ranging from extensive hazard data requirements to only partial or no hazard data requirements. Such differences in hazard data requirements are in general justified by differences of intended use of products and substances and likely exposures to the hazardous chemicals concerned. Data requirements are the most demanding for substances that are designed purposely to be very biologically active and/or to which there are high exposures for humans or the environment, such as pesticides, biocides and food additives. Less hazard data is required for chemicals that are not designed purposely to be biologically active and to which exposures are expected to be lower (compared to pesticides or biocides) such as food contact materials or cosmetics.

The legislation with less stringent requirements (toys, textiles, environmental legislation) are entirely dependent on the generation of data under other legislations (primarily the CLP and REACH), on the data from academic literature or on data supplied voluntarily at the own-initiative of the industry parties concerned.

Hazard data requirements underlying the legislative framework are considered in principle by most stakeholders to be adequate, but there are some gaps that affect the achievement of the

[80] FC+ Study p. 79-84

[81] E. Ingre-Khans, M. Agerstrand, A. Beronius and C. Ruden, Transparency of Chemical Risk Assessment Data under REACH, Environ. Sci.: Processes Impacts, 2016, 18, 1508-1518.

[82] M. Agerstrand, M Brenig, M. Fuhr and J. Schenten, Environ. Sci.: Processes Impacts, 2017, 19, 1466.

objectives of the EU chemicals policy. These are linked to the availability and regulatory uptake of test methods and guidelines. These are:

- Lack of information requirements for certain environmental adverse effects e.g. soil biota, reptiles, and other terrestrial animal species. Current data requirements rarely extend beyond toxicity to the aquatic environment.
- Lack of information requirements for certain human health adverse effects e.g. neurotoxicity, immunotoxicity and epigenetics[83]. The two elements contained within the Extended One Generation Reprotoxicity Study test guideline that have been developed specifically to detect neurotoxic and immunotoxic effects are optional and are rarely performed.[84]
- A lack of information requirements as regards identification of endocrine disruptors. While existing data requirements in some cases allows to detect some of the adverse effects caused by chemicals having endocrine disrupting properties, the existing data requirements do not allow to identify endocrine modes of action, which is required to identify endocrine disruptors.

F. Exposure data requirements and assessment

Exposure to hazardous chemicals can occur during each of the four key phases of a product life cycle: production, use, end-of-life, and reuse/recovery. Hence exposure scenarios developed under the different pieces of the EU chemicals legislation need to adequately capture these four aspects.

Whilst the importance of developing robust and realistic exposure scenarios is generally well recognised and incorporated in the EU chemicals legislation, detailed examination of the exposure assessment step under the different pieces of legislation has revealed a number of issues and weaknesses.

Exposure scenarios used in setting 'safe' exposure limits, are established based on intended and foreseeable use of the product (e.g. cosmetic, plant protection, biocidal, detergent products) or foreseeable/predictable situation (e.g. occupation or industrial settings). Exposure data requirements will therefore vary accordingly. The main difficulty is in determining realistic, acceptable and robust exposure scenarios for several reasons:

- Exposure assessments typically make use of a combination of models, laboratory data and monitoring to calculate the potential exposure within a given scenario. In order to successfully conduct exposure assessments, the models in use have to be underpinned by data, and likewise real world analysis is needed to validate results. Additional

[83] Study of heritable changes in gene expression that does not involve changes to the underlying DNA sequence. Epigenetics literally means "above" or "on top of" genetics. It refers to external modifications to DNA that turn genes "on" or "off." These modifications do not change the DNA sequence, but instead, they affect how cells "read" genes. Epigenetic changes alter the physical structure of DNA. Epigenetic changes can be heritable to the next cell generations (mitotic) but also to the next generation of an organism (meiotic).

[84] The Test Guideline is designed to provide an evaluation of reproductive and developmental effects that may occur as a result of pre- and postnatal chemical exposure as well as an evaluation of systemic toxicity in pregnant and lactating females and young and adult offspring. For more detailed description please consult https://www.oecd-ilibrary.org/environment/test-no-443-extended-one-generation-reproductive-toxicity-study_9789264185371-en

monitoring to validate models is often a step that is overlooked in EU risk assessment processes and this undermines the quality of the results.[85]

- There is also evidence that for hazardous chemicals with a broad range of applications in a myriad of different consumer products, industry and public authorities may be unaware of many uses. As an example, a recent Swedish KEMI market survey report[86] on articles treated with biocides revealed a significant lack of knowledge and awareness by industry about just how widespread the uses are of biocidal products in consumer products placed on the market in Sweden.
- In addition, exposure scenarios and the underlying models make assumptions about the volumes of chemicals used and, therefore, about the volumes emitted to the environment (of a potential concern for both the environment and human health (consumers/general public). There are, however, no requirements on producers to make available substance-specific information on actual amounts marketed. This makes it difficult for authorities to make ex-post assessments of the overall load of chemicals to the environment. As an initial step, the Commission recently began to tackle this issue for veterinary antibiotics where reporting obligations on volumes used have been introduced. As an initial step, the Commission recently began to tackle this issue for veterinary antibiotics where reporting obligations on volumes used have been introduced.[87]
- Yet, even when all uses and amounts are known, determining realistic exposure scenarios can still be problematic where consumer behaviour is difficult to predict. Determining and characterising exposure in an occupational setting by way of comparison is relatively more straightforward, as the exposure scenario is more controlled and predictable.[88]

Each exposure scenario/model that is developed as a part of the risk assessment decision-making process assumes certain worker/consumer behaviours happen and certain risk management controls are implemented e.g. the application of pesticides by farmers. It is important that these assumptions are actually tested and checked in reality in order to validate and calibrate them. Real life monitoring to validate exposure models is often a step that is overlooked in EU risk assessment processes.

Another factor to consider is the capacity of SMEs to perform the risk assessment at the workplace based on the exposure scenarios provided in the safety data sheets (SDS) due to the limited resources and expertise. ECHA together with industry organisations developed a set of tools to simplify and harmonise the elaboration of exposure scenarios for the chemical safety report and their incorporation in the SDSs.[89]

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[85] FC+ Study p. 51

[86] Market survey on articles treated with biocides, KEMI PM 6/16

[87] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jp

[88] FC+ Study p. 68

[89] Many guideline documents are available on https://echa.europa.eu/safety-data-sheets

G. Test methods/guidelines

The EU chemicals *acquis* relies on the availability of recognised and standardised test methods to identify the different hazard properties of a substance or a mixture. Validated test methods and guidelines help to ensure comparability and reproducibility of data produced and thus increase the reliability and quality of data. International agreement on the validated test guidelines (under OECD) ensures the mutual acceptance of the data among countries and regions, which lowers the technical barriers to trade and reduces also the number of animals used for testing. For these reasons, the EU and its Member States always develop test guidelines under the OECD programme for chemical testing.

The existing test guidelines cover the majority of known adverse effects on human health. However, recent reviews[90] and consultation with Member States authorities pointed to some gaps in existing OECD guidelines, which means that certain hazards might not be identified and addressed. The main gaps concern:

- Standardised test methods and guidelines are lacking for investigating certain environmental adverse effects, for example: soil, biota, reptiles, and other terrestrial animal species.
- Inadequate coverage and identification in existing test methods and guidelines of certain hazards, such as neurotoxicity, immunotoxicity and epigenetics[91].
- As regards endocrine disruption, there are no suitable models for some endocrine-related diseases such as breast and hormonal cancers, endometriosis, metabolic syndrome, insulin resistance or IQ drop. Furthermore, methods for detection of endocrine pathways other than oestrogenic, androgenic, thyroidal and steroidogenic in mammals and fish are missing.
- Current chemical safety tests may need to be adapted or newly developed to capture different peculiarities of nanomaterials.

5.2.2 Policy on protection of animals used for scientific purposes

Identifying the hazardous properties of chemicals in terms of potential effects on human health and the environment has traditionally relied on the use of animals in laboratory testing. The efforts to avoid or reduce the use of animals for testing purposes by using information from alternative (non-animal) test methods has become in the recent years a stated objective under several pieces of the EU chemicals legislation e.g. the Biocidal Products Regulation, the Plant Protection Products Regulation and the Cosmetic Products Regulation, complemented by the Directive on animals used for scientific purposes[92]. The Cosmetic Products Regulation is the most stringent legislation as it prohibits testing finished cosmetic

[90] CuBA study p. 368.

[90] EU OSH (2017): What are the main work-related illnesses and injuries resulting in death and in DALY: HYPERLINK "https://visualisation" https://visual isation. osha.europa.eu/osh-costs

[91] Epigenetics literally means "above" or "on top of" genetics. It refers to external modifications to DNA that turn genes "on" or "off." These modifications do not change the DNA sequence, but instead, they affect how cells "read" genes. Epigenetic changes alter the physical structure of DNA. Epigenetic changes can be heritable to the next cell generations (mitotic) but also to the next generation of an organism (meiotic).

[92] 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

products and cosmetic ingredients on animals and marketing finished cosmetic products and ingredients in the EU which were tested on animals. Some testing strategies have been developed, also leading to an overall reduction of the use of animals.[93]

Significant amounts of resources have been directed to the development and promotion of alternative (non-animal) tests. Over the last decade, EU funding in the field of research into alternatives has remained stable with, on average, more than EUR 35 million per year awarded to new research projects. In addition, the Commission is also operating the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) with an annual budget since 2012 of approximately EUR 6.5 millions[94].

Several alternative chemical hazard assessment methods are available for topical toxicity, genotoxicity and skin sensitisation, including OECD test guideline methods[95], and have become part of the standard data requirements in the regulatory context. In addition to these *in vitro*[96] methods, grouping and read across approaches[97] are frequently used in the regulatory context. However, not all of them are used to the same degree. In general, the use of read-across and grouping is predominant, according to ECHA's evaluation reports. Under REACH (which is outside the scope of the Fitness Check), they are used mainly to wave the obligation on registrants to generate animal data but less for regulatory decisions.

Although a lot has been invested in the development of the non-animal test methods, their uptake and use in regulatory hazard/risk assessment remains relatively limited due to the following reasons:

- Complete replacement is not currently possible because alternative methods are not available for all endpoints, in particular in view of systemic/chronic toxicity. Although classification and labelling is possible with validated in vitro tests for the endpoints mentioned above i.e. skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation, sub-categorisation for classification categories is not yet possible in all cases[98].

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[93] See for example the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) Strategy to replace, reduce and refine the use of fish in aquatic toxicity and bioaccumulation testing available at https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eurl-ecvam-strategy-replace-reduce-and-refine-use-fish-aquatic-toxicity-and-bioaccumulation

[94] REACH REFIT, Annex IV

[95] Skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation

[96] The term *in vitro* ("in the glass") refers to the technique of performing a given experiment in a test tube, or, generally, in a controlled environment outside a living organism. For a more detailed description of different alternative methods please refer to EURL ECVAM FAQs https://eurl-ecvam.jrc.ec.europa.eu/faqs_animal_testing_2013

[97] Read-across involves the use of relevant information from analogous substance(s) (the 'source' information) to predict properties for the 'target' substance(s) under consideration. If the grouping and read-across approach is applied correctly, experimental testing can be reduced as there is no need to test every target substance. For more information please refer to ECHA's guidance and other publications available here https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

[98] Regulatory fitness check of CLP and related legislation - Case study 4, p. 9-12

- Industry as well as public authorities are reluctant to accept the available new testing methods as their interpretation requires a different type of expertise. There is also some uncertainty on the industry side about the regulatory acceptance of data generated via these new test methods. As the acceptance of alternative methods is lower in other countries, it might also mean that industry will have to conduct additional tests for different approval procedures[99].

While a lot has been done to improve and develop alternative methods, the EU funding allocated to development and refinement of animal test methods (e.g. for neurotoxicity) has been minimal and is currently mainly part of the basic research. In addition, the activity on the improvement of animal models under OECD, in particular for mammalian endpoints, is low.

However, it should be noted that because there are still some gaps for particular human health effects which are not covered by the existing test guidelines, new methods for the assessment of these hazards are needed, i.e. the development of both animal and non-animal tests. The aim is to use the best science available to identify hazards relevant for human health and the environment. Data gathering can be based on use of animal data, alternative methods, or a combination of both, what counts is that it is fully accepted for the regulatory decision making. This implies allocation of adequate resources for both testing approaches, animal and non-animal. This also implies removing barriers for acceptance of available non-animal methods e.g. improving cooperation and exchange of information between 'non-animal' and 'animal' communities and to make comparisons of available information from non-animal data and animal data. In addition, introduction of more alternative test methods into the standard data requirement, where necessary and possible, would further increase the acceptability of non-animal data for regulatory decision making.

5.2.3 Triggering Hazard/Risk (Re-)Assessment

A. Triggering of hazard/risk assessments

Triggering the hazard and risk identification/assessment is the first step to be taken for an effective hazard and risk assessment to occur. Without a trigger (mandatory or not), potential risks would not be identified and managed. The obligation to perform hazard and risk assessments sits primarily with the industry in line with the principle of reverse burden of proof[100]. It is only in the event of suspicion about a potential hazard or risk that Member State and/or EU regulatory authorities take the initiative to carry out risk/hazard assessment.

Industry performed hazard/risk assessments are triggered by the legal obligation to ensure the safety of the products placed on the market or safe use of chemicals. The effectiveness of the triggering, i.e. whether they are done and to what quality, is influenced by the following aspects:

- The obligation to gain authorisation to place a substance or product on the market. This works well as the producer/applicant has a commercial interest to gain

[99] Regulatory fitness check of CLP and related legislation - Case study 4, p. 19-20

[100] Reverse burden of proof means that industry is responsible for ensuring the safe use of their chemicals and therefore carrying out the risk assessment and ensuring the risk management of their chemicals, including testing. Public authorities are responsible for checking if this obligation is properly implemented and, where not, to quickly and efficiently propose measures to manage potential risks appropriately.

approval/authorisation e.g. the Plant Protection Products Regulation, the Biocidal Products Regulation.

- CE marking requirements. When a CE marking is required in order to place a product on the market, it can have a similar effect to what is described above for authorisation.
- Existence of a prescription for how the hazard and/or risk assessment should be performed and documented. Where there is no obligation to document the hazard and/or risk assessment it is often difficult to know and verify whether the hazard and risk assessment has been performed. For example, the Cosmetic Products Regulation requires the responsible party to ensure that the product has undergone a safety assessment and that a cosmetic product safety report is developed for that product (see Annex I of the Regulation). On the other hand, the General Product Safety Directive (GPSD) is an example where the form of risk assessment and its documentation is not specifically prescribed.
- Existence of an obligation to communicate the outcome of the assessment to public authorities and/or downstream users. The existence of such an obligation makes the control and enforcement of performance of assessment by public authorities easier. For example, some legislation requires industry to communicate the performed hazard /risk assessment along the supply chain (REACH chemical safety data sheets) or submit it to the regulatory agency (CLP self-classifications) and some legislation does not require communicating the outcome to anybody (e.g. the GPSD).

Where there is only a general obligation for industry to ensure the safety of the products placed on the market, i.e. no legal requirement to perform a risk/hazard assessment, ensuring that this obligation is respected relies on Member States and in particular on market surveillance activities carried out at national level. The recent ECHA report[101] has shown that the compliance with the general safety obligation is challenging.

Authority-initiated hazard and/or risk assessment occurs in two situations:

1. Where the industry is submitting an application to require the approval or authorisation. This is a well prescribed and effective process with legal deadlines on authorities to finalise the assessment and decide on the approval/authorisation. It is the best incentive for industry to make studies on their substances/products, submit data to authorities, build collective knowledge and demonstrate their safety.
2. In case of specific suspicion of a potential risk to human health or the environment. The triggering is thus dependent on the knowledge or suspicion of potential risks or hazard and on the resources and priorities of the competent authorities.

The authorities' decision to investigate suspected chemical hazards and/or risks is based on the information from hazard and risk assessments performed by industry, from the academic research and in some cases from the hazard and exposure data generated by the authorities themselves. The introduction of REACH registration obligations and the CLP self-classification requirements has led to a significant improvement in the knowledge and identification of most hazardous substances. The experience shows that the availability of, and access to, chemicals data help to evaluate the hazard profile of a chemical and triggers the risk assessment process relatively quickly. However, as explained above, some difficulties

[101] https://echa.europa.eu/-/inspectors-find-phthalates-in-toys-and-asbestos-in-second-hand-products

have been identified regarding the access and availability of these data to public authorities and other experts involved.

The triggering of authority-performed hazard/risk assessments e.g. by the Commission under the Water Framework Directive and the Industrial Emissions Directive or by a Member State under the Cosmetic Products Regulation through a safeguard clause,[102] is in general rather slow. Experience shows that it usually takes several years[103] between when the first concerns and evidence were published in the academic journals and when the regulatory hazard and risk assessments are triggered. This is mainly because it is time consuming to continuously monitor scientific papers and publications and there is no mechanism for identifying early warnings. Furthermore, in some cases, reference to only one scientific article or review can be considered as an insufficient basis for triggering an authority-initiated risk assessment as it may be challenged by evidence reported in other articles. Last but not least, availability of and limited resources at Member State level following the financial crisis can lead to streamlining resources for risk/hazard assessment where suspicion is considered to be stronger and more evidence is available.

Respondents to the open public consultation were asked to indicate their satisfaction with risk assessment and characterisation[104]. These elements of the EU chemicals legislations received the lowest weighted score from Group 1 citizens (2.5 (28)) and Group 4 NGOs and others (2.6 (45)). This compares with scores of 3.2 from Group 2 Industry association/business (177) and 3.7 from Group 3 Public authority (33).

B. Triggering of hazard/risk re-assessments

Triggers for risk/hazard re-assessment vary between different pieces of legislation depending on their specific aims and provisions. Legislation governing for example toys, explosives, medical devices, and pressurised equipment requires existing hazard and/or risk assessments already performed by industry to be continually updated. The legislation itself does not give a specific frequency or conditions that would trigger a reassessment. However there is a requirement to take account of the "generally acknowledged state of the art" meaning when new scientific knowledge and/or evidence appear. While there could be a degree of ambiguity as to what this term means, guidance documents and harmonised standards are available e.g. the Toy Safety Directive.[105]

Other industry-driven legislation typically states specific occurrences and conditions that will trigger a new assessment or review. For example, reassessment can be required:

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[102] FC+ Study p. 59

[103] Polychlorinated Biphenyls (PCBs) are among a group of man-made chemicals that are known as Persistent Organic Pollutants (POPs). PCBs were commercially produced world-wide on a large scale between the 1930s and 1980s. In the 1970s, owing to severe concerns pertaining to their human toxicity, suspected carcinogenicity, and environmental persistence, several countries limited the use of PCBs. Finally in 1985, the use and marketing of PCBs in the European Community were very heavily restricted. Measures regarding the disposal of PCBs and PCTs and equipment containing PCBs were taken in 1996. In 2001, the Commission adopted a Community Strategy on Dioxins, Furans and PCBs aimed at reducing as far as possible the release of these substances in the environment and their introduction in the food chains.

[104] Question 17

[105] FC+ Study p. 64

- if there are changes in the design or formulation of a product or working conditions (e.g. asbestos).
- after specified time limits for product or active substance approval (e.g. the Biocidal Products Regulation, the Plant Protection Products Regulation, the Ecolabel Regulation). For biocidal products for example, evidence suggests that this is rarely done during the life of the approved/authorised substance/product, and rather done at the time of the renewal of the approval/authorisation.[106]
- in cases where new scientific or technical data become available (e.g. food contact materials, detergents).[107]

It is noted that a key factor in the triggering of a review of re-assessment of chemical substances and products across the chemicals legislation framework is the surveillance and monitoring of products at Member State level. The ability and capacity to monitor compliance is likely to vary considerably between Member States.

For the Commission-driven risk assessment (i.e. under the Industrial Emissions Directive and the Water Framework Directive), there are specified time periods for review and re-assessments to be made.

All the factors identified above for triggering of the initial authority performed assessment are also valid for re-assessments. The effective triggering of re-assessments tends only to happen when there is an automatic trigger in the legislation such as expiration of the approval of active substances for plant protection products (usually 10-15 years). Earlier re-assessments for plant protection products are possible based on new evidence (was done for neonicotinoid pesticides) but rare. The few examples of where re-assessments have been triggered as a result of new evidence coming to light include harmonised classifications under the CLP Regulation and in the Cosmetic Products Regulation which led to revision of Annex II. There are also examples of re-assessments of acceptable levels of exposure, such as amendments of the Environmental Quality Standards (EQS)[108] under the Water Framework Directive or in food law including the food contact materials legislation. The EQS Directive includes a requirement for the results of monitoring of priority substances under the Water Framework Directive to trigger reviews under certain other pieces of legislation if additional measures appear necessary to meet the relevant standards.

Overall, however, re-assessments are rarely triggered when new evidence emerges unless it is linked to the legally required re-approval/authorisation of product in order to keep it on the market.

5.2.4 Hazard classification

The communication of chemical hazard properties to downstream users is an important risk management measure that helps ensure the safe handling of chemicals and mixtures. It needs to be underpinned by reliable, robust hazard classification. Hazard classification is also crucial for other risk management processes within the framework of EU chemicals legislation, such as restrictions or authorisations.

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[106] FC+ study p. 64

[107] FC+ Study p. 64

[108] Directive 2008/105/EC as amended by Directive 2013/39/EU – Article 7a

A. CLP classification

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 to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). Harmonised classifications are listed in Annex VI to the CLP Regulation. Provisions linked to the harmonised hazard classification of chemicals serve as the basis for risk assessment and risk management measures under several pieces of downstream chemicals legislation.

Under the CLP, a substance must be self-classified by manufacturers, importers or downstream users when it has no harmonised classification in Annex VI to the CLP and it presents hazardous properties. All relevant hazard classes must be assessed by the manufacturer or importer and the self-classification must be applied to all hazard classes for which the classification criteria are fulfilled. This classification and labelling information for the substances to be placed on the market is then notified by manufacturers and importers to the Classification and Labelling Inventory (CLI) held by ECHA.

Mixtures must always be self-classified before being placed on the market, as they are not subject to CLH. Classifying mixtures follows a similar process. They can be classified based on data on the mixture itself, data on similar tested mixtures, or data on the individual components in the mixture.

1) Harmonised classification

The CLH process is considered by public authorities and industry stakeholders to be more effective than it was under the Dangerous Substances Directive (DSD) mainly due to its globally harmonised approach via the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Indeed, before the adoption of the GHS in 2003 and still under the previous Directive led system, different systems for the classification and labelling of substances and preparations/mixtures existed in different jurisdictions around the world. Whilst many of the requirements of the different legal jurisdictions were similar, their differences were significant enough to result in multiple labelling requirements for the varying health and safety information that had to be provided for the same product in different countries and/or markets. As a result of these multiple systems of classification, there was recognition that companies involved in the international trade in chemicals had to closely follow the laws and regulations in each of the destination countries, prepare different labels and Safety Data Sheets (SDS) for the different jurisdictions, and keep themselves up to date with any changes to the regulations operating in multiple countries/jurisdictions.[109]

There are currently 4573 harmonised classifications (September 2017), most of which originate from harmonised classifications decided under the DSD that were incorporated into the new CLP regime. By January 2017, 323 CLH proposals have been submitted to the Risk Assessment Committee (RAC) since the CLP Regulation came into force in January 2009. As a point of reference, there are total of about 142 000 substances (July 2018) in the CLP inventory, most of which are self-classified by industry. Many of these may not require a harmonised classification. However, ECHA considers the number of harmonised

[109] 1st FC Study, Annex II p. 4

classifications low compared to the likely number of chemicals which merit a harmonised classification.[110]

In addition, most of the new CLH proposals relate to active substances under the Plant Protection Products and Biocidal Products Regulations. The need for harmonised classifications under these Regulations is constraining the degree to which Member States are able to focus on other industrial chemicals. ECHA suggests that for industrial chemicals (i.e. those falling under REACH) between 10 and 20 substances per year go through the CLH process[111]. One of the reasons for this is the fact that the preparation of CLH proposals places a high burden on Member States. Another reason is that the workload is unevenly shared amongst Member States due to lack of resources allocated to this work and/or experience and expertise in some Member States. The Registry of Intentions available on ECHA's website[112] and the survey carried out for the purposes of this Fitness Check both show that a small number of Member States are considerably more active than others in bringing forward and developing proposals.[113]

Under the CLP, both companies and Member States are able to submit proposals to ECHA for the harmonised classification of a substance. Only Member States may propose a revision of an existing harmonised entry, for any substance that is under the scope of the CLP Regulation or when a substance is an active substance in biocidal or plant protection products. The fact that the Commission currently lacks the legal basis to initiate a CLH proposal or to ask ECHA to develop dossiers hinders the effectiveness of the harmonised classification process.

2) Self-classification

The CLP Regulation requires industry to 'self-classify' all substances placed on the market irrespective of tonnage. It also introduced a new obligation for industry to notify the outcome of the self-classifications to the Classification and Labelling Inventory (CLI), managed by ECHA, to promote harmonisation. However, in many instances there are 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'. Furthermore, there are concerns about the reliability of some of the self-classifications. Possible reasons for this situation are the following:

- ECHA is not allowed to share the names of notifiers so that they cannot contact each other in order to agree on a classification.
- Errors of notifiers or use of an inadequate set of data when notification was done. There are no legal provisions allowing ECHA to correct or delete obvious mistakes in the CLI.
- Lack of engagement of notifiers to find an agreement.
- Objective reasons such as differences in impurities or physical states.

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[110] ECHA Report on the Operation of REACH and CLP 2016 p. 117

[111] Report on the Operation of REACH and CLP 2016, ECHA 2016 https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf/4c958d7a-3158-447b-9e81-d8bae9a7e7f9

[112] https://echa.europa.eu/registry-of-intentions

[113] 1st FC Study Annex II, pp. 47-48

- Classification done by 3rd country exporters according to their national requirements, etc.

These variations in self-classification affect the value of the CLI as a hazard communication tool and are leading to confusion or even misinformation on chemical hazards. In this regard, two pilot projects were launched in 2015 and 2016 by ECHA to invite notifiers to come to an agreed classification for the same substance. Despite these efforts, the aim of agreeing on a single classification for each of the selected substances was not achieved.

The lack of a legal basis for ECHA or Member State authorities to perform quality checks of self-classifications can also lead to internal market issues when industry competitors deliberately notify particular chemicals used only by their competitor(s) as more being hazardous than they are in reality.

3) Mixtures classification under the CLP

For mixtures, the CLP Regulation provides for an elaborate classification system and allows the use of test data for mixtures to be included in the hazard evaluation even though these data may be difficult to interpret. This classification system follows the hierarchy:

- using available test data;
- using data on similar mixtures or ingredients on the basis of bridging principles; or
- using the calculation method (based on the ingredients of the mixture).

As data on mixtures is often not available and the generation of new animal test data is discouraged, duty holders, in particular smaller companies, often rely on the other two approaches i.e. bridging principles or calculation methods.

The lowering of generic concentration limits for some hazard classifications under the CLP Regulation compared to the levels prescribed under the previous regime (i.e. the Dangerous Substances and the Dangerous Preparations Directives repealed by the CLP Regulation), in particular for skin and eye irritation or corrosion, has resulted in more stringent classification when applying calculation methods. Stakeholders representing the detergent sector stated that it leads to over-classifications. Similarly, because SMEs are more likely to depend on the calculation methods to classify mixtures (due to cost considerations), they are also more likely to place more conservative hazard classifications on their products than companies that can do the necessary testing.

