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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 FV2
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 FV2.

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PART 2/3

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}

1 Annex 1 Procedural information

1.1 Lead DGs and internal references

The "Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries" (FC Chemicals) was co-led by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. The chemicals legislation covered by this exercise was identified in 2013[1] and 2014[2] as one of the policy areas, in which further efforts at the EU level can be made to facilitate the implementation of legislation and where after conducting a regulatory Fitness Check, rules can be simplified and burdens reduced. It was included as item 2015/GROW+/050 in the Agenda Planning (AP) and as Commission's REFIT Initiative in the Commission Work Programme of 2015[3] (item 52).

This initiative is linked to other actions related to chemicals legislations such as the REACH REFIT Evaluation[4] and the Circular Economy Action Plan[5] (including the EU Strategy on Plastics[6] and the work on the chemicals, waste and product Interface[7]).

1.2 Organisation and timing

An Inter-service Group to steer and provide input for the FC chemicals report was set up in March 2015 with representatives from the Directorate Generals for Environment (ENV); Internal Market, Industry, Entrepreneurship and SMEs (GROWTH); Health and Food Safety (SANTE); Employment, Social Affaires and Inclusion (EMPL), Mobility and Transports (MOVE), Justice and Consumers (JUST), TRADE, Joint Research Centre (JRC-Ispra) and the Secretariat General (SG).

The group met 14 times during the evaluation process (Table 1).

DATE	TOPICS OF DISCUSSION

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Regulatory fitness and Performance (REFIT): Results and Next Steps' COM(2013) 685 final, 2 October 2013

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Regulatory fitness and Performance (REFIT): State of Play and Outlook', COM(2014) 368,18 June 2014

[3] Annex III of COM(2014) 910 final

[4] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions; 5 March 2018; COM(2018) 116 final and SWD(2018) 58 final

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Closing the loop – An EU action plan for the Circular Economy', COM/2015/0614 final, 2 December 2015

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'A European Strategy for Plastics in a Circular Economy', COM/2018/028 final, 16 January 2018

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Options to address the interface between chemical, product and waste legislation', COM(2018)32 final, 16 January 2018

10 March 2015	Introductory meeting
15 July 2015	1st FC Study: kick-off meeting
23 October 2015	1st FC Study: Inception Report meeting
11 April 2016	1st FC Study: 1st Interim Report meeting
6 September 2016	1st FC Study: 2nd Interim Report meeting
13 October 2016	FC+ Study: kick-off meeting
28 October 2016	1st FC Study: Final report
16 November 2016	FC+ Study: Inception Report meeting
1st March 2017	FC+ Study: Interim Report meeting
28 September 2017	ISG meeting: Progress Update
31 May 2018	ISG meeting: 1st draft discussion (Sections 1-4, 5.5 EU Added Value, Annexes)
8 June 2018	ISG meeting: 1st draft discussion (Sections 5.1 Effectiveness and 5.2 Efficiency)
19 June 2018	ISG meeting: 1st draft discussion (Sections 5.3 Coherence and 5.4 Relevance)
29 June 2018	ISG meeting: Final draft discussions

Table 1 ISG meeting dates and topics of discussion

1.3 Exceptions to the better regulation guidelines

No exceptions were made to the Better Regulation Guidelines[8] during this Fitness Check.

1.4 Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present Fitness Check and issued its positive opinion on 14 September 2018. The Board made several recommendations to further improve the report. Those were addressed in the revised report as follows:

RSB recommendations	Modification of the report
(B) Main considerations The Board finds the fitness check to be thorough, robust and well organised. The Board gives a positive opinion, but considers that the report could be further improved with respect to the following key aspects:	
(1) The report does not sufficiently investigate stakeholder concerns.	This recommendation has been addressed by adding relevant stakeholder views, by complementing Annex 2 Synopsis Report, by including additional references to studies in Annex 4.
(2) The report does not draw evidence-based conclusions on which issues to prioritise for	'Main Conclusions' section has been revised. Cross-references to the relevant assessment

[8] https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

follow-up.	sections have been included. The conclusion boxes and 'Main Conclusions' have been aligned. Clarifications and additional elements of information (e.g. the scope of the Fitness Check and of its supporting studies, how the study findings were used, baseline and points of reference) also allow to better understand what is the evidence for the assessment and thus for drawing conclusions.
(3) The report does not sufficiently examine the potential for simplification and burden reduction.	How this recommendation has been taken into account is reflected in 'Main Conclusions' section and in the conclusion boxes where great care was taken to clearly identify areas with potential for simplification and burden reduction.
(C) Further considerations and recommendations	
The report should provide more granular and systematic reporting of the stakeholder consultations. It should dig more deeply into areas of stakeholder concern, try to corroborate with other evidence, and express a considered view on the magnitude of the problems. The synopsis report should provide a more detailed analysis of the consultations of all stakeholders, including points raised in position papers.	This recommendation has been addressed by adding relevant stakeholder views in sections 5.2.1, 5.2.3, 5.2.4, 6.1.1, 6.1.2, 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, 7, 8.2.1, 8.3.1. Additional information was included in the Synopsis Report (Annex 2). Annex 4 Table 3 clarifies where the findings and stakeholder opinions presented in each sub-section come from.
The report should more transparently explain how it has made use of the background studies, and built on their conclusions. It should also clarify the departures from the studies' conclusions and stakeholders' views.	This recommendation has been addressed by including additional information in section 4.1.1. A new section 4.1.3 was introduced to clarify how the studies' findings and stakeholder views were used for the purposes of this Fitness Check. In addition, Annex 4 was amended. The table 'Legislation within the scope of the Fitness Check' comprises additional columns to clarify which study cover which piece of legislation. Three tables were added (time period, legal scope and coverage by studies; where the FC findings come from; related individual evaluations).
There are some discrepancies between the final conclusions and those in the main body	The conclusion boxes and 'Main Conclusions' Section have been aligned.

of the report. It is difficult to tell what is most important. In its conclusions, the report should more systematically identify and prioritise areas for policymaker attention based on relevance and magnitude of the issues at stake, the available evidence, and on responding to stakeholders.	'Main Conclusions' section has been revised.
The fitness check is a REFIT initiative, yet the report is largely silent on the scope for simplification and burden reduction. The report should elaborate on the potential to simplify or reduce burdens, for example on SMEs. It should consider whether current outcomes could be achieved at a lower cost, e.g. by streamlining reporting requirements.	In the main document, additional clarification elements have been added. The revision of the 'Main Conclusions' section provide more clarity on these aspects.
The report should clarify what it uses as benchmarks or a baseline. The fitness check relies on different studies, each with their specific focus and timeline, and the report could better explain when comparisons draw on different sources. This would provide a more accurate picture on how the EU chemicals acquis has delivered on overarching objectives of high level of protection of human health and environment, while supporting the functioning of and competitiveness in the internal market.	This recommendation has been addressed by clarifying section 2.3 Baseline, as well as by the information and clarifications of Section 4 and in Annex 4.
The scope of the fitness check could be clearer. Given the interlinkage of chemicals legislation, the report should better clarify the rationale for excluding some legislation from its scope. On this basis, the report should avoid referring to legislation outside the scope when explaining the effectiveness and efficiency of the EU chemicals acquis.	This recommendation has been addressed by including additional elements of explanation in Section 2.1.3 Scope of the Fitness Check.

1.5 Evidence, sources and quality

The analysis underpinning this FC was undertaken via several thematic studies commissioned by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs (see Annex 3 explaining the methodology applied):

- The 1st FC Study[9] was completed in January 2017. It includes an evaluation of the CLP Regulation and the interplay between the CLP and related legislation, in particular, other legislation governing hazard identification, classification and communication ('horizontal links') and downstream legislation that establishes risk management measures directly or indirectly triggered by a CLP hazard class ('vertical links').
- In 2014, the Commission launched a study analysing cumulative costs of the most relevant EU legislation for the EU chemical industry. It was completed in July 2016.[10]
- The FC+ Study[11] was completed in November 2017. It complements the 1st FC Study by reviewing those pieces of legislation that operate independently of CLP for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process.
- The CuBA Study[12] draws together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation. It was completed in August 2017.

Stakeholder consultation and targeted data collection were also an important element of the FC Chemicals exercise (see Annex 2).

[9] Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. The evaluation report is available online http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/. Annex I-V is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. Annex VI is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/.

[10] The study is available here http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

[11] Study supporting the Fitness Check on the most relevant chemicals legislation. The study is available here https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en.

[12] Study on the cumulative health and environmental benefits of chemical legislation. The study is available here https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

2 Annex 2 Synopsis report: stakeholder consultation activities

2.1 Consultation activities - introduction and approach

Stakeholder consultation was a key component of this Fitness Check to identify the most relevant issues, to collect data in response to the evaluation questions (outlined in the Fitness Check roadmap[13]) and to ensure a balanced and comprehensive assessment of the legislative framework. All the information thus gathered contributed helped to describing and possibly quantify the issues raised all along this document.

The objectives of the consultation activities were to:

- Identify inconsistencies, overlaps, regulatory gaps, obsolete measures and cases of excessive regulatory burdens.
- Collect information and evidence related to effectiveness, efficiency and relevance of the provisions and mechanisms of the chemicals legislation.
- Identify consequences or effects (whether socio-economic, environmental or health-related) of the legislation that were not originally planned.
- Collect relevant information on the implementation of the chemical-related provisions of the legislation.
- Collect qualitative and (wherever possible) quantitative data on costs and benefits of the implementation of chemicals legislation.
- Identify provisions and mechanisms that work well and the added value of EU regulation in this area.
- Collect information in order to support the evaluation of whether procedures are sufficiently transparent and take into account the needs of both citizens and other stakeholders.

The consultation strategy developed for the purpose of this Fitness Check[14] comprised:

- an open public consultation (from 4 March to 27 May 2016);
- an SME panel through the Enterprise Europe Network (from 30 May to 18 July 2016),
- consultation as part of case study work;
- targeted consultation of different stakeholder groups to gain some of the additional evidence needed for the evaluation (and which was not covered by a case study or was at too detailed a level for the Open Public Consultation;
- A stakeholder workshop conducted in April 2016 as a part of the 1st FC Study, a stakeholder workshop conducted in May 2017 as part of te 2nd FC Study, A stakeholder workshop conducted in January 2017 as a part of the CuBA Study, and two stakeholder validation workshops conducted during 2015 as a part of the CCA1 Study; and
- 2 Eurobarometer surveys (Special Eurobarometer 456[15] November-December 2016 and Special Eurobarometer 468[16] September-November 2017).

[13] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf

[14] Consultation strategy for the Fitness Check on chemicals legislation (excluding REACH) http://ec.europa.eu/DocsRoom/documents/17109/attachments/1/translations

[15] https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG

[16] https://data.europa.eu/euodp/data/dataset/S2156_88_1_468_ENG

The open public consultation was conducted in English, German and French. The SME panel and the Eurobarometer surveys were conducted in all EU languages. Information on the results of open public consultation, SME panel and workshops were made available on both DG GROW[17] and DG ENV[18] websites.

Further details regarding the targeted data collection, including the SME Panel consultation and the Eurobarometer surveys, is provided under Section 5 below and in Annex V of the 1st FC Study report. Findings from the targeted data collection are reported on in Annexes II to IV, as part of the evaluations carried out for these tasks. It should also be noted that the findings from these consultations form an important part of the evidence base used in developing the conclusions presented in the main evaluation report of the 1st FC Study.

2.2 Stakeholder groups covered by the consultation activities

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

- Public authorities, notably competent authorities responsible for the implementation and enforcement activities
- Industry associations covering both the chemicals industry and downstream sectors (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators)
- Companies in both the chemicals industry and downstream sectors, focusing in particular on Small and Medium-sized Enterprises (SMEs) (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators)
- Civil society organisations – NGOs (e.g. environmental, health, animal welfare)
- Consumer associations
- Trade unions
- Other interested groups such as academics / research institutes
- Consumers / workers /citizens.

Table 2 demonstrates how each of the tools mentioned above was used to collect information from different categories of stakeholders.

	Public authorities	Industry associations	Companies / SMEs	NGOs	Consumer associations	Trade unions	Academia / research institutes	Consumers / workers / citizens
Public consultation	√	√	√	√	√	√	√	√
SME panel			√					
Targeted interviews	√	√	√	√	√	√	√	
Stakeholder workshop	√	√		√	√	√	√	
Expert group	√							
Eurobarometer								√

[17] http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

[18] http://ec.europa.eu/environment/chemicals/better_regulation/index_en.htm

Table 2 Different stakeholder groups consulted

These different consultation activities and tools allowed receiving feedback from all stakeholder groups. A summary of these views is provided below.

2.3 Outcome of the consultation activities

2.3.1 Summary of Stakeholder views on the five evaluation criteria

A. Effectiveness

The EU chemicals legislation is considered to be moderately effective in reaching its goal of protecting human health (all stakeholder groups). Regarding its goal of protection environment, citizens and industry associations and companies considered it to be mostly effective while public authorities considered it to be moderately effective. Civil society considered it to be slightly effective.

The EU chemicals legislation was considered by citizens, industry and companies and public authorities as mostly effective in ensuring a well-functioning internal market while civil society considered it to be moderately effective. Regarding this particular aspect, SME Panel Results showed that the EU chemicals legislation is considered to be sufficiently harmonised across Member States for the proper functioning of the European single market while there were some negative opinions on the extent to which EU chemicals legislation is consistently enforced by Member States.

While citizens, industry and companies and civil society considered the legislation moderately effective in stimulating competitiveness and innovation, public authorities were of an opinion that it is mostly effective in reaching this objective.

The main reason for lower effectiveness was that legislation is not adapted at issues at stake (human health and environment (citizens, industry and companies, public authorities), internal market (civil society), competitiveness and innovation (citizens, industry and companies) and/or that legislation is not effectively implemented (human health and environment (public authorities and civil society), competitiveness and innovation (civil society).