In principle, the bridging principle method[114] (bridging principles are basic principles used to classify un-tested mixtures under the CLP Regulation and the UN Global Harmonised System (GHS)) could address this issue. However, there is a lack of clarity with respect to how to apply these principles which hampers the effectiveness of this method. It also leads to discrepancies in interpretation and acceptance of classification by Member States. The Commission is now taking steps to address this issue, including guidance on the harmonised application of the legal requirements.

Issues with mixture classification have also been raised by metal industry stakeholders in relation to metals and metal alloys e.g. the alloy used in Euro coins and the stainless steel-nickel-cobalt alloys used as medical implants. While the metal alloys are to be classified

[114] ECHA Guidance on the Application of the CLP Criteria Version 5.0 – July 2017, p. 68-72

following the CLP chemical mixtures classification rules, this stakeholder group believes that it leads to metallic alloys receiving classifications that do not match their real hazard properties. They also believe that this situation could have negative consequences on metals recycling and thus on the realisation of circular economy with some unintended consequences in downstream legislation (e.g. the Toy Safety Directive, the Transport of Dangerous Goods Directive, the Industrial Emissions Directive).

It should be noted that the Commission has already been made aware of these concerns and acknowledged the issue. A more in-depth assessment is provided in one of the Fitness Check supporting studies[115]. As part of this more detailed analysis, a specific case study was carried out.[116] More recently (end of June 2018) the issue was discussed at the REFIT Platform (brought up by the Federation of Finnish Technology Industries).[117] The Commission has started to address it, in particular through the bio-elution project [118] [119] (involving industry stakeholders) which is reviewing possible test methods for assessing the bioavailability/exposure to metals in alloys[120]. The issue of biological availability[121] has been discussed by the Commission, at CARACAL meetings and at industry workshops[122], also involving ECHA. While the issue is also acknowledged and understood by national authorities, views are mixed as to how to address it as some of them fear that it might have a negative impact on the application of the CLP classification criteria and their fitness for

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[115] 1st FC Study Annex II p. 27 and onwards.

[116] 1st FC Study Annex VI Case study 2

[117] This stakeholder group called upon the Commission to review the current classification rules for metallic alloys and issue a guidance on the interpretation of article 1.3.4 of the CLP in the context of the circular economy, as well as to support to support the efforts of the metal industry in developing a new test method in order to improve the classification of metallic alloys to be based on their intrinsic properties. A joint opinion is expected to be adopted in October 2018.

[118] Biological availability in the context of Art. 12(B) CLP, 19th Meeting of Competent Authorities for REACH and CLP (CARACAL), 12 – 13 November 2015, Brussels, 03/11/2015, Doc. CA/90/2015

[119] Bioaccessibility testing (Bioelution) of metals, inorganic metals compounds and metals-containing materials: simulated gastric fluid, Joint Research Centre, European Commission 2016 https://tsar.jrc.ec.europa.eu/test-method/tm2016-02

[120] The bioelution test is a test whereby the bioaccessibility of metals/alloys is tested in synthetic gastric fluid and other fluids (simulating other body fluids such as saliva).

[121] Bioavailability (or biological availability) is defined in the CLP Annex I as being the extent to which a substance is taken up by an organism, and distributed to an area within the organism. Bioavailability is dependent upon physico‐chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. The bioavailability of metals is influenced by physical factors such as temperature, phase association, adsorption and sequestration (Tchounwou, PB, Yedjou, CG, Patlolla, AK, Sutton, DJ, (2012): Heavy metal toxicity and the environment). It is also affected by chemical factors that influence speciation at thermodynamic equilibrium, complexation kinetics, lipid solubility and octanol/water partition coefficients (Hamelink, JL, Landrum, PF, Bergman, HL, Benson, WH, (1994): Bioavailability: Physical, Chemical and Biological Interactions).Based on the properties of a metal in its pure form, the classification may also apply to the alloy, although, the metal, as part of an alloy, may be held more strongly within a matrix. In other cases, some metals may be more biologically available in an alloy form and may therefore be under classified.

[122] See, for example, workshop summary available at: http://www.reach‐metals.eu/force‐download.php?file=/images/BioelutionWorkshop/report%20em%20bioelution%20workshop%2022052014.pdf

purpose, taking also into account that they are closely linked to development at UN level (via the GHS).

B. Other hazard classification

Other regulations such as the Plant Protection Products and Biocidal Products Regulations and REACH identify other additional hazard classes not covered by the CLP Regulation. These are:

1. Persistence, Bioaccumulation and Toxicity – PBT;
2. very Persistent, very Bioaccumulative – vPvB;
3. Endocrine Disruption – ED; and
4. Neurotoxicity.

PBT/vPvB criteria are included in Annex XIII to REACH, as well as in the Plant Protection Products Regulation and the Biocidal Products Regulation referring to or drawing from the criteria in REACH. The current legal provisions are effective in identifying these substances.[123] ECHA carried out an analysis of the work done by authorities on carcinogenic, mutagenic or toxic to reproduction substances (CMRs), PBT/vPvB and ED properties.[124] Regarding PBTs/vPvBs, the analysis considered all known or potential substances having these properties before the SVHC Roadmap implementation. A total of 1699 substances have been looked at. Among these, 250 were pre-listed as (potential) PBTs/vPvBs out of which 13 were identified as requiring further work.[125] The outcome of the PBT/vPvBs assessment done under the Plant Protection Products Regulation and Biocidal Products Regulation is mentioned in the assessment report of the approval of the substance. A list of the status of each approved active substance is also publicly available on CIRCABC, and regularly updated.[126]

Few EDs have been identified so far under the Plant Protection Products and Biocidal Products Regulations. This due to the fact that the most toxic pesticidal substances (many of which would also have been identified as EDs according to the WHO-UNEP Report 2012) have been already withdrawn from the market since 1993 based on Directive 91/414/EEC, Directive 79/117/EC, or the Plant Protection Products Regulation because they had unacceptable risks to the human health and the environment.

5.2.5 Communication of hazards and risks to consumers, professional users and public authorities

The communication of hazard, risk and safety information about chemical substances and mixtures to users, consumers and workers as well as public authorities is a key measure to promote the safe use of chemicals, to mitigate risks and to help users make informed

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[123] ECHA "Authorities to focus on substances of potential concern – Roadmap for SVHC identification and implementation of REACH management measures – Annual report' (2018)

[124] https://echa.europa.eu/svhc-roadmap-to-2020-implementation

[125] ECHA "Authorities to focus on substances of potential concern – Roadmap for SVHC identification and implementation of REACH management measures – Annual report' (2018) p. 13

[126] https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en ; https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

product/substance related choices. Various communication measures exist across the legislative framework.

A. Communication to consumers and workers through labelling

The CLP Regulation is the key piece of chemicals legislation governing the labelling of hazardous chemicals and mixtures. Some product-specific legislation provides for supplemental labelling information in addition to the CLP label (e.g. detergents, biocidal products), while labelling of certain product groups (cosmetic products, medicinal products) is fully exempted from the CLP and is regulated solely by product-specific legislation. Treated articles with biocides have also to comply with some labelling rules, and consumers can request some information.

A recent Eurobarometer survey[127] indicated that 70% of EU citizens find information on the hazards of chemicals on the label useful. It also showed that, for the 4 out of the total of 9 pictograms that were addressed by the survey, there are varying levels of awareness and comprehension. While 'flammability' is well recognised and understood (92% of respondents have seen it before and 96% could correctly state its meaning), it is less the case for the 'environmental' hazard pictograms (47% of respondents have seen it before and 83% could correctly state its meaning), 'serious health hazard' pictograms (20% of respondents have seen it before and 69% could correctly state its meaning), and 'exclamation mark' pictograms (63% of respondents have seen it before and 17% could correctly state its meaning). Nevertheless, when they see one of the chemical hazard pictogram on an unfamiliar product, most respondents (76%) read the safety instructions (57% read the safety instructions on the product label, while 19% say they go further by reading the safety instructions on the product label and then trying to find further information from other sources). The Eurobarometer Survey also found that even in Member States where understanding of the issues surrounding chemical products is high, the comprehension of some of the hazard pictograms is relatively low. In part, this is an issue of citizen education and awareness raising by Member States. Opportunities to use digital tools have not yet been explored and used to their full. Hazard communication to workers and professional users is considered to be more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers; in part due to employee training.[128] [129].

At a more general level, another recent Eurobarometer survey[130] found that less than half of the respondents (45%) feel well informed about the potential dangers of the chemicals

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[127] Special Eurobarometer 456

[128] 1st FC Study p. 70

[129] Open public consultation Question 17: To what extent are the following elements of risk management satisfactory? Industry stakeholders attributed the highest score to hazard and risk communication measures to workers (4/5; 177 respondents). The highest score from Group 1 Citizens is 3.1 for hazard and risk communication measures to workers (28) while Group 4 NGOs and others assigned the score of 3.2 (45 respondents). Similarly, respondents to the question 28 "Indicate the extent to which communication of hazards to workers and consumers is effective" considered the CLP labels in communicating risks to consumers being less effective than to workers.

[130] Special Eurobarometer 468, Attitudes of European citizens towards the environment

European Commission, October 2017

contained in consumer products. However, again, this proportion varies considerably between Member States.

Furthermore, industry stakeholders expressed concern about labels becoming overloaded with information, making it difficult for consumers to focus on the essential hazard information.[131]

B. Hazard/risk communication to downstream users of chemicals

Complementary to the CLP labelling requirements are the requirements under REACH to communicate hazard and risk information to downstream users in the value chain via safety data sheets. This requirement ensures the passing on of information on hazards of substances, risks associated with their use and/or the necessary risk management measures down the supply chain to ensure safe use. In addition, downstream users need to pass information on how they use chemicals up the supply chain. These requirements are applicable to all chemicals and mixtures that are hazardous according to the criteria in the CLP Regulation, that are persistent, bioaccumulative and toxic/very persistent and very bioaccumlative substances (PBT/vPvB) substances according to criteria specified in REACH and all other substances of very high concern (SVHCs) identified under REACH. However, the requirements do not apply to the mixtures in the finished state, intended for the final user as medical products for human health or veterinary use, as cosmetic products and as additives and flavourings in food- and feed-stuffs.

These provisions were evaluated as part of the REACH evaluation. It showed that there has been a continued increase in the information passed through the supply chain, though it needs to be made more efficient (e.g. reduce costs of producing and supplying Safety Data Sheets), especially for SMEs. Improvement is also needed in the ability of companies to develop specific exposure scenarios, in particular for mixtures, and in helping with implementing the obligation to notify substances of very high concern in articles.

This Fitness Check showed that the interface between these provisions and the CLP Regulation functions well. The CLP criteria are used to trigger the obligation to develop a safety data sheet and the safety data sheet must provide information on all hazards covered by the CLP Regulation. The safety data sheets also have to contain information on whether the substance or mixture meets the criteria for PBT or vPvB. However, safety data sheets are not required to contain information on whether a substance is an endocrine disruptor or whether a substance is in the nano form (except labels on biocidal products and, under certain circumstances, also treated articles with biocides which need to include this information). This lack might constitute a gap and impact the ability of companies along the supply chain to protect workers from exposures to substances with these properties.

C. Alert and rapid response systems

The EU has established two alert systems to enable rapid exchange of information between Member States and the EU authorities in emergency situations when products, food or feed pose an immediate risk to health and safety of consumers:

1. The Rapid Alert System for non-food dangerous products (RAPEX) covers such as toys, textiles, cosmetics, etc. Third countries like China[132] and international

[131] 1st FC Study p. 24; see also Annex III, Section 7.3; Case Study 5

[132] Notifications included in the Rapid Alert System concern dangerous products produced all over the world. China remains the number one country of origin but figures have gradually been going down since 2013. In

institutions are also involved. The presence of harmful chemicals is one of the most notified risks in RAPEX. Even though the major increase in RAPEX notifications over the last four years is a clear indication that market surveillance under the General Product Safety Directive has been successful, in an increasingly global market with more and more products coming to the EU from third countries, there is a need for further co-ordination of market surveillance activities between the Member States, including cooperation with customs authorities. This aspect is being addressed by the Commission as a part of its new 'Goods Package' via the proposed Regulation on Compliance and Enforcement[133].

2. The Rapid Alert System for Food and Feed (RASFF) was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. It also covers the cases where undesirable chemicals in food cause food poisoning e.g. not labelled allergens Most issues are related to food contact materials regarding the migration of chemicals from the food contact material into food e.g. formaldehyde, plasticizers, volatile organic compounds etc. The majority of notifications concerned in 2016 the presence of heavy metals[134]. In 2016, 50 notifications were identified as triggered by a food poisoning event. In 6 cases consumers suffered from allergic reactions due to the presence of an allergen that was not indicated on the label.

Therefore these two systems are effective tools for allowing public authorities to rapidly take appropriate risk mitigation measures.

D. Information tools

The Classification and Labelling Inventory (CLI), maintained by ECHA and containing classification and labelling information about more than 129 000 substances, is one of the main information tools to communicate hazard information on substances and is used by industry as well as public authorities. Relevant information from the CLI and other sources is provided in Infocards and Brief Profiles on ECHA's website, thereby increasing accessibility for citizens. The issues mentioned above resulting in variations in self-classification prevent it from reaching its full potential as an information tool and reduce its effectiveness in terms of health/environmental protection and single market.

2016, the percentage of notifications for which China (including Hong Kong) was indicated as country of origin went down to 53%, a drop of 9% compared to 2015. Since 2006, the Commission works in close collaboration with China in order to reduce the presence of unsafe products on our markets. A specific module of the Rapid Alert System was created to allow for swift flagging of notifications concerning unsafe products from China. The Chinese authorities investigate these cases in order to trace back the manufacturers, exporters and businesses concerned with the aim of making them aware of product safety rules in Europe. Where necessary, they take further measures to ensure that those products are no longer produced and shipped to Europe.

[133] The draft Regulation on Compliance and Enforcement will help create a fairer internal market for goods, through fostering more cooperation among national market surveillance authorities. This will include sharing information about illegal products and ongoing investigations so that authorities can take effective action against non-compliant products. The Regulation will also help national authorities to improve checks on products entering the EU market. Since 30% of goods in the EU are imported, the Commission further proposes to reinforce inspections of ports and external borders.

[134] https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2016.pdf

A multitude of tools and systems to trace substances in articles and handle the information flow along supply chains have been developed by companies, industry sector associations, authorities and international bodies in order to comply with the various requirements under different EU and international legislation[135], but the systematic use of these tools is still limited to pro-active actors and not widespread across different supply chains.

5.2.6 Legislative gaps affecting the effectiveness

The Fitness Check found a number of gaps in legislative provisions that affect the effectiveness of the chemicals legislation. These are briefly described below and additional assessment can be found for some of them also in the assessment of coherence (Section 7 in the main document and Annex 7) or relevance (Section 8 in the main document) of the EU chemicals legislation.

Combination effects of chemicals are required to be assessed under two pieces of legislation, i.e. the Plant Protection Product Regulation and the Maximum Residue Levels (MRL) Regulation when the methodology becomes available. Although EFSA has made significant progress in developing such a methodology, the legislative provisions have not yet been applied because the methodology is not yet considered finalised and ready for use.[136] However, under other pieces of chemicals legislation, there are no specific requirements to assess the combination effects systematically nor to take it into account in the risk assessment, which can be seen as a gap of the framework.

Exposures to substances in articles cannot be sufficiently addressed by the existing legislation due to information gap on their presence and possibly missing legislative specific provisions. In relation to this however, the recently revised Waste Framework Directive provides the legal basis for the establishment of an ECHA-managed database on the presence of SVHCs in consumer goods ('articles') with access provided to waste treatment operators as well as consumers upon request.[137]

In addition, as the REACH evaluation has shown, it creates an unequal level playing field between imported articles and those produced in the EU. For example, EU companies are at a competitive disadvantage in relation to imported articles containing CMR substances because they are generally not used in the EU in consumer articles.[138]

Protection of vulnerable groups is covered by specific legislation targeting identified exposure scenarios of these groups, such as the Toy Safety Directive, the Pregnant and the Young

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[135] Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH. Published: 11/08/2017. https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF

[136] Please note that while this document was in its finalisation process, in June 2018, EFSA published a "Draft guidance on harmonized methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals." In addition, EFSA published a "Statement on genotoxicity assessment of chemical mixtures." Public consultations on both documents are open until September 15 and September 9, 2018, respectively. Source: https://www.efsa.europa.eu/en/press/news/180626

[137] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste; Recital 38 and Article 1

[138] REACH REFIT SWD SWD(2018) 58 final p. 35

Workers Directives. However, the same groups can be exposed to hazardous substances via other routes of exposure, which fall under the scope of other legislation with no specific provisions regarding the protection of vulnerable groups. This is a gap in protection of vulnerable groups. For example, toys for children under 3 shall not contain carcinogenic, mutagenic and toxic for reproduction substances (CMRs) according to the Toy Safety Directive, while these substances can be used for example in carpets/pats/textiles which have similar exposure potential.[139] [140]

Endocrine disruptors are specifically addressed in several pieces of legislation in a similar way to CMRs and persistent, biocaccumlative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances (i.e. REACH, the Plant Protection Products and the Biocidal Products Regulations) and their identification is progressing. However, the data/information requirements are insufficient to identify endocrine disrupting properties. Also, some other pieces of legislation are lacking specific provisions in order to ensure a coherent approach (see Section 7 Coherence and Annex 7).

5.2.7 Application of the Precautionary Principle

The precautionary principle enables a rapid response to be given in the face of a possible danger to human, animal or plant health, or to protect the environment. In particular, where scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.

It is laid down in article 191(2) of the TFEU. It is explicitly taken into account in the design of various pieces of chemicals legislation (e.g. those requiring safety assessments such as the Biocidal Products Regulation and the Plant Protection Products Regulation, the Water Framework Directive, the POPs Regulation and the RoHS Directive, as well as REACH (many persistent, biocaccumlative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances are regulated on a precautionary basis)).

While the principle has not been legally defined, its implementation/application is elaborated in the Commission's Communication[141]. The evaluation of the scientific uncertainties in the chemical risk assessment by policy makers leads to the decision whether to apply the precautionary principle or not. In other terms, it is a question of how effectively the EU's chemical risk assessment and management processes are working in terms of detecting and acting upon early warnings and avoiding late lessons versus taking over precautious, unnecessarily restricting measures and unwarranted recourse to the precautionary principle, as a disguised form of protectionism for example.

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[139] FC+ Study p. 108

[140] The Commission adopted a Decision to amend the REACH Regulation and restrict the use of the phthalates (DEHP, BBP, DBP and DIBP) in consumer products on the EU market that will complement the existing restriction on three other phthalates (DINP, DIDP and DNOP) in toys and childcare articles (Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP))

[141] COM/2000/0001 final

The precautionary principle should not be confused with the element of caution that scientists apply in their assessment of scientific data e.g. generic risk management approach based measures and application of safety factors are examples of preventative action and not the application of precautionary principle. Whereas both the precautionary and prevention principles can be strictly divided conceptually, it is not always straightforward to separate them as clearly in their application. Some legal instruments based on a general preventive approach nonetheless integrate a precautionary approach for specific substances where risks to health and the environment or the thresholds needed to limit hazards are not identifiable (e.g. the Seveso III Directive aims at prevention, preparedness and response to accidents involving dangerous substances in industry in the EU, the Industrial Emissions Directive takes into account the whole environmental performance of a plant through granting a permit).[142]

Where a scientific uncertainty is encountered, the challenge is therefore in finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken. An examination of the benefits and costs of action and lack of action is another general principle of application for measures adopted on the basis of the precautionary principle. Whatever is the measure decided, it remains subject to review, in the light of new scientific data, and should allow assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The following examples show cases where the precautionary principle was applied (non exhaustive):

- The "Community strategy for endocrine disruptors" adopted in 1999 and updated in 2001, 2004 and 2007.
- Ban of Bisphenol A (BPA) in polycarbonate infant feeding bottles in 2011.
- Setting lower specific migration limits for Bisphenol A for varnishes or coatings applied to materials and articles intended to come into contact with food in 2018. Similarly, BPA should not migrate from varnishes and coatings applied to materials or articles specifically intended to come into contact with food intended for infants and young children[143].

A number of stakeholder groups including NGOs, trade unions, and some Member State Competent Authorities have raised concerns that in the assessment of chemicals, authorities often hesitate to introduce risk management measures in situations where the precautionary principle applies and prefer to wait and request additional data to reduce the level of uncertainty.[144] The BPA case shows however that this not always the case. Indeed, while still

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[142] The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 93

[143] 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

[144] This situation is illustrated by the outcome of risk assessment carried out in 2001 and 2003 for penta-brominated diphenyl ether (PBDE) and octa-brominated diphenyil ether (OBDE) which led to a ban in 2004 (under the legislation preceding REACH though). At the same time, for deca-BDE it was decided to proceed with the scientific research required to resolve the uncertainty, rather than take a precautionary approach. However, on the basis of the evidence gathered after the additional testing, it was decided to ban deca-BDE in 2008. Source: The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 50

facing uncertainties including about the potential replacement substances and their safety and effectiveness, the Commission has mandated EFSA to undertake a full re-evaluation of BPA on the basis of the results of anticipated new studies and scientific data. Following the principles established in the 2000 Communication mentioned above, the Commission will then decide what and if any further action is necessary to protect consumers the precautionary principle.

5.2.8 Balance and Mix Between the Risk Management Measures based on 'Generic' and 'Specific' Risk Considerations

Risk management measures in the EU chemicals legislation are taken considering the risks to human health or the environment associated with exposure to hazardous chemicals. As described in more depth in Annex 8, there are two basic approaches to risk management used, often in combination, in the EU chemicals *acquis*: one based on specific risk approach (SRA) and one based on generic risk consideration (GRC). Under the GRC approach, hazards are assessed generically and without considering specific exposure scenarios based on the hazard of a substance or mixture. Under the SRA both the hazards and the potential specific exposure scenarios (levels, specific situations or uses) of humans and the environment to the substance or mixture in question are assessed at the same time. One could also note that even when the GRC approach is applied, a specific risk assessment in some cases will still be carried out including when considering a possible derogation from an automatically triggered measure.

Respondents to the open public consultation were invited to indicate to what extent they find that the chemicals legislation framework overall should be more oriented towards SRA, GRC or should remain as it is. The preferences of the different groups varied quite considerably. Industry and in particular bigger companies tended to prefer a more extensive use of SRA approaches[145] while NGOs tended to have a higher preference for more GRC approaches[146]. The most common response among Member State competent authorities was that the current application of GRC and SRA approaches within the framework of EU chemicals legislation is well balanced and should remain as it is[147]. Responses from citizens were mixed[148], providing equal support for more SRA and for more GRC approaches, but a majority of citizens (ca. 60%) did not know how to answer or did not provide an answer to the question.

Respondents were also asked to provide comments on their preference. The main comments received are summarised below.

Category of respondents	GRC approach	SRA approach
Business and industry	• More convenient to maintain innovation and competitiveness for a sustainable	• In general more appropriate to define the most effective risk management

[145] 72% (151) from Group 2 (business/industry) was in favour of SRA

[146] the most common response from Group 4 (NGOs and others) was for generic risk considerations (41% or 23), but there were also 25% (14) who agreed that there should be more orientation towards specific risk assessment and 16% (9) who thought the legislation should remain as it is

[147] (37% or 18) but 29% (14) provided no answer

[148] with almost half stating (49% or 31) 'I don't know'; the next most common response is 17% (11) for both specific risk assessment and generic risk considerations

	risk management if the approach taken is proportionate and does not 'overuse' the precautionary principle or overestimate exposure. • Has greater regulatory predictability and clarity. • Can result in absurd situations e.g. the prohibition of the use of ethanol in cosmetic products, whilst alcohol-containing food and beverages and perfumes would not be affected.	measure whilst preserving societal benefits.
NGOs and other civil society organisations	• Areas for extension include, but are not limited to, food contact materials, toys, furniture and certain construction materials and certain human health and environmental impact endpoints that give rise to concerns equivalent to that of CMRs, PBT, and EDs; this includes neurotoxicity, immunotoxicity, terrestrial toxicity and persistent, mobile and toxic (PMT) substances.	• Too slow.
Citizens	• Especially important with regard to substances that are not controlled, cannot be easily traced and where it is not possible to calculate "safe" levels (EDs, PBTs) or where there is uncertainty due to poor and little scientific information, such as for nanomaterials?	• Too slow.
Government and public authorities	• GRC approach provide greater predictability and provide clear indication which properties of substances should be avoided	• SRA approach is less predictable and more costly for the economic operators.

Table 1 Main comments received from stakeholders

Overall, findings of this Fitness Check show that both the GRC and SRA have their role to play in the EU chemicals legislative framework and that the current balance between the use of generic and specific risk management approaches works well, each under particular circumstances (see Table 2):

	Advantages	**Drawbacks**
Generic Risk Considerations (GRC)	Provide a clear signal to all the actors involved (enforcement authorities, industry and downstream users) on the types of hazardous substances which should be avoided	Automatically triggered risk management measures may lead to disproportionate outcomes and unintended (legal and/or socio-economic) consequences if a mechanism for derogation is absent or not appropriate
	The outcome of the risk management decision making process is more predictable (compared to SRA)	Potential consequences of automatically triggered measures in downstream legislation might influence the upstream

		scientific debate leading to the classification
	Might be more appropriate for substances of higher concern and where vulnerable populations are at risk and/or cannot be protected through e.g. training or protection equipment (e.g. children under the Toy Safety Directive)	Less appropriate where exposures are minimal or would not occur through the route of exposure of concern and therefore can lead to over-regulation for non-relevant routes of exposure
Specific Risk Assessments (SRA)	Allow more targeted and differentiated consideration of exposures and thus risks and therefore more appropriate identification of actual risks and of risk management measures	The process might be slower compared to GRC and often more costly
	Allow more targeted consideration of costs and benefits of various risk management options	Predictability of risk management decisions can be more difficult

Table 2 Main comments received from stakeholders regarding the GRC and SRA application

Where a derogation mechanism is connected to the GRC approach (i.e. a derogation from e.g. an automatic restriction or ban if certain conditions are fulfilled, such as demonstration of negligible exposure), industry stakeholders stated that it helps to ensure that the risk management measure stipulated will not lead to disproportionate costs or unintended effects e.g. regrettable substitutions.

5.2.9 Member States and EU Authority/Agency resourcing and capacity

One of the biggest challenges of chemicals risk management has always been to conduct robust risk and hazard assessments for a large number of chemicals present on the market in a timely manner given the resources of public authorities. In order to cope with these constraints, the EU legislation has progressively put the burden of proof on industry. This has helped to improve the knowledge on chemical hazards, to progress in assessing hazards and risks, and to take appropriate risk management measures to protect human health and the environment while enhancing the internal market.

Despite the reversal of the burden of proof, the effectiveness of the EU chemicals legislation continues to depend on the capacities and expertise of Member States and EU authorities (Agencies and the Commission). These entities are essential for almost every step of the risk management process, from triggering the assessment to enforcement of risk management measures.

The Fitness Check showed that workload distribution between Member States authorities is unequal.[149] Moreover, stakeholders has expressed concern about the current pace and the capacity of Member States and EU risk assessment bodies to conduct the needed hazard and risk assessments of chemicals at a pace sufficient to achieve the EU chemicals legislation objectives, in particular regarding assessments of biocidal active substances, recycled plastic food contact materials and harmonised classification dossiers. Stakeholders also highlighted

[149] 1st FC STUDY Annex II, pp. 47-48

the importance of enforcement of the legislation by Member States. According to these stakeholders more efforts should be put in ensuring the compliance.

5.2.10 Regulatory design aspects: regulatory 'silos' and missing links among legislation

The different pieces of the EU chemicals legislation share, in principle, the same objectives. The exact focus and coverage differ depending on the scope and intentions of the legislator. Whereas some are focused on protection of human health and the environment, others focus only on one of these. Some pieces of legislation, when assessing the risk for human health and the environment, consider a specific route of exposure (dermal, oral, inhalation) while others consider all possible routes. Some legislations cover the risk from specific uses or products (e.g. toys, cosmetics, plant protection products, food contact materials, etc.) while others are cross-cutting and apply to chemicals in general (e.g. the CLP). Same substances are used in different areas covered by individual legislation and overarching legislation and thus in some case subject to different rules.

The delineation between the different pieces of legislation is clear and the existing linkages function well. The attribution of tasks and responsibilities is clear and appropriate.

However, this clearly delineated legal framework sometimes leads to the situation that the focus of a risk assessment is too narrow and does not take into account overall exposure to a hazardous substance from various sources (so called aggregate exposure) or via various routes of exposure (inhalation, dermal, oral). In other words, one piece of legislation will not take into consideration for example the outcome of the risk assessment carried out under another piece of legislation unless required to do so. This also applies to sharing information and data as described above. Thus, the risk assessment even though corresponding to the legal scope, in practice, can be only partial, i.e. not covering all exposure routes or uses. An example of such a case is Bisphenol A (BPA) assessment, which was evaluated several times by EFSA between 2006 and 2015 first to assess the dietary exposure and then to assess non-dietary sources, such as exposure through the skin due to contact with thermal paper (used in receipts) and cosmetics. It concluded that there is no health concern for BPA at the estimated levels of dietary exposure. However, also taking into account other possible sources of exposure, a new temporary Tolerable Daily Intake was established. In June 2017, BPA was identified as a substance of very high concern (SVHC) due to its endocrine-disrupting properties. The entry was updated in January 2018 in order to reflect an additional reason for inclusion in the SVHC list but this time due to its endocrine disrupting properties causing adverse effects to the environment.

In addition, because of the missing interlinkages between different pieces of legislation, a concern identified under one may not trigger assessment or risk management measures under another. One example is the missing link between the Water Framework Directive and REACH and the Plant Protection Products Regulation. Once a substance is identified as priority substance under the Water Framework Directive, Member States shall ensure that its concentration in surface waters is below the specified environmental quality standard level. However, often, in order to achieve this, a restriction under REACH or the Plant Protection Products Regulation is needed. However, the process of identifying a substance as priority substance does not trigger any risk management or assessment process beyond the Water

Framework Directive. Regarding biocides, a note was made in 2014 to clarify the interaction between the Biocidal Products Regulation and the Water Framework Directive.[150]

5.2.11 Substance-by-substance approach vs. grouping approach to avoid regrettable substitutions

One unintended consequence of the existing approach of assessing substances on a 'substance-by-substance' basis relates to regrettable substitution i.e. a banned or restricted hazardous substance substituted by another one just as hazardous, or may be less toxic but carrying a greater potential for release. In these cases, similar risk management measures are taken once more data and information becomes available about the substitute. The use of TCEP as a flame retardant in children's toys is an example of regrettable substitution. [151] It replaced other brominated flame retardant subject to risk management measures in the EU, even though it is itself a carcinogen category 2 and a toxic for reproduction category 1B and was recommended by ECHA for inclusion in REACH Annex XIV (Authorisation List).[152]

When regrettable substitution takes place, it impacts the correct functioning of the EU chemicals legislation both in terms of its effectiveness to provide high level of protection of the environment and human health, and its efficiency due to industry's investment in substances that are shortly to be banned.

An alternative to substance-by-substance approach is to assess substances as part of a group or category[153]. In the grouping approach not every chemical needs to be tested for every endpoint. Endpoint information for one chemical (part of the group) is used to predict the same endpoint for another chemical (also part of the group), considered to be "similar" in aspects relevant for assessing the hazard.[154] The similarities may be based on the following:

- a common functional group (e.g. aldehyde, epoxide, ester, specific metal ion);
- common constituents or chemical classes, similar carbon range numbers;
- an incremental and constant change across the category (e.g. a chain-length category);
- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt).

An advantage of a chemical category assessment approach is that identification of consistent patterns of effects within a category in itself increases confidence in the reliability of the results for all the individual chemicals in the category, compared to evaluation of data purely

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[150] CA-Sept14-Doc.4.2 - Final - Links between BPR and WFD on approvals of AS.doc

[151] 1st FC Study p. 61 and 104; see also case study 11 in Annex VI

[152] https://echa.europa.eu/documents/10162/13640/axiv-bd_tcep_20101217_en.pdf/f448e657-47e5-43ee-9358-4e2a2c7817cb

[153] There are two approaches to chemical grouping: the category approach and the analogue approach. The category approach to the grouping of chemicals reduces the need for *in vivo* testing, as not every chemical in the group will need to be tested. Data for the chemicals and endpoints that have been tested for can be used to estimate the corresponding properties for the untested chemicals and endpoints. The analogue approach can be used when the target and source chemicals share a common mode of action. All groups of chemicals are not based on the same properties, and each group can be defined by different criteria, depending on the regulatory purpose and/or risk management measures.

[154] OECD Guidance on grouping of chemicals; 2nd edition; 2014

on a chemical-by-chemical basis. The grouping approach can help gaining efficiencies, reducing costs and improving animal welfare through reducing the number of in vivo testing.[155]

[155] OECD Guidelines ibidem

6 Annex 6 Efficiency

This Annex 6 corresponds to Section 6 Efficiency in the main document. The evaluation of efficiency looks at the costs and benefits of the EU chemicals *acquis* and then at whether there are excessive cost burdens and opportunities to reduce these whilst either maintaining effectiveness or improving it. In doing so, the efficiency assessment answers the following evaluation questions:

- What are the costs associated with the implementation of the legislative framework for chemicals? What are the key drivers for these costs?
- What are the benefits associated with the implementation of the legislative framework for chemicals? What are the key drivers for these benefits?
- To what extent are the costs proportionate to the benefits?
- What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

The three first of these evaluation questions are dealt with together and the fourth separately.

6.1 What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?

The wide scope of this Fitness Check, involving a large number of Directives and Regulations and a variety of chemical risk assessment and management processes that have evolved over more than 50 years, resulted in the use of a simple counterfactual of no EU or Member State chemicals legislation as the main point of reference for the analysis. In reality, each Member State would have had its own national legislation in the absence of any EU legislation but to agree on what the situation might have been would be too hypothetical, and would be subject to multiple interpretations.

For reasons outlined in more detail below it was not possible to quantify the overall cumulative costs and benefits of the EU chemicals legislation. However, where it was possible to derive robust estimates of individual cost/benefits elements this was done. Please see Section 4 Methodology in the main document and Annex 3 for more details about which baselines and points of reference where used and how costs and benefits were calculated, including the application of alternative valuation techniques, such a willingness-to-pay.

The inability to arrive at overall estimates for the cumulative benefits and costs of the EU chemicals *acquis*, coupled with the partial picture on the costs and benefits at the specific legislation level, means it is also not possible to arrive at a single cost-benefit ratio. This meant it was not possible to assess the proportionality of the overall costs and the benefits. However, there is growing evidence[156] that, in many instances, the health and environmental benefits of reduced hazardous chemical exposures outweigh regulatory costs.

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[156] Emerging Findings from Defra's Regulation Assessment, Published February 2015 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406225/defra-regulation-assessment-2015.pdf)

Annex 11 gives an overview of the individual costs and benefits identified in the Fitness Check.

6.1.1 Costs and cost drivers: overview

The 'costs' follow from the drivers, and relate primarily to the direct regulatory costs and to the enforcement costs, which are incurred primarily by industry and by EU and Member State authorities. Indirect costs and the costs of risk management measures triggered under downstream legislation are not assessed here, but the Fitness Check does consider those processes and whether they themselves are working properly.

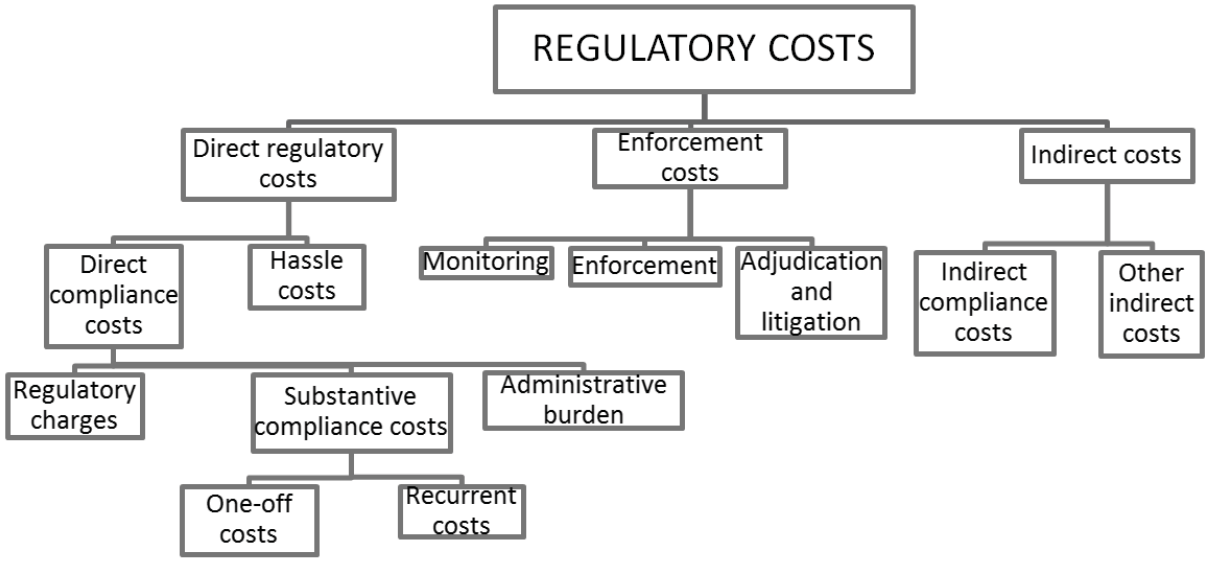

Figure 9 Categories of regulatory costs

All stakeholders recognise that the costs of the chemicals legislation can be significant, especially for SMEs[157]. This perception, however, varies between stakeholder groups. Industry, for example, considers costs of understanding and keeping up to date with changes in legal requirements as particularly significant, whereas other stakeholder groups consider this to be a less significant part of overall costs. Similarly, training, inspections and administrative requirements are perceived as more significant by industry compared to other stakeholder groups. Risk management measures, and to a slightly lower degree labelling and packaging requirements are considered of high cost significance by all actors. Classification requirements are perceived to be relatively significant by industry and public authorities but to a lesser degree by NGOs/others.

The following sections explore the main cost drivers. As the other major horizontal piece of EU chemicals legislation that acts as a basis and complement to the REACH Regulation, particular attention was given to the examination of both the transition and on-going costs of the CLP Regulation.

[157] Question 20 of the Open Public Consultation; 89% (159) of Group 2 Industry association/business, 70% (30) of Group 4 NGOs and others, 64% (23) of Group 3 Public authorities and 31% or 8 of Group 1 Citizens respondents thought costs for small and medium sized enterprises were the most significant.

Given the differences in the organisation of public administrations across the EU, enforcement costs imposed on public authorities at national level are analysed from a cost drivers' perspective. [158]

6.1.2 Direct regulatory costs

When the costs of the most relevant EU legislation with a bearing on the chemical industry were cumulated, the estimated average annual total direct cost borne by the six subsectors (i.e. organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) during the period 2004-2014 was around EUR 8 billion. This represented around 1.7% of their turnover and 9% of the value added (including REACH and for the chemical sector only; it does not include costs borne by downstream industries e.g. CLP labelling costs).[159] Table 3 below presents the list of pieces of legislation by legislative package covered by the CCA1 Study.

Legislative package	Legislation covered by CCA1 Study
Emissions and industrial processes package	IED Waste Framework Directive and related (ELV, Batteries, PPWD) Seveso Directives Water Framework Directive
Chemicals package	CLP Plant Protection Products Regulation Biocidal Products Regulation REACH Annex XIII POPs Regulation
Workers safety package	Carcinogens and mutagens at work Directive Young people at work Directive Pregnant workers Directive Signs at work Directive Chemical Agents Directive
Product specific, customs and trade and transport package	Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive FCMs Regulation General Product Safety Directive PIC Regulation RoHS Directive Inland transport of dangerous goods Directive

Table 3 Pieces of legislation by legislative package covered by the cumulative cost assessment

Among the legislation packages, the emissions and industrial processes package represents approximately 33% of the regulatory cost (4% of the subsectors' value added), the chemicals

[158] Quantification of costs incurred in the EU was carried out only in respect to the CLP Regulation. See 1st FC Study Annex II p. 211

[159] Ibidem

package 29% (3.5% of value added) and workers' safety 24% (2.9% of value added). The evidence suggests that the costs have remained relatively stable over the last decade[160].

However, the figure of EUR 8 billion cannot be considered as an entirely accurate estimate of the cost of the chemicals *acquis* due to differences of scope and in the methodology applied:

- The period covered corresponds only partly to the one covered by this Fitness Check.
- Costs correspond to only six subsectors (organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) and not all the industry and companies.
- While the OSH Framework Directive, *per se*, is not in the scope of this Fitness Check, it can be reasonably assumed that the costs related to occupational health and safety legislation in the chemicals sector derive primarily from the daughter regulations (the Chemical Agents Directive, the Carcinogens and Mutagens Directive, etc.) which are within the scope of the Fitness Check. That said, it should also be noted that the estimated occupational health and safety costs probably include costs of worker safety protection beyond specific risks posed by exposure to hazardous chemicals(e.g. falls from heights, electrocution, burns, etc.) which are substantive but are not within the scope of the Fitness Check.
- Regarding the emissions and industrial processes legislative package, it should be noted that the EU Emissions Trading System (ETS) related legislation is not in the scope of this Fitness Check. In this legislative package, most of the monetary obligations are due to ETS. Therefore, the regulatory costs of emissions and industrial processes legislative package as assessed for the purposes of this Fitness Check can be estimated to represent EUR 2.6 billion (instead of EUR 3.1 billion).
- Costs presented above also include regulatory costs for several pieces of legislation that are not in the scope of this Fitness Check (REACH, Sustainable Use of Pesticides Directive, Large Combustion Plant Directive, EU Emissions Trading System (ETS) Directive, National Emissions Ceilings (NEC) Directive, Air Quality framework Directive and related, OSH Framework Directive, Directive on Personal Protective Equipment, Construction Products Regulation, Paints Directive, Tyre Labelling Regulation, Drug Precursors Regulation). In addition, several other pieces of legislation although within the scope of this Fitness Check, were not covered by the abovementioned cumulative cost assessment attempt (see Figure 10).

[160] CCA1 Study p. 114

COVERED ONLY BY CCA1	COVERED BY CCA1 AND FC CHEMICALS	COVERED ONLY BY FC CHEMICALS
REACH Sustainable Use of Pesticides Directive ETS Directive Air Quality legislation OSH Framework Directive Directive on Personal Protective Equipment Construction Products Regulation and Directive Deco Paints Directive Ethanol Denaturation Regulation and Directive Tyre Labelling Regulation Drug Precursors Regulation National Emission Ceilings (NEC) Directive	CLP Plant Protection Products Regulation Biocidal Products Regulation REACH Annex XIII Inland Transport of Dangerous Goods Carcinogens and Mutagens at Work Directive Young People at Work Directive Pregnant Workers Directive Signs at Work Directive Chemical Agents Directive Industrial Emissions Directive (repealing IPPC and Large Combustion Plants Directives) Waste Framework Directive and related (ELV, Batteries and PPWD) Seveso Directive Water Framework Directive RoHS directive PIC (Import and Export of Dangerous Chemicals) Regulation POPs Regulation Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive Food Contact Materials Regulation General Product Safety Directive	Test Methods Regulation Good Laboratory Practice Directives Protection of Animals Used for Scientific Purposes Directive Pressure Equipment Directive Medical Devices Directives Aerosol Dispensers Directive Drinking Water Directive EU Ecolabel Regulation Contaminants in Food and Feed Regulation and Directive Residues of Pesticides Regulation Urban Waste Water Directive Marine Strategy Framework Directive Waste Shipments Regulation Asbestos Directive

Figure 10 Comparison of pieces of legislation covered by the Fitness Check and by the CCA1 Study

Therefore, additional cost elements were gathered where possible and qualitative assessment is presented where quantitative assessment couldn't be done.

It was not possible within the scope of this Fitness Check to determine to what extent these costs have had an effect on the trade and the competitiveness of the EU chemical sector[161].

[161] Commission study on the impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry (CCA2 Study) is on-going.

A. Regulatory charges

Regulation charges correspond to fees, levies or taxes imposed by the legislation on stakeholders. For the pieces of legislation in the scope of this Fitness Check, these charges are imposed on industry and, ultimately, on consumers. In principle, fees and charges should reflect the cost recovery principle. Table 4 provides a list by piece of legislation.

Legislation		Description charges and fees to be paid
Covering hazard identification, classification and risk assessments	CLP[162]	ECHA shall levy a fee for a request to use an alternative chemical name for a substance in mixtures and for submission of proposals for harmonisation of classification and labelling. Where the applicant, i.e. a manufacturer, importer or downstream user, is an SME, the Agency shall levy a reduced fee.
	Plant protection products[163]	Member States may recover the costs associated with any work they carry out within the scope of the Plant Protection Products Regulation, by means of fees or charges. They shall ensure that these fees or charges are established in a transparent manner and correspond to the actual total cost of the work involved except if it is in the public interest to lower the fees or charges. Most countries charge a fee for the evaluation of new active substances. EFSA does not charge a fee for its scientific evaluations of active substances used in plant protection products in the EU.
	Biocidal products[164]	ECHA levies a fee for: work in relation to active substances; work in relation to Union authorisation of biocidal products; work to be carried out in relation to establishment of technical equivalence; applications for mutual recognition; requests for inclusion in the list of relevant persons; and requests for confidential treatment of information submitted to the Agency. ECHA also levies an annual fee for every biocidal product or biocidal product family authorised by the Union. Reductions of fees to SMEs established in the Union. Member States directly charge applicants fees for services under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority. Member States may levy annual fees with respect to biocidal products made available on their markets. Member States set and publish the amount of fees payable to their competent authorities. Fees are set to ensure that the revenue derived is, in principle, sufficient to cover the cost of the services delivered and no more.
Covering risk management measures	Waste legislation[165]	In line with the extended producer responsibility (EPR) principle, the producer of the product to become waste might be subject to payment of modulated fees reflecting their life-cycle including their repair, re-use, disassembly and recycling. Such fees do not necessarily take into account chemical components such as additives

[162] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32010R0440

[163] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009R1107

[164] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528

[165] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008L0098

		potentially hampering the recyclability of waste. But, this aspect might be further developed in order to support the shift towards more circular economy starting already at the design and production of goods phase.
	Export and import of hazardous chemicals[166]	Member States are permitted to charge administrative fees, in order to cover their costs in carrying out export notification procedure.
	Residues of pesticides[167]	Member States may recover the costs of work associated with setting, modifying or deleting maximum residue levels (MRLs), or with any other work arising from obligations under the Residues of pesticides Regulation, by means of a fee or charge. The fee should cover the cost of the work involved.
	Detergents[168]	If a manufacturer of a detergent containing surfactants, for which the level of ultimate aerobic biodegradation is lower than that stipulated in Annex III, asks for derogation, the request can be made dependent upon the payment to the Member State's competent authority of a fee. Such fees, if any, should not exceed the cost of processing the application.
	Fertilisers (Regulation (EC) No 2003/2003)[169]	Member States may subject fertilisers marked 'EC fertiliser' to official control measures for the purpose of verifying that they comply with the Fertilizers Regulation. Member States may charge fees not exceeding the cost of tests needed for such control measures, but this shall not oblige manufacturers to repeat tests or to pay for repeated tests where the first test was made by a laboratory which fulfilled the conditions of Article 30 and where the test showed compliance of the fertiliser in question.

Table 4 Regulatory charges imposed by the EU chemicals legislation

While creating business opportunities for innovative and specialised SMEs, chemicals legislation also remains a key challenge for them. Therefore, mitigating measures such as reduced fees have been introduced under some pieces of legislation (the CLP Regulation, the Biocidal Products Regulation). Such support measures are useful to assist SMEs in complying with their legal obligations.

However, the SMEs fee reduction mechanism does not exist under all pieces of legislation (e.g. the Plant Protection Product Regulation, the Waste legislation, the Residues of pesticides Regulation, the Export and import of hazardous chemicals Regulation, the Detergents Regulation and the Fertilizers Regulation). Where the mechanism exists, the level of fees reduction can vary, as it is up to Member States to define it which can lead to uneven application even though Member States usually have to ensure that the fee or charge corresponds to the actual cost of the work involved, and covers the cost of the services delivered.

[166] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:en:PDF

[167] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R0396

[168] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0648

[169] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:304:0001:0194:en:PDF

B. Substantive compliance costs

Substantive compliance costs are the investments and expenses incurred to comply with legal obligations or requirements, defined as "individual provisions inducing direct changes in costs, time expenditure or both for its addressees", which "oblige addressees to comply with certain objectives or orders, or to refrain from certain actions". It also covers "cooperation with third parties or to monitor and control conditions, actions, figures or types of behaviour". Compliance costs include capital costs[170], financial costs[171] and operating and maintenance costs[172], and can be broken down into: one-off/transition costs and recurrent (on-going) costs.

1) One-off and transition costs

One-off costs are often the result of a regulated group e.g. manufacturers, having to adjust and adapt to the changes in legal rules. For example, if new equipment needs to be purchased or if one-off changes in production processes need to be made. So one-off costs exclude costs that need to be borne on a regular or recurrent basis in the future.

The transition costs from previous legislation (i.e. the Dangerous Substances Directive (DSD) and Dangerous Preparations Directive (DPD))[173] to the CLP generated such costs for chemicals industry i.e. substances and mixtures manufactures and formulators[174]. These CLP transition costs are estimated ex-post to range from EUR 0.9 - 2.2 billion[175] with a mid-range best estimate of between EUR 1.4-1.6 billion. The range reflects uncertainties in the unit costs (± 30%), as well as uncertainties over the numbers of mixtures affected, including associated assumptions about staff training costs, IT costs, the number of mixtures subject to costs, the costs of reclassification, labelling, and Safety Data Sheet (SDS) preparation, etc.[176]

The largest transition costs were related to re-classification (a cost range of EUR 159- 295 million for individual substances and EUR 300 – 376 million for mixtures), to changes in labelling requirements (cost range of EUR 108- 200 million for substances and EUR 107 – 134 million for mixtures) and to updating and redistributing safety data sheet (a cost range of

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[170] CAPEX: occur when a company acquires or upgrades physical assets such as property, industrial buildings or equipment. Once the asset is in place, capital costs generally do not change with the level of activity and are thus functionally equivalent to "fixed costs". In cost-benefit analysis, capital costs are usually "annualised" over the period of the useful life of the equipment.

[171] Financial costs are costs related to the financing of investment, and are thus normally considered in relation to CAPEX. However, they can also emerge with respect to OPEX whenever a new legal provision changes the structure of the working capital.

[172] OPEX: include annual expenditures on salaries and wages, energy inputs, materials and supplies, purchased services, and maintenance of equipment. They are functionally equivalent to "variable costs."

[173] By 1 December 2010 for substances and by 1 June 2015 for mixtures.

[174] 1st FC Study Annex II p. 70 Table 6-8 outlines the sectors which are considered to have incurred transition costs, together with the number of companies assumed to be affected. SMEs account for 95% of all companies, whilst manufacturers / formulators of mixtures make up around two-thirds of the companies.

[175] Estimates based on the number of substances (over 99 000) and the number of mixtures (2 – 2.5 million) subject to reclassification, labelling and safety data sheets preparation. Source: 1st FC Study p. 45 and Annex II p. 58-85

[176] 1st FC Study p. 45 and Annex II p. 58-85

EUR 100- 184 million for substances and EUR 112 – 141 million for mixtures)[177]. The DSD/DPD to CLP transition costs[178] turned out higher than the original ex-ante estimates in the Impact Assessment done for the proposed CLP Regulation, where total costs were estimated at around to EUR 391 million. This difference is largely due to an underestimate of the number of affected substances and sectors in the 2006 impact assessment.[179]

Transition costs can also occur where substance specific risk management measures need to be taken because a substance previously not classified as, for example, a carcinogenic, mutagenic or toxic for reproduction (CMR) substance is reclassified as one following the introduction of the CLP Regulation leading to a ban of the substance and the need to find a less hazardous substitute. The impact of these costs, however, can vary. For example, the removal of substances from cosmetics use requires manufacturers to reformulate and, in some instances, to stop the manufacture of a particular product line altogether. Costs can be very low, for example, where a substitute is readily available, and significantly higher, where it is not, or where reformulation involves significant change to the production process. For example the costs of reformulating and remarketing a cosmetic product due to a change in a key ingredient were estimated to range from EUR 12 000 to EUR 920 000 depending on the role of the ingredient, the availability of alternatives etc.[180]

2) Recurrent costs

a) General overview

Recurrent costs are the substantive compliance costs sustained by the regulated stakeholders (chemicals industry for example) on a regular basis e.g. continual re-training of employees or repeated testing. The main recurrent costs come from:

- the obligation to identify/generate and provide data for chemical hazard classification and risk assessment;
- the risk assessment step and testing and within this the exposure assessment in particular[181];
- the implementation of risk management measures e.g. hazard communication through labelling.

More generally, the significance of the recurrent costs typically depends on the overall complexity and stringency of the legislation. The higher the potential hazard and risks of a

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[177] Total classification, labelling and SDS costs for substances are estimated at around EUR 522 million (±EUR 157 million); the comparable costs for mixtures are estimated at EUR 651 million (upper bound estimate for the number of mixtures). For more details see 1st FC study, Annex II p. 75 and Table 6-16 (p. 83)

[178] The types of costs taken into account include those related to classification, labelling, SDS revision and distribution, packaging costs, upgrading IT systems, staff training, CLI notification costs and costs associated with reformulation or the withdrawal of products.

[179] i.e. 30 000 substances compared to the figure of 99 000 assumed in the 1st Fc study. In addition, the 2006 study did not cover all of the sectors which would be affected by CLP, with the 2006 analysis assuming less than 20 000 companies (1 150 large and 18 780 SMEs) would be affected compared to 31,000 for this study, with this having a significant affect on the mixture - related costs. 1st FC Study p. 45 and for more details Annex II p. 85

[180] 1st FC Study table 4-4 p. 51

[181] Interviews were carried out as part of the FC+ Study

substance for the environment and/or human health, the higher will be the level of safety requested. This also means the level of information and assessment requested will be higher: as is the case for the Plant Protection Products and the Residues of Pesticides Regulations where the substances and products, are by design, lethal to the target plants and organisms.