B. Efficiency

All stakeholder groups identified costs due to the EU chemicals legislation as the most significant for SMEs while industry association and companies pointed out that bigger companies also face significant costs. Public authorities and civil society recognised the significance of costs for public authorities at both national and EU level. The main benefits generated by the EU chemicals legislation are reducing the damage to the environment and to eco-systems (citizens) and reducing the exposure to toxic chemicals of consumers, citizens and workers (industry and companies, public authorities and civil society).

C. Coherence

Industry association and companies as well as civil society representatives during the open public consultation were of an opinion that the EU chemicals legislation framework is internally inconsistent. Citizens and public authorities remained neutral (neither agreed nor disagreed) while 1/3 of public authorities also considered the EU chemicals legislation to be internally inconsistent. All stakeholders also agreed that the EU chemicals legislation contains gaps, missing links and has overlaps (except civil society on the latter). A more in-depth

analysis based on further comments and position papers received shows however that although such issues were indeed identified, they most often affect specific aspects of functioning of some pieces of legislation within the scope of this Fitness Check while not necessarily being relevant to the functioning of the whole framework. Therefore, the opinion that the EU chemicals legislation is internally inconsistent needs to be nuanced and used with caution given also that the share of opinions neither agreeing nor disagreeing was significant. Moreover, these views are also contrasted by generally positive opinion of SMEs (SME Panel) on the overall internal coherence of the EU chemicals legislation.

D. Relevance

Stakeholders from all groups considered that not all relevant considerations are taken into account in regulatory decision-making on risk management. Regarding the way the EU legislative framework addresses emerging areas of concern, opinions varied: slightly (civil society), moderately (citizens and public authorities) and mostly (industry associations and companies) sufficiently.

E. EU Added value

Industry and companies, public authorities and civil society considered the EU chemicals legislation to have a high level of added value while citizens considered the added value to be moderate.

2.4 Open public consultation

The objective of the 12 weeks open public consultation[19] was to obtain stakeholder views on the functioning of the legislative framework for chemicals[20]. The questionnaire available in English, German and French, had five parts (35 questions). Respondents also had the opportunity to submit any additional comments and upload position papers[21].

[19] from 4 March to 27 May 2016

[20] Its results were analysed by the contractors as part of the 1st FC Study commissioned by the European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs) and led by Risk & Policy Analysts Ltd. (RPA).

[21] Analysis of responses to the closed questions has been undertaken using Excel. The number and percentage of responses is broken down by group, allowing a comparison of the views of the four groups. Analysis of the open-text responses involved reviewing each comment, identifying the key points that are being made, recording these key points as 'themes' and then comparing other comments to see if they make the same point. Due to the number of open-text responses received, it was necessary to start by taking a sample of the responses when applying this approach. . In addition, the manual analysis of the open text responses to the OPC for each group was supported by automated analysis using NVivo software to ensure that all comments have been taken into account. In addition to these formal analyses for the purposes of reporting on the OPC, the study team searched responses using a series of different key words to pull out responses to feed into the Task 1 to 3 evaluation work.

2.4.1 Participants to the public consultation

The Commission received 356 valid responses. This included 57 responses (16%) from citizens, 93 responses (27%) from companies, 103 responses (29%) from industry associations, 46 responses (13%) from public authorities, 37 responses (10%) from NGOs, consumer associations, trade unions and academia and 17 responses (5%) from others. The input is to be considered balanced. In addition, 21 position papers were submitted.

The majority of respondents (56%) belonged to Industry and business, top four fields of interest or activities being manufacture of other chemical products (65 responses or 31%), manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (50 responses or 24%), manufacture of paints, varnishes and similar coatings, printing ink and mastics (35 responses or 17%), manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (34 responses or 16%). Table 3 below presents respondents from Industry and business group by size.

Group	Type	Number	Percentage
Group 2 - Industry, business	Large company (250 employees or more)	64	48%
	Medium-sized enterprise (under 250 employees)	22	17%
	Small enterprise (under 50 employees)	23	17%
	Micro-enterprise (under 10 employees)	17	13%
	Self-employed	6	5%

Table 3 Number and percentage of industry/business responses by size

The majority of businesses who replied to the open public consultation operate at the EU (34% or 71) or global (37% or 77) levels with 22% (47) of responses operating at the regional level. Government or public authority, and intergovernmental organisations responses were mainly from those operating at a regional level (51% or 25), with just 8% at the national level (4) and 14% at the local level (7). The highest number of responses from NGOs, consumer associations, trade unions, academia and other was from those who operate at the EU level (36% or 20), followed by the regional level (29% or 16).

A. Main outcomes of the public consultation[22]

1) Citizens

Citizens said to be the most affected by the CLP Regulation (45%), Biocidal Products Regulation (30%) and REACH Annex XIII (25%).

They considered the EU chemicals legislation:

- Important in protecting human health and stimulating innovation and competition and very important in protecting the environment and ensuring a well-functioning internal market.
- Mostly effective in protecting the environment and ensuring a well-functioning internal market and moderately effective in protecting human health and stimulating

[22] Annex V of the 1st FC study available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/ provides a detailed report of the answers received

innovation and competition. Main reason for lower effectiveness: legislation is not adapted to issues at stake.

- Having a moderate level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with the stability of the legal framework ('Moderately satisfied') and the least satisfied with international collaboration and harmonisation ('Slightly satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers ('Moderately satisfied') and the least satisfied with risk assessment and characterisation ('Slightly satisfied'). Citizens also thought that the quality requirements for safety data for chemicals were appropriate (41%).

Stakeholders from this group considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (45%) and that the EU legislative framework addresses emerging areas of concern moderately sufficiently. No answer to the question whether chemicals legislation framework overall should be more oriented towards generic risk considerations or specific risk assessment was provided by 49 % of this stakeholder group (while 11% provided 'I don't know' answer).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the damage to the environment and to eco-systems (58%), reducing the exposure to toxic chemicals of consumers, citizens and workers (54%).

31 % of respondents from this group thought that there were significant costs for small and medium enterprises due to EU chemical legislation. Regarding such costs, respondents ranked classification requirements for substances and mixtures and chemical labelling and packaging requirements as the main cost drivers (25%).

The current elements relating to CLP classification criteria[23] were considered overall moderately satisfactory while responses from these stakeholders to the question whether the CLP Regulation cover all relevant hazards were mostly ‘I don’t know’. The current elements of the procedures for harmonised classification and labelling (CLH)[24] were considered slightly satisfactory with exception to quality of scientific data and related information which was considered moderately satisfactory. The effectiveness of the CLP labels in communicating hazards to workers and consumers was considered moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (59%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, citizens considered it overall moderately effective.

46% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links (compared to 33% neither agreeing nor disagreeing and 21% disagreeing) and

[23] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[24] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

has overlaps (52%). Regarding the internal consistency, this stakeholder group mostly neither agreed nor disagreed.

2) Industry associations and companies, including SMEs

Industry and companies said to be the most affected by the CLP Regulation (92%), REACH Annex XIII (78%) and Waste Framework Directive (73%).

They considered the EU chemicals legislation:

- Important in protecting human health and stimulating innovation and competition and very important in protecting the environment and ensuring a well-functioning internal market.
- Mostly effective in protecting the environment and ensuring a well-functioning internal market and moderately effective in protecting human health and stimulating innovation and competition. Main reason for lower effectiveness: legislation is not adapted to issues at stake (human health, environment, innovation and competition) or legislation is not effectively implemented (internal market and competition).
- Having a high level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with the speed with which hazards/risks are assessed and with which identified risks are addressed ('Moderately satisfied') and the least satisfied with predictability of the outcomes assigning ('Slightly satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers and risk managements measures regulating the safe use of chemicals ('Mostly satisfied') and the least satisfied with risk management measures restricting or banning the use of chemicals (Moderately satisfied'). This group also thought that the quality requirements for safety data for chemicals were appropriate (63%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (72%). Respondents gave consideration that "impact assessment should be systematic and better address employment and competitiveness issues across the industry chain". According to these stakeholders, the EU legislative framework addresses emerging areas of concern mostly sufficiently. These stakeholders were also strongly in favour of specific risk assessment (72%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of workers to toxic chemicals (85%), reducing the damage to the environment and to eco-systems (84%) and reducing the exposure of consumers and citizens in general to toxic chemicals (79%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (89%) as well as for large enterprises (89%). Regarding costs for companies, respondents ranked understanding and keeping up-to-date with changes in legal requirements as the main cost driver (84%).

The current elements relating to CLP classification criteria[25] were considered moderately satisfactory except the appropriateness of classification criteria and methods for substances which was considered mostly satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were 'yes' for environmental (82%), physical (85%) and human health risks (86%). The current elements of the procedures for harmonised classification and labelling (CLH)[26] were considered moderately satisfactory. The effectiveness on the CLP labels in communicating hazards to workers was considered mostly effective while to consumers moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (40%) answered that enforcement is not harmonised across Member States.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, industry and companies considered it moderately effective. Industry association guidance and materials were considered more effective.

45% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links (compared to 27% neither agreeing nor disagreeing and 29% disagreeing) and has overlaps (75%). 60% of respondents agreed that the EU chemicals legislation framework is internally inconsistent.

3) Public authorities (Member State, national and regional authorities)

Public authorities said to be the equally the most affected by the CLP Regulation and the Plant Protection Products Regulation (64%) and Biocidal Products Regulation (56%).

They considered the EU chemicals legislation:

- Important in protecting human health and very important in protecting the environment, ensuring a well-functioning internal market and stimulating innovation and competition.
- Moderately effective in protecting human health stimulating innovation and competition and mostly effective in protecting the environment and ensuring a well-functioning internal market. Main reason for lower effectiveness: legislation is not adapted to issues at stake and legislation is not effectively implemented (human health, environment internal market).
- Having a moderate level of added value.

To these stakeholders, the EU legislative framework has had a significant contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with time to allow duty holders to adapt to legal changes ('Mostly satisfied') and the least satisfied with speed with which identified risks are addressed ('Moderately satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard identification criteria ('Mostly satisfied') and the least satisfied with hazard and risk communication to consumers as well as risk management measures restricting or banning the use of chemicals ('Mostly satisfied'). Public authorities

[25] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[26] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

also thought that the quality requirements for safety data for chemicals were appropriate (51%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (71%). Respondents gave consideration that "the combined effects and vulnerable groups are mentioned in occupational safety and health legislation but it is not very clear how to enforce them". According to these stakeholders, the EU legislative framework addresses emerging areas of concern moderately sufficiently. This group of stakeholders was in favour of staying with the current approach i.e. both generic risk considerations and specific risk assessment (37%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of consumers and citizens (95%) and workers (92%) to toxic chemicals and reducing the damage to the environment and to eco-systems (89%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (64%). 33% of responses from this group mentioned significant costs for national authorities and 25% who indicated significant costs for authorities at EU level. Regarding costs for companies, respondents ranked risk management measures under different legislation as the main cost driver (42%).

The current elements relating to CLP classification criteria[27] were considered moderately satisfactory except for the appropriateness of classification criteria and methods for substances and for international harmonisation through the GHS which was considered mostly satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were ‘yes' for environmental (44%), physical (71%) and human health risks (63%). The current elements of the procedures for harmonised classification and labelling (CLH)[28] were considered mostly satisfactory. The effectiveness on the CLP labels in communicating hazards to and to consumers mostly effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (58%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, public considered it mostly effective.

57% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links and has overlaps (50% against 44% neither agreeing nor disagreeing). Regarding the internal inconsistency, this stakeholder group mostly neither agreed nor disagreed (47% compared to 32% agreeing that the EU chemicals legislation framework is internally inconsistent).

4) Civil society (non-governmental organisations (NGOs), consumer organisations, trade unions, academia and others)

NGOs and others said to be the most affected by the CLP Regulation (76%), the Chemical Agents Directive (73%) and the Waste Framework Directive (57%).

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[27] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[28] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

Civil society considered the EU chemicals legislation:

- Moderately important in protecting human health and the environment and important in ensuring a well-functioning internal market and stimulating innovation and competition.
- Moderately effective in protecting human health, ensuring a well-functioning internal market and stimulating innovation and competition while slightly effective in protecting the environment. Main reason for lower effectiveness: legislation is not adapted to issues at stake.
- Having a high level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with stability of the legal framework ('Mostly satisfied') and the least satisfied with speed with which identified risks are addressed, as well as public awareness and outreach ('Moderately satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers ('Moderately satisfied') and the least satisfied with risk assessment and characterisation, risk management measures restricting or banning the use of chemicals as well as risk management measures regulating the safe use of chemicals ('Slightly satisfied'). This group thought that the quality requirements for safety data for chemicals were not appropriate (41%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (85%). Respondents gave consideration that "risk assessments… do not take into account the specific risk that chemical substances… pose to women and children". According to these stakeholders, the EU legislative framework addresses emerging areas of concern slightly sufficiently. This group of stakeholders was in favour of generic risk considerations approach (41%) with still a strong preference for specific risk assessment (25%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of workers (91%), consumers and citizens (80%) to toxic chemicals and reducing the damage to the environment and to eco-systems and encouraging research and innovation, generating jobs and improving competitiveness (70%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (70%). These stakeholders were the most likely to indicate that there were significant costs for national authorities (42%) and authorities at EU level (40%). Regarding costs for companies, respondents ranked risk management measures under different legislation as the main cost driver and understanding and keeping up-to-date with changes in legal requirements (42%).

The current elements relating to CLP classification criteria[29] were considered overall moderately satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were ‘yes' physical risks (70%) and 'no' for human health (53%) and environment risks (56%). Transparency of the

[29] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

procedure for harmonised classification and labelling (CLH)[30] was considered mostly satisfactory, involvement of stakeholders moderately satisfactory, and quality of scientific data and related information and speed of procedures both slightly satisfactory. The effectiveness on the CLP labels in communicating hazards to workers was considered mostly effective while to consumers moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (63%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, citizens considered it overall moderately effective.

79% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links but disagreed that it has overlaps (45% against 20% neither agreeing nor disagreeing and 35% agreeing). 60% of respondents agreed that the EU chemicals legislation framework is internally inconsistent.

2.5 Other consultation activities

2.5.1 Eurobarometer surveys

Two Eurobarometer surveys (Special Eurobarometer 456 November-December 2016 and Special Eurobarometer 468 September-November 2017) were carried out by TNS Political & Social network in the 28 Member States of the European Union. Around 28 000 EU citizens from different social and demographic categories were interviewed for each. The methodology used is that of Eurobarometer surveys as carried out by the Directorate-General for Communication ("Strategic Communication" Unit)[31]. A technical note concerning the interviews conducted by the member institutes of the TNS Opinion & Social network can be found in the full version of the reports[32]. It also specifies the interview methods and the confidence intervals.

The key findings of the Special Eurobarometer 456 survey of relevance for this Fitness Check can be summarsied as follows:

- Less than half of respondents say they feel well informed about the potential dangers of the chemicals contained in consumer products, although there is considerable variation by Member State.
- Almost half think that chemical products are safe for human health and the environment, although perceptions of safety vary considerably between Member States. At the same time half of respondents say that the current level of regulation and standards in the EU is not high enough and should be increased.
- Awareness and comprehension of four (out of nine) CLP[33] hazard pictograms was tested. Awareness and comprehension vary across pictograms. Overall, the findings on

[30] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

[31] http://ec.europa.eu/commfrontoffice/publicopinion

[32] Special Eurobarometer 456 https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG and Special Eurobarometer 468 https://data.europa.eu/euodp/data/dataset/S2156_88_1_468_ENG

[33] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation')

the varied comprehension of CLP hazard pictograms suggest that there is scope for improving the effectiveness of consumer communication and labelling.

The key findings of the Special Eurobarometer 468 survey of relevance for this Fitness Check can be summarsied as follows:

- More than four in five respondents (84%) are worried about the impact on their health of chemicals present in everyday products.
- When asked to identify the most effective ways of tackling environmental problems, more than a third (35%) favour investment in research and development to find technological solutions. There is also relatively high support for tighter legislative control, specifically introducing heavier fines for breaches of environmental legislation (34%), ensuring better enforcement of legislation (31%) and introducing stricter environmental legislation (30%).

2.5.2 SME panel[34]

Consultation was undertaken through the SME panel among the members of the Enterprise Europe Network (EEN) to ensure that the impacts and opinions of small and medium-sized enterprises are represented within the analysis. There was a total of 209 responses from companies with fewer than 250 employees[35]. The survey was very similar to that of the OPC to provide consistency. .

Opinions of SMEs on the EU chemicals legislation overall are generally positive. There are some negative opinions on the extent to which EU chemicals legislation is consistently enforced by Member States. Respondents also considered the EU chemicals legislation to be sufficiently harmonised across Member States for the proper functioning of the European single market[36].

Regarding costs, some 60% of all SME respondents identified that they incurred significant costs on an annual basis in complying with the CLP Regulation or other chemicals legislation. The main cost drivers identified were training likely linked to the need for staff to understand the new pictograms and hazard and precautionary statements (89%) and costs associated with understanding and keeping up-to-date with changes in legal requirements (45%). In addition, 50% of all respondents reported a short-term increase in costs due to implementation of CLP. However, a significant proportion of respondents (31%) reported that they had not incurred any short-term costs (they had also not seen any benefits from implementation of CLP).

The EU chemicals legislation framework was also considered coherent[37].

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[34] Annex V of the 1st FC study provides a detailed report and is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. The European Commission commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to conduct this study.

[35] 1-9 employees (21%), 10-49 employees (42%), 50-249 employees (37%)

[36] 98 agree or strongly agree compared with 32 neutral and 31 who disagree/strongly disagree and 41 'I don't know' responses

[37] 93 agree or strongly agree compared with 47 neutral and 27 who disagree/strongly disagree and 37 'I don't know' responses

2.5.3 Targeted data collection

Targeted data collection has been conducted in support of the three main tasks of the 1st Fitness Check study[38] regarding different aspects of the CLP implementation. When sending out the surveys, recipients were encouraged to also send the links to national associations (e.g. national consumer associations, national trade unions) to gather a broader range of information than just that of the EU-level organisation. Targeted questionnaires were developed for the following stakeholders:

- Industry (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators (industrial chemicals, plant protection products, detergents and cosmetics). 250 companies in total provided responses[39].
- Non-industry stakeholders including trade union/worker representative organisations, consumer associations, environmental NGOs and health-related NGOs. Seven replies in total were received.
- Authorities and expert groups. Responses were submitted by 14 authorities from 11 different Member States.

In addition, a separate questionnaire was developed and submitted to the Expert Group on Toy Safety. In total there were 10 responses to the questionnaire sent to the Expert Group on Toy Safety, and a further two additional consultation responses. These included responses from EU authorities, a market surveillance authority, a health and environmental NGO, national and EU industry representatives and a consumer organisation.

2.6 Stakeholder Workshops

2.6.1 Workshop of 19 April 2016[40]

Conducted as a task under the 1st FC Study, the objectives of the workshop discussions were to identify what works well within the chemicals legislative framework and why and the associated impacts, as well as what does not work well, why not and the associated impacts. Registration for the Workshop was open to all. The number of registrants exceeded the capacity of the venue (90 people) and a selection of registrants was invited to attend, ensuring a balanced representation of relevant stakeholder groups. The workshop provided an early check on preliminary study findings, identify potential gaps and opportunities for further investigation and to collect ideas and information from stakeholders.[41]

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[38] reported in Annexes II, III and IV of the study

[39] 12% micro enterprises, 13% small, 21% medium, 54% large

[40] The workshop was organised by the Commission assisted by Risk & Policy Analysts Ltd. (RPA) in charge of the 1st Fitness Check study. The workshop report can be found here: http://ec.europa.eu/DocsRoom/documents/17110/attachments/1/translations

[41] Full report of discussions held during the breakout sessions can be found http://ec.europa.eu/DocsRoom/documents/17110/attachments/1/translations

2.6.2 Workshop of 4 May 2017[42]

Conducted as a task under the 2nd FC Study, the objective of the workshop was to gather expert stakeholder inputs on how the current EU chemicals regulatory framework is functioning with a particular focus on specific risk assessment processes applied under EU chemicals legislation. The workshop brought together senior representatives from the European Commission, Member State officials, industry and civil society. The workshop was attended by a total of 76 people. Four morning presentations were followed by an exchange of views and several breakout sessions.[43]

2.6.3 Workshop of 17-18 January 2017[44]

The workshop brought together experts from Member State authorities, industry, non-governmental organisations (NGOs), international organisations, trade unions and academia. The two-day interactive workshop was an opportunity to discuss and validate the preliminary study findings, to engage with stakeholders and to communicate to a wide audience the substantial benefits that the body of EU chemical legislation has achieved to date. It also addressed the health and environmental costs still incurred within the EU as a result of on-going exposures to hazardous chemicals. In advance of the workshop, a summary report on the provisional findings of the study was provided to participants. The workshop was attended by a total of 47 people and a list of the workshop participants is included in Appendix B of the Workshop Report.

2.6.4 Workshops conducted in 2015

Two workshops were organised as part of the CCA1 Study, to validate the estimated costs as a percentage of both the value added and the revenue of the reporting companies, before the grossing up of costs for the EU level and the estimation of absolute values. The first validation workshop targeted companies and industrial associations. The second workshop, organised by the European Commission, was open to a wider audience of stakeholders such as industry, trade unions, NGOs and Commission services.

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[42] A second workshop was organised within the FC+ Study and conducted by Amec Foster Wheeler Environment & Infrastructure UK Limited. The workshop report can be found here: https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF

[43] Appendix B of the FC+ Study (https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF) describes key points of discussions held during the breakout sessions

[44] A two-day workshop was organised as a part of the Study on the Cumulative Health and Environmental Benefits of Chemicals Legislation conducted by Amec Foster Wheeler Environment & Infrastructure UK Limited. The workshop report can be found in annex/attachment to the main study report here: https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

3 Annex 3 Methods and analytical models

The purpose of this Annex is to summarise the main methodologies applied and the information sources used for the "Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries" (FC Chemicals). As described in the Section 4. Methodology, a number of thematic studies have been carried out by external consultants for the Commission services. In addition, other sources of information were used (see Annex 2 Synopsis report).

3.1 The key supporting studies of the Fitness Check on chemicals legislation

3.1.1 Study on the regulatory fitness of chemicals legislation (excluding REACH), in particular the CLP Regulation and related legislation (1st FC Study)

A. Methods and analytical models

The first Fitness Check study ('1st FC study')[45] was conducted between July 2015 and December 2016 and published in January 2017. The study evaluated the CLP Regulation ((EC) No 1272/2008) and its interface with other related chemicals legislation in terms of effectiveness, efficiency, coherence, relevance and EU added value. Mapping was undertaken to establish the scope of relevant legislation followed by desk research and a suite of stakeholder consultation activities, which assisted in answering a range of evaluation questions. The evaluation considered the rules and processes for classifying the hazards of substances and mixtures, the methods of communication of the associated hazard information and the properties of concern that require consideration. It also considered linkages between the CLP Regulation and downstream legislation, with a focus on assessing risk management based on generic risk considerations (triggered automatically by a CLP classification).

As the different pieces of legislation within the scope of the Fitness Check only have high-level general objectives in common (see Table 1 in Annex 4), for which few quantifiable indicators exist, and as there is no single baseline for a framework of +40 pieces of legislation implemented at different times with different scopes, it was clearly going to be challenging to try and assess the effectiveness and efficiency at the framework-wide level. Therefore, the study focused on the CLP Regulation and on specific issues at the interface between the CLP Regulation and downstream legislation. As a result, a number of different reference points and timeframes were used (see Annex 4 for more detail). For example, the reference point for assessing the costs of transition to the CLP Regulations was the previous Dangerous Substances and Dangerous Preparations Directives (67/548/EEC and 1999/45/EC) over a time period of 2008-2015 whilst the assessment of on-going costs of meeting the requirements of the CLP Regulation were assessed in present time (2016) using a zero-counterfactual (i.e. a scenario of no regulation in place at the Member State level in the absence of EU legislation) as the point of reference. The (partial) assessment of human health and environmental benefits of the CLP Regulation also used a zero counterfactual and considered benefits generated under the previous DSD/DPD regime together with those generated after the implementation of the CLP Regulation thus covering a timeframe of 2000-2016.

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[45] The evaluation report is available online http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/. Annex I-V is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. Annex VI is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/.

The assessment of on-going cost reflects the cost implications of a situation where there are no other regulatory requirements on manufacturers and importers of hazardous substances and mixtures (i.e. a 'zero counterfactual'). The reality is that, had the DSD, DPD and subsequently the CLP Regulation not been introduced to provide overarching requirements, some/all Member States are likely to have introduced their own requirements under national legislation. Some or all might have been similar in emphasis and requirements to the CLP Regulation, while others might have varied significantly. Clearly there is no definitive way of knowing either way; hence, there is no means of identifying whether costs would have been higher or lower than those presented in the study assessment. Thus, when considering the individual cost components presented below from the perspective of the burden on industry, it should be borne in mind that similar costs might have been incurred under an alternative non-EU regulatory reality, with this also being the case for health and environmental benefits.

The study was organised into four tasks:

1. Evaluating the implementation of the CLP Regulation,
2. Evaluating the horizontal links between EU legislation on hazard identification and communication,
3. Evaluating the vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification, and
4. Supporting the Commission in organising an open public consultation, SME panel and workshop. A number of industry sector and stakeholder specific surveys and workshops were also organised (see Annex 2). In line with the Fitness Check roadmap, when analysing risk management measures under Task 3, the study distinguished risk management based on generic risk considerations (i.e. risk management measures automatically triggered by a hazard classification under CLP, without further assessment of the risk) and risk management based on specific risk assessment (i.e. risk management measures following an assessment of both the hazards and specific exposure).

The evaluation methodology was developed around the needs of these four tasks. The work included a literature review to obtain key information from impact assessments, position papers, academic and scientific research etc.; legal mapping to identify relevant legislation and specific provisions within this; consultation activities including the Open Public Consultation, a Stakeholder Workshop, an SME Panel, consultation as part of case study work as well as targeted consultation (including surveys) of key stakeholder groups; and case study research involving a more in-depth examination of some of the more pertinent issues identified as part of initial research (see Table 1). Importantly, the aim of the case studies was not to re-consider specific decisions that have already been taken; instead, it was to examine the mechanisms and procedures of the CLP Regulation and to assess whether the current linkages are appropriate (which may necessitate examining some of the impacts of past decisions). The study assessed the costs of transition to the CLP Regulation from the two Directives that it replaced (the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD)) in 2008 as well as the on-going regulatory costs faced by industry and by EU and Member State authorities. This included consideration of the cost impacts ('transition costs') of moving from a Directive based system to a Regulation, any national differences in implementation of the CLP Regulation, and the costs (and benefits) of the harmonisation of information requirements across the national Poison Centres. It also examined the impacts from different provisions, for example, CLP packaging requirements

(in particular child resistant closures and tactile warning devices), labelling requirements, obligations placed on regulators and authorities, etc. The work drew on the Fitness Check cumulative costs (CCA1) and the cumulative benefits (CuBA) studies, as well as the 2006 Impact Assessment for the implementation of CLP.