In addition, the importance of these costs varies depending on the procedures that industry must comply with e.g. authorisation to place on the market. The Biocidal Products Regulation, the Plant Protection Products Regulation and the Residues of Pesticides Regulation in this regard have emerged as the lengthiest and most complex regulations, implying higher cost burden than, for example, the Cosmetic Products Regulation and the Toy Safety Directive (see Figure 11). For the Biocidal Products Regulation, it shall be noted however that, in most cases, industry can place their substances/products on the market during the assessments of authorities, which also allows them to recover some costs during that period. An element of caution should be applied to this comparison as there are considerable differences in the scope and potential hazard and risks of substances and products used.

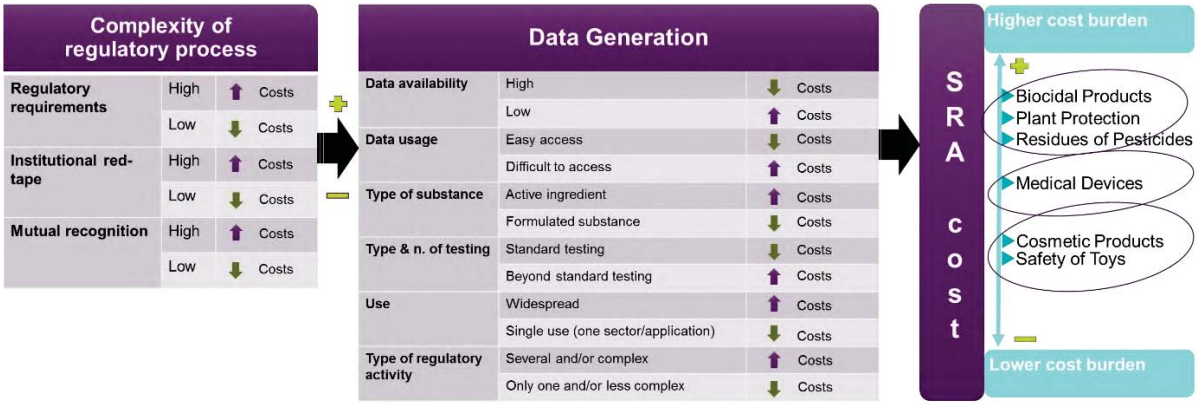

Figure 11 Legislation clustering according to cost influencers[182]

"Understanding and keeping up-to-date with changes in legal requirements" was identified during the Open Public consultation and the SME Panel Survey as a significant driver of costs by the highest number of companies (84% (147) of companies for the former and 45% of SME respondents for the latter), with the costs of risk management under the different legislation ranked second (73% or 127).[183] Training staff to ensure compliance with legal requirements was also identified as an important cost driver (61% (106) by respondents from industry associations and companies).

b) Main recurrent cost drivers

The costs of the classification of a substance are driven mainly by the CLP Regulation and are often dependent on data availability, accessibility and usability (as explained in Section 5.2.1 in the main document and Section 2.1.4 in Annex 4). The variety of cases and the conditions

[182] FC+ Study p. 84

[183] 1st FC study p. 48

of data usage and sharing vary legislation-by-legislation and according to specific cases within the same legislation[184]:

- Data on assessment of biocidal active substances and, in the future, for biocidal products, are publicly available on the ECHA website. For biocides, plant protection products and residues of pesticides, only vertebrates studies are subject to mandatory data sharing. For biocides, this mandatory data sharing is also extended to all toxicological and ecotoxicological data (including on invertebrates) for certain procedures[185]. As hazard and exposure data is lacking, companies have to undertake their own testing and, in some cases, corrections after testing. A similar problem for lack of toxicological data was reported for food contact materials.
- Under the Toy Safety Directive, publicly available information is reported fairly usable for toxicological testing.
- Under the Cosmetic Products Regulation, hazard can be obtained from the ingredient supplier (toxicological data from the product safety report) and exposure assessment data from the cosmetic producers.

In general, when data are publicly available, the risk/hazard assessment process is less costly. Similarly, low data access and usability affects costs upward. Testing as part of the data generation process to prepare and file an application for a regulatory approval of a substance or a mixture (e.g. under the Cosmetic Products Regulation, the Toy Safety Directive, the Detergents Regulation, the Biocidal Products Regulation, etc.) is another important cost driver for the industry. [186]

Annual costs arising from the CLP Regulation are estimated to amount to EUR 1.3 billion (EUR 0.97-1.7 billion).[187] The main cost element is staff costs related to compliance activities such as reviewing classifications, redesigning labels etc. (EUR 957 million[188]). These annual costs represent less than 0.1% of the total turnover for the sectors and approximately 1.1% of the value added[189]. These costs, however, do not include the poison centre reporting obligations, which currently depend on national legislation but that will be harmonised progressively at the EU level after 2020.[190] [191] Per company, the costs of the CLP

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[184] FC+ Study p. 81-85

[185] Article 95 of the Biocidal Products Regulation (Regulation (EU) No 528/2012)

[186] FC+ Study p. 79-84

[187] 1st FC STUDY Annex II, p. 95

[188] 1st FC study, Annex II section 7.2.3.4 and Table 7-5 (p. 89)

[189] Based on Eurostat data for 2012-13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1, and 24.4)

[190] These costs were estimated to amount to EUR 1.7 billion (Source: Study on the harmonisation of the information to be submitted to Poison Centres; Amec Foster Wheeler; March 2015). Recent analysis, however, cast some doubt on whether the numbers of notifications used for those studies are not significant overestimates. The details will also be reassessed in a study to be launched in early 2018, which may also lead to a revision of the Annex affecting the numbers of notifications to be expected.

[191] Although there is no evidence available yet, the CLP-related costs are expected to have significantly decreased after 2015 for individual hazardous substances and from 1 June 2017 for mixtures. Source: CCA1 study p. 104

implementation are estimated at EUR 34 000 (EUR 24 000 - 44 000) for SMEs and EUR 247 000 (EUR 173 000 - 321 000) for larger companies[192].

Respondents to the Open Public Consultation[193] from Industry associations and companies were of the opinion that classification requirements for substances and mixtures (57% (100)) and chemical labelling and packaging requirements (59% (102)) result in significant costs.

In cases where a substance or a product requires an authorisation or an approval in order to be placed on the market (e.g. Plant Protection Products and Biocidal Products Regulations), the requirements associated with the authorisation process i.e. starting from the dossier preparation until obtaining the final authorisation, can impose substantial costs on the industry. The total costs for the pesticides industry are estimated at approx. EUR 122-189 million per year. The regulatory charges (fees) represent a small share of the total costs for the industry[194]. The costs for pesticides maximum residue level (MRLs) procedures are estimated at around EUR 55 million per year for the industry[195]. Industry stakeholders explained that the process can be costly and time-consuming, to a level where only the larger companies in the sector can afford to go through the authorisation process for both the active ingredients (EU level authorisation) and the plant protection product (Member State level authorisation), as they can more easily absorb and/or pass on the costs of conducting the risk assessment to the end users. [196]

According to some industry stakeholders[197], the EU Union product authorisation process under the Biocidal Products Regulation is considered to be too costly. It was explained that national authorisation is generally favoured when only a limited number of markets are served (less than 10 EU markets). Some companies (particularly SMEs), by reason of their size, due to their focus on niche markets or language barriers, may rather be interested in operating in one or few Member States only. The spatial element is also to be taken into account. Some countries may be chosen for the authorisation of biocidal products depending on the market needs (e.g. wood preservatives in northern countries). There might be different driving factors motivating the applicants' choice of the countries responsible for the assessment of the applications like the amount of the fees charged, but also the expertise on a given product-type. Nevertheless, as the EU Union product authorisation process was only introduced in

[192] Assuming that the costs are evenly spread across the 30 850 SME substance and mixture manufacturers and 1 057 larger substance and mixture manufactures. 1st FC study p. 88 Section 7.2 Annex II

[193] Question 21

[194] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available

[195] Ibidem

[196] FC+ Study p. 86

[197] This survey was carried out by Ecorys (2016), Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision, Final report to the European Commission Directorate-General for Health and Food Safety. 12 large companies and 14 SMEs participated in the survey

2013 and as it will cover all product types by 2020, it might be necessary to wait some additional time before seeing its use more widely.[198]

Annual costs incurred by the detergents industry as a direct result of the Detergents Regulation are estimated to range between EUR 63.7 – EUR 149 million (appr. EUR 764 million – EUR 1.8 billion in total since 2005). Depending on the sector, compliance with occupational health and safety legislation, e.g. investments in workers' health protection equipment, can also lead to significant costs.

Even though an in-depth analysis of the main cost drivers related to other risk management measures has not been carried out due to the wide scope of the Fitness Check and their diversity, it appears clearly that such costs exist e.g. labelling requirements (the CLP or sector specific legislation) including the label design, printing, as well as additional translation costs, or some packaging requirements such as child resistant closures that increase production costs.[199] Specific protection measures are to be taken in order to provide individual and collective protection of workers in a professional environment e.g. production or use of hazardous chemicals in products manufacturing. For the soaps and detergents sector, for example, the worker safety legislation implies the second most important regulatory cost, representing 21% of the legislation costs, equivalent to approximately 2% of the value added.[200] Most of the cost is generated by the obligations for investments on workers' safety and health protection equipment.

3) Administrative costs

Administrative costs are those borne by businesses, citizens, civil society organisations and public authorities as a result of the administrative activities performed to comply with the information obligations included in the legal rules. Administrative burden is the result of regulatory requirements: accordingly, they do not include so-called "business-as-usual costs". Given the wide scope of this Fitness Check, these costs are very difficult to assess, in particular because of the lack of monitoring at EU level and the scarcity of data.

Administrative burden represent approximately EUR 950 million for chemical sector (2004-2014)[201]. Administrative burden corresponds to:

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[198] The recent Commission's report to the European Parliament and to the Council (COM(2018) 342 final) gives some preliminary conclusions indicating that Union authorisation is attractive under the current fee rates, particularly with regard to biocidal product families. Moreover, applications for Union authorisation are serving as reference products for national applications. This will help applicants, and particularly SMEs, to obtain authorisation for their existing products at Member State level.

[199] The CLP related costs are provided in the Annex II of the 1st FC Study

[200] CCA1 Study p. 137

[201] CCA1 Study p. 115 and onwards. The identified costs cover costs for several subsectors of chemicals industry (i.e. organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products). The following pieces of legislation are covered: the CLP Regulation, the Plant Protection Products Regulation, the Biocidal Products Regulation, REACH, the Inland transport of Dangerous Goods Directive, the Carcinogens and Mutagens at work Directive, the Young people at work Directive, the Pregnant workers Directive, the Signs at work Directive, the Chemical Agents Directive, the IED, the Waste Framework Directive and related (ELV, Batteries, PPWD), the Seveso Directives, the Water Framework Directive, the RoHS Directive, the Export and import of hazardous chemicals (PIC) Regulation, the POPs Regulation, the Toy Safety Directive, the Cosmetic Products Regulation,

- The amount of work necessary to fulfil information obligations, retrieve data on applications from downstream users, monitor emissions data, or prepare technical dossiers for the purpose of registration, authorisation, classification and labelling[202].
- The obligation of reporting and information and the preparation of companies for inspections.[203]
- Personnel cost for the preparation of audits and carrying out regular health checks. Implementation of risk assessments and investigations e.g. for existence of hazardous, carcinogen and mutagen substances, are required and information on the findings should be communicated to the competent authorities and to workers.[204]

From a qualitative assessment perspective, the information obligations for safety reports, authorisation dossiers, etc., under regulations such as the Plant Protection Products Regulation, the Biocidal Products Regulation, the Cosmetic Products Regulation, and others, are a key driver of administrative costs. However, under the Biocidal Products Regulation there is a possibility to authorise a group of similar biocidal products ('biocidal product family') via one single application for authorisation, which reduces the administrative burden for both companies and authorities.

Another factor that can increase the administrative costs is the pace of the risk assessment process. The risk assessment processes can take anywhere between months and several years depending on the legislation and on the specific case. Laboratory/consultancy and industry stakeholders considered the risk assessment process under the Biocidal Products Regulation and to the Plant Protection Product Regulation to be one of the longest. The whole process from start to final product authorisation can take up to 10-15 years. In part, this can reflect delays both from the applicant in submitting missing data and delays caused by the evaluating authorities.[205] For the Biocidal Products Regulation, it should be noted, however, that, in most cases, industry can place their substances/products on the market during the authority assessment period which allows industry to recover some costs.

4) Hassle costs

Often linked to administrative burden measurements, hassle costs are a residual category of the direct costs. These are more subjectively felt costs related to the overlap of regulatory requirements on specific entities, be they citizens or businesses. Hassle costs can include costs related to administrative delays (when not directly attributable to an information obligation) and relatedly, the opportunity cost of waiting time when dealing with administrative or litigation procedures.

Industry stakeholders have pointed out that the potential for disagreement between the RAC and EFSA regarding the proposed classification of an active substance used in plant

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the Detergents Regulation, the Fertilisers Regulation, the Explosives Directive, the FCMs Regulation, the General Product Safety Directive

[202] CCA1 Study p.101

[203] CCA1 Study p.110

[204] CCA1 Study p. 83

[205] FC+ Study p. 82

protection products can have significant impacts for industry due to the uncertainty that it creates regarding the outcome of the assessment (approval/partial approval/no approval).[206]

They have also highlighted that the complications and delays increasing the overall costs are greater in cases where the level of mutual recognition at Member State level is generally low (or there is otherwise a differentiated approach for different parts of the EU). A lack of mutual recognition is reportedly often linked to different requirements at Member States level and to disagreements, non-acceptance or lack of trust in assessments of reference Member States, misinterpretation or misuse of emergency use of authorisation between different Member States. Data generation costs are typically influenced upward because of additional testing or information requirements from the national authorities.[207]

C. Enforcement costs

The legal rules have to be monitored and enforced by public authorities to be effective. These enforcement activities imply costs to the administration.

It is not possible to provide quantified figures of costs of enforcement of the EU chemicals legislation at national level. These costs may vary greatly amongst legislation depending also on the regulatory option chosen (e.g. self-regulation, providing information and guidelines, market-based instruments, more or less stringent and prescriptive regulatory actions). Differences in enforcement costs vary also from one Member State to another depending on the national administrative choices and the related functional costs. [208]

From a qualitative perspective, however, the costs for public authorities[209] include costs associated with:

- Implementation activities: these activities include participation in expert groups and scientific bodies, research and regulatory proposals, risk assessments, etc. The implementation of chemicals control legislation is time- and resource-intensive. Therefore, the fact that many Member States are lacking resources leads to differences in their involvement in bringing forward harmonised hazard classification dossiers, for example.
- Compliance monitoring and enforcement activities: the costs will depend on the way in which the compliance monitoring and the inspection are organised at the national level and on the regimes in place under the related chemicals legislations. Data available from the REACH-EN-FORCE projects indicate that on average over 2 000 inspectors are trained on REACH and CLP per annum, at an annual cost of around EUR 1.7 million. [210]

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[206] 1st FC Study p.62

[207] For example, for Plant Protection Products, art. 40 introduces a zonal rapporteur who should assess the application for the entire zone and not only for the Member State regarding the application. The zonal application should then be mutually recognised; however, this may be complicated where requests for additional data from other Member States in the same zone (to ensure acceptable risk) may arise. Source: 1st FC Study Annex IV p. 160

[208] Quantification of costs incurred in the EU were carried out only in respect to the CLP Regulation. See 1st FC Study Annex II p. 211

[209] 1st FC Study p. 51-52

[210] 1st FC Study p. 88

- Reporting activities (even though not all pieces of legislation are subject to reporting obligation). In this regard, Member State authorities noted that there are substantial costs incurred by the enforcement agencies related to unnecessarily bureaucratic reporting duties. For example, respondents to the Open Public Consultation noted that chemical data needs to be reported to numerous authorities due to numerous requirements. This includes the potential need for a company to undertake reporting to ECHA, the Commission (ozone depleting substances, etc.), to other national authorities (workers' safety, Seveso, the environment, VOCs, fluorinated gases, etc.). This leads to costs both for authorities and for enterprises, which are significant.[211]

For illustrative purposes, the overall costs for Member States generated by the Plant Protection Products Regulation for the approval and authorisation procedures are estimated at approx. EUR 44 million annually. The costs for the Residues of Pesticides Regulation (which sets maximum residues levels (MRLs) of pesticides on food products) procedures are estimated at around EUR 5 million annually for the 28 Member States. [212]

At the EU level, data taken from the publicly available reports setting out ECHA's budgets indicate that the average annual costs to ECHA associated with implementing CLP are estimated to be approximately EUR 2.57 million.[213] This figure constitutes the cost of providing guidance, running helpdesks, overseeing committees and forums, etc. The total cost to ECHA of implementing CLP over the period 2010 to 2016 is over EUR 22.8 million, equivalent to 17% of the combined the REACH and the CLP budget.[214] The total capital costs to ECHA of developing the Classification and Labelling Inventory (CLI) were approximately EUR 1 million, with annual operating expenditure of around EUR 0.2 million.[215]

Respondents to the Open Public consultation identified costs to public authorities as significant[216].

D. Indirect regulatory costs .

Indirect costs are costs incurred in related markets or experienced by consumers, government agencies or other stakeholders that are not under the direct scope of the regulation. These

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[211] 1st FC Study p. 52. This issue is being examined as part of Fitness Check on environmental monitoring and reporting (SWD(2017) 230).

[212] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available

[213] European Chemicals Agency, Budget 2018, MB/45/2017 Final, Brussels, 14 December 2017, Public https://echa.europa.eu/documents/10162/23601668/mb_45_2017_budget_2018_en.pdf/20014aa3-a68b-107f-ffdf-61171e273eeb

[214] 1st FC Study p. 52

[215] 1st FC Study p. 46

[216] Question 20. 40% or 17 of Group 4 NGOs and others respondents also identified significant costs for authorities at EU level and costs for authorities at national level (42% or 18). The proportion of Group 3 (representing governments and public authorities) identifying significant costs at the EU level was 25% (9) and at the national level was 33% (12). The majority of Group 3 respondents (56% or 20) to question 22 replied that there are specific requirements in the EU legislative framework which lead to particularly significant costs for authorities. Main comments received were related to market surveillance, inspections and enforcement of existing requirements.

costs are transmitted through the value chain and expressed as changes in the prices, availability and/or quality of the goods or services produced in the regulated sector.

Indirect compliance costs can arise due to the fact that, for example, a specific substance is banned for further use and therefore must be substituted. The development costs for substitution can be seen as direct one-off compliance costs even if they are occurring in downstream sectors, but they then lead to indirect costs transmitted through changes in the prices of the final goods, when the banned substance was used in their production. Changes in these prices then ripple through the rest of the economy, causing prices in other sectors to rise or fall and, ultimately, affecting the welfare of consumers.

It was possible to quantify such costs regarding the transition to the CLP Regulation costs. Indirect transition reformulation costs for manufacturers of mixtures are estimated at between EUR 67.7 million and EUR 141 million (depending on the assumptions for numbers of mixtures and the fraction of mixtures assumed to be reformulated). No estimate of the associated losses from withdrawing product lines from the market could be developed.[217]

6.1.3 Benefits

A. General overview on main aspects related to benefit assessment

Just like the costs, the benefits can be classified as direct and indirect (see Figure 12). Direct benefits will affect the stakeholders within the scope of the legislation e.g. industry, consumers, workers, etc. Indirect benefits will go beyond the target groups of the legislation and affect other groups e.g. bring benefits throughout the value chain or even become diffuse and benefit the whole society (e.g. reduced exposure to hazardous chemicals through general environment).

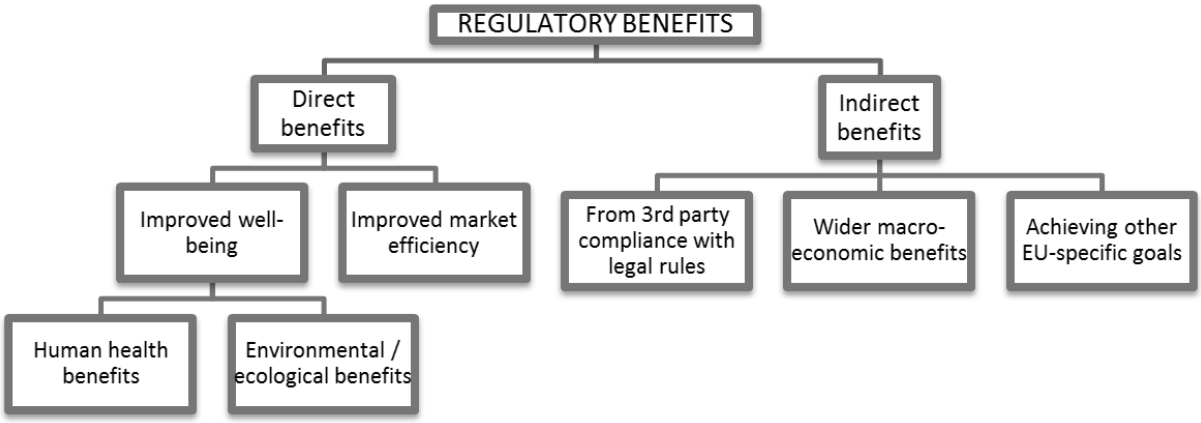

Figure 12 Categories of regulatory benefits

The direct human health and environment benefits resulting from the EU chemicals legislation are assessed below. Where the data and methodology allowed for reasonably robust and transparent benefit estimates to be calculated, quantified figures are provided. .

The benefits of improved market efficiency are typically evaluated from the perspective of market prices, competition, production and supply of goods. No estimates based on these

[217] 1st FC Study Annex II p. 83-84

criteria have been made for the purpose of this Fitness Check, mainly due to its wide scope and to the scarcity of data. Therefore, these aspects are analysed in Annex 5 Effectiveness from a wider macro-economic angle and from a qualitative perspective, including the impacts on innovation and competitiveness, as well as achieving the objective of awell-functioning internal market.

Regarding the indirect regulatory benefits for 3rd parties from compliance with the legal rules, it seems that the EU chemicals legislation has produced spill-over effects going beyond the EU borders e.g. due to the fact that imported articles shall comply with the EU legislation in order to be placed on the market. Another example is the Cosmetic Products Regulation, which is often used as a reference and a regulatory model worldwide, in particular in relation to animal testing. However, such benefits have not been assessed for the purpose of this Fitness Check.

The framework of EU chemicals legislation also contributes directly to meeting the EU's international obligations and commitments including the achievement of the 2030 UN Sustainable Development Goals (SDGs), the World Summit on Sustainable Development WSSD 2020 Goal, and the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006).

The EU chemicals legislation plays an important role in the shift towards a more circular economy, which itself contributes to achieving other EU commitments, including the fight against climate change. However, such benefits have not been assessed for the purpose of this Fitness Check. Nevertheless, the impacts of the EU chemicals legislation on achieving the circular economy goal are described in the main document (Section 8.1.2 Relevance).

B. Cumulative health and environmental benefits

Significant benefits in terms of protecting human health and safeguarding the environment have been delivered over the last 50 years by the EU chemicals legislation to industry, to public authorities and regulators as well as to consumers and citizens and to society and the economy more generally. Table 5 provides a list of benefits and direct beneficiaries.

Category of benefits		Direct beneficiaries and benefits	
Health	**'Physical' benefits**	Workers, consumers and citizens	Reduced morbidity and mortality health impacts (e.g. reduced number of cancers, cardiovascular disease, allergies, reproductive illnesses, neurological disease, etc.) from reduced exposures of hazardous chemicals. This includes avoided suffering and health effects through higher income (due to avoided lost earnings as a result of avoided illness) and longer life expectancy
	Monetised benefits	Consumers and citizens	Avoided healthcare costs, avoided suffering (assessed through willingness to pay techniques), value of avoided life years lost due to premature death, productivity losses due to lost work hours as a result of illness and/or premature death
		Industry	Avoided health costs and productivity losses; a less hazardous working environment can reduce the costs that companies face (healthcare costs, insurance costs, lost productivity, fines, etc.) .
		Member States	Reductions in the damage costs associated with chemical exposures (healthcare costs; environmental clean ups, etc.)

Avoided environmental damage	Society	Various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs
	Industry	Reductions in the costs associated with environmental remediation and clean ups.
	Members States	Reductions in the costs associated with environmental remediation and clean ups.
Regulatory	Member States	Reductions of some of the burden faced by Member States, by enabling them to share efforts (and hence resources) at the European level in the implementation of the legislative framework

Table 5 Benefits and direct beneficiaries

The available evidence suggests that the benefits of EU chemicals legislation are significant. Important benefits arise, for example, from avoided healthcare costs and productivity losses. There are, however, a number of health and a significant number of environmental benefits for which it is not yet possible to estimate the value in monetary terms. Therefore, the estimates presented for the purposes of this Fitness Check do not give the full picture of benefits.

Some of the biggest, currently measurable, health benefits of EU chemicals legislation are associated with reductions in the exposure to carcinogenic pollutants. However, one should keep in mind that, while the extent of cancer incidence due to occupational exposure has been extensively studied, the impacts from environmental exposure to carcinogens are harder to estimate. It is in an occupational setting where the link between exposure to certain chemicals and cancer is the most clear[218]:

- It has been estimated that in the EU between 91 500 – 150 500 people with past exposure to carcinogenic substances at work were newly diagnosed with cancer in 2012. Moreover, between 57 700 – 106 500 cancer deaths were attributed to work-related exposure to carcinogenic substances in 2012. As a result, cancer has been designated as the first cause of work-related deaths in the EU. Direct costs of work-related cancer in terms of healthcare and productivity losses amount at least to some EUR 4-7 billion per year. The indirect costs may reach as much as about EUR 242 – 440 billion each year.[219]
- Based on reductions in exposure to a group of 13 carcinogens since 1995 that have been targeted by EU occupational health and safety legislation, the total number of cancer deaths avoided across the EU is estimated to be around 1,4 million. [220]

Other examples below include the estimated benefits from reduced exposures to lead, hexavalent chromium, allergens, phthalates, to pesticides and polychlorinated biphenyls (PCBs) (see Table 6). Annex 5 provides more information regarding the historical and ongoing exposure.

[218] CuBA Study, p. 45

[219] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee Of the Regions, COM(2017) 12 final

[220] CuBA Study p. 18 and p. 57

The Benefits	Estimated Benefit Value (€) for the EU	What's Included?
Avoided cancers due to reduced exposures to **hexavalent chromium** at workplace	**Hexavalent Chromium: EUR 100 million/yr** and EUR **4 billion in total** between 1995-2010	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced neurotoxicological disease and related deaths due to reduced exposures of children to **lead**[221] through general environment	**EUR 450 billion/yr**	• Avoided lifetime earnings losses due to reduced IQ as a result of exposure to lead during childhood
Reduced asthma cases and related fatalities due to reduced exposures to **allergens** and other hazardous chemicals attributed either to air pollution or exposure at workplace	**EUR 250 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced female reproductive disease as a result of reduced exposure to **DEHP (phthalate)** via a variety of consumer products	**EUR 7 billion** cumulatively from 1996 - 2008 (i.e. approx. **EUR 580 million/yr**)	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income)
Reduced male reproductive disease (infertility) as result of reduced exposure to **DBP (phthalate**[222]**)** via **a** variety of consumer products	**EUR 6.7 billion** cumulatively from 1996 – 2008 (i.e. approx. **EUR 560 million/yr**)	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income)
Reduced cases of skin sensitisation (allergic reaction) as a result of reduced exposure to **allergens** at workplace	**EUR 160-190 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced incidence of chromium VI allergy cases associated with skin sensitisation and damage due to exposure from articles of leather[223]	**EUR 350 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Increased consumer surplus

[221] Lead in European children's blood has substantially decreased over last four decades due to the removal of lead from petrol, as well as from other exposure sources such as paints and pipework. The corresponding effects regarding children are reduced damage to the intellectual development /loss of intellectual capacity, reflected in higher lifetime earnings potential and avoided disability adjusted life years (DALYs)).

[222] The reduction in the manufacture, use and exposure to phthalates in the EU has decreased significantly from the mid-1990s.

[223] Chromium VI is not intentionally used in the manufacturing of articles of leather, but may be formed during the tanning process, or can be released during storage and the lifecycle of leather articles. It is associated with skin sensitisation and damage. It was estimated that 0.84-2.31 million individuals are sensitised in the general population of the EU-27. It is also estimated that at least 45% of the new chromium allergy cases in the EU-27 were due to exposure from articles of leather. The only way of preventing allergic reactions for allergy sufferers is to avoid contact with leather goods that contain chromium (VI).

The Benefits	Estimated Benefit Value (€) for the EU	What's Included?
Reduced environmental and pollination impacts as a result of better control and management of **pesticides** (e.g. neonicotinoids)[224]	**EUR 15 – 50 billion/yr**	• Value of eco system services • Agricultural value of pollination services provided by pollinating insects
Avoided drinking water treatment costs as a result of reduced **pesticide contamination** of surface and groundwater reserves	**EUR 500 million/yr**	• Avoided water treatment costs
Avoided clean-up costs association with PCB use in the past caused by the contamination[225]	**Cumulative cost of EUR 0.4 - 1.9 billion/yr** for the period 1971 to 2018 (EUR 20 – 90 billion in total)	• Remediation and waste management costs excluding any health and environmental impact costs

Table 6 Selected monetised environmental and health benefits of reduced hazardous chemical exposures[226]

Additional benefits result from the regulatory framework on plant protection products and/or biocidal products helping to reduce the development of resistance of unwanted pests/organisms, which can have serious impacts on agriculture, health, environment, the functioning of society and the economy.

Regarding enhancement of the single market, competitiveness and innovation objectives, these benefits have been examined in the main document Sections 5.1.2 Effectiveness and 9. EU added value and in Annex 5 Section 1.2. There have been positive impacts of the EU chemicals legislation in terms of an efficiently functioning internal market. Benefits in terms of innovation and positive impact on the EU industry's competitiveness are more complex.

More generally speaking, the EU chemicals legislation plays an important role in the shift towards a more circular economy.[227] It also contributes directly to the achievement of the 2030 UN Sustainable Development Goals (SDGs[228]).

Respondents to the Open Public Consultation[229] agreed that the EU chemicals legislation and chemical-related legislation generate benefits from reducing the exposure of consumers and

[224] Bees play a significant role in the food production process and provide ecosystem services (e.g. pollination) beneficial to human nutrition. Neonicotinoids are likely to be contributing to the observed beehive collapse syndrome in Europe.

[225] These clean-up costs are associated with PCB use and waste management (remediation and waste management costs; but not including any health and environmental impact costs) caused by the contamination that could have been saved.

[226] Study on the cumulative health and environmental benefits of chemicals legislation

[227] For example, see the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); 16 January 2018

[228] https://www.un.org/sustainabledevelopment/sustainable-development-goals/

[229] Question 19: What are the significant benefits generated for EU society by the EU chemical and chemical-related legislation?

citizens to toxic chemicals[230], reducing the exposure of workers to toxic chemicals[231] and reducing damage to the environment and ecosystems[232].

Respondents to the Open Public Consultation[233] indicated that EU chemical legislation and chemical-related legislation generate benefits by:

- Encouraging research and innovation, generating new jobs and improving competitiveness: NGOs and others have the highest response to this benefit at 70% (31), while respondents from the other groups are much less likely to identify this as a significant benefit of EU chemicals legislation. Only 10% (17) of Industry association and companies respondents identified this as a benefit compared with 41% (15) from Public authority and 27% (7) from Citizens.
- Stimulating competition and trade within the EU single market: the percentage of respondents from all groups is much lower for this benefit with the highest proportion identifying this as a significant benefit coming from Public authority at 22% (8). Just 5% (8) of Industry association and companies respondents identified this as a significant benefit, slightly higher than the 4% (1) from Citizens.
- Stimulating international trade between the EU and other countries: again the level of agreement that this is a significant benefit was lower, and lower than for within the EU single market for all groups except Citizens (here 8% highlighted this as a benefit but the number of responses is very low, at 2). The highest level of agreement came from Public authority at 19% (7) while just 4% (7) of Industry association and companies thought this was a significant benefit.

6.1.4 Are costs and benefits proportionate?

The inability to arrive at single overall figures for the cumulative benefits and costs of the EU chemicals *acquis*, coupled with the partial picture on the costs and benefits at the specific legislation level, means it is not possible to arrive at a single cost-benefit ratio nor is it possible to determine whether or not costs are proportionate at the framework-wide level. .

It appears from the analysis above that the benefits directly or indirectly generated by the EU chemicals legislation are significant while costs to companies and public authorities are also significant.[234] These views are shared by different stakeholders although the perception of the importance of the costs and therefore of whether costs are proportionate to benefits varies amongst different groups and even within the same category. The real question is not about the *acquis* overall, but about specific elements of it, for example:

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[230] 95% (35) of Public authority, 80% (35) of NGOs and others, 79% (140) of Industry association and companies and 54% (14) of Citizens respondents.

[231] 92% (34), of Public authority, 85% (151) of Industry association and companies, 91% (40) of NGOs and others and 54% (14) of Citizens.

[232] 89% (33) of Public authority, 84% (148) of Industry association and companies, 70% (31) of NGOs and others and 58% (15) of Citizens.

[233] Question 19: What are the significant benefits generated for EU society by the EU chemical and chemical-related legislation?

[234] FC+ Study p. 138

- Industry stakeholders from the pesticides sector (including biocides) explained that the processes of substance approval and product authorisation can be costly and time-consuming, to a level where only the larger companies in the sector can afford to go through them as they can more easily absorb and/or pass on the costs of conducting the risk assessment to the end users.[235]
- Another specific example is the EU decision to adopt changes in labelling requirements under the CLP Regulation (in line with their adoption at the UN GHS level). This is triggered by the adoption of changes under the UN Global Harmonised System (GHS) which requires all signatory countries to then implement via their respective national legislation. For EU countries this is done via the CLP Regulation. According to industry stakeholders, such changes led to significant costs while the associated health and environmental benefits were considered to be marginal (at best).[236]
- Risk prevention is commonly regarded as most effective and efficient if it is implemented from the top-down, e.g. via substitution of hazardous chemicals with safer alternatives or technologies. Depending on the situation, the effects of substitution will be perceived as proportionate or disproportionate by different stakeholders e.g. if a less hazardous alternative already exists available investments in research and development will have less of an economic impact whose absorption will also depend on the size of the company and its activity and the place in the value chain.[237]
- Amongst Member States, the UK is the only country to have tried to provide an estimate of the costs and benefits of chemicals legislation. The environment ministry quantified the costs and benefits of 428 of its environmental regulations affecting UK businesses, just over half of which were derived from EU or international legislation. The most positive cost-benefits ratio amongst the different policy area clusters was for regulations on 'chemicals and genetically modified organisms' with a ratio of 1:18.9 (with 82% of the costs coming from EU legislation) i.e the benefits outweigh the costs by a factor of 18.9.[238]

6.2 What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

This sections looks at factors that affect the efficient functioning of the EU chemicals legislation beyond the sole cost-benefit point of view.

6.2.1 Reliance on the CLP Regulation as the basis for hazard classification and labelling

The CLP Regulation is the primary basis for identifying hazards and then providing hazard classification across almost all other pieces of EU chemicals legislation. The clear separation

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[235] FC+ Study p. 86

[236] 1st FC Study p. 60

[237] 1st FC study p. 61 and Annex IV p. 111

[238] "Emerging Findings from Defra's Regulation Assessment First update covering 2012 Published February 2015", DEFRA

of the hazard assessment step from risk assessment and risk management steps helps ensure the independence and objectivity of the scientific assessment of inherent properties of chemicals. Doing this on the basis of centralised hazard assessment (e.g. in CLP; or for PBT/vPvB in REACH) provides a consistent scientific base for the different legislative areas, focuses the use of scientific experts where it makes most sense and avoids duplication under different pieces of legislation. On the other hand, differing exposure, risk and socio-economic patterns depending on the uses of chemicals justify separate legislation with different approaches on risk assessment and management. This interplay between central and independent hazard assessment and the link between individual pieces of downstream legislation provides a good balance between consistency, predictability and flexibility.

The underlying principle of CLP is 'self-classification', with industry responsible for assessing, classifying and labelling substances and mixtures that it wishes to place on the EU market. For substances that are particularly hazardous and that are widely used in the EU, Member State authorities or industry itself can propose harmonised classifications on which the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) provides opinions. Based on those opinions, the Commission, through the comitology procedure, makes a decision on the proposed harmonised classification and, if agreed, the substance and its harmonised classifications are included in Annex VI of the CLP regulation. When a substance or mixture is classified for one or several hazards, the relevant information is communicated to other actors in the supply chain, including to consumers, via the labels of products placed on the market and, where relevant, via safety data sheets.

This architecture of self-classification backed up by harmonised classification for substances of concern, provides a clear and consistent approach to identifying, characterising and classifying hazardous chemicals. It ensures that the science of chemical hazard assessment and classification is done separately but then fed into decision-making in the risk assessment and risk management decision steps. It allows classification of a wide range of chemicals without creating a disproportionate burden on administration while focusing resources of public authorities to the most relevant substances for public health and the environment. With a few exceptions (e.g. PBT and vPvB and EDs), it provides harmonised hazard classifications as a basis for risk assessment under the various pieces of downstream chemicals legislation. Furthermore, where no harmonised classification exists, basing the system on self-classifications allows for faster evaluation by companies.

Criteria of hazard identification existing under other pieces of legislation are largely coherent and do not reduce the efficiency of the central hazard identification system of chemicals legislation. There is though a debate about whether criteria for PBTs and vPvBs, as well as EDs should be integrated into the CLP.

Whilst CLP is considered an efficient aspect of the EU chemicals legislation, the fact that its enforcement is not yet uniform across the EU has efficiency implications. Most industry stakeholders (64%) and a significant percentage (one third) of other stakeholders believe that the implementation of CLP is not enforced in a harmonised way in many Member States. Lack of harmonisation and enforcement can generate additional costs to industry from having to meet varying national requirements as well as lost opportunities due to unnecessary internal market barriers.

Harmonised classifications rely on the initiative of either companies or Member State authorities to create and submit a proposal to ECHA for a harmonised classification which is eventually adopted by the Commission. Resource and expertise constraints in a number of

Member States hinder their ability to make these proposals with knock-on effects, for example, on the approval of active ingredients under the Plant Protection Products Regulation. The fact that the workload in developing harmonised classification dossiers is shared unequally between Member State Competent Authorities has also been identified as a factor that negatively affects efficiency (cf. Chapter 3 Implementation and state of play).

There are inefficiencies in relation to consumer labelling under the CLP Regulation as highlighted above in terms of proportionality of costs for companies to change some aspects of labelling and the effectiveness of the communication.[239] In addition, the length and amount of hazard and precautionary statements that need to be printed on some labels lead some consumers to become inured to the hazards that mixtures (mainly) pose, reducing the ability of the hazard communication to deliver its intended benefits.[240] The existing provisions and requirements do not take into account opportunities offered by digitalisation which could help reaching consumers more effectively, increase the amount of available information e.g. via printing Q-R codes to be scanned with a mobile phone, and at the same time reduce costs related to labelling.[241]

6.2.2 Efficiency of risk management related processes

The identification and adoption of risk management measures can be taken following two different approaches, either through a specific risk assessment (SRA) or through generic risk considerations (GRC) (see Section 2.1.5 and Annex 8 for a more detailed description of the two approaches). In many instances, a combination of both approaches is tailored to, and used in, different pieces of EU chemicals legislation. For the most part, stakeholders (industry, NGO, academia and Member States) agree that it is appropriate for different pieces of legislation to have different approaches as they are concerned with different sectors and end-users. However, their views on the efficiency of use of both approaches are mixed and there has been criticism of both approaches to risk management.[242] A key consideration in the assessment of the efficiency of chemicals legislation, i.e. the interplay of different pieces of legislation that are part of this framework, is the question of when specific risk assessment or generic risk considerations approaches are most efficient. Since it is also directly and significantly related to the question of the effectiveness of the framework of EU chemicals legislation, this issue is mainly described and assessed in the main document Section 5 and in Annex 5. A more general description of the functioning of the framework is provided in Annex 8. The main discussion elements are summarised below.[243]

Risk prevention is commonly regarded as most effective and efficient if it is implemented from the top-down, e.g. via substitution. Whether or not more cost effective ways exist to achieve the same goal is difficult to judge because this is likely to differ across different cases and the application/use of a PBT/vPvB, CMR or other hazardous substance. From their perspective, industry stakeholders argue that substitution can be an expensive and resource

[239] 1st FC Study p. 23; see also Special Eurobarameter Survey 456, published June 2017

[240] 1st FC Study p. 61

[241] 1st FC Study Annex Annex II p. 134

[242] 1st FC Study Annex IV p. 122

[243] For more details see 1st FC Study Annex III p. 88 and onwards (Section 6.5) and Annex IV p. 78 and onwards (in particular Sections 5.3 and 6.3 and 6.4)

intensive exercise, especially if new chemistries or technologies are required. Research has found that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure (see below on grouping approach). However, robust comparative risk analyses need a high level of information and can be resource and time intensive as described above and in other parts of this document.

Automatic bans on hazardous substances based on GRC can also be criticised as a more expensive form of risk management as they require immediate reformulation of products, although a possibility for derogations may exist. Moreover, the SRA approach could also result in reformulation if the substance is found to exhibit an unacceptable risk. Risk assessments will also have associated costs as they can require extensive monitoring, modelling and testing, with the latter being particularly expensive.

In terms of the speed of risk management, NGOs and Member States believe that the automatic triggers help to prevent exposure to harmful substances in a fast and efficient way and this is considered to be a benefit. They highlight that the costs of inaction can be high and this needs to be taken into account.[244] By contrast, industry associations are more generally in favour of specific risk assessment as they believe this allows for a more accurate and tailored approach to identifying any necessary risk management measures and because it avoids the potential elimination of useful applications of hazardous chemicals that would otherwise be banned using the generic risk consideration approach. [245]

The following aspects related to hazard and risk assessment efficiency within particular pieces of EU chemicals legislation merit to be highlighted:

1. The Plant Protection Products and the Biocidal Products Regulations

The risk assessment requirements under the Plant Protection Products and Biocidal Products Regulations are demanding. They reflect the fact that plant protection and biocidal products are, by design, hazardous to the target organisms or plant species which are to be controlled (agricultural pests, vectors of diseases, pathogens, organisms degrading materials, etc.). Usually their use patterns involve widespread and/or various kinds of exposure scenarios, noting that exposures in closed systems or at local level are also technically possible in some cases. This results, unsurprisingly, in a high cost and potentially lengthy risk assessment processes that are particularly challenging for SMEs. In this regard, the following efficiency factors were identified:

- The requirement to firstly approve active ingredients at the EU level and then, additionally and separately, authorise the products that are to be placed on the market at the Member State level (within a mutual recognition zonal system for plant protection products; a EU wide mutual recognition system for biocidal products) imposes additional costs and delays. It was reported by the industry stakeholders to be one of the most burdensome, and cost-variable elements. The Biocidal Products Regulation also offers the possibility for

[244] 1st FC Study Annex IV p. 114

[245] Ibidem

companies to obtain Union authorisation of their products, which allows them to place them directly on the entire EU market.

- In some cases delays make risk assessment and authorisation process lengthy (delays being attributed to delays to the applicant in submitting missing data or to the evaluating authorities). In some cases, active substances or products can be placed on the market in the meantime. However, delays can create a situation where the regulatory requirements have changed in the meantime. Additional testing and updates become therefore necessary and create additional burden leading to additional costs.
- Once a harmonised classification for an active ingredient is agreed under CLP, a transition time of 18 months from its entry into Annex VI is allowed for. During this period, industry must take the necessary measures in order to comply with the new obligations. Industry considers this period to be too short in some cases for them to manage compliance with classification and labelling obligations along complex supply chains[246]. Targeted consultation found that almost 70% of products, whether substances or mixtures, would normally retain the same labels for over 24 months with only 30% normally changing their labels within this time frame (for reasons of marketing, changes in consumer demand, reformulation, etc.).[247] One should also keep in mind that it takes some additional time to correct obvious mistakes with the Adaptation to Technical Progress (ATPs) or in the different language versions.
- In the case of biocidal products, this transition period is perceived as insufficient as the registration process may take longer. More importantly, though, it may also be too short for downstream users (i.e. formulators) to identify how best to respond. The need to act quickly (e.g. to a substance newly being classified as a carcinogen) may lead to investment in short term solutions, such as increased personal protection, or to regrettable substitutions by another substance within the same family that has a negative side effect.
- Whilst not yet widely used, the EU-level 'Union Authorisation' process under the Biocidal Products Regulation aims to reduce the cost burden of making different applications to different Member States, when commercialisation is foreseen for several EU countries. Furthermore, the Biocidal Products Regulation offers the possibility to authorise a group of similar biocidal products ("biocidal product family") via one single application for authorisation, which reduces the administrative burden for both companies and authorities.

2. The Food Contact Materials Regulation:

Regarding food contact materials (FCMs), approximately 1 000 substances have so far been approved for use in plastic food contact materials. However, in all materials around 10 000 possible substances[248] are being used. The current risk assessment rate by EFSA is approximately 50 substances per year, which suggests a major resourcing and efficiency issue.

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[246] Open Public Consultation question 33. The most common response from Group 2 Industry association/business is that the transition period is sufficient at 43% (70). However, 41% of respondents (66) of Group 2 Industry association/business consider the transition period to be too short.

[247] 1st FC Study p. 60

[248] European Food Safety Authority, Database on Food Contact Materials, available on https://webgate.ec.europa.eu/foods_system/main/?event=display

It should be also noted that the Food Contact Materials (FCMs) legislation[249], the RoHS Directive[250], the Urban Waste Water Treatment Directive[251], as well as the Plant Protection Products and the Residues of Pesticides Regulations[252] are currently undergoing their own evaluations as a part of the Commission's Better Regulation programme, where questions of efficiency, amongst others, will be carefully evaluated and examined.

6.2.3 Potential for obtaining a derogation

The availability of derogations from automatically triggered risk management measures on particular hazards (e.g. bans or restriction) based on generic risk considerations is important to ensuring the overall efficiency of the legislative framework. This aspect was identified as affecting the correct functioning of the EU chemicals legislation from the efficiency perspective.

Several regulations include the possibility of obtaining a derogation, considering proof of negligible exposure or negligible risk and based on technical/scientific grounds. For legislation within the scope of this Fitness Check, only the Biocidal Products Regulation (inspired by provisions in the REACH Regulation) and the RoHS Directive, explicitly address the broader socio-economic considerations as a part of their derogation requirements.[253] The fact that the potential for derogations from the automatic bans or restrictions vary between some EU chemical regulations creates a degree of incoherence with a potential impact on the efficiency of the framework (see in the main document Section 7.1.4).

Substances that are classified as CMR (categories 1A and 1B) are prohibited from use in cosmetic products, unless all the conditions for derogation apply. A ban also applies on substances classified as CMR category 2, unless considered safe for use in cosmetic products following an assessment by the Scientific Committee for Consumer Safety (SCCS). The timeframe for submitting evidence to, and gaining the opinion of the SCCS for derogation has been highlighted by industry stakeholders as a concern. They do not believe that there is enough time (15 months under the Cosmetics Regulation) to complete this process before a CMR 1A/B substance is banned in cosmetics, with this possibly leading to disproportionate impacts. The cosmetics industry considers that it takes around 2 years to produce the risk assessment that must be put into the dossiers.[254] However the Commission has recently drafted guidelines for the implementation of the provisions of the Cosmetics Regulation on CMR substances which shows that there is enough time for the adoption of a Commission measure to either ban or provide an exemption to the ban within that 15 month period, provided industry produces or collects data in view of an application dossier for an SCCS assessment already when the CMR classification process is at an early stage (preparation of the RAC opinion).

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[249] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en

[250] Restriction of the use of certain hazardous substances in electrical and electronic equipment; http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm

[251] http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4989291

[252] https://ec.europa.eu/food/plant/pesticides/refit_en

[253] 1st FC Study p. 71

[254] 1st FC study Annex IV p. 82

6.2.4 Use and access to data

Currently, useful hazard and risk assessment data often sit in regulatory clusters linked to particular agencies, scientific committees and legislative risk assessment processes for individual regulations and, for a variety of reasons, including data confidentiality and intellectual property rights, is not readily shared or available to other users. In addition, the exchange and re-use of information between clusters is insufficient. Given the costs of generating many of these data, the ability to avoid duplication of testing and data generation is a significant efficiency issue also helping to avoid longer-than-necessary timeframes.[255] It is the case for example when companies are seeking a derogation, as the timeframes to obtain it can be relatively short in comparison with the time it takes for new and sufficient data to be gathered to prove safe use.[256]

There are cases where one piece of legislation is dependent on another for the flow of information, particularly monitoring data. If the information flow is not fluid and timely, it can lead to delays in the decision making process In the context of the Water Framework Directive, the need was recognised a few years ago for a mechanism to generate monitoring data to inform risk assessments relevant to the review of the priority substances list when existing sources of exposure data are not adequate. This led to the establishment of a watch list mechanism in 2013 and a first watch list in 2015, which was recently revised. Several of the substances on the first list, including several pharmaceuticals, are still on the list, demonstrating how long it can take to gather the data needed to inform a decision on whether to regulate such 'emerging pollutants'.[257] The availability of adequate data might not always coincide with the review of the priority substances list or other relevant controlling legislation, leading to a delay in taking appropriate action even when a risk can be identified. Better links with risk assessments carried out under other legislation might help, i.e. better access to risk assessment (including exposure) data, faster feedback of monitoring data to that other legislation, and prompt action to introduce additional measures where necessary, as indicated in Article 7a (on coordination) of the Environmental Quality Standards (EQS) Directive[258].

The use of Good Laboratory Practice (GLP) has played an important and useful role in standardising quality requirements for test facilities and in ensuring repeatability and consistency in data generation (see in the main document Section 5.2.1). The GLP Directives have helped to avoid double testing and thereby help saving time and resources. In addition, the avoidance of double testing helps to ensure that no unnecessary animal tests are conducted. In this sense, it is considered as one the most efficient elements of the EU chemicals legislation[259]. Regarding non-GLP data, e.g. peer reviewed scientific journal papers, it can be challenging to assess whether it is robust or otherwise, meaning that potentially robust and viable data is still rejected in some cases. If this is the case, most likely

[255] FC+ Study p. 79-84

[256] Ibidem

[257] FC+ Study p. 57 (the watch list mechanism was established in 2013, the first list in 2015)

[258] Directive 2008/105/EC as amended by Directive 2013/39/EU

[259] FC+ Study p. 139

gathering additional GLP compliant data will be required. This creates additional cost and delays in reaching conclusions and leads to less efficient risk assessment process.[260]

6.2.5 Grouping approach vs. substance-by-substance approach

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. The EU chemicals acquis adopts a substance-by-substance approach to risk assessment and risk management.[261]

The substance-by-substance approach is often the most pragmatic approach to conducting specific risk assessments.[262] Much of the hazard and exposure data needed are held by industry with analyses completed on single substances. Indeed, hazard data on chemicals are usually focussed on single substances rather than groups of chemicals and, equally, defined uses of chemical substances are also based on individual substances. Moreover, most OECD test guidelines and, also, alternative *in silico* approaches (i.e. performed on computer or via computer simulation) work on a substance-by-substance basis. Although the substance-by-substance approach is good at identifying the hazards of a specific substance and the risk from the situation in which it is used, stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing substances as groups. The efficiency of the risk assessment process could be improved, both in terms of protecting human health and the environment, as well as in terms of avoided costs to industry for further replacement by alternatives e.g. pre-empting industry's investment in substances that are likely to be banned subsequently. However, further grouping of chemicals if envisaged, should be designed and integrated in the current framework without leading to longer decision-making processes.

6.2.6 Organisational efficiency of the EU Agencies

At the EU level, risk assessments are conducted by a number of different agencies and scientific committees depending on the chemical legislation in question. It should be noted that the EU level committees that formulate opinions on whether or not a hazardous substance is suitable for use work to different timeframes and follow different committee procedures. Moreover, the answer to the question of whether or not a process is "fast enough" is subjective and depends on stakeholder interests (e.g. possibility to commercialise a product (companies), time and effort required for process to be completed and for considering all evidence (public authorities), time allowed for taking part in discussions (NGOs) etc.). As explained above through examples, too rigid timelines and uncertainty about when a decision will be taken can have negative efficiency implications. The length of time that some elements of the legislation take to address some health and environmental impacts are also

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[260] Ibidem

[261] It can however be noted that some that some grouping consideration has been made in certain cases, like for the renewal of approval of anticoagulant rodenticides (PT14) as all these substances shares more or less the same hazard properties. Similar approach has also been discussed concerning the approval and future renewal of approval of antifouling active substances (PT21).

[262] FC+ Study p. 90 and p. 143

seen as a major source of inefficiency. A key example cited is the timeline for endocrine disruptors.

Table 7 lists EU Agencies and Scientific Committees involved with hazardous chemical risk assessment.