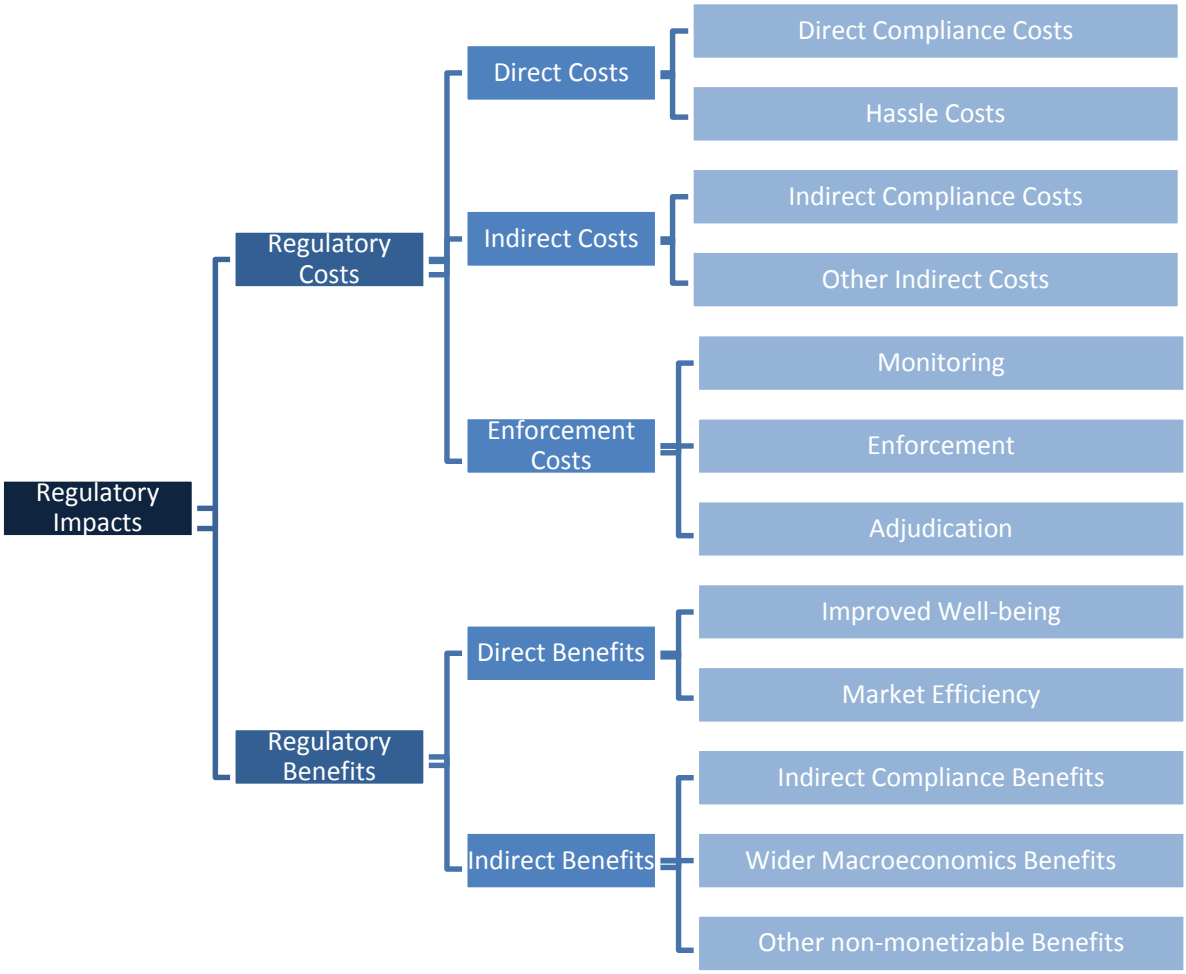
With respect to calculating the costs of transition to CLP, the approach followed the cost assessment model set out in the Better Regulations Toolbox, as illustrated in **Error! Reference source not found.** below. The cost types outlined in this diagram are described in further detail as follows:

- Direct Costs: Within this category are two sub-categories of costs: direct compliance costs and hassle costs. The first of these consists of regulatory charges which include fees, levies and taxes; substantive compliance costs which entail the costs of investing in human and physical capital, as well as other expenses incurred in complying with legal requirements introduced by new legislation; and, administrative burdens which encompass the costs borne in performing administrative activities for complying with the information obligations set out under the legislation. Hassle costs include the costs associated with corruption, annoyance and waiting times. Note that direct compliance costs can be further categorised as CAPEX where they relate to capital expenditure, OPEX where they are annual operating costs and administrative costs where they relate to reporting obligations. This study also categorised regulatory charges under the monetary obligations category.
- Indirect Costs: Indirect costs are those incurred in the sector targeted by the legislative measures, which are not directly related to the measure, or by other sectors or stakeholders which are not directly targeted by the legislative measure (i.e. downstream sectors). These indirect costs can be transmitted through price increases or changes in the supply of certain goods and services to the market. In some cases, this can have a multiplier effect (for example if a substance is withdrawn when the impact downstream was actually higher than the cost of keeping it on the market). For the purposes of this study, our attention will be focused on the indirect costs relating to re-formulating products or removing certain product lines from the market due to the changes induced by the CLP Regulation.
- Enforcement Costs: Enforcement costs are those incurred by Member States, public bodies and the European Commission through activities relating to the implementation of legislative measures. Costs can be categorised under the following: monitoring; enforcement; adjudication.

Case study #	Case study title	Case study description
1	Impacts of differences in the uptake of UN GHS **building blocks** for costs, competitiveness health and the environment	Different countries have adopted different building blocks both in terms of hazards covered and sectors covered. Consideration will be given to differences in the potential costs and benefits for chemical suppliers, as well as for consumers (public health) and the environment. The focus is on building blocks within the GHS which have (not) been implemented in the EU and North American countries and any differences in costs and benefits arising as a result.
2	Suitability of the CLP Regulation **classification**	It may be the case that there is a gap in the legislation as the CLP contains no criteria for the classification of metal alloys, with this potentially impacting on their treatment under other horizontal

Case study	Case study title	Case study description
	criteria for metals	legislation, e.g. REACH, waste legislation, etc. The case study would identify problems arising from this gap. It could also consider the extent to which default classification rules under the CLP regulation may trigger under/over classification of metals more generally.
3	Lack of consistency in **parallel hazard assessments** under different legislation	Different bodies are responsible for the hazard assessment and classification of a substance/mixture under the CLP, Biocides and PPP. This case study would focus on the coherence of the parallel procedures under these three Regulations and, time permitting, also take into account other legislation such as the CAD (depending on the scope of other case studies and hence resources available).
4	Relevance and coherence as regards the introduction of **new test methods** and GLP within chemicals legislation	The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. This case study would examine the relevance of the CLP classification criteria in terms of their ability to respond to changes in scientific methods, and the horizontal coherence of these also taking into account prohibitions on animal testing under the Cosmetics Regulation.
5	Coherence of classifications, definitions and the **labelling requirements for detergents**	This case study will explore whether there are any negative impacts on industry and on the single market as a result of a lack of coherence in the definitions of 'placing on the market' and 'manufacturer' between the CLP Regulation and Detergents legislation. It will also examine requirements under the Cosmetics and the Biocidal Products Regulation.
6	Inconsistencies in assessment procedures for **PBT and vPvB** as properties of concern	The CLP Regulation does not include classification and labelling requirements based on PBT and vPvB properties. This case study looks at whether there are inconsistencies or overlaps in the identification or risk management of PBTs, what types of risk management measures are triggered by PBTs, what issues arise in relation to the coherence of risk management, whether the current processes are effective and views on integration of PBT/vPvB into CLP.
7	**SME awareness** of ATPs and changes in classification and of labelling and packaging requirements	This case study focus on the awareness of SMEs of the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years. It will also look at issues regarding SME understanding of packaging requirements under CLP and international transport legislation.
8	Awareness of Chemical Safety Assessment and labelling requirements for **Toys**	The TSD lays down toy safety rules which include requirements for Chemical Safety Assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.), and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. This case study would examine SMEs awareness of this range of obligations. The case study will examine the awareness of SMEs in of labelling requirements, including traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings.

Case study	Case study title	Case study description
9	**Consumers comprehension** of and relevance of safety information on product **labels**	The focus of this case study will be on the hazard pictograms that the CLP introduced when implementing the GHS. Research suggests that comprehension of the various pictograms amongst EU citizens is variable; findings indicate that a low percentage of citizens may understand all of the hazard pictograms or equally understand only a few of the pictograms. Some EU legislation uses different safety phrases and does not rely on the pictograms. Similarly, where the GHS building block for consumer products has not been implemented (e.g. North America) different communication tools may be used
10	Linkages with **Occupational Health and Safety Legislation**	The case study is looking at whether there are overlaps and inconsistencies between CLP and OSH legislation: • If there are inconsistencies or overlaps what causes these? • What are the implications of these? • Do the inconsistencies give rise to incoherence? • Are there measures that could be taken to address them? Formaldehyde will be used as a case study substance to illustrate some of the issues.
11	**Risk management procedures triggered by harmonised classifications** under the CLP Regulation	This is an overarching case study involving a comparative assessment of the procedures triggered by a CMR or other health classification (e.g. sensitiser). It will cover REACH, PPPR, BPR, cosmetics, toys, food contact materials and CMD. This case study will also consider selected substances, such as lead, TCEP, gallium arsenide, etc. This case study will also include a comparison between RMM based on generic risk considerations and specific risk assessment.
12	Use of CLP classifications for **waste management**	There appears to be national, regional and local authorities using CLP classification criteria and packaging requirements as the basis for the sorting and recycling of domestic wastes. These are unintended uses of the packaging and labelling aspects of the CLP Regulation and may be leading to a lack of coherence and impact on achievement of other EU objectives related to recycling and the circular economy. In addition, consistencies have been identified with regard to the linkages between CLP and the Waste Directive, in particular in relation classification for toxic to the aquatic environment and bioavailability. This case study will examine the consequences of both of national implementation of waste legislation, as well as what the constraints are to recycling if a waste is classed as hazardous and whether a logic can be developed with regard to bioavailability considerations.
13	**Linkages between the CLP and Seveso III** Directive, including risk management under Seveso III	Seveso III aligns, amongst others, requirements for establishments using or storing hazardous chemicals with the CLP Regulation. Due to the alignment some establishments may change tier or fall out of scope all together because for some hazard classifications the criteria in DSD are CLP are not identical. The case study will review the procedures for risk management under Seveso as a potential example of best practice, and the procedures for excluding substances from the scope of the Directive and whether the linkages between CLP and Seveso III are efficient and effective.



In line with the approach to calculating the transition costs of CLP, the study employed the methodology set out in the Better Regulations Toolbox which categorises costs under the types listed in **Table 5**. The cost elements which make up our model for ongoing costs are listed under each relevant cost type.

Type of Cost	Cost elements for which estimates have been generated
Direct Costs	
Regulatory Charges	Fees or penalties paid in complying with regulation
Substantive Compliance Charges	Costs of updating IT systems Costs of training staff to understand updates in requirements of CLP Costs of employing FTEs for compliance activities Costs of Child Resistant Closures and Tactile Warning Devices
Administrative Burdens	See Chapter 8
Hassle Costs	Costs of checking CLI
Indirect Costs	
Indirect compliance Cost	Opportunity cost of removing a product line from the market

Table 5 Data collected for each cost type for ongoing costs

The Standard Administrative Costs Model acted as the basis for estimating administrative costs to industry, and complementary approaches were adopted for the estimation of compliance costs. Where appropriate, separate consideration was given to SMEs compared to larger companies. In this respect, efforts were made to ensure SME views were represented, for example, through use of the Commission's SME Panel, discussions with national associations, and separate analysis of cost information provided by SMEs where relevant.

All assumptions in this respect are made clear in the more detailed study Task reports (see the 1st FC study, Annex II: Evaluating the implementation of the CLP regulation pp55-125). In addition to developing its own estimations, the study used figures from other sources, in particular in relation to costs and benefits of measures under downstream legislation with vertical linkages to CLP for risk management purposes.

The final report[46], its annexes[47] and case studies[48] are available online.

B. Evidence base and limitations

As with any study of this scale, numerous challenges were encountered in gathering the data needed to provide a robust evidence base, as well as in providing quantitative estimates of impacts. Although extensive efforts were made to overcome the challenges and to ensure that accurate and reliable information acted as the basis for the evaluation, many remained and some could not be overcome. There are therefore limitations that ultimately impact on the study conclusions. These include limitations stemming from the following (with further details provided in Annex I of the 1st Study Report):

- The broad scope of the study and the number of pieces of legislation to be considered.

[46] http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/

[47] http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/

[48] http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/

- The lack of available information on the scale of some of issues identified (both positive and negative) and the subsequent need to rely on information provided by stakeholders.
- The limited response received from civil society stakeholders. However, further desk-based research of published information from NGOs was undertaken to inform the study.
- The limited data available to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms).
- The inability or unwillingness of companies to provide certain data creating difficulties in quantifying some aspects of the impacts (e.g. costs and benefits) of the CLP Regulation and other legislation.
- The lack of up-to-date information regarding the effect of the CLP Regulation on consumer behaviour.

3.1.2 'Study supporting the Fitness Check on the most relevant chemicals legislation' (FC+ Study)

A. Methods and analytical models

The FC+ Study[49] was completed in November 2017. It complemented the 1st FC Study by reviewing those pieces of legislation within the scope of the Fitness Check that operate independently of the CLP Regulation for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process. Following the completion of an initial mapping stage it was possible to identify which legislation either relied solely on CLP for hazard identification and characterisation, or had been significantly covered by the work in the 1st FC Study. Such legislation was then marked as 'out of scope' for the FC+ study. The remaining 27 pieces of legislation either had hazard identification and characterisation completely independent of CLP or had elements which were partially independent and thus had not been fully covered in the 1st FC Study, or included specific risk assessment approaches that were not wholly linked to hazard identification under CLP. The legislative scope of the study is summarised in Table 6 below.