EU AGENCY AND SCIENTIFIC COMMITTEES	KEY CHEMICALS LEGISLATION ADDRESSED	RISK ASSESSMENT ASPECTS
European Chemicals Agency (ECHA) – Risk Assessment Committee (RAC); Socio-economic assessment committee (SEAC); Member State Committee (MSC); RAC and MSC is supported by expert groups on PBTs, EDs, CMRs	• REACH Regulation • Biocidal Products Regulation • CLP Regulation	• All REACH processes (Registration, Evaluation, Restriction, Authorisation) • All Biocidal Products Regulation processes (assessment of active substances; classification and labelling of active substances) • All processes related to Classification and Labelling Regulation – maintaining inventories of self-classifications and harmonised classifications; assessing harmonised classification and labelling;
European Food Safety Authority (EFSA)	• Plant Protection Products Regulation • Residues of Pesticides Regulation • Food Contact Materials legislation • Contaminants in food and feed legislation	• All plant protection product processes – assessment of active substances for plant protection products • Assessment of the safety of substances in certain materials e.g. plastic and estimated safe levels of exposure e.g. TDI • All food and feed contaminants - Maximum residue levels for veterinary drugs, pesticides; • Emerging issues related to food/feed – scientific opinions
European Medicines Agency (EMA)	• Veterinary and human medicinal substances ('pharmaceutical') legislation[263]	• Health risks of pharmaceutical (human and animal) active ingredients. • Environmental risks partially addressed
Scientific Committee on Consumer Safety (SCCS)	• Cosmetic Products Regulation • Toy Safety Directive	• Determination of human health risks of substances used in cosmetics and toys (environmental risks addressed under REACH) • Emerging issues – questions from the Commission – scientific opinions
Scientific Committee on	• Occupational safety and health	• Risk assessment and

[263] Not within the scope of this Fitness Check

Occupational Exposure Limits (SCOEL)	(OSH) legislation (Carcinogens and Mutagens at Work Directive, Chemical Agents Directive, Pregnant Workers Directive, etc.)	determination of occupational exposure limits of chemicals in the workplace
Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)	• Toy Safety Directive	• Covering health, environmental and emerging risks and broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies
Water Framework Directive Expert Group	• Water Framework Directive	• Prioritisation of substances and derivation of EQS
RoHS Expert Working Group	• Restriction of Hazardous Substances Directive	• Risk assessment of selected hazardous chemicals in the use of electronic equipment

Table 7 EU Agencies and Scientific Committees involved with hazardous chemical risk assessment

At a general level, the assessment of chemical risks to human health and the environment is divided between three independent EU agencies, namely ECHA (RAC) for industrial chemicals (including biocides), EFSA for pesticides and food contact materials, and the European Medicines Agency (EMA) for pharmaceutical products. This division of responsibilities and resources is considered to be appropriate and efficient by the majority of stakeholders. For example, the transparency and clear procedural requirements for hazard, risk and socio-economic assessments at the European Chemicals Agency (ECHA) are perceived by industry stakeholders as particularly efficient as they helped to overcome undue delays and transparency deficits of earlier legislation such as the Dangerous Substances Directive (DSD) and the Existing Substances Regulation (ESR, preceding REACH). Those procedures could also be seen as a model for other legislative areas involving regulatory agencies.

The majority of stakeholders consider the division of responsibilities and resources for the assessment of chemical risks to human health and the environment between ECHA's Risk Assessment Committee (RAC) for industrial chemicals (including biocides, also with ECHA's Biocidal Product Committee (BPC) involvement), EFSA for pesticides and food contact materials, and the European Medical Agency (EMA) for pharmaceutical products to be appropriate and efficient.

It should be noted, however, that there are a number of scientific committees and expert working groups associated with particular pieces of 'downstream' EU chemicals legislation that operate alongside and, sometimes in duplication, to the three main EU agencies, in particular to ECHA and its Risk Assessment Committee (RAC). Some examples of such cases of duplication are provided in Section 7 Coherence in the main document as well as Annex 7. Both for the sake of improved coherence and efficiency, there may be opportunities to simplify the risk assessment setup by bringing the risk assessment activities currently done by some of these scientific committees and expert working groups together under the remit of ECHA. It should be noted that the REACH Review recognised that further activities are needed to clarify the interface between REACH and other pieces of EU legislation. In this

regard, one of the announced actions was to enhance the role of ECHA's risk assessment committee (RAC), involving also social partners, to provide scientific opinions under the occupational safety and health (OSH) legislation while respecting the role of the Advisory Committee on Health and Safety at Work.[264]

6.2.7 Reporting obligations related to poison centres

Reporting obligations related to poison centres were one of the requirements under CLP that drew the highest level of concern from industry stakeholders, mainly related to the cost implications. Such reporting requirements were originally established under the Dangerous Substances Directive, but were not enforced across all Member States, which led to considerable inconsistency. This impaired effectiveness of obligations also led to a lack of harmonisation across the single market.

A new Annex to CLP adopted in 2017, which will apply as of 1 January 2020, will reduce the burden on companies due to diverging requirements in each Member State. Nevertheless, there are also concerns about certain requirements in the harmonised format which may potentially create significant costs and administrative burden. As those concerns (which are also reflected in many of the received comments) have been raised only at a very late stage in the adoption process, they will be assessed in a separate ongoing study. Moreover, as the Fitness Check is an evaluation of experiences with existing legislation, future potential impacts of the new Annex VIII are not reflected in this Fitness Check.

[264] Action 12 (COM(2018) 116 final; 5 March 2018). See also SWD p. 102-103 (COM(2018) 116 final; 5 March 2018)

7 Annex 7 Coherence of hazard/risk assessment and risk management procedures (CMRs, PBTs/vPvBs, EDs)

This Annex provides more detailed assessment of coherence of hazard/risk assessment and risk management procedures when dealing with specific substances such as carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative, toxic / very persistent and very bio-accumulative (PBTs/vPvBs) and endocrine disrupting chemicals (EDs). The aim was to identify inconsistencies, contradictions, duplications, overlaps or missing links in each of the risk management steps, starting from data gathering to deciding appropriate risk management measures for these substances.

Where coherence with REACH and other pieces of legislation that are, in principle, outside the scope of this Fitness Check[265] was considered important for a better understanding of the broader picture, then the relevant specific aspects of the legislation was included in the analysis.

It should also be noted that there are different information requirements and different approaches and stringency in identifying/applying risk management measures. These differences are highlighted in the assessment below. However, they do not automatically imply incoherence. Where these differences affect the correct functioning of hazard/risk assessment and risk management procedures, they are presented as coherence issues. One should also note that evidence was not always available regarding their overall, across the legislation impacts.

The assessment of hazard/risk assessment and risk management procedures when dealing with CMRs, PBTs/vPvBs and EDs helped answer the following evaluation questions:

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

7.1 Carcinogenic, Mutagenic and Reprotoxic Substances (CMRs)

7.1.1 Context and state of play

Substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) are of specific concern due to the long term and serious human and animal health effects that can arise following exposure to these types of substances. Where exposure to CMRs is likely to be widespread and difficult to reliably control, the EU chemicals legislation takes a generic approach to risk management and imposes automatic bans or restrictions (sometimes with a derogation clause) on the use of such substances.

[265] Such as for example legislation covering medicinal for human use (Directives 2001/83/EC) and veterinary products (Directive 2001/82/EC) regarding PBT/vPvBs assessment

7.1.2 Coherence of criteria for identification of CMR

The CLP Regulation sets out clear criteria for the classification of CMRs in two categories with more severe (category 1) or lower hazardousness (category 2), as set out in its Annex I. A substance that fulfils these criteria is subject to harmonised classification and labelling and is listed in Annex VI of the CLP.

The Plant Protection Products Regulation, Biocidal Products Regulation, the Medical Devices Regulation, the Cosmetic Products Regulation and the Toy Safety Directive all refer to the CLP for classification of these properties. There is, however, legislation which either does not refer to the CLP for CMR identification purposes (e.g. the Water Framework Directive) or does not contain any reference to CMRs (e.g. the Food Additives Regulation, the Detergents Regulation, the General Product Safety Directive (GPSD)). This is also the case for the Occupational Safety and Health (OSH) legislation, which does not regulate the reproductive toxicants as a specific category or, alternatively, together as a group with the carcinogenic and mutagenic substances. The Carcinogens and Mutagens Directive draws mainly on the CLP for the identification of carcinogens and mutagens, however it also covers carcinogenic substances which are not classified under the CLP because they are not intended to be placed on the market (process generated chemical agents that have carcinogenic properties such as elemental carbon used as a surrogate of exposure to diesel exhaust particles, exhaust fumes and wood dust). A similar approach is adopted in the Chemical Agents Directive in the sense that it also includes those substances/mixtures/processes that would not perhaps under any circumstances be classified under the CLP Regulation but that workers might still be exposed to in the workplace.

The Pregnant Workers and Young Workers Directives both make reference to chemicals that are hazardous. In the case of the Young Workers Directive, Member States must prohibit the employment of young people for work involving exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. However, these properties are not further defined in the Directive and there is no link to the CLP Regulation.

During the public consultation, NGOs and others[266] identified a gap with respect to the identification of substances having 'properties of concern' , such as certain flame retardants and plasticisers classified as CMRs, and which are used in a range of consumer products, such as textiles, furniture, carpets, etc. On the basis of generic risk considerations, CMRs are banned or restricted under the Toy Safety Directive in order to protect children from potentially harmful exposures. However, in practice, children also play with/on carpets and furniture in which CMRs are not automatically banned or restricted. NGOs and others point out that studies have proven that chemicals such as flame retardants and plasticisers used in these product groups can be found in house dust where the inhalation is considered to be an important exposure route for children.

7.1.3 Coherence of risk assessment factors

One aspect that needs to be highlighted is the issue of non-threshold CMRs i.e. where a no-effect level cannot be established. Since, by definition, a non-threshold CMR creates a

[266] This group comprises non-governmental organisations, consumer associations, trade unions, academia or a research or educational institutes, other

potential risk at any level of exposure, it becomes important to define what the acceptable level of risk is. This issue was raised by some Member States regarding the differences in derivations of Occupational Exposure Limit Values (OELVs) between ECHA's Risk Assessment Committee (RAC) and the Scientific Committee for Occupational Exposure Levels (SCOEL). According to these consultees, the issue arises from differences in the methodologies that are adopted by the two committees, as well as their remits with respect to the interpretation of data. In this respect, consultees note that the RAC must follow the risk assessment guidance developed for use under REACH while SCOEL consists of a panel of experts which is able to interpret the scientific data and take into account broader factors when setting Binding Occupational Exposure Limit Values (BOELVs).[267] These differences have sometimes led to significant divergences, leaving downstream users confused when applying the conditions described in the exposure scenarios attached to the safety data sheets (SDS). The issue is recognised by the EU agencies and scientific committees and efforts are being made to ensure greater consistency.[268]

7.1.4 Coherence of risk management measures

When a substance is identified as a CMR, manufacturers, importers and downstream users must classify it according to the CLP Regulation.

For Category 1 CMRs (the most hazardous category of CMRs), regulations that address the use of mixtures and, to some extent, articles for consumer uses apply automatic cut-offs (bans, restrictions) based on generic risk considerations. However, for legislation that addresses medical and veterinary products and food additives, there is no automatic cut-off and the specific risk assessment approach is applied on a case-by-case basis.

Category 2 CMRs are only restricted based on generic risk considerations in regulations that specifically cover vulnerable populations (e.g. children under the Toy Safety Directive) or uses that involve direct and difficult to control exposures to consumers (e.g. cosmetics, food contact materials).

Legislation	Risk management measures	
	CMR category 1a and 1b	CMR category 2
CLP Regulation (EC) No 1272/2008	Labelling	
Plant Protection Product Regulation (EC) No 1107/2009	Cut–off criteria for approval of active substances covered by the Plant Protection Products Regulation No possibility of derogation for carcinogenic Category 1A	No cut-off criteria

[267] 1st FC Study Annex IV p. 92

[268] REACH REFIT SWD p. 102-103; see also Communication on Safer and Healthier Work for All (COM(2017) 12 final). Please note that from 2019, the scientific evaluation of the relationship between the health effects of hazardous chemical agents and the level of occupational exposure is conducted by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). More information is available at https://echa.europa.eu/fr/-/echa-to-provide-recommendations-for-occupational-exposure-limits

Legislation	Risk management measures	
	CMR category 1a and 1b	**CMR category 2**
	Non-threshold carcinogenic Category 1B, or toxic for reproduction category 1A	
Biocides Regulation (EU) No 528/2012	For active substances, cut-off criteria and prohibited for use in biocidal products. Derogations are foreseen (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered). Active substances which are meeting the exclusion criteria (e.g. CMR Category 1A and 1B) will not be approved for more than 5 years, and their approval not renewed for more than seven years. Products containing those active substances can only be authorised in Member States where the conditions for derogations are met Products classified CMR Category 1a and 1b cannot be authorised for use by the general public.	No cut-off criteria, treated as any other substance which is not classified CMR 1a and 1b or PBT/vPvB.
Cosmetic Products regulation (EC) no 1223/2009	Cut-off criteria unless the use of CMRs comply with the following conditions: 1) compliant with the food safety requirements 2) no suitable alternative substances available 3) application for a particular use of the product category with a known exposure 4) and evaluated and found safe by the scientific committee SCCS, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups	Cut-off criteria unless the substance is evaluated by the Scientific Committee (SCCS) and found safe for use in cosmetic products
REGULATION (EC) No 1935/2004 on materials and articles intended to come	No cut-off criteria. The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.	

Legislation	Risk management measures	
	CMR category 1a and 1b	CMR category 2
into contact with food		
COMMISSION REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	CMRs are not automatically banned in FCMs but authorisation based specific risk assessment is required for the use of CMRs in FCMs including when used in material that is separated from the food by a functional barrier	
Toy Safety Directive 2009/48/EC	Cut-off criteria for substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or category 2 under Regulation (EC) No 1272/2008. Possible derogation or setting up of migration limits (instead of the CLP concentration limits) according to certain criteria, and assessed by the Scientific Committee(SCCS)	
Medical Devices Regulation	No cut off criteria or specific restriction, but a statement that the devices "shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles". Provisions addressed to the manufacturers when they design and produce the medical devices	
Directive 2004/37/EC carcinogens or mutagens at work[269]	If these substances cannot be substituted, the employers have to apply hierarchical risk management measure to reduce the exposure of these substances at the workplace.	
Chemicals Agents Directive 98/24		Risk management measures applied following the hierarchical approach to reduce the exposure of these chemicals at the workplace
Water Framework Directive	Annex VIII to the WFD provides an indicative list of main pollutants that should be addressed by Member States in relation to the quality of surface and ground water and includes inter alia "substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties"	

Table 8 Risk management measures for CMRs

Although the different pieces of legislation employ different explicit risk management measures, for the pieces of legislation relying on the CLP for CMRs classification i.e. the Biocidal Products Regulation, the Cosmetic Products Regulation, the Plant Protection Products Regulation, the Toy Safety Directive, the Carcinogens and Mutagens Directive, the

269 Reproductive toxins (R) are not covered by the Carcinogens and Mutagens Directive.

Regulation on Plastic Materials and Articles intended to come into contact with food, and the Prior Informed Consent Regulation, they are coherent. These differences appear justifiable as the target population and the use scenarios are different. It is clear that the Occupational Safety and Health (OSH) legislation such as the Carcinogens and Mutagens Directive will not employ the same risk management measures as the Cosmetic Products Regulation, as they have different targets. The OSH legislation focuses on reducing exposures in a work environment, whilst the Cosmetic Products Regulation focuses on reducing exposure from a product which has been placed on the market.[270]

7.2 Persistent, Bio-accumulative, Toxic (PBTs) and very Persistent and very Bio-accumulative (vPvBs)

7.2.1 Context and state of play

The EU policy for substances that are persistent, bio-accumulative, toxic / very persistent and very bio-accumulative (PBTs / vPvBs) is to eliminate, where possible and feasible, their uses given their particularly high hazard and negative long- term effects on the environment and human health. The following pieces of legislation deal with substances that have PBT/vPvBs properties:

- REACH (Annex XIII for identification criteria);
- The Biocidal Product Regulation;
- The Plant Protection Products Regulation;
- The Veterinary Medicinal Products Directive (not within the scope of this Fitness Check);
- The Medicinal products for human use Directive (not within the scope of this Fitness Check);
- The Water Framework Directive.

7.2.2 Coherence of criteria for identification of PBTs/vPvBs

The CLP Regulation does not contain criteria for PBTs/vPvBs identification as these criteria are not set under the UN Globally Harmonised System (GHS) either. Whilst the possibility of including specific harmonised criteria for the identification of PBTs/vPvBs under the GHS has been proposed, to date no decision has been taken. The lack of criteria/hazard class and labelling requirements for PBT/vPvB properties under the CLP Regulation is however not necessarily a cause of incoherence as requirements relating to PBTs/vPvBs substances in different EU chemicals legislation refer back to the well-established PBTs/vPvBs criteria set out in REACH[271]. Moreover, it was considered that both 2nd and 3rd Revisions (2007 and

[270] 1st FC Study Annex VI Case Study 11 p. 65-68

[271] The Biocidal Products Regulation refers to the REACH Regulation Annex XIII while the Plant Protection Products Regulation includes its own criteria for the identification of a PBT/vPvB, which are identical to those of REACH Annex XIII before its revision. The Medicinal Products Directive (Directive 2001/83/EC) does not explicitly include a PBT/vPvB assessment but draft guidelines for the environmental risk assessment do, and refer to REACH Annex XIII.

2009) of the GHS allowed appropriate classification and labelling of substances that meet PBT or vPvB screening criteria to take place[272].

An inconsistency exists between the Plant Protection Products Regulation and the Biocidal Products Regulation. While the Plant Protection Products Regulation includes a list of criteria for the identification of a PBT/vPvB that are identical to those set out in REACH Annex XIII before its revision in 2011, the Biocidal Products Regulation refers directly to the REACH criteria and, therefore, remains consistent with REACH Annex XIII and its updates. For the time being, there has been at least one identified inconsistency case regarding the acetamiprid assessment which was not identified as 'Persistent' under the Plant Protection Products Regulation and therefore re-approved for 15 years but was identified as 'very persistent' under the Biocidal Products Regulation and therefore identified as candidate for substitution being also 'toxic', and to be approved for 7 years only. It is therefore possible that other (not minor) inconsistencies will arise in the future.

Whilst outside the scope of this Fitness Check, some inconsistencies were identified with respect to PBTs/vPvBs and the regulations covering medicinal for human use[273] and veterinary products[274] that affect the overall functioning of the EU chemicals acquis with respect to ensuring a high level of protection of human health and the environment. Unlike the situation for industrial chemicals and for biocides and plant protection products, the medicinal products for human use and veterinary products legislation does not explicitly include an assessment of PBT/vPvB hazards and risks. PBTs/vPvBs screening and assessment in medicinal products for veterinary use can be performed if required, on the basis of different guidance documents[275]. Guidelines on how the evaluation of the potential environmental risks arising from the use, storage, and disposal of the medicinal product for human use[276] make reference to Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) and Technical Guidance Documents for PBTs/vPvBs screening and assessment[277]. One of the intentions of the revision of this guidance (launched in 2016) was to review whether the approaches for PBTs/vPvBs are still relevant[278].

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[272] Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals; Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals; 18th session, Geneva, 9 – 11 December 2009; Proposal to consider the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances transmitted by the representatives of the European Commission; UN/SCEGHS/18/INF.4

[273] Directive 2001/83/EC

[274] Directive 2001/82/EC

[275] The current Committee for Medicinal Products for Veterinary Use (CVMP) guideline on 'Environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev.1) specifies the need for a PBT screening of veterinary medicinal products. It refers to EU Technical Guidance Documents for industrial chemicals and biocides for cut-off values for each of PBT/vPvB criteria. The guidance also specifies the how the PBT characteristics should be assessed by making cross reference with the REACH guidance documents.

[276] EMEA/CHMP/SWP/4447/00 (2006) complemented by Q&A EMA/CHMP/SWP/44609/2010

[277] replaced by REACH 'Guidance on information requirements and chemical safety assessment' (ECHA, 2008)

[278] EMA/CHMP/SWP/65429/2016

Table 9 provides a summary of the PBT/vPvBs identification criteria laid down in different pieces of legislation.

Legislation	Use of the REACH Annex XII criteria?	Use of weight of evidence?	Constituents > 0.1%? If transformation products/metabolites are PBT, the parent substance is identified as PBT?
Biocides Regulation	Yes	Yes	Yes
Plant Protection Products Regulation	Criteria similar to REACH Annex XIII (i.e. the criteria listed in Annex XIII before its revision in 2011)	Yes	Metabolites/breakdown products are taken into account
Veterinary medicinal products Directive	On the basis of the draft guidance referring to REACH Annex XIII criteria (see EMA/CVMP/ERA/52740/2012[279])		
Medicinal products for human use Directive	On the basis of the technical CHMP guideline referring to REACH Annex XIII criteria (see EMEA/CHMP/SWP/4447/00 corr1[280] and EMA/CHMP/SWP/44609/2010[281])		
Water Framework, Directive	Mentions persistent hydrocarbons and persistent and bioaccumulable organic toxic substances (Annex VIII) without definition. Refers to the documents from the old TGD (Technical Guidance Document for Risk Assessment in support of Commission Directive 93/67/EEC) and REACH (1907/2006/EC).		

Table 9 Coherence of criteria for identification of PBTs/vPvBs

7.2.3 Coherence of information requirements

Under REACH, the requirement for definitive testing is done under dossier or substance evaluation on a case-by-case, stepwise approach in order to avoid unnecessary animal testing. For pharmaceuticals and veterinary medicinal products, there is no testing requirement for PBT/vPvB assessment, so only screening analysis is performed. Under the Plant Protection Products Regulation and the Biocidal Products Regulation, the authorisation dossier must contain the necessary information to allow a definitive PBT/vPvB assessment.

Industry stakeholders responding to the open public consultation were of the opinion that any differences and inconsistencies in conclusions of the PBT/vPVB hazard and risk assessments across the legislation mainly originate from the variations in the use of the weight of evidence. Under REACH, any available data including e.g. information from non-

[279] Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products

[280] Guideline on the environmental risk assessment of medicinal products for human use

[281] Q&A on the guideline

standardised testing and monitoring data may be used in a weight of evidence approach. This also applies to the Biocidal Products Regulation, which refers to the REACH criteria and guidance documents while the Plant Protection Products Regulation defines data requirements for active substances and for products in two different Regulations and additional communications. Under the Water Framework Directive the assessment is based on "all available information", which includes several information sources, such as existing (regulatory) lists and risk assessments, data on hazardous properties, as well as modelled or measured data on environmental concentrations. The information is evaluated based on expert judgement. Some inconsistencies may also arise due to the timing of the decision making processes on PBT/vPvB properties. Due to the timelines of the Biocidal Products Regulation (and its review programme), it may not always be possible to obtain all necessary data within a substance approval procedure to finally conclude on the PBTness of a substance.[282]

7.2.4 Coherence of risk assessment

As already explained above, there has been at least one identified inconsistency case due to differences in the assessment of acetamiprid. It was not identified as 'Persistent' under the Plant Protection Products Regulation and therefore re-approved for 15 years but was identified as 'very persistent' under the Biocidal Products Regulation and therefore identified as candidate for substitution being also 'toxic', and to be approved for 7 years only. It is therefore possible that other (not minor) inconsistencies will arise in the future.

7.2.5 Coherence of risk management measures

PBT/vPvB risk management measures are summarised in Table 10.

EU legislation	Risk Management Measures (RMMs)
REACH Regulation (EC) No 1907/2006	Registration: Positive conclusion on PBTness triggers obligations (e.g. minimisation of emission, proposal of RMM) Authorisation: If identified as SVHCs and then prioritised (Annex XIV listing) PBT/vPvB substances could be subject to authorisation to be granted via the socio-economic assessment route. Restriction: Alternatively PBT/vPvB substances could be subject to restriction on the basis of a socio-economic analysis and a risk assessment (no threshold substance: any release of these substances to the environment induces an environmental risk)

Biocidal Products Regulation (EU) No 528/2012	*For active substances*:
	• PBT/vPvB :
	  ○ Exclusion criteria and prohibited for use in biocidal products.
	  ○ Derogations are foreseen (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered).
	  ○ If the condition for derogation is met, it will not be approved for more than 5 years, and their approval not renewed for more than seven years.
	• 2 out of 3 P/B/T criteria :

[282] 1st FC Study p. 79; see also Annex III p. 35 and Annex VI Case Study 6

EU legislation	Risk Management Measures (RMMs)
	○ Identified as candidate for substitution criteria. ○ Approved, and renewed, for a maximum period of 7 years. *For biocidal products*: • PBT/vPvB: ○ Products containing PBT/vPvB active substances can only be authorised in Member States where the conditions for derogations are met (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered). If authorised, authorisation only valid for a maximum period of 5 years ○ Products containing PBT/vPvB substances (active substances or co-formulant) cannot be supplied to the general public. Derogation possible if it would result in disproportionate negative impacts for society when compared to the risks. • 2 out of 3 P/B/T criteria : ○ Biocidal products containing active substances meeting 2 out of 3 P/B/T criteria are subject to a comparative assessment before granting an authorisation ○ If authorised, authorisation only valid for a maximum period of 5 years
Plant Protection Products Regulation (EU) 1107/2009	Active substances identified as PBT are not approved. No derogation applicable. Substitution of active substances which meet 2 out of 3 PBT criteria • Approved for 7 years instead of 10 years • Shorter period of authorization • Exception to mutual recognition
Veterinary medicinal products,Directive 2001/82/EC	For PBT/vPvB substances, an emission assessment should be performed, followed by an identification of risk management options, including risk mitigation measures. This should be taken into account in the benefit/risk analysis of the veterinary medicinal products for deciding on marketing authorisation. However, as the assessment of PBT/vPvB properties of VMP is not mentioned in the Directive text, it is not clear yet to what impact a PBT/vPvB assessment will have in the authorisation of VMPs.
Medicinal products for human use, Directive 2001/83/EC	The outcome of the environmental risk assessment (e.g. the PBT/vPvB assessment) is not considered in the benefit/risk analysis, and as such it cannot serve as a ground for refusal by the marketing authorisation. There are no consequences for human medicinal products (HMPs) for having PBT/vPvB properties. If a substance is identified as a PBT/vPvB substance, this is however communicated in the Summary of Product Characteristics (SmPC) under section 5.3, and special precautions for disposal are stated under section 6.66, again without any consequences for its application and use.
Water Framework, Directive 2000/60/EC	PBT and vPvB substances are addressed as priority substances through Annex X.

Table 10 Risk management measures

Substances that are identified as PBT/vPvBs can be dealt with under REACH (registration of the substance and authorisation/restriction). The main difference is related to the fact that under REACH and the Biocidal Products Regulation, in contrary to the Plant Protection Products Regulation, a socio-economic analysis, including an analysis of alternatives, is part of the risk assessment as this is required for the authorisation and restriction procedures for PBT/vPvB substances.

Comparing the Plant Protection Products Regulation and the Biocidal Products Regulation, both do not authorise active ingredients or products placed on the market identified as PBTs/vPvBs. The main difference lies in the possibility to gain a derogation from the automatic ban based on a specific risk assessment and consideration of socio-economic factors, which is possible under the Biocidal Products Regulation but not under the Plant Protection Products Regulation.

Regarding medicinal products, some guidance documents for Veterinary Medicinal Products (VMPs) and Medicinal Products for human use specify how the outcome of PBT/vPvB assessment should be used in the authorisation procedures. There has also been an increased focus on PBT/vPvB assessment as part of the environmental risk assessment (ERA)[283]. The European Commission adopted recently an EU strategic approach to pharmaceuticals in the environment. The actions announced include considering the findings of this and recent REACH Review as regards links with the medicinal products legislation in relation to environmental protection. This could, among other things, help to clarify the PBT/vPvB requirements.[284]

7.3 Endocrine disruptors (EDs)

7.3.1 Context and state of play

The Commission adopted its first 'Community strategy for endocrine disruptors[285]' in 1999. Several EU legislative acts – i.e. Cosmetic Products Regulation[286], the Water Framework

[283] EMA/CVMP/ERA/52740/2012 (came into force starting from 1st of April 2016) is intended to provide guidance on how PBT/vPvB substances are screened and assessed in accordance with Annex XIII of Regulation (EC) No 1907/2006 and its guideline documents (ECHA 2014a-d), with focus on the scientific data/information, parameters, test conditions and default values that should be used for the assessment. It also addresses general principles on how VMPs containing a substance that has been identified as PBT should be further assessed, within the context of the environmental risk assessment (ERA) and benefit-risk assessment of the product concerned.

[284] 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)

[285] An endocrine disruptor (ED) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations" (World Health Organisation; Global assessment of the state-of-the-science of endocrine disruptors; WHO/PCS/EDC/02.2). ED chemicals occur in a variety of chemical classes including synthetic drugs, pesticides, compounds used in industry and in consumer products, industrial by-products and pollutants, including some metals (EFSA, 2013b). Humans are not only exposed to EDs through direct usage or consumption, but such chemicals might also be dispersed during production, use and disposal and hence lead to human exposure via the environment (Goldenman et al., 2017).

[286] Article 15(4) 'When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties'

Directive[287], REACH, the Plant Protection Products Regulation[288], the Biocidal Products Regulation, the Medical Devices Regulation[289] – contain provisions on endocrine disruptors (EDs).

Horizontal criteria for identifying substances with ED properties have not been set in EU legislation. The absence of horizontal criteria (i.e. applicable across all EU law) has been criticized by a number of different stakeholder groups including both NGOs and industry, as well as national authorities[290] and was identified as an area for action in the EU's 7th Environment Action Programme. The issue is recognised in the Commission's recently adopted strategy on endocrine disruptors which underlines the need to work on a horizontal approach for the identification of endocrine disruptors across EU legislation building on the criteria developed for pesticides and biocides.[291]

Criteria for the identification of EDs have been so far adopted under two pieces of EU chemicals legislation. Under the Biocidal Products Regulation and the Plant Protection Product Regulation the Commission set scientific criteria for the determination of ED properties in 2017[292] and 2018[293], respectively. The two sets of criteria are essentially identical and are applicable to all new and ongoing active ingredient applications for approval from 7 June and 10 of November 2018, respectively. A common ECHA/EFSA guidance document, drafted with the support of the Joint Research Centre (JRC) has been established for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009[294].

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[287] Annex VII 4. Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment.

[288] As well as Regulation 283/2013 setting out data requirements for active substances for PPPR and Regulation 284/2013 setting out the data requirements for active substances for plant protection products formulations

[289] Regulation (EU) 2017/745 Annex I 10.4.1. b) "Devices, or those parts thereof or those materials used therein that: are invasive and come into direct contact with the human body, (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of [REACH] or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of [the Biocidal Products Regulation], in accordance with the criteria that are relevant to human health amongst the criteria established therein."

[290] FC+ Study p. 118

[291] 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)

[292] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

[293] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36

[294] http://www.efsa.europa.eu/en/efsajournal/pub/5311; https://echa.europa.eu/fr/-/guidance-on-identifying-endocrine-disruptors-published

The first agreed OECD test method specifically designed to detect endocrine disrupting properties became available starting from 2007[295]. Prior to this, identification of EDs was hampered by the lack of internationally agreed test methods. There are now more than 40 test methods agreed under OECD for the testing and assessment of EDs.[296] Moreover, many methods, even if not specifically designed to identify EDs, include endpoints allowing such identification. Some of these test methods have been included in Regulation (EC) No 440/2008, laying down test methods pursuant to REACH. As announced in the Communication on endocrine disruptors[297], the Commission is working on updating data requirements in the different legislative frameworks (REACH, the Biocidal Products and the Plant Protection Products Regulations) to improve the identification of endocrine disruptors. However, these pieces of legislation contain at the moment some but limited data requirements on endocrine disruption.

For instance, according to the data requirements for plant protection products, if nervous system, immune system or endocrine system are specific targets in short term studies at dose levels not producing marked toxicity, supplementary studies, including functional testing, shall be carried out. Specific studies shall also be required if there is evidence that the active substance may have endocrine disrupting properties. Such data can also be requested from companies applying for substance approval for biocidal products. There is no such obligation under the Cosmetic Products Regulation.

In general, data on exposure to endocrine disruptors is lacking.

7.3.2 Coherence of legal provisions and of criteria for identification of endocrine disruptors (EDs)

As criteria for the identification of EDs currently exist only for the Plant Protection Products and Biocidal Products Regulations, the below-mentioned different pieces of legislation refer to ED properties with some differences in the wording used:

- The Water Framework Directive makes reference to "substances which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment".
- Under the Plant Protection Products Regulation, a substance shall only be approved if it is not considered to have endocrine disrupting properties that may cause adverse effect in humans or on non-target organism.
- Under the Biocidal Products Regulation, a substance shall not be approved for use in biocidal products if it is considered having endocrine-disrupting properties that may cause adverse effects in humans. Furthermore, a biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine disrupting properties.
- REACH makes reference to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the

[295] OECD TG 440

[296] https://www.oecd.org/chemicalsafety/testing/GD150_2017%20v3%2006122017b_clean.pdf

[297] COM(2018)734

environment which give rise to an equivalent level of concern to that of CMR substances categories 1A or 1B, or PBTs/vPvBs.

- The Medical Devices Regulation makes reference to substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in REACH or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 on biocidal products, in accordance with the criteria that are relevant to human health amongst the criteria established therein.

Although all provisions refer to ED properties, some provisions also make a reference to adverse effects and describe causal relation between the endocrine disrupting properties and adverse effect and some provisions provide additional qualifiers for the adverse effect. The language of the existing provisions in terms of strength of scientific evidence can be summarised as follows:

Provisions in (related to)	Endocrine disrupting properties	Adverse effect	Strength of evidence for causal relationship
REACH	X	X[a]	for which there is scientific evidence of probable
Medical Devices Regulation	X	X[a]	for which there is scientific evidence of probable serious effects to human health + reference to REACH and Biocidal Products Regulation
Plant Protection Products Regulation (approval)	X	X	that may cause
Biocidal Products Regulation (approval)	X	X	that may cause
Biocidal Products Regulation (consumer ban)	X	X	considered as having endocrine-disrupting properties that may cause adverse effects in humans
			where it has endocrine disrupting properties
Water Framework Directive	X	-	which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment
Plant Protection Products Regulation (data requirements)	X	-	may have endocrine disrupting properties

a – an additional qualifier for the adverse/serious effect exists which requires to demonstrate whether the endocrine mediated effects are of an equivalent level of concern to that of CMRs, PBT or vPvB

Such differences in wording might create uncertainty as regards which chemicals are considered by the legislative provisions and what level of evidence is required to identify such chemicals. However, there is no evidence yet suggesting that differences in the data required under these different pieces of legislation have had a significant impact on the coherence of the legislation.

7.3.3 Coherence of risk management measures

Significant progress has been made in introducing specific provisions on EDs into EU legislation. The Water Framework Directive, REACH, the Plant Protection Products Regulation and the Biocidal Products Regulation are central pieces of legislation aiming at the

protection of human health and the environment, which now include specific provisions for endocrine disruptors. It can be noted that since 1990s as consequence of the EU legislation regulating biocidal products and plant protection products, many of the adverse effects often associated to endocrine disruption have already been detected in the context of the evidence provided for approval of active substances used in these products. Where a risk was identified, those substances were removed from the market due to other toxicological properties[298]. The Regulation on medical devices has recently become the first product specific legislation that contains specific provisions laying down requirements applicable to EDs.

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
Water Framework Directive	Through Annex VIII providing an indicative list of main pollutants, including EDs that should be particularly addressed by Member States in relation to the quality of surface and ground water	The same as for human health
	Through Annex X (list of priority substances i.e. pollutants which are toxic, persistent and liable to bio-accumulate, or which give rise to an equivalent level of concern, which may include endocrine disruptors. Measures to be put in place meeting EQS in the short term and at phasing out emissions, discharges and losses within 20 years.	The same as for human health
REACH	Through placing substances on the "candidate list" and if prioritised in accordance with Article 58(3) listed in Annex XIV (List of Substances Subject to Authorisation) Once a substance is subject to authorisation, if it is possible to establish a threshold value for adverse effect, the use of the substance can be authorised via the so called 'adequate control route'. If no threshold value can be established or if the adequate control route is not feasible, an authorisation may only be granted via the so-called 'socio-economic route' when the socio-economic benefits of using the substance outweigh the risks to human health and the environment.	The same as for human health
Plant Protection Product Regulation	An active substance can only be approved if it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a	An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that

[298] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf p. 239-240

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
	plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005	may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible
	If an active substance is considered to have endocrine disrupting properties that may cause adverse effect in humans, it shall be approved as a candidate for substitution in accordance with Article 24 of the Regulation.	-
	If a substance is deemed to be an endocrine disruptor, it shall not be considered a substance of low risk	-
Regulation 283/2013 setting out data requirements for active substances for PPPR	If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies designed on an individual basis shall be required by the competent authority (I) to elucidate the mode / mechanism of action and (II) to provide sufficient evidence for relevant adverse effects.	As regards the effects on birds, other terrestrial vertebrates and aquatic organisms, consideration shall be given to whether the active substance is a potential endocrine disruptor according to Union or internationally agreed guidelines. If as a result of this assessment, the active substance is identified as a potential endocrine disruptor, the type and conditions of the study(ies) to be performed shall be discussed with the national competent authorities.
Regulation 284/2013 setting out the data requirements for active substances for plant protection products formulations	No specific provision related to endocrine disrupting properties of plant protection products. However, it refers to Section 5 of Regulation (EU) 283/2013 (where endocrine disruptors are mentioned), indicating that in some cases of specific concern or data missing, tests referred to in Section 5 of Regulation (EU) 283/2013 need to be carried out also for formulations of plant protection products.	-
Commission Communication in the framework of the implementation of Commission Regulation 283/2013 and Regulation	Provides a list of all test methods and guidance documents relevant to the assessment of ED properties for active substances of plant protection products.	

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
284/2013		
Biocidal products regulation	Active substances shall not be approved if they are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified as substances of very high concern in accordance with REACH due to their endocrine disrupting properties.	There is no explicit mentioning of endocrine disrupting effects in relation to environmental impacts, but the procedure for the identification of substances of very high concern in REACH is applicable to substances with endocrine disrupting properties both to human health and the environment. Equally, information requirements for active substances specified in Annex II to the BPR require data sets as regards endocrine disrupting properties for both human health and ecotoxicological impacts. Following discussions with the expert group (meetings of the Competent Authorities on Biocidal Products), it has been agreed that active substances identified as having endocrine disrupting properties to the environment would normally be identified as candidate for substitution[299].
	A biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine disrupting properties.	The same as for human health
	As regards mammalian toxicity studies the Regulation stipulates that if there is any evidence from in vitro, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required as additional data set to (I) elucidate the mode / mechanism of action and (II) provide sufficient evidence for relevant adverse effects.	As regards ecotoxicological studies, the Regulation requires "identification of endocrine activity" as an information requirement in the additional data set.
Regulation on Medical Devices	Devices, their parts or materials used that are invasive and come into direct contact with the human body e.g. administer medicines, and are used to transport or store such medicines, shall only contain endocrine disruptors in a concentration that is above 0,1 % weight by weight (w/w) where justified. The justification of the presence of endocrine-disrupting substances shall be based upon: a) an analysis and estimation of potential	-

[299] CA-March18-Doc.7.3a-final- EDs- active substances under assessment.docx

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
	patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account of whether the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines. Finally, the Commission shall mandate scientific committee to prepare guidelines for ED substances that shall encompass at least a benefit-risk assessment of the presence of ED substances.	
Cosmetic Products Regulation	When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties. The review was published together with the Communication on the ED framework.[300]	-

Despite this progress, there are still many pieces of legislation dealing with protection of human health and the environment from exposure to chemicals that do not contain specific risk management provisions as regards EDs e.g. the Cosmetic Products Regulation, the Toy Safety Directive, and the OSH legislation. NGOs and civil society representatives, as well as some Member State authorities[301] consider the regulatory action taken so far to be inadequate, and have called for stricter and broader EU measures. This could be a potential gap in

[300] COM(2018)739 final

[301] Council conclusions on the protection of human health and the environment through the sound management of chemicals (15046/16); 6 December 2016

identifying and addressing human health and environmental concerns for EDs, although legislative provisions addressing human health and environmental risks as regard chemicals in general apply also to endocrine disruptors. Gaps of particular concern could be the one in protection of vulnerable groups, such as children and pregnant women. For example, while under the OSH legislation special attention is required for pregnant workers and young workers identified as vulnerable populations, there is no specific requirement to identify and manage EDs as a risk to the pregnant workers or workers in general and, therefore, no legal obligation on employers to reduce exposures to potential EDs [302] The same is true for the Toy Safety Directive which aims to provide special protection to children but does not contain specific provisions for EDs.

[302] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

8 Annex 8 EU Approaches to Chemicals Risk Management

This Annex provides additional elements of description of the EU approach to chemicals risk management.

The primary objectives of EU chemicals legislation are:

- A high level of protection of human health from the adverse effects of hazardous chemicals.
- A high level of protection of the environment from the adverse effects of hazardous chemicals.
- Supporting and enhancing the efficient functioning of the internal market for chemicals and the competitiveness and innovation of EU industry and business.

Specific pieces of legislation may have more specific objectives related to chemicals, such as protecting selected vulnerable groups, encouraging substitution to less hazardous alternatives, reducing the number of animals used for testing chemicals, increasing the free movement of specific products or encouraging improvements in the occupational safety and health of workers.

Furthermore, some of the legislation within the scope of this Fitness Check may also include objectives that concern other policy areas, such as ensuring agricultural productivity and sustainability or promoting products that have a high level of environmental performance.

The framework of EU chemicals legislation is based on a range of legal acts dealing with hazard identification and classification, risk assessment, and risk management. (Risk management is the determination of risk management measures such as ensuring communication of hazardous properties of chemicals towards their users, incentivising substitution where less hazardous alternatives exist, restricting the use of hazardous chemicals to uses and situations where the exposures are negligible or can be reliably controlled, prohibiting testing on animals, etc.)

In addition, the EU has committed to several objectives related to chemicals in the global context. The EU (European Parliament and Council, 2002) and its Member States, committed to the sound management of chemicals throughout their life cycle in 2002, often referred to as the 'WSSD 2020 goal'[303]. In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals and waste. The EU played a leading role in developing these agreements, which form the backbone of international policy relating to the sound management of chemicals.

In 2015, the EU committed to the United Nations' 2030 Agenda for Sustainable Development including the Sustainable Development Goals (SDG) (UN, 2015). Several of the SDGs relate directly or indirectly to chemicals and chemical policy:

- SDG 3.9: "By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination".

[303] It was expanded upon in paragraph 23 of the Johannesburg Plan of Implementation (JPOI) (UN, 2002).

- SDG 6.3: "By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally".
- SDG 12.4: “By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment”.

8.1 The framework of EU chemicals legislation

8.1.1 Historical and international dimension

The EU legal framework for chemicals comprises not only chemicals legislation in the strict sense of the word – directly regulating chemical substances and mixtures – but also legislation regulating conditions under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, in which chemicals are used (e.g. toys, medical devices and food contact materials). Furthermore, there are chemicals-related provisions in several pieces of environmental legislation such as the Water Framework Directive, the Waste Framework Directive and the Industrial Emissions Directive.

The development of EU legislation on chemicals (see Figure 13) started in 1967 with the adoption of a Directive[304] that harmonised the Member States' rules for classification, packaging and labelling of chemical substances across the then European Economic Community. This enabled the free circulation of chemicals, without the need to re-classify, re-package and re-label the chemical product when trading it across national borders. The establishment of a Community-wide harmonised system of communicating hazards to the users of chemicals also made it easier for them to take appropriate safety measures.

[304] Dangerous Substances Directive 67/548/EEC

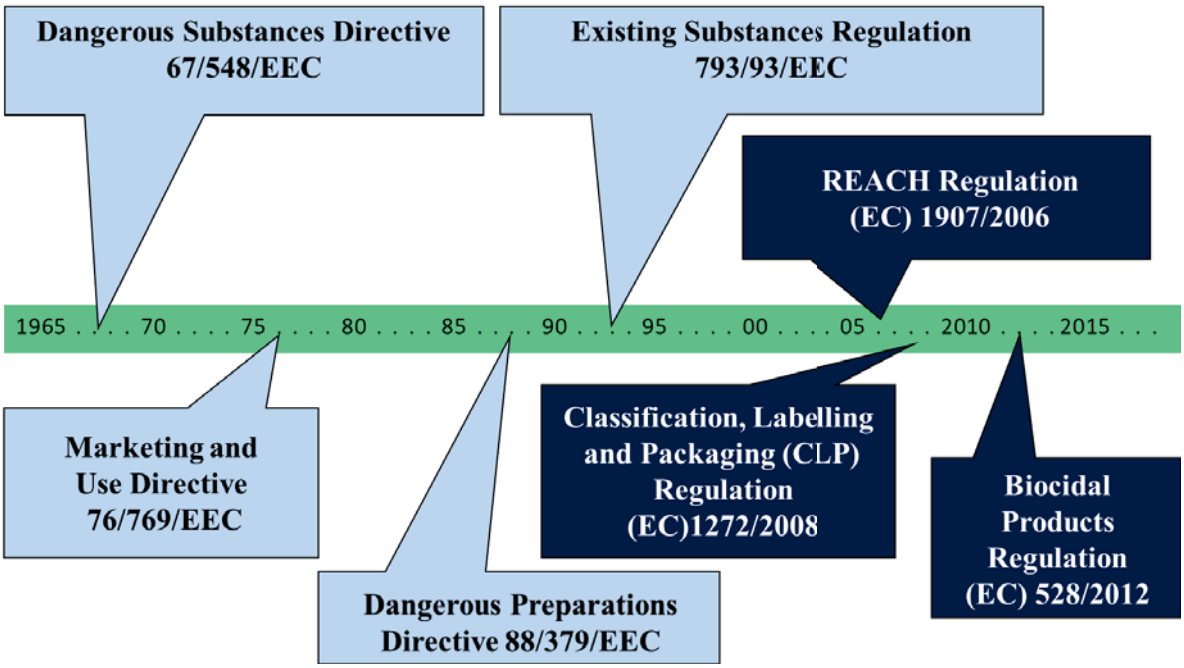

Figure 13 Development of EU chemicals legislation since 1967

In 2001 the European Commission adopted a White Paper setting out the strategy for a future chemicals policy, ultimately leading to the adoption of the REACH Regulation in 2006 and the establishment of the European Chemicals Agency in Helsinki (ECHA).

The EU has committed to a number of legally binding international agreements related to chemicals, which are implemented through EU chemicals-related legislation:

- The Globally Harmonized System of Classification and Labelling of Chemicals (GHS): an international standard that addresses the classification of chemicals by types of hazard and proposes harmonised hazard communication elements, including labels and safety data sheets, ensuring that information on physical hazards and toxicity from chemicals will be available during handling, transport and use. The GHS provides a basis for the harmonisation of rules and regulations on chemicals at national, regional and global levels, thereby facilitating trade. GHS is implemented in the EU through the CLP Regulation.
- The Basel Convention: covers transboundary movements and disposal of wastes defined as "hazardous wastes" based on their origin and/or composition and their characteristics, as well as two types of wastes defined as "other wastes" - household waste and incinerator ash.
- The Minamata Convention: limiting anthropogenic releases of mercury and its compounds. Under the treaty, new mercury mines are banned and existing mines are to be phased out, the use of mercury in a number of products and processes reduced and/or eliminated, and measures are implemented to control emissions to air as well as releases to land and water.
- The OSPAR Convention: (Convention for the Protection of the Marine Environment of the North-East Atlantic) combines and updates the 1972 Oslo Convention on dumping waste at sea and the 1974 Paris Convention on land-based sources of marine pollution. It includes a 'Strategy with regard to Hazardous Substances' which aims at the cessation of discharges, emissions and losses of

hazardous substances by 2020 in order to achieve 'close to zero' concentrations in the marine environment.

- The Rotterdam Convention: promotes shared responsibility and cooperative efforts among parties in international trade of certain hazardous chemicals in order to protect human health and the environment from harm, including legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure;
- The Stockholm Convention: is a global treaty covering chemicals that are persistent and spread widely in the environment, accumulate in living organisms and have adverse effects to human health or to the environment (so called Persistent Organic Pollutants, POPs). The parties are required to take measures to eliminate or reduce the release of POPs into the environment.

EU chemicals legislation has been a model for policy development in other parts of the world. Also, the extensive and continuously improving knowledge base resulting from the implementation of different pieces of EU legislation is, in many instances, made available to governments, industry and stakeholders beyond the EU.

8.1.2 Types of legislation within the scope of the Fitness Check

The +40 piece of chemicals and chemicals-related legislation that fall within the scope of the Fitness Check can be categorised in a number of different ways. One useful way to approach it is as follows:

1) Legislation covering chemical hazard identification and classification[305]: CLP Regulation (1272/2008/EC), Plant Protection Products Regulation (1107/2009/EC), Biocidal Products Regulation (528/2012/EU), Chemical Agents Directive (98/24/EC), Asbestos Directive (2009/148/EC), Carcinogens and Mutagens at Work Directive (2004/37/EC).

2) Legislation covering chemical risk assessment and risk management measures:

a) Worker safety and transport legislation: Carcinogens and Mutagens at Work Directive (2004/37/EC), Young People at Work Directive (1994/33/EC), Pregnant Workers Directive (1992/85/EEC), and the Chemical Agents Directive (98/24/EC).

b) Environmental protection legislation: Water Framework Directive (2000/60/EC), Industrial emissions (integrated pollution prevention and control) Directive (2010/75/EU), and the Urban Waste Water Directive (91/271/EEC).

c) Chemicals control legislation: Biocidal Products Regulation (528/2012/EU), Plant Protection Products Regulation (1107/2009/EC), Export and Import of Hazardous Chemicals Regulation (649/2012/EU), Persistent Organic Pollutants Regulation (850/2004/EC), Contaminants in Food and Feed Regulation (315/93/EEC) and Directive (2002/32/EC), and the Residues of Pesticides Regulation (396/2005/EC).

d) Products control legislation: Toy Safety Directive (2009/48/EC), Cosmetic Products Regulation (1223/2009/EC), Detergents Regulation (648/2004/EC), Drinking Water Directive (98/83/EC), Medical Devices Directive (93/42/EEC) Pressure Equipment Directive (2014/68/EU), Food Contact Materials Regulations (10/2011/EC and 450/2009/EC), and the General Product Safety Directive (2001/95/EC).

[305] sometimes together with risk assessment and risk management measures

3) Supporting and horizontal legislation: Test Methods Regulation (440/2008/EC), Good Laboratory Practice Directives (2004/9/EC and 2004/10/EC, Protection of Animals Used For Scientific Purposes Directive (2010/63/EU).

A. Horizontal Legislation Applicable to chemicals in general

There are two pieces of legislation applicable to a broad set of chemicals: the CLP Regulation and the REACH Regulation[306] (not in the scope of this Fitness Check except its Annex XIII[307]). The CLP Regulation implements the GHS in the EU and requires manufacturers, importers and downstream users to classify the hazards of a chemical, and label it accordingly, based on available data.

The CLP Regulation sets out three types of hazard classes: physical hazards, health hazards and environmental hazards. When relevant information (e.g. toxicological data) on a substance or mixture meets the classification criteria in CLP, the hazards of a substance or mixture are identified by assigning a certain hazard class and category.

The CLP Regulation stipulates the criteria and procedures for EU-wide harmonised classification and labelling (CLH) and for self-classification by industry (manufacturers, importers, downstream users, distributors, producers of articles) before substances and mixtures are placed on the market. The same obligation is upon manufactures and importers if substances, not placed on the market, are subject to registration or notification under REACH. The CLP Regulation does not cover classification for transport purposes (which is covered by Directive 2008/68/EC).

There are strong linkages between the CLP Regulation and the downstream legislation:

1. Horizontal: downstream legislation specifies properties of concern, outlines requirements for communicating properties of concern and/or sets packaging requirements for chemicals;
2. Vertical: draws on CLP classification for risk management purposes.

Some pieces of legislation in the scope of this Fitness Check do not however refer to the CLP Regulation. For examples, the Detergents Regulation sets specific rules regarding the information that manufacturers placing on the market the substances and/or mixtures shall hold at the disposal of the competent authorities of Member States. These rules on information as well as those on labelling apply without prejudice to the CLP Regulation.

Global conventions for restriction of chemicals based on the intrinsic properties of chemicals include the Stockholm Convention on Persistent Organic Pollutants (POP), the Convention on Long-Range Transboundary Air Pollution (CLRTAP), and the Minamata Convention on mercury.

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[306] REACH establishes procedures for collecting and assessing information on the properties and hazards of substances. Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance. After evaluating selected substances to clarify initial concerns for human health or for the environment authorities namely ECHA and Member States, can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorisation.

[307] REACH has undergone its 2nd evaluation. The relevant document and information are available https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

While REACH is not in the scope of this Fitness Check (except Annex XIII), in practice many interlinkages exist between REACH and the various pieces of legislation covered by this Fitness Check evaluation. Assessment of the most relevant chemicals legislation would not be complete if and where these interlinkages were not taken into account. According to REACH companies (manufacturers and importers of chemicals) need to register chemicals and mixtures manufactured or imported in quantities at or above 1 tonne per year. Information requirements for the registration dossier increase with the annual quantity manufactured or imported. The registration dossier shall contain hazard information and, where relevant, an assessment of the associated risks, and suggestions for how these risks can be controlled. REACH covers in principle all chemicals and mixtures unless they are exempted, i.e. regulated under another specific legislation, such as the plant protection products regulation. Within REACH, chemicals posing unacceptable risks to health or to the environment can be restricted, subject to authorisation or phased out. REACH further defines 'substances of very high concern' (SVHC) and requires that companies request authorization for use of these substances.

B. Legislation regulating the use of chemicals or their use in products and consumer goods

Sector specific legislation (e.g. the Cosmetic Products Regulation, Toy Safety Directive) or substance specific legislation (e.g. POPs Regulation) is in place for chemicals with potentially high risks for human health or for certain categories of population e.g. workers, consumers, children, live-stock and/or the environment. Other product-specific legislation with a chemical risk management focus includes legislation for chemical products that are expressly designed to be toxic (e.g. the Plant Protection Products and Biocidal Products Regulations) or designed to be biologically active (e.g. pharmaceuticals legislation) and/or include widespread and long-term exposures (e.g. feed and food additives legislation) or direct exposure in the product use phase (e.g. the Cosmetic Products Regulation, Food Contact Materials legislation). These pieces of legislation generally require approval/authorisation of the chemical and/or product before it can be placed on the market. For cosmetics however, products need to undergo a safety assessment by a qualified assessor. There is no pre-market authorisation but products need to be notified to the Commission prior to placing on the market. There is a system of prior approval / authorisation for listed substances. Regarding food contact materials, the authorisation is required only for those made out of plastics. The authorization procedures typically include the need to conduct a specific risk assessment of the chemicals/products taking into account chemical hazards and the specific use conditions and exposure scenarios.