	(Partially) In Scope	Out of Scope
Independent of CLP	**Utilises both CLP and other approaches for specific components.**	**Legislation which is either:** **a) fully dependent on CLP and/or;** **b) fully covered by the First Study**
Detergents regulation	Safety of Toys Directive	REACH Annex XIII[b]
Explosives Directive	Cosmetic products regulation	Regulation on Classification, labelling and packaging of substances and mixtures

[49] The study is available here https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en.

(Partially) In Scope		Out of Scope
		(CLP)[a,b]
Pyrotechnic articles Directive*	Medical devices (regarding medical devices; regarding active implantable medical devices; regarding in vitro diagnostic medical devices.	Test methods regulation[a,b]
Asbestos Directive (human health only)	Pressure equipment directive	Aerosol dispensers directive[b]
Water Framework Directive	Industrial emissions (integrated pollution prevention and control) Directive	Carcinogens and mutagens at work Directive[a,b]
Urban Waste Water Directive	Waste shipments Regulation	Fertilisers regulation[b]
Marine Strategy Framework Directive	Export and import of hazardous chemicals Regulation (PIC)	Young people at work Directive[a,b]
Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive	EU Ecolabel Regulation	Pregnant workers Directive[a,b]
Batteries Directive	Biocidal products Regulation	Chemical Agents Directive[a,b]
Packaging and Packaging Waste Directive	Plant protection products Regulation	Waste framework Directive and List of Waste[a,b]
Persistent organic pollutants Regulation	Food contact materials Regulations**	End of life vehicles Directive[a,b]
Drinking Water Directive	General Product Safety Directive	Tobacco Directive*[b]
Protection of animals used for scientific purposes Directive		Active and Intelligent Materials Regulation (food contact)**[b]
Contaminants in food and feed Regulation and Directive		Landfill of Waste Directive*[b]
Residues of pesticides Regulation		Environmental Liability Directive*
		Major-accident hazards involving dangerous substances (Seveso) Directive*[b]
		Signs at work Directive*[b]

(Partially) In Scope	Out of Scope
	Good laboratory practice*[b]
	Inland transport of dangerous goods Directive*[b]

Table 6 Overview of legislation within the scope of the FC+ Study

* Additional to the 41 pieces of legislation included within the 1st FC Study. Further legislation was discussed at the inception meeting based on those covered by the 1st FC Study. As these pieces of legislation were fully reviewed as part of the 1st FC Study they were treated as out of scope (with the exception of the Pyrotechnic Articles Directive) of the FC+ Study, but have been included in Table A3.4 for completeness.

** The Fitness Check Roadmap identifies 'Food contact materials' as relating to 2011/10/EC on the use of plastics materials and articles intended for food contact and 2009/450/EC active and intelligent materials intended for food contact. Following completion of Task 1, 2009/450/EC on active and intelligent materials is out of scope of the FC+ Study. 2011/10/EC on plastic materials and articles is partially witnin scope. This included discussion of overlaps with EC/1935/2004, which is the Framework Directive for Food Contact Materials and which covers non-plastic materials.

The FC+ Study was completed through a combination of desk-based research including literature review, policy review and taking into account the findings of the First Study. It has also included a significant amount of stakeholder engagement including interviews with Commission Services, Member State Competent Authorities, industry, NGO groups and academics. As part of the study, a one-day workshop was held in Brussels for approximately 70 delegates that spanned these different stakeholder groups to discuss the functioning of EU chemicals legislation.

The main focus of this study was on the use of specific risk assessment approaches within EU chemicals legislation, particularly in cases where the hazard identification and characterisation stages are either fully independent or partially independent of hazard classification through the CLP regulation. More particularly, the following aspects were covered:

1. Science, data and knowledge;
2. Risk management based on specific risk assessment (SRA);
3. The role and use of generic and specific risk management approaches within EU chemicals legislation;
4. Coherence of data, science, and risk management procedures and measures;
5. Gaps in the EU chemicals acquis as regards achieving high level protection of human health and the environment, as well as for the functioning of the internal market and competitiveness.

The report briefly sets out the history of and rationale for chemicals legislation, and in particular the approach to risk assessment and risk management. It includes a review of:

- The use of specific risk assessment approaches, and their use as compared to the identification of risk management measures based on generic risk considerations.
- The different types of risk management measures and the circumstances under which different measures are selected.

The approach developed for the study included five tasks, detailed within **Table 7**. Additionally, a 'Task 0' was used as a cross-cutting task to manage all of the data gathering aspects needed to support the later tasks.

Task number	Title of the task	Aims of the task
0	Data and information collection and management	This was a cross-cutting task to manage the data gathering and compilation. It included the development of evaluation questions under the fitness check and the identification of the project's data needs. This included a mechanism to fulfil these data needs through a combination of policy review, literature search, a workshop and targeted stakeholder engagement. This included the use of targeted interviews across a range of stakeholder groups (industry, member state authorities, European Commission, EU agencies, and organisations representing civil society).
1	Mapping out of legislation and legislative links	The objective of Task 1 was to identify and map the EU legislative framework for hazard identification, risk assessment (both generic and specific) and linked risk management measures. This task also included reference to the First Study to understand work already completed and avoid duplication. Sub tasks included: 1A: Map links between hazard identification other than CLP and risk management measures (RMMs) taken as a consequence (in view of generic risk considerations or after specific risk assessment (SRA) 1B: List and map out all other provisions that provide for SRA, identify/describe the SRA procedures and describe links with RMMs taken as a consequence. 1C: Compile an overview table on whether approach is based on (i) generic risk consideration (GRC), (ii) SRA, or (iii) combination of both. 1D: Design an overall intervention logic.
2	Evaluation of risk assessment procedures	The objective of Task 2 was to provide an analysis of specific risk assessment procedures and to evaluate these based on the criteria from the better regulation toolbox for evaluations. This included a comparative analysis of approaches based on specific risk assessments, generic risk considerations and how these approaches contrast and compare to work effectively. Sub tasks included: 2A: Describe the SRA procedures not directly triggered by CLP classification, identify their similarities and differences 2B: Analyse SRA based on the five evaluation criteria 2C: Compare procedures based on GRC (mainly from FS[50]) and those based on SRA against criteria (looking for positives and negatives)
3	Evaluation of risk management measures and risk management approaches	The objective of Task 3 was to assess risk management measures. This included a review of the relationship between risk management measures and generic and specific risk assessments, the selection and grouping of risk management measures and further analysis for the coherence and consistency in how such measures practically meet policy goals. Sub tasks included: 3A: Identify, analyse and categorise the various types of RMMs based on SRA (not directly triggered by a CLP hazard classification) 3B: Identify, analyse and categorise the various types of RMMs based on GRC (other than the ones resulting from CLP hazard classification).

[50] First Study (European Commission, 2017a)

Task number	Title of the task	Aims of the task
		3C: Comparative assessment of the categories of RMM adopted following SRA with those adopted following GRC, as identified in the first study (FS) (based on evaluation criteria) 3D: Analyse and assess the RM approaches on their own, and in comparison, with one another. 3E: Analyse whether there are cases where the link between an identified hazard and RMM should be adopted based on GRC instead of the existing SRA approach. 3F: Analyse whether there are any ineffective, inefficient or irrelevant links between chemicals management and identified hazard classes i.e. cases in which a SRA approach should be adopted instead of the existing link between identified hazard and a risk management measure based on GRC.
4	Analysis of the coherence of the legal framework	The objective of Task 4 was to analyse the coherence of the legislative approach and procedures regarding hazard identification, generic risk considerations, specific risk assessment or risk management measures. Sub tasks included: 4A: Based on Task 1 mapping and FS, compare the various ways the links between legislation are formulated and implemented at the level of SRA, RA procedures, and related RMM and analyse the links in order to identify gaps, overlaps, contradictions, inconsistencies, synergies and virtuous interactions. 4B: Analyse to what extent a given chemical or category of chemicals is treated consistently by the legislative framework (cases where different pieces of legislation involve different kinds of RMM applied to the same or similar substances).
5	Validation and discussion workshop	The objective of Task 5 was to engage with relevant stakeholders to explore the outputs from the preceding tasks and further enrich the outputs to draw conclusions for the evaluation. Sub tasks included: 5A: Preparation for the workshop; 5B workshop; and 5C post workshop collation of information.

Table 7 Overview of the methodology used for the current study

A series of assessment themes were developed to look at the function of risk assessment approaches under the EU legislation within the context of specific topics and included:

- Data requirements and limitations;
- Exposure scenarios – data, theory and reality;
- Hazards with equivalent risk of concern to CMRs;
- Regrettable substitutions – single substance by single substance review vs group assessment;
- Effectiveness and efficiency of specific risk assessment approaches; and
- Lessons learnt from 30 years of managing CMRs.

The assessment themes were used alongside the evaluation questions to provide common topics as a means of further comparison and review of the risk assessment approaches under

different legislation. Appendix B of the FC+ Study provides a copy of the workshop report, including further details on how the focus themes were explored.

B. Evidence base and limitations

This sub-section provides further details of the types of information that have been gathered and used for the FC+ Study. It also provides further details on the limitations of the study, including details of what information sets were not used/available and the possible limitations as to what can and cannot be concluded from the results.

As part of the approach to data gathering and analysis for the FC+ Study the following types of information have been used:

- A range of different types of literature, which included:
  - The legislation itself.
  - Policy and technical guidance documents: This is literature developed by the European Commission, EU agencies and industry to provide further details on how the obligations of legislation should be met. This includes details on how specific risk assessment processes should work, and further guidance on any problematic issues or areas where the legislation may have required further elaboration.
  - Peer-reviewed scientific literature: This includes a range of journal papers reviewing particular scientific or technical issues that relate to EU chemicals policy. It also includes journal papers assessing the role of policy and science and how academic research can inform policy.
  - Non-peer reviewed scientific literature: This includes a number of research studies published through non-governmental organisation (NGOs), industry and others relating to both scientific topics (such as chemical effects on human health) but also the functioning and effectiveness of EU policy to protect human health.
  - Government reports: This includes a number of member state level reports on scientific and technical issues (such as endocrine disrupting chemicals) but also national level actions related to EU policy, particularly EU directives and regulations.
- Targeted stakeholder engagement 1. As part of Task 0 and the development of evaluation questions, interview guidelines were developed. These were then used as part of a broad interview campaign with 68 stakeholders from a range of different backgrounds, including Commission services (18 stakeholders), EU agencies (3 stakeholders), member state authorities (16 stakeholders), industry representatives (21 stakeholders), NGOs and academics (10 stakeholders)[51].
- Targeted stakeholder engagement 2. In addition to the first stakeholder engagement process, a second set of questions were developed looking at efficiency and in particular the economic costs of compliance with the different pieces of EU legislation. This second survey was aimed at consultancies and laboratories and was used to generate data and complete processes needed for

[51] The original proposal for this study included a questionnaire (which was potentially to have been run online). Based on the emerging study findings, it was confirmed that such a questionnaire was unlikely to yield useful results and so more emphasis was placed upon targeted interviews and other forms of engagement and data collection

applications to EU agencies for a sub-set of the legislation in scope. The data gathered from five laboratory consultancies was intended to provide an indication of possible costs of the existing processes as a means of informing the evaluation of their efficiency.

- Workshop engagement. As part of the FC+ Study a workshop for approximately 80 delegates was organised. Ahead of the workshop a 'thought starter' paper was developed based on the focus themes and issued to the delegates. The workshop included a number of presentations detailing the initial findings of the study, followed by break-out sessions with groups of approximately 15 each to openly discuss each of the themes and obtain feedback and suggestions for use in the study.
- Final report of the First Study, which along with the key headline findings also included:
    - A series of case studies which explored in detail different aspects of the risk assessment approaches and risk management measures used across the European Union.
    - Results of a public consultation. As part of the work from the First Study a public consultation was undertaken to seek the opinions of a wide range of stakeholders. While the current study did not include such a public consultation, it has been possible to review the results from the consultation completed under the First Study to support the findings of the current work.
    - Outcome of the Fitness check SME Panel. The present study considered implications for SMEs in various cases, and the SME panel from the First Study was taken into account.

The following limitations should be considered when assessing the results and findings of the FC+ Study:

- The data gathered for use in the analysis under the FC+study included a mixture of peer-reviewed literature and referenced materials alongside opinion gathered from targeted consultation. Wherever possible the study tried to make use of published references to help support the analysis supplemented by the opinions of the stakeholders contacted, and to select stakeholders likely to have the best insights into how well legislation is working. All interviewees were asked to point to evidence supporting the information and opinions that they provided. However, the diversity of the topic and data scarcity for some aspects has meant that the opinions provided by stakeholders remain an important source of information, particularly where this relates to the opinion of experts, who have worked in the field for many years. Where the analysis has relied on the opinions of stakeholders, the study aimed to gather a measured and balanced set of opinions from different groups. However, the following key limitations should be kept in mind:
- Stakeholders were identified based on their active engagement with specific pieces of legislation. However, involvement in the study was on a voluntary basis. Therefore, it could be perceived that those who felt strongly about particular processes or pieces of legislation were more likely to take part. To offset this possible limitation stakeholders included regulators, industry and NGOs, as well as officers of the European Commission and EU agencies responsible for chemicals legislation.

- In a limited number of cases particular stakeholder groups (e.g. industry, regulators, NGOs) dominated the responses for certain aspects of legislation. The FC+ Study report states where this is the case.
- The stakeholder engagement, while broadly diverse, could still be argued to be a relatively small sub-set compared to the size and scale of the EU chemicals industry. While a full public consultation was not used for the FC+ Study, it could be argued that there are limitations in how strongly the conclusions can be argued. To offset this limitation the work completed under the study included a review of the findings of the 1st FC Study to enable a more complete analysis, and evidence was sought wherever possible to back up opinions. Findings from the 1st FC Study (including its public consultation and SME panel) have been used to help corroborate findings in the FC+Study where appropriate.
- The available economic data on costs and efficiency reported in a quantitative fashion was very limited. Literature data, and two stakeholder engagements were used to gather quantitative and qualitative information on the functioning and efficiency aspects of the risk assessment and risk management processes used under the EU legislation. However, it was not possible to provide extensive costed examples related to efficiency within the scope of the FC+ Study.
- The available information on specific pieces of legislation varied, with some legislation and risk assessment processes well covered by multiple different stakeholder groups and literature/data sources. Other pieces of legislation were not as well covered and the analysis relied more on policy guidance documents and review of the legislation to ascertain how the processes function and what potential issues may exist. Table 8 provides an overview of which legislation was (relatively) data rich and which was data scarce.

Legislation	Data availability
Detergents regulation	Moderate levels of data
Explosives Directive	Data scarce
Pyrotechnic Articles Directive*	Data scarce
Asbestos Directive (human health only)	Data scarce
Water Framework Directive	Moderate levels of data
Urban Waste Water Directive	Moderate levels of data
Marine Strategy Framework Directive	Moderate levels of data
Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive	Moderate levels of data

Legislation	Data availability
Batteries Directive	Moderate levels of data
Packaging and Packaging Waste Directive	Moderate levels of data
Persistent organic pollutants Regulation	Data Rich
Drinking Water Directive	Moderate levels of data
Protection of animals used for scientific purposes Directive	Data Scarce
Contaminants in food and feed Regulation and Directive	Moderate levels of data
Residues of pesticides Regulation	Data rich
Safety of Toys directive	Moderate levels of data
Cosmetic products regulation	Moderate levels of data
Medical devices (regarding medical devices; regarding active implantable medical devices; regarding in vitro diagnostic medical devices)	Data Scarce
Pressure equipment directive	Data Scarce
Industrial emissions (integrated pollution prevention and control) Directive	Moderate levels of data
Waste shipments Regulation	Moderate levels of data
Export and import of hazardous chemicals Regulation (PIC)	Moderate levels of data
EU Ecolabel Regulation	Moderate levels of data
Biocidal products Regulation	Data Rich
Plant protection products Regulation	Data Rich
Food contact materials Regulations	Data Rich

Legislation	Data availability
General Product Safety Directive	Moderate levels of data

Table 8 Overview of available data by legislation (data rich – data scarce)

3.2 The complementary studies

3.2.1 Cumulative Cost Assessment for the EU Chemical Industry (the CCA1 Study)

A. Methods and analytical models

In 2014, the Commission launched a study analysing cumulative costs of the most relevant EU legislation for the EU chemical industry during the period 2004-2014. The EU legislation subject to analysis includes chemicals legislation, energy, emissions and industrial processes, workers' safety and health and product-specific legislation. The study objectives were to:

- provide for quantification of the cumulative costs related to those packages of EU legislation with the highest cost impact, and quantify the cumulative costs in the subsectors of the chemical industry;
- demonstrate how the costs have changed over time; and
- compare the costs with relevant financial indicators for the chemical industry.

The study was completed in July 2016. The CCA1 study conclusions are available online[52].

The study covered the whole chemical sector, although cost is assessed only for the subsectors for which the available data are sufficient to produce reliable estimations. These are, according to the statistical classification of economic activities in the European Community (NACE): 20.13 — inorganic basic chemicals; 20.14 — organic basic chemicals; 20.16 — plastics in primary forms; 20.20 — pesticides and agrochemical products; 20.41 — soaps and detergents, and cleaning and polishing preparations; 20.30 — paints, varnishes and similar coatings and 20.59 — other chemicals products.

Among the pieces of legislation affecting the EU chemical industry, only those incurring high cost directly to chemical companies were included. Legislation that affects upstream non-chemical companies, which then pass on costs to the chemical industry through the prices of inputs, was not within the scope of the study. Similarly, indirect costs — such as opportunity cost due to forgone business or transaction cost and costs related to national legislation exceeding EU requirements — were not taken into account.

As opposed to other methods assessing the costs of policies, the CCA1 Study provides a quantitative assessment of all costs (monetary obligations, capital expenditure, operating expenses and administrative burden) incurred by EU chemical companies with regards to the EU legislation most relevant to them. The study did not assess the benefits of EU legislation and did not aim to provide insights related to the proportionality of costs and benefits of legislation, nor its efficiency or effectiveness. The main steps for implementing the cumulative cost assessment and the methodology for estimating legislation costs are summarised in Figure 2 and Figure 3 respectively.

Furthermore, a cumulative approach is to be distinguished from a non-cumulative approach as traditionally used in a cost-benefit analysis (CBA). The standard cost-benefit approach

[52] http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

examines the incremental costs and benefits related to policy proposals against a baseline. This implies that a CBA focuses on the net change in costs and benefits, relevant to a specific policy decision, not the aggregate (or cumulative) level of regulatory costs and benefits (European Commission, 2015). On the other hand, the cumulative cost assessment (CCA) focuses on the whole sector, rather than on a particular policy proposal or legislation, and aggregates the costs generated by all relevant existing EU legislation. Hence, this cumulative cost assessment did not focus on a policy field and did not aim at assessing whether the regulatory framework is fit for purpose in a policy field, which is an approach used when conducting fitness checks.

While there is no recognised standard methodology for the assessment of cumulative impacts, the methodology of this study drew on previous similar cumulative cost assessment exercises performed by Member States and the European Commission. For the overall CCA approach the previous studies on the aluminium and steel industries have been consulted. In particular, for the estimation of the various types of costs, CCA studies are based on established methodologies that have been used for several years by Member States and the European Commission, including the Standard Cost Model, or the Cost-driven Approach to Regulatory burden (CAR) developed for the Dutch Government. The Standard Cost Model methodology (SCM) is used by several Member States (Network Standard Cost Model, 2005), as well as the European Commission, as part of its REFIT programme and the "Better Regulation Toolbox" (European Commission, 2015). The CAR methodology, used by the Dutch government (SIRA, 2015), is similar to the SCM, yet its scope is broader regarding the types of cost covered and gives more emphasis to linking legislation cost with the cost structure of companies.

Methodologies to measure legislation burden follow the principle, summarised by the European Commission in its presentation of the SCM: "the purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in different regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates" (European Commission, n.d.)

To facilitate the collection of data and the estimation of costs, the pieces of legislation were grouped into seven packages on the basis of their overarching and specific policy objectives as follows: chemicals, energy, emissions and industrial processes, workers' safety, product-specific, customs and trade, and transport legislation.

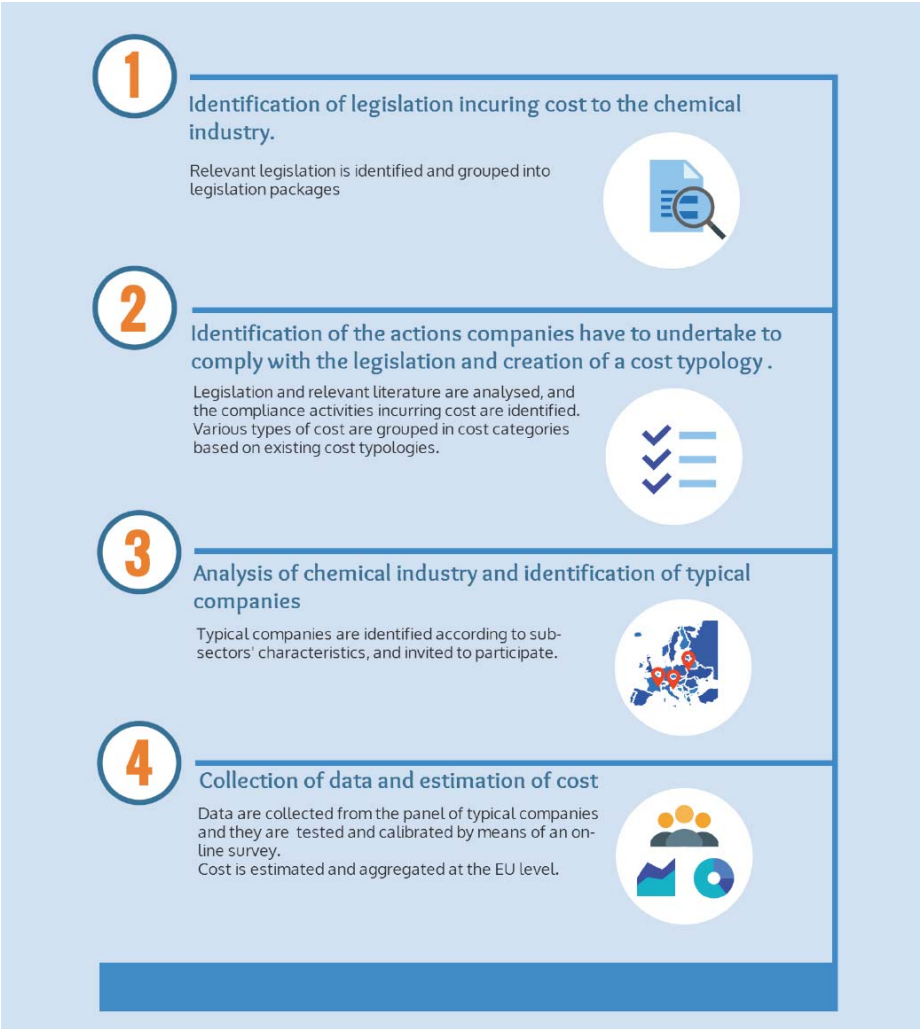


Figure 2 Steps for implementing the cumulated cost assessment

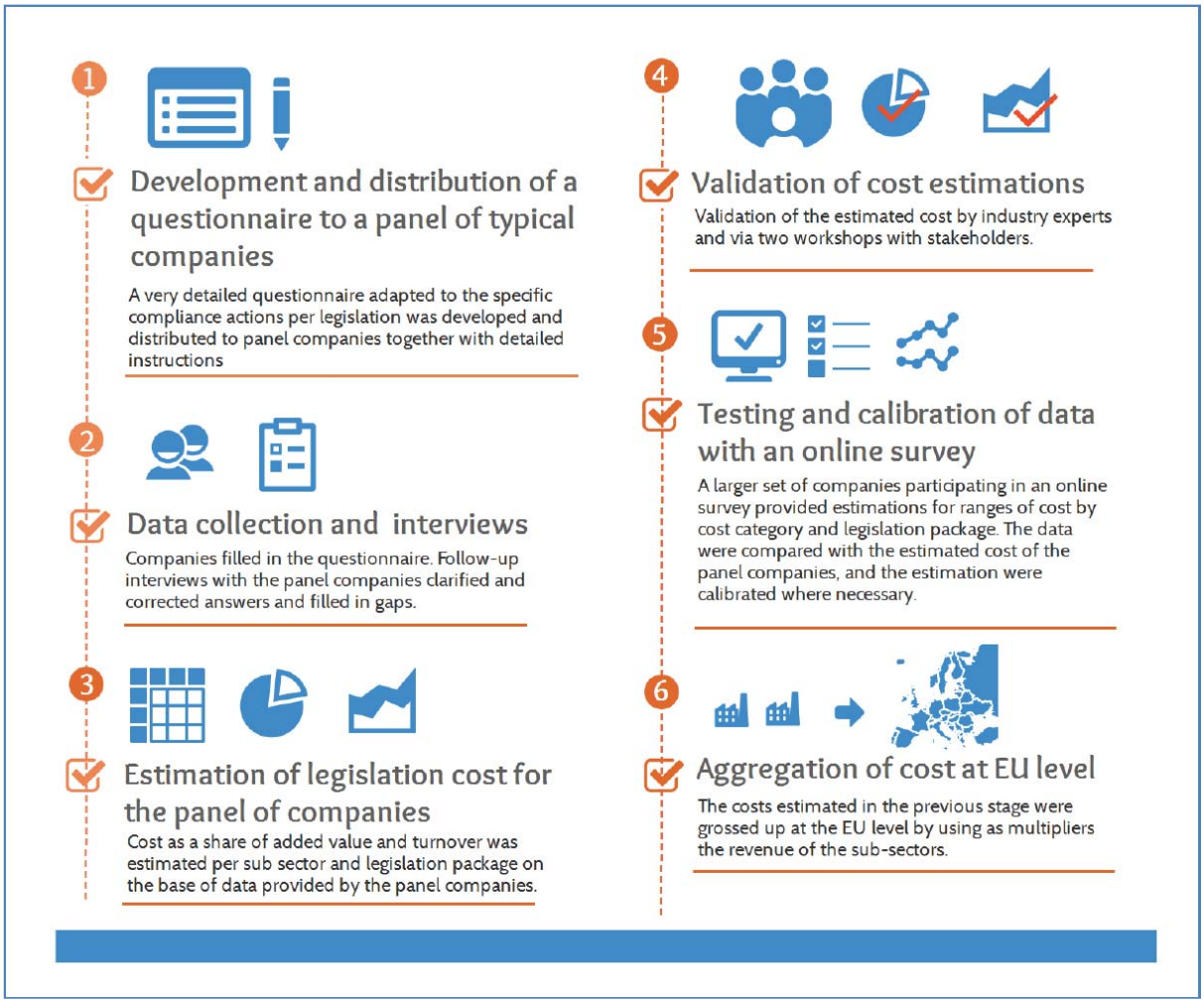


Figure 3 Methodology for estimating legislation cost

To facilitate the collection of data and the estimation of cost, the pieces of legislation have been grouped into seven packages based on their overarching and specific policy objectives. In some packages, pieces of legislation were further grouped into sub-categories based on the similarity of their cost generation mechanism. Framework legislation (e.g. the Waste or Air Quality Framework Directive) and their "daughter" legislation are presented together, as the former sets the general principles while the latter sets the implementation measures and therefore costs. The results of this grouping, indicating the relevance of packages to specific subsectors, are shown in Table 9 below.