Product-specific legislation adopted for the following product groups in the EU: toys, electrical and electronic equipment, construction products, medical devices, and food packaging materials, generally builds on the hazard information (i.e. classifications) provided by the CLP regulation. In some cases, it is specified that products may not contain chemicals classified as having specific hazard properties, such as CMR (e.g. the Toy Safety Directive). In other cases, the use of specific chemicals in products can be restricted (e.g. the RoHS Directive on the restriction of the use of certain hazardous chemicals in electrical and electronic equipment, or the Cosmetic Products Regulation). There are also pieces of legislation that specify the allowed maximum concentration/residue levels in products (e.g. the Construction Products Directive).

C. Legislation ensuring protection of specific categories of population

One group of people distinguished from the legal perspective is consumers. The General Product Safety Directive (GPSD) aim is to ensure that only safe products are made available on the market. The GPSD applies not only safety criteria defined in EU legislation (i.e. product-specific legislation such as Cosmetic Products Regulation), but in the absence of these, any relevant national standards, Commission recommendations or codes of practice relating to the safety of products. The GPSD establishes obligations for both businesses and Member States' authorities. Businesses should place only products which are safe on the market and inform consumers of any risks associated with the products they supply. Member States, are responsible for market surveillance i.e. through different national measures and in close collaboration with customs, national competent authorities check whether products available on the market are safe, and, if proven dangerous, take any measure deemed necessary to remove them from the market, ensure that product safety legislation and rules are applied by manufacturers and business chains and apply sanctions when necessary. Member States should also send information about products posing a risk found on their markets and the measures they have undertaken to remove them to the Rapid Alert System for non-food dangerous products (RAPEX).

Another group that benefits from specific legal provisions is workers. This is addressed via the EU's framework of occupational safety and health (OSH) legislation which comprises the. OSH Framework Directive and its 23 related daughter Directives (7 of these being in the scope of this Fitness Check). At EU level, minimum standards for the protection of workers from exposure to chemicals at work are set through the Carcinogens and Mutagens Directive (Directive 2004/37), the Chemical Agents Directive (Directive 98/24) and the Asbestos Directive (2009/148). They complement action under the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (‘REACH’) and other pieces of chemicals regulation by focusing on specific situations at the workplace.

D. Environmental legislation with a chemicals risk management component

The Water Framework Directive (WFD) and the Marine Strategy Framework Directive (MSFD) establish objectives to be reached in the aquatic environment. Rules and requirements set in the Drinking Water Directive's (DWD) can also be put in this category and linked to some extent to the protection of the aquatic environment as its objective is to protect human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. Another example of legislation taking into account the perspective of the receiving environment is the Industrial Emissions Directive (IED).

The EU Waste legislation covers several Directives[308]. The Waste Framework Directive 2008/98/EC first adopted in 1975 and fundamentally revised in 1991, 2008 and 2018 follows a holistic approach and defines key concepts. It also made a contribution to the simplification and streamlining of legislation by integrating the Directive on hazardous waste and the waste oil Directive. The old PCB/PCT Directive 76/403 was revised in 1996. The Sewage Sludge

[308] Add references to the WFD, PPWD, ELV, WEEE

Directive prohibits use of untreated sludge on agricultural land and lists threshold values for concentrations of heavy metals. The Urban Waste Water Treatment Directive aims at protecting the environment from adverse effects of wastewater discharges from cities and the industrial sectors.

Regarding waste shipments outside Europe, the EU is a party to the Basel Convention. It is an international treaty that was designed to prevent transfer of hazardous waste from developed to less developed countries. The Basel convention was transposed into Union law by the Waste Shipment Regulation[309] in 2006, amended in 2014[310]. Amendment became applicable as of 1 January 2016 and aims at improving enforcement and inspections.

The Seveso III Directive lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection throughout the Union in a consistent and effective manner. The Directive covers establishments where dangerous substances may be present (e.g. during processing or storage) in quantities exceeding certain thresholds. Depending on the amount of dangerous substances present, establishments are categorised in lower and upper tier, the latter are subject to more stringent requirements. The Seveso III Directive relies on the CLP classification.

8.2 Main steps: from risk assessment to risk management measure

Risk assessment involves analysing the inherent hazardous properties of a substance and the extent of exposure to that substance. The human health and environmental risk of hazardous chemicals are addressed via the hazard and risk assessment procedures and requirements set out in the different key pieces of EU chemicals legislation such as the CLP, the Plant Protection Products and Biocidal Products Regulations, etc. The main steps of these procedures involve:

- Hazard identification (based on toxicity tests and other relevant information);
- Dose (concentration) – response (effect) assessment;
- Exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical);
- Risk characterisation; and
- Risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

[309] Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on Shipments of Waste

[310] Regulation (EU) N° 660/2014

8.2.1 Risk management approaches

There are two basic approaches to risk management often used in combination, in the EU chemicals *acquis* (see Figure 14*):* one based on specific risk assessment (SRA) and the other one based on generic risk considerations (GRC).

The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on generic risk considerations, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRC-based approach is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. For example, under the Cosmetic Products Regulation any substance classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMR) categories 1A/B and 2 is banned from use in cosmetics, given the fact that direct, widespread exposure of humans is taking place through the application of a cosmetic product on the skin. Similar approaches have been taken for active ingredients in plant protection products and biocides, for substances in toys, etc.

The decision to link particular hazard properties (e.g. CMR, PBT[311], EDs[312]) to automatic risk management measures without the intervening step of a specific risk assessment is done on the basis of generic risk consideration without prejudice to performing also a full risk assessment for the other properties of the substances which are not linked to the related hazard properties. In the legislation evaluated in this Fitness Check, the generic risk consideration approach is typically applied for the following use applications and the following substances:

1. Use applications:
    - When there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management (e.g. labelling obligations under CLP, labelling requirements and use instructions under the Plant Protection Products and the Biocidal Products Regulations);
    - For use in widely dispersive or open applications which result in a significant exposure of humans or the environment (e.g. plant protection products);
    - For use in applications where the exposure is considered to be more difficult to control and monitor (e.g. plant protection products);
    - For use in applications resulting in exposure of vulnerable groups (e.g. children).
2. Substances:
    - For substances with hazard properties that result in severe adverse effects on human health or the environment should exposures occur (e.g. CMRs, PBTs, EDs, chemicals with STOT[313] properties); and
    - For substances where it is difficult/impossible to identify a safe threshold and, therefore, where most specific risk assessments are likely to identify risks that

[311] Persistent Bioaccumulative and Toxic

[312] endocrine disruptors

[313] Single Target Organ Toxicity

lead to a need for risk management measures (e.g. PBTs, vPvBs, respiratory sensitisers).

On the other hand, in the case of the specific risk assessment (SRA) approach, the exposure assessment is performed on a case-by-case basis when each substance is risk assessed under a specific legal framework. The risk management measures are triggered based on the outcomes of the specific risk assessment which considers the use of the substances and in which both the hazards and the potential specific exposure scenarios for humans and the environment to the hazardous substance or mixture in question are assessed at the same time.

The specific risk assessment approach is used more widely for uses which are not necessarily or obviously going to lead to widespread and difficult to control exposures and/or where the hazard properties of a substance are of less concern.

In many instances, individual pieces of chemical legislation use a combination of both of these approaches. For example, the Cosmetic Products Regulation applies the specific risk management approach to establish lists of authorised substances (positive lists, in case of case of no or no unacceptable risk) as well as, where necessary, restrictions on the use of certain substances in certain situations (negative lists, in case of unacceptable risks), but also the generic risk management approach to CMRs (substances identified and classified as a CMRs categories 1A/B and 2 are banned and cannot, therefore, be used in cosmetic products subject to strict derogations).

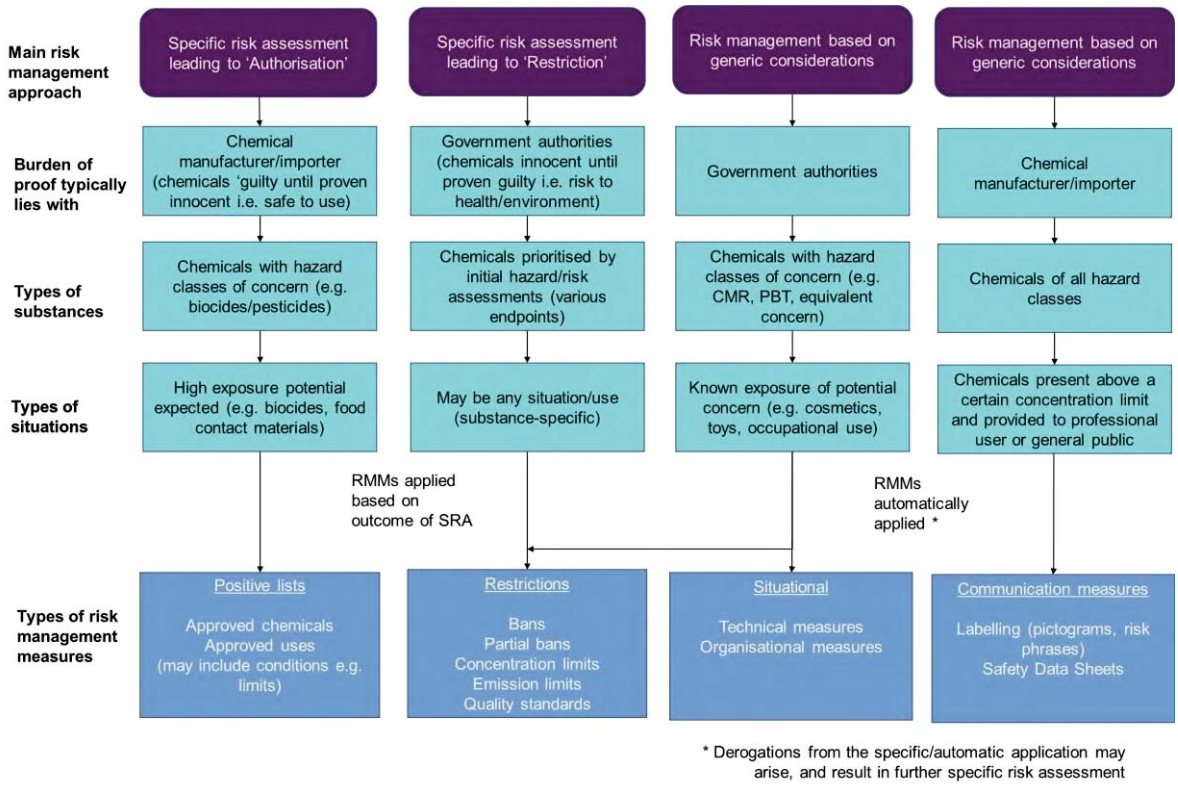

Figure 14 Main risk management approaches in the EU chemical legislation

8.2.2 Risk assessment and risk management processes and bodies involved

The necessary hazard identification, exposure assessment and risk assessment of chemicals are undertaken through a number of separate (but closely aligned) processes and EU expert committees/bodies associated with different pieces of EU legislation. As Figure 15 shows, these committees/expert groups are mainly established in association with different pieces or groups of legislation. As the same substance can be used for several different purposes/applications, it can be assessed by different committees or EU Agencies.

EU AGENCY AND SCIENTIFIC COMMITTEES	KEY CHEMICALS LEGISLATION ADDRESSED	RISK ASSESSMENT ASPECTS
European Chemicals Agency (ECHA) – Risk Assessment Committee (RAC); Socio-economic assessment committee (SEAC); Member State Committee (MSC); RAC and MSC is supported by expert groups on PBTs, EDs, CMRs	• REACH Regulation • Biocidal Products Regulation • CLP Regulation	• All REACH processes (Registration, Evaluation, Restriction, Authorisation) • All Biocidal Products Regulation processes (assessment of active substances; classification and labelling of active substances) • All processes related to Classification and Labelling Regulation – maintaining inventories of self-classifications and harmonised classifications; assessing harmonised classification and labelling;
European Food Safety Authority (EFSA)	• Plant Protection Products Regulation • Residues of Pesticides Regulation • Food Contact Materials legislation • Contaminants in food and feed legislation	• All plant protection product processes – assessment of active substances for plant protection products • Assessment of the safety of substances in certain materials e.g. plastic and estimated safe levels of exposure e.g. TDI • All food and feed contaminants - Maximum residue levels for veterinary drugs, pesticides; • Emerging issues related to food/feed – scientific opinions
European Medicines Agency (EMA)	• Veterinary and human medicinal substances ('pharmaceutical') legislation[314]	• Health risks of pharmaceutical (human and animal) active ingredients. • Environmental risks partially addressed
Scientific Committee on Consumer Safety (SCCS)	• Cosmetic Products Regulation • Toy Safety Directive • General Product Safety Directive	• Determination of human health risks of substances used in cosmetics and toys (environmental risks addressed under REACH)

[314] Not within the scope of this Fitness Check

		• Emerging issues – questions from the Commission – scientific opinions
Scientific Committee on Occupational Exposure Limits (SCOEL)	• Occupational safety and health (OSH) legislation (Carcinogens and Mutagens at Work Directive, Chemical Agents Directive, Pregnant Workers Directive, etc.)	• Risk assessment and determination of occupational exposure limits of chemicals in the workplace
Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)	• Toy Safety Directive • General Product Safety Directive	• Covering health, environmental and emerging risks and broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies
Water Framework Directive Expert Group	• Water Framework Directive	• Prioritisation of substances and derivation of EQS
RoHS Expert Working Group	• Restriction of Hazardous Substances Directive	• Risk assessment of selected hazardous chemicals in the use of electronic equipment

Figure 15 EU Agencies and Scientific Committees involved with hazardous chemical risk assessment

Risk management measures can be taken following the ordinary legislative procedure (co-decision) e.g. adoption of EU Binding Occupational Exposure Limits under the Carcinogens and Mutagens Directive, the comitology procedure for implementing acts e.g. requirements of the labelling of plant protection products and the procedure for delegated acts e.g. under the Biocidal Products Regulation specifying scientific criteria for the determination of endocrine-disrupting properties.

9 Annex 9 Glossary

ATP	Adaptation to Technical Progress
BPR	Biocidal Products Regulation
CLI	Classification and Labelling
CA	Competent Authority
CAD	Chemical Agents Directive
CARACAL	Competent Authorities for REACH and CLP
CBA	Cost-benefit analysis
CCA	Cumulative cost assessment study
CCH	Conformity check
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CoRAP	Community Rolling Action Plan
COSME	Competitiveness of Small and Medium-sized Enterprises
CSR	Chemical Safety Report
CVR	Cardiovascular and Respiratory
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive
DSD	Dangerous Substances Directive
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECVAM	European Centre for the validation of alternative methods
EDs	Endocrine Disruptors
EEA	European Environment Agency
EEB	European Environmental Bureau
EEN	Enterprise Europe Network
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENES	Exchange Network on Exposure Scenarios
EOGRTS	Extended One-Generation Reproductive Toxicity Study
ES	Exposure Scenario
ESR	Existing Substances Regulation
ETS	EU Emission Trading System
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
FCMs	Food Contact Materials
FORUM	Forum for Exchange of Information on Enforcement
GDP	Gross domestic product
GFL	General Food Law
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GLP	Good Laboratory Practice
GPSD	General Product Safety Directive
GRC	Generic Risk Considerations
HMP	Human Medicinal Products
HPVCs	High Production Volume Chemicals

IATA	Integrated Approach to Testing and Assessment
ICCM	International Conference on Chemicals Management
IED	Industrial Emission Directive
IOELVs	Indicative Occupational Exposure Limit Values
IOMC	Internet-based Toolbox for Decision Making in Chemicals Management
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
MS	Member State(s)
MSC	Member State Committee
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJEU	Official Journal of the European Union
OPC	Open Public Consultation
OSH	Occupational Safety and Health
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCBs	Polychlorinated Biphenyls
PfAs	Proposals for Amendments
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
PPPR	Plant Protection Products Regulation
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
RMM	Risk management measure
RMOA	Regulatory Management Options Analysis
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
SAICM	United Nations Strategic Approach to Chemicals Management
SCCS	Scientific Committee on Consumer Safety
SCOEL	Scientific Committee for Occupational Exposure Levels
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SDGs	Sustainable Development Goals
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum

SMEs	Small and Medium Sized Enterprises
SRA	Specific Risk Assessment
STOT	Single Target Organ Toxicity
SUBSPORT	Substitution Support Portal
SVHC	Substance of Very High Concern
t/y	Tonnes per year
TBT	Tributyltin
TSD	Toy Safety Directive
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
US EPA	Environmental Protection Agency of the United States
US	United States
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
VMPs	Veterinary Medicinal Products
vPvBs	Very Persistent and Very Bioaccumulative substances
WEEE	Waste Electrical and Electronic Equipment
WHO	World Health Organisation
WoE	Weight of Evidence
WSSD	World Summit of Sustainable Development
WTO	World Trade Organisation

10 Annex 10 Evaluation questions

Effectiveness:

1. To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?
2. What are the consequences or effects (whether socio-economic, environmental or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?
3. What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?
4. To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedure)?

Efficiency:

1. What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits? A specific focus will be given to SMEs.
2. What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

Coherence:

1. To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
2. What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

Relevance:

1. To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)
2. To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?
3. To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

EU added value

1. What is the added value of regulating the risk management of chemicals at an EU rather than at national level?

11 Annex 11 Overview of costs – benefits identified in the Fitness Check

OVERVIEW OF COSTS – BENEFITS IDENTIFIED IN THE FITNESS CHECK[315]					
COSTS	**QUANTIFICATION**	**STAKEHOLDERS AFFECTED**	**LEGISLATION**	**TIME PERIOD**	**SOURCE**
DIRECT COSTS					
MONETARY OBLIGATIONS (FEES AND CHARGES)	Several million EUR per year for fees to ECHA for CLP and biocides[316].	Industry and companies	CLP Biocidal Products Regulation	2004-2014	CCA1 Study
COMPLIANCE COSTS ONE-OFF COSTS	Transition costs to the CLP **EUR 1.4-1.6 billion**	Substances and mixtures manufactures and formulators	CLP	2006	1st FC Study
RECURRING COSTS	Annual costs arising from the CLP Regulation **EUR 1.3 billion (EUR 0.97-1.7 billion**)	Substances and mixtures manufactures and formulators	CLP	Since 2008	
	Annual regulatory costs for industry due to the Plant Protection Products Regulation are estimated at **EUR 122-189 million**	Pesticides industry	Plant Protection Products Regulation	Since 2009	Evaluation of the EU legislation on plant protection products and pesticides residues supporting study
	The costs for pesticides maximum residue level (MRLs) procedures are estimated at around **EUR 55 million** per year for the industry		Maximum residue levels of pesticides Regulation	Since 2005	
	Annual costs that the detergents industry has incurred as a direct result of the Detergents	Detergents industry	Detergents Regulation	Since 2005	Study supporting the Evaluation of Regulation (EC) No

[315] Please note that the quantification of costs and benefits in this table is partial. Given the broad scope of this Fitness Check, it has not been possible to provide a comprehensive assessment of all costs and benefits. Also, individual estimates as well as being partial are often subject to considerable uncertainty. The cost estimates in the CCA1 study do not relate to the same scope as the fitness check. See discussion in the methodological annex.

[316] The CCA1 study reports estimates for monetary obligations (fees) but these are approximately 10 times higher than the actual fee income of ECHA, so the estimates do not seem reliable. Moreover, the largest part of the fees is related to REACH, which is out of scope of the fitness check. Average annual ECHA fees for CLP are in the magnitude of 100 000 EUR and average annual ECHA fees for biocides have gone from approximately 300 000 EUR in 2013 to 7.6 million EUR in 2016. No information is available on fees at the national level.

	Regulation are estimated to range between **EUR 63.7 – EUR 149 million** (appr. EUR 764 million – EUR 1.8 billion in total since 2005).				648/2004 (Detergents Regulation)
	The main recurrent costs come from the obligation to provide data for chemical hazard classification, the risk assessment step and testing and within this the exposure assessment in particular and the implementation of risk management measures e.g. hazard communication through labelling	Industry and companies	Potentially all EU legislation in scope	2016	FC+ Study
ADMINISTRATIVE BURDEN	Administrative costs are those borne by different actors in complying with information obligations. They include • The obligation of reporting: • Retrieving data on applications from downstream users and labelling. Another factor that could increase the administrative costs is the pace of the processes for the specific risk assessments. Costs of reporting for MS for the CLP Regulation and the Asbestos Directive were between **EUR 30 000 and 100 000 per year**; the POPs Regulation and the Regulation on Export and Import of Hazardous Chemicals were	Businesses, citizens, civil society organisations and public authorities	Potentially all EU legislation in scope	Since 2004	CCA1 Study, 1st FC Study, FC+ Study Fitness Check of Reporting and Monitoring of EU Environment Policy (SWD(2017)230)

	under **EUR 30 000 per year**				
HASSLE COSTS	Costs related to delays and diverging requirements at national level	Industry and companies	Potentially all EU legislation in scope	2000-2016	1st FC Study
TOTAL DIRECT COSTS:	SEVERAL BILLION EUROS PER YEAR				
ENFORCEMENT COSTS (RECURRING)	CLP related activities by ECHA approximately **EUR 2.57 million**	EU and national authorities, ultimately borne by taxpayers	CLP	2000-2016	1st FC Study
	CLP (and REACH) training for inspectors around **EUR 1.7 million**				
	MRL procedure costs for EFSA and the Commission **EUR 3 million** The overall costs for Member States generated by the Plant Protection Products Regulation for the approval and authorisation procedures are estimated at approx**. EUR 44 million annually**. The costs for MRL procedures are estimated at **around EUR 5 million** annually for the 28 Member States		Residues of pesticides Regulation Plant Protection Products Regulation Residues of pesticides Regulation	Since 2005	Evaluation of the EU legislation on plant protection products and pesticides residues supporting study
	From a qualitative perspective, however, the costs for public authorities[317] include costs associated with: • Implementation		Potentially all EU legislation in scope	Since 2000	1st FC Study

317 1st FC Study p. 51-52

	activities: participation in expert groups and scientific bodies, research and regulatory proposals, risk assessments, etc. • Compliance monitoring and enforcement activities: • Reporting activities (even though not all pieces of legislation are subject to reporting obligation).				
INDIRECT COSTS	Indirect regulatory costs of the EU chemicals legislation were impossible to assess due to the large number of pieces of legislation and to the complexity of the value chains.	Companies, ultimately at least partially passed on to consumers	Potentially all EU legislation in scope		
	Indirect transition reformulation costs for manufacturers of mixtures are estimated at between **EUR 67.7 million and EUR 141 million**. No estimate of the associated losses to removing product lines from market could be developed.[318]	Industry and companies	CLP	2006	1st FC Study
BENEFITS	**QUANTIFICATION**	**STAKEHOLDERS AFFECTED**	**LEGISLATION**	**TIME PERIODE**	**SOURCE**
DIRECT BENEFITS					
HEALTH IMPACTS	Reduced morbidity and mortality health impacts (e.g. reduced	Workers, consumers and citizens	Potentially all EU legislation in scope	Since 1970s	CuBA Study

[318] 1st FC Study Annex II p. 83-84

	cancers, cardiovascular disease, allergies, reproductive illnesses, neurological disease, etc.) from reduced exposures of hazardous chemicals Avoided healthcare costs, avoided suffering (assessed through willingness to pay techniques), value of avoided life years lost due to premature death, productivity losses due to lost work hours as a result of illness and/or premature death	All			
	Reduced poisoning incidents, occupational skin and respiratory diseases and occupational cancers **EUR 391 – 512 million per year** **EUR 217 – 338 million per year**	Citizens, workers Ultimately also beneficial for companies	Dangerous Substances and Prepares Directives CLP	2000-2008 Since 2008	1st FC Study
	Avoided cancers due to reduced exposures to hexavalent chromium at workplace **EUR 100 million per year (and EUR 4 billion in total)**		The Carcinogens and Mutagens at Work Directive The Chemical Agents Directive	1995-2010	CuBA Study
	Reduced neurotoxicological disease and related deaths due to reduced exposures of children to lead through general environment **EUR 155-183 billion per year**		1st Directive concerning the lead in petrol (78/611/EEC; not in the scope of the Fitness Check) Lead in paints (Directive 76/769/EEC amended in 1989; not in the scope of the Fitness Check) Toy Safety Directive (1988)	Since 1970s	CuBA Study

Waste legislation Dangerous Substances and Preparations Directives and CLP		
CLP REACH (not in the scope of this Fitness Check) Chemical Agents at work (and Occupational Safety and Health (OSH) Framework Directive in general) Industrial Emissions Directive (combined with Air Pollution legislation that is not in the scope of the Fitness Check)	2004-2013	CuBA Study
Legislation on consumer products (cosmetics (2005), food contact materials (2007), electrical equipment (2015), medical devices) The Water Framework Directive (2000) The Existing Substances Regulation (not in the scope of the Fitness Check) 1994-2006	1996 – 2008	CuBA Study
CLP (preceded by the Dangerous Substances and Preparations Directives) REACH	2004-2013	CuBA Study

Reduced asthma cases and related fatalities due to reduced exposures to allergens and other hazardous chemicals attributed either to air pollution or exposure at workplace **EUR 250 million per year**
Reduced female reproductive disease as a result of reduced exposure to DEHP (phthalate) via a variety of consumer products **EUR 580 million per year (EUR 7 billion cumulatively)** Reduced male reproductive disease (infertility) as result of reduced exposure to DBP (phthalate) via a variety of consumer products: **EUR 560 million per year (EUR 6.7 billion cumulatively)**
Reduced cases of skin sensitisation (allergic reaction) as a result of reduced exposure to allergens at workplace

	EUR 160-190 million per year				
	Reduced incidence of chromium VI allergy cases associated with skin sensitisation and damage due to exposure from articles of leather **EUR 350 million per year**		CLP REACH (not in the scope of the Fitness Check)	Since 2012	CuBA Study
ENVIRONMENTAL IMPACTS	Various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs	All	Potentially all EU legislation in scope	Since 1970s	CuBA Study
	Reductions in the costs associated with environmental remediation, waste management and clean ups	Industry and companies Public authorities			
	Reduced environmental and pollination impacts as a result of better control and management of pesticides (e.g. neonicotinoids) **EUR 15 – 50 billion per year**	All	Plant protection products related related legislation	Since 1980s	CuBA Study
	Avoided drinking water treatment costs as a result of reduced pesticide contamination of surface and groundwater reserves **EUR 500 million per year**		Plant protection products related related legislation Water related legislation (1st Water quality legislation and the Water Framework Directive, Drinking Water Directive, Ground Water Directive, EQS Directive) POPs Regulation	Since mid-1970s	CuBA Study
	Avoided clean-up costs associated with PCB use in the past caused by the contamination Cumulative benefit of **EUR 20 – 90 billion**		CLP Directive 96/59/EC on the disposal of PCBs and PCTs (not within the scope) The POPs Regulation	1971-2018	CuBA Study

			(2004) Hazardous Waste List		
OTHER DIRECT BENEFITS	Encouraging research and innovation, generating new jobs and improving competitiveness	All	Potentially all EU legislation in scope	Since 1970s	CuBA Study
	Stimulating competition and trade within the EU single market	Industry and companies			
	Stimulating international trade between the EU and other countries	Industry and companies			
INDIRECT BENEFITS	Contribution to achieving objectives defined in other policy areas (Circular Economy, agriculture)	All	Potentially all EU legislation in scope	Since 1990s	CuBA Study
	Contribution to achieving the EU international commitments (the UN Sustainable development goals, fight against climate change, resource efficiency etc.)				