National legislation that is not related to EU legislation is excluded from the study. Companies participating in the panel and the online survey were therefore asked to report only the costs associated with the requirements set out in the EU legislation. However, in the case of energy taxes a distinction between the costs generated by the EU policy and those by the national legislation was not possible. Therefore, the estimated cost in this case includes also the effects of national legislation.

In addition, to the selected subsectors, a rough picture of legislation's effects on the wholesale costs of chemical products (NACE 46.75) is presented, based on information collected during the study.

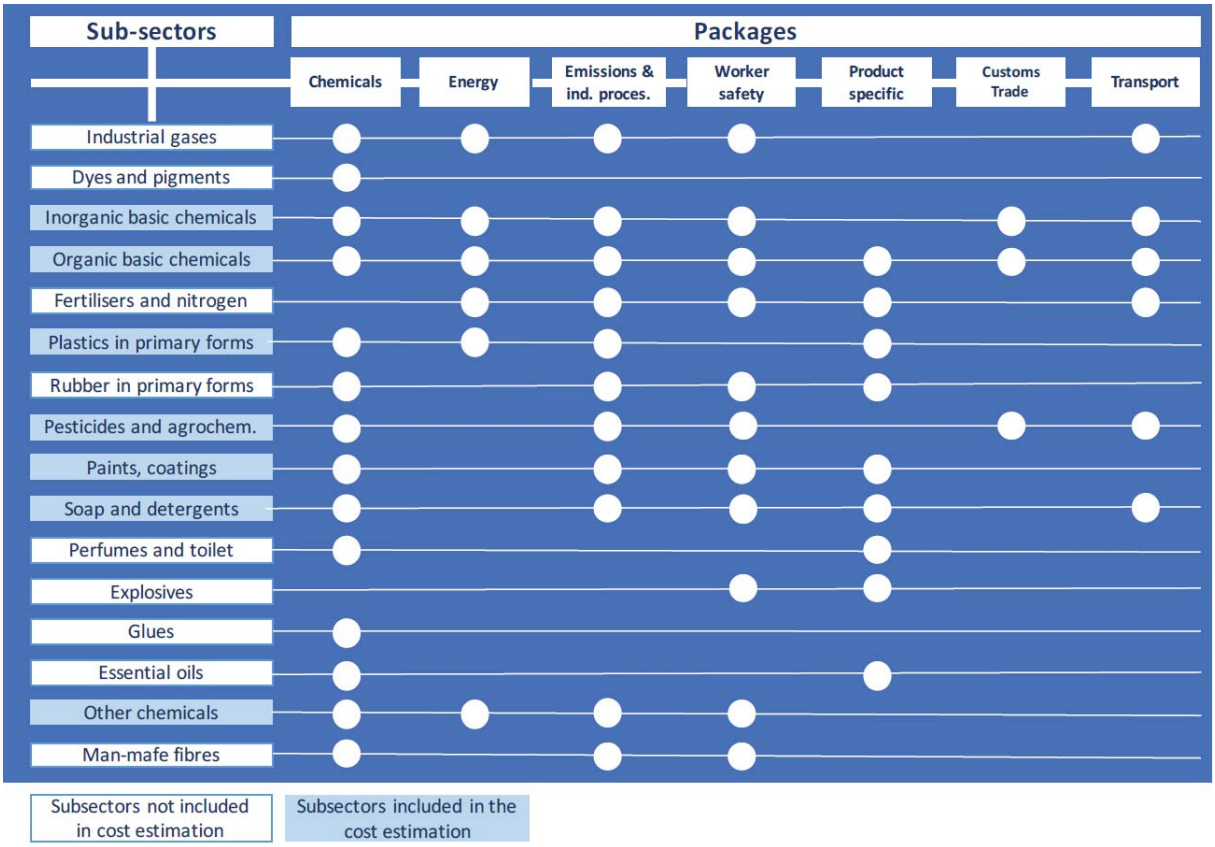


Table 9 Legislation packages per subsector

B. Evidence base and limitations

Data collection in the CCA1 study did not rely on statistical methods. Detailed data were collected from a panel of 31 typical companies[2], which were selected according to a set of criteria. The estimated costs for this panel of companies were validated in two workshops with industry experts and stakeholders. Then the data were adjusted based on the results from an online survey that addressed a larger sample of 90 companies. The results from the online survey appeared to be in line with the cost figures provided by the panel companies, supporting the premise that the initial panel consisted of typical firms. Finally, the data were grossed up to represent the whole population of each subsector by multiplying the turnover of each subsector by the adjusted cost per turnover of the typical companies of the sub sector. The grossing up by using multipliers that represent the whole population of a particular group relies on the hypothesis of full compliance, which however is not always the case. Therefore, in certain cases, it could lead to an overestimation of absolute values by assuming that all companies fully comply with the legislation.

Despite its significant advantages regarding feasibility, the method is less accurate when compared to statistical methods, and it can only provide an estimate of the order of magnitude of cost borne by companies due to EU legislation. Furthermore, the cost estimates derived in the CCA1 study cannot be considered as an entirely accurate estimate of the cost of the EU chemicals *acquis* due differences of scope between the study and Fitness Check and certain limitations with the methodology applied:

- The period covered (2004-2014) 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.
- 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.
- 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 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).

3.2.2 Study on the cumulative health and environmental benefits of chemical legislation (CuBA Study)

A. Methods and analytical models

The CuBA Study pulled together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation. It was completed in August 201753.

The study aimed at answering the following questions:

1. In terms of avoided damage to human health and to the environment, what has been achieved through chemicals legislation adopted by the European Union since 1967.
2. Recognising substantial progress has been made, what is the nature and scale of contemporary damage to human health and the environment that can be attributed to chemicals exposure today, under current legislation?
3. Given the current situation, what are the key emerging and evolving risks to European economy and society caused by chemical exposure and what are the major gaps in our current understanding of the risk and effects of legislation that now need to be addressed?

53 https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

The overall approach and model used to arrive at the estimates – both physical and monetary – of the environmental and human health benefits of EU chemicals legislation are outlined in Figure 4, Figure 5 and Figure 6 below.

First, the study identified the receptor (i.e. specific health or environmental effect of concern). Background information is also presented. Second, it examined chemical substances that are known or suspected to cause this damage and the strength of that relationship. Third, it evaluated the end impacts (i.e. what does the evidence show that chemicals substances actually cause; this may include cancer, mild mental retardation, imposex, infertility or egg shell thinning). Fourth, what is the exposure route and what legislative action has been taken to address this damage?

Fifth, sixth and seventh, as far as available evidence permits, what has been the result. This may include changes in emissions/exposure or evidence of changes in biological concentration of chemicals in human blood, breast milk, urine, or water, for example. It includes physical improvements, such as improvements in water quality, fish populations, biodiversity, for example and in some cases includes monetary estimates of the benefits.

Finally, for each health and environmental impact end point, information on the current health burden is summarised, alongside an evaluation of knowledge and data gaps, which may continue to inform future policy action. Each chapter in the main study report is supplemented by a technical annex, with further detail on specific legislation is provided (the same individual piece of legislation may be referred to more than once), technical analysis is explained and references are provided. This is provided as a separate document with separate chapters for each chapter in the main report. This is referred to as the 'technical appendix'[54].

[54] Study on the cumulative health and environmental benefits of chemical legislation, Final Report – Technical Appendix

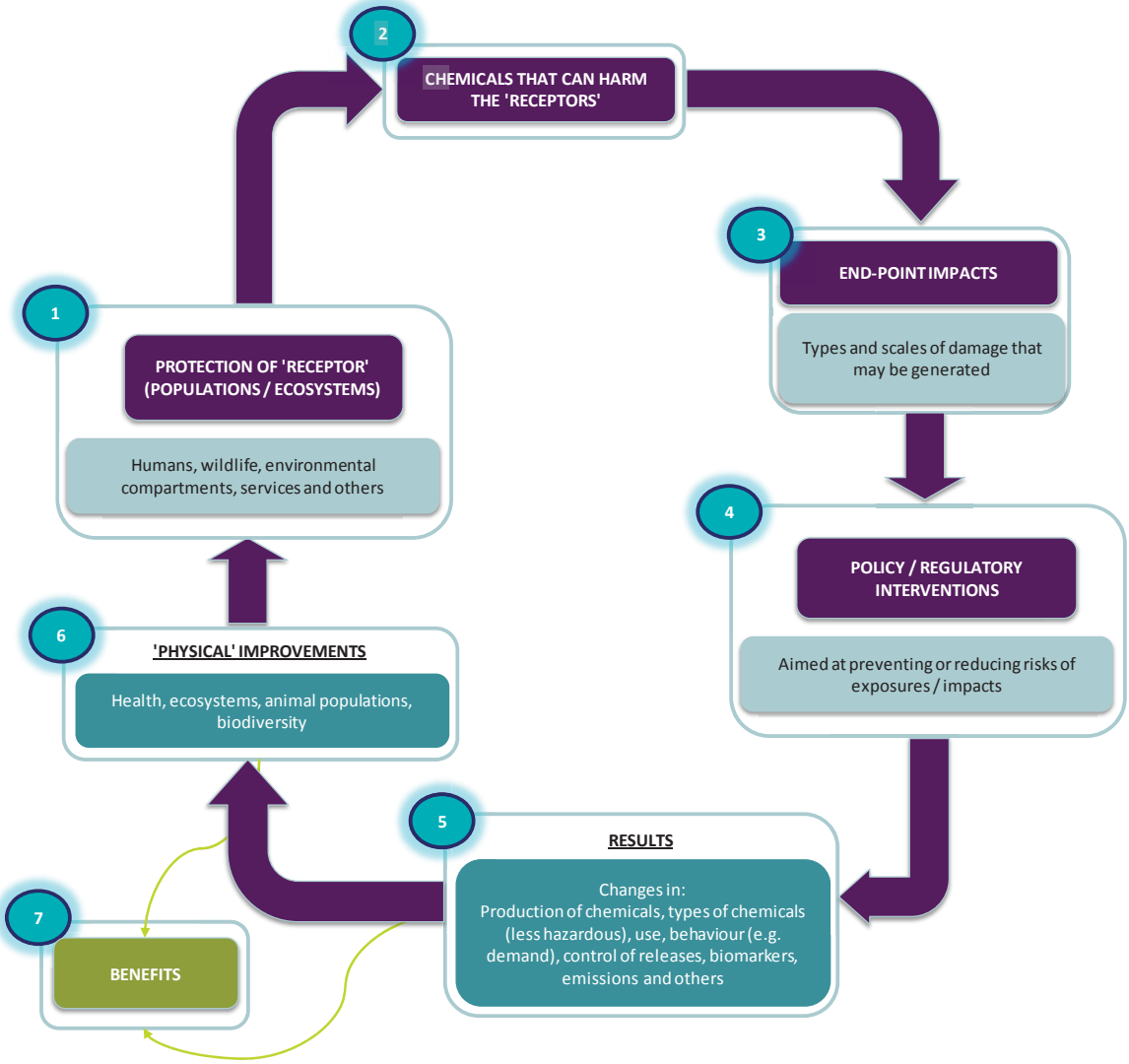


Figure 4 Overall structure of the analysis

Legislative scope*:* The CuBA Study covered "chemicals and related legislation". This included the chemicals legislation covered by Annex I to the study entitled "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps". This list was published in the context of the 2013 Review of REACH. It covered relevant legislation between 1967 and September 2011. A review undertaken at the start of the project also identified legislation implemented between September 2011 and August 2015 that was also of relevance. In total over 200 individual pieces of legislation were identified – including many amendments and revisions. This included, for example, legislation on biocides, occupational exposure to chemicals and pesticides (i.e. where legislation has been introduced with the primary aim of to addressing the harmful effects of chemicals). The scope also included some key pieces of legislation such as the Water Framework Directive (WFD) and Industrial Emissions Directive (IED) that, although not specifically or solely aimed at chemicals risk management, contain specific articles which address emission control of some specific chemicals and hence have contributed to the outcomes. Whilst volatile organic compounds VOCs were considered in the context of paints and solvents, combustion by-

products such as NO_x, SO_2 or PM are not, as these are addressed by air quality and industrial emissions legislation, amongst others. The overlap between the broader legislative scope of the CuBA Study and the Fitness Check evaluation is summarised in Annex 4 of this Staff Working Document.

Geographical scope: The focus of the CuBA study was the European Union. Clearly, the number of Member States continues to evolve[55]. This is referred to where relevant on a case-by-case basis.

Approach to assessment of benefits: Assessing the effects of chemicals legislation of the scope attempted by the CuBA Study was challenging. It required various data, on uses, emissions and exposure, on legislative provisions and the effects of these, on health and environmental indicators and the associated changes in specific effects. Moreover, some assumptions had to be made, in particular in the selection of dose-response functions, willingness to pay (WTP) values, disability adjusted life year (DALY) losses and values, amongst others. These are set out in the main study report with further detail in the technical appendix. This is complicated by the multiple causal factors involved, the time period in question and the number of individual pieces of legislation that have been considered alongside the latency of the diseases. As such there has been no single approach taken; the study pieced together the available evidence, but in general did not attempt to generate new primary data. Whilst new primary data was not generated, new analysis and, therefore, information was generated where practicable. Broadly, there are three routes to identifying the impacts, which combine a "top down" and "bottom up" approach (see figure 3).

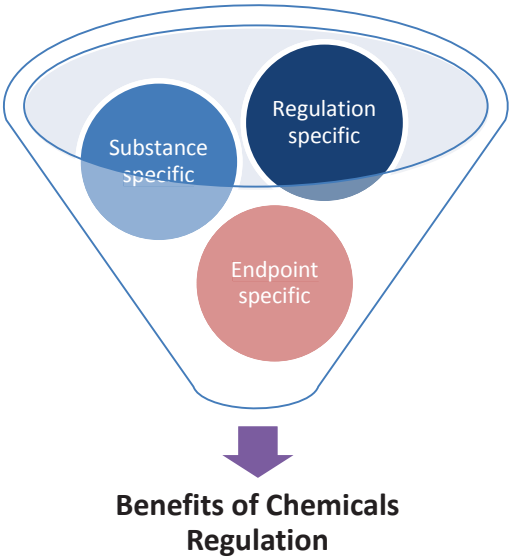


Figure 5 Assessing benefits - three windows

- Evidence which relates to a chemical substance. This includes data on production of carcinogens, on emission of heavy metals or data on chemical concentration in human

[55] 1967 founding Members: Belgium, Germany, France, Italy, Luxembourg and the Netherlands. 1973 Denmark, Ireland and the UK; 1981 Greece, 1986 Spain and Portugal; 1995 Austria, Sweden and Finland. In 2004 Cyprus, the Czech Republic, Estonia, Hungary and Lithuania, Latvia, Malta and Poland, Slovenia and Slovakia. Bulgaria and Romania joined in 2008, Croatia in 2013. https://europa.eu/european-union/about-eu/countries_en

samples (biomarkers), for example. In combination with an understanding of the human or environmental damage caused by these substances this provides a picture of likely changes in the ultimate effects and on the role of legislative action – alongside other factors – in any change.

- Evidence which relates to a specific (or group of) chemical regulation. This includes evidence where the benefits from specific action, such as restrictions on use of chemicals (e.g. under the REACH regulation) have been considered. This provides a relatively straightforward answer as to the effects, but examples of ex-post, rather than ex-ante evidence are comparatively few.
- Evidence which relates to an health or environmental impact endpoint, for instance cancers, reproductive health disorders or water quality, drawing out – as far as practicable – the role of chemical exposure. This is rather more straightforward for the human health effects given the high level data published by bodies such as the WHO, than for the environmental effects.

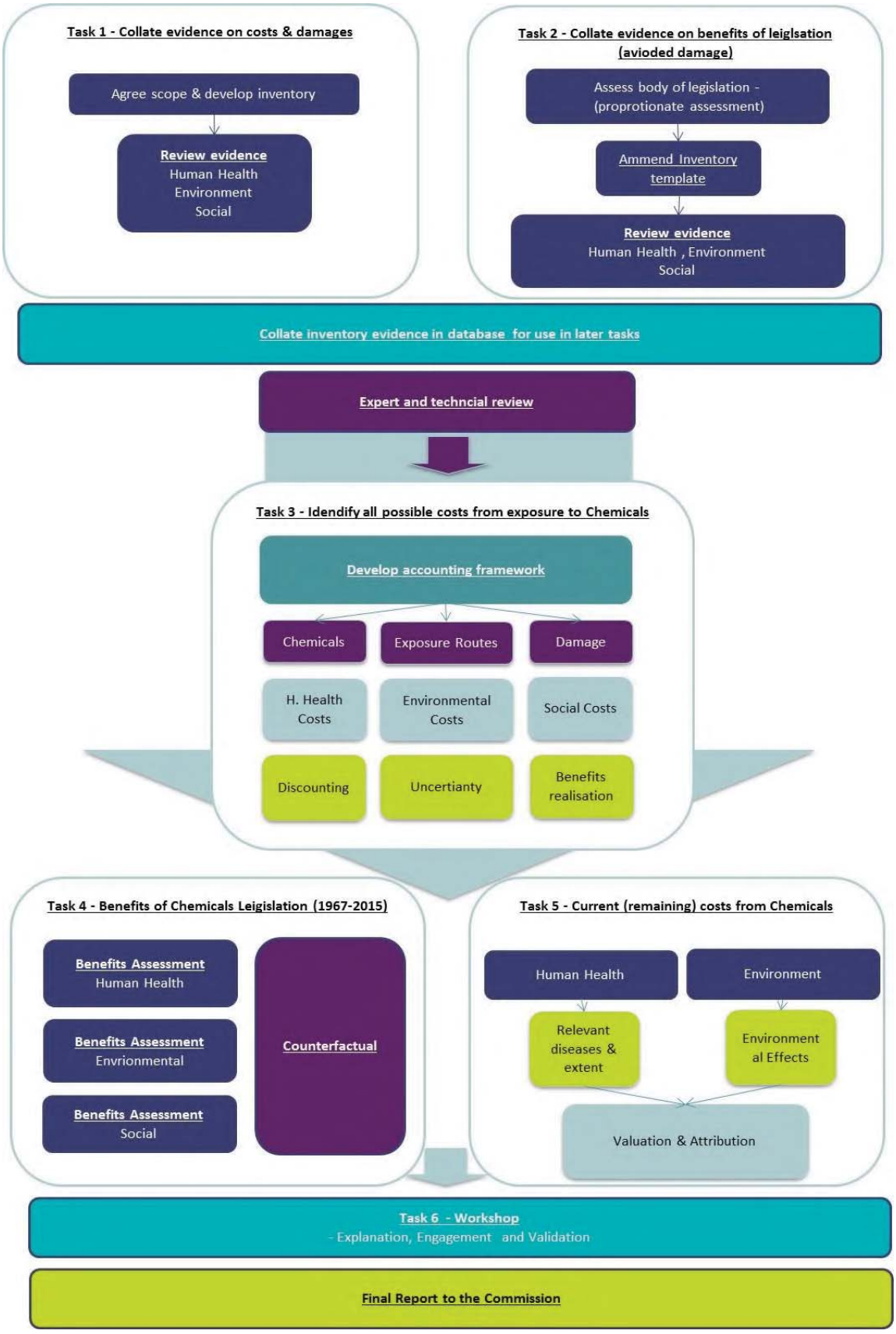


Figure 6 Method overview

There are several *potential* drivers in changes in the manufacture/use of dangerous chemicals in Europe, of which regulation is arguably the most important. These include efficiency gains, initiatives by industry carried out on a voluntary basis, alongside wider changes in economic structure. Given the legislative, geographical and temporal scope of the CuBA Study, it was not practicable to evaluate each casual factor in detail. However, the study drew extensively on a wide literature which has sought to evaluate the role that regulation has played specifically, evaluated the casual factors qualitatively in several case study examples, which suggest the role of regulation in driving the benefits observed has been significant.

"Any report on the "economic cost" of impacts on human health, be it from air pollution or any other source, involving as it does a "valuation" of life and of health, needs to explain as clearly as possible what precisely is meant by the terms "value" and "cost". This is a non-trivial task. For the use of these terms is frequently misunderstood.

The world is not yet free of the illusion that the wealth of the world subsists in gold (or some other form of money): the "chrysohedonistic illusion". Even though an explicit rejection of this view characterises the founding works of economic science in the mid-eighteenth century following through to today, long after gold has given way to paper money, it is all too frequently supposed that what economists really mean by "value", or by "cost", is a given sum of money.

It is therefore as well to begin by stating that this is not so: money is not the thing being measured but the instrument with which we measure it. Of course, money plays several roles wherever it is present rival schools of economic thought hold rival views on the roles that it plays. In the context of the present analysis, however, and irrespective of these otherwise rival views, all economists can agree that money serves here merely as a common unit of account, an imperfect instrument with which to measure certain non- monetary phenomena: namely, the several various items that all of us as individuals "value" in the ordinary sense of the word.

So, what is it that we as individuals' value and that economists as observers seek to measure? They include:

consumption – and, with it, the sacrifice of some items of consumption in order to secure others, including the sacrifice of current consumption in the act of investment in order to secure greater future consumption;

- leisure – and the sacrifice of some leisure in the act of labour in order to secure consumption;
- health – and the sacrifice of some part of consumption in order to secure health;
- life – and the sacrifice of some part of consumption in order to preserve it.

"Value" as used here – also called "utility" – is simply a measure of these items that we all value in the ordinary sense of the word "cost" is a measure of their loss, absolutely or as a means of securing other valuable items. The task of the economist then becomes one of aggregating at a social level these millions of individual valuations at their marginal rates of substitution"[56]

[56] OECD (2014), The Cost of Air Pollution: Health Impacts of Road Transport, OECD Publishing. http://dx.doi.org/10.1787/9789264210448-en

Quantification and monetisation of benefits: Where a quantitative or monetised estimate of benefits of chemicals legislation was derived, this took into account both 'direct financial' benefits (including the avoided cost of diagnosis and treatment and productivity savings from avoided loss of working days or reduced cognitive potential) and wider 'personal valuation' or intrinsic benefits (including willingness to pay (WTP) to avoid a health condition and the associated loss of function/quality of life or environmental outcome). Monetary benefit estimates in this study used a wide range of available unit values including WTP data, values of statistical life (VOSL) and life-year lost (VOLY) as well as average treatment and environmental abatement measure costs. The approach to valuation was an important aspect in the study and in the field of policy assessment more generally. These issues were considered - based on first principles - in 2014 by the OECD, quoted in full below, and provide a useful reflection on what it is that policy analysts aim to assess and value.

Case studies and discounting: Case studies form part of the CuBA Study analysis of cancers, neurodevelopment, cardiovascular and respiratory diseases and reproductive health. The case studies provided quantitative estimates of human health benefits based on specific chemical, effect relationships (e.g. lead and its effects on IQ). These, in turn, drew on dose-response relationships and other data drawn from secondary evidence. The case studies evaluated and compared effects over time. Because they were drawn from different secondary data sources, the time periods were not always consistent. The results were presented in two ways.

- First, the study provided a "snapshot" by comparing the difference in the health damage at the beginning of the case study period to that at the end. This enabled the study to draw conclusions regarding how much damage has reduced for individuals/groups of people.
- Second, the study provides a "cumulative" benefit estimate, whereby all the benefits for each and every year within the case study period were estimated. Average annual benefits were then presented, based on this cumulative figure.

Both the cumulative and snapshot benefit estimates presented in the CuBA Study are undiscounted values. Discounted values of these benefits were noted where applicable in the footnotes. The discount rate used in the case studies followed that used in the underlying source analysis. The values presented in the study are undiscounted due to different time periods of the case studies used, ranging from 1982-2015 up to 2000-2014 and the fact that the periods covered by the case studies was in the past.

Interpretation of "cumulative": The study did not seek to attribute specific impacts to each and every individual piece of legislation. This was considered impracticable and would not permit an overview of what has been achieved. However as far as the evidence allowed, the assessment attributed benefits to groups of legislation. The focus is on "cumulative" benefits (avoided health and environmental damage) delivered through the cumulative effect (accumulation) of various different pieces of legislation, each addressing a risk or group of risks. The study did not arrive at a single number to represent the cumulative benefit accrued to the EU as a result of avoided health and environmental damages due to chemical exposure as a result of legislation between 1967 and 2015. Rather, various analyses were undertaken – using a range of quantitative, qualitative and case study evidence.

Counterfactual and the role of Member State legislation: The history and evolution of EU environmental (and chemical) legislation is inextricably linked to Member State action. That

was fully recognised here[57]. The scope of the CuBA Study was not to assess implementation at Member State level, nor to narrowly examine the added value of EU chemicals and chemicals related legislation above and beyond what Member States might have done in the absence of EU action (i.e. the marginal benefit of EU action). This was considered impracticable on this scale. The study considered benefits from chemicals and chemicals-related legislation in the EU, compared to a reference point of no legislation (either EU or Member State). Where meaningful and possible, benefits that could be attributed specifically to EU chemicals and chemicals-related legislation were identified. This includes for example, cases where there was no Member State legislation prior to the promulgation of the EU legislation. That was not to ignore or downgrade the role of Member States in the development of policy, rather it was an acknowledgement that they cannot meaningfully be separated. In terms of the counterfactual, this was quantified in a small number of cases, but was more often descriptive (i.e. evaluating the problem and nature of harm before implementation and how was this ultimately addressed). Again this reflects the myriad factors at play and the different time periods over which benefits were assessed.

B. Evidence base and limitations

The CuBA Study aimed to assimilate a very large body of information, this was collated in an "inventory" of information conducted as part of Task 1 and Task 2 of the study. Whilst secondary data was applied in novel ways – for instance in case study analysis - the purpose of the study was not to generate new primary evidence; however, elements of new analysis were undertaken, based on existing data sources. Equal focus was placed on both qualitative and quantitative information and on health and environmental issues; the available studies, data and other evidence varies significantly in terms of its robustness, and this was taken into account in the work.

Similarly, the analysis did not focus solely on monetary/economic data, but sought to draw out physical improvements where possible. This approach was important not only in the context of practicability, but also in terms of presenting the study outputs and key messages in a range of different ways. Where a quantitative estimate of monetary benefits of chemicals legislation was derived, this took into account both 'direct' benefits (including the avoided cost of diagnosis and treatment and productivity savings from avoided loss of working days) and 'full' benefits (including willingness to pay to avoid the condition and the increased consumer surplus). The CuBA Study excluded an analysis of the administrative and compliance costs of legislation that had been considered elsewhere. Similarly, issues typically referred to as "social" benefits, such as effects on innovation and employment were excluded.

A 'three tiered' approach was adopted to categorise data and information in terms of its robustness for the purposes of the CuBA assessment:

- Tier 1 evidence: a relationship (between a chemical substance and a particular health and environmental impact) where the science, methodologies and data are reasonably robust and will allow for a high level of certainty and could be used as the basis for good, defensible benefit estimates.
- Tier 2 evidence: relationships where the science, methodologies and data are less robust but there is sufficient evidence to suggest probable health or environmental

[57] A good overview is provided in Haigh (2016) EU Environmental Policy: Its journey to centre stage. Routledge.

impacts. This evidence will be presented with acknowledgement of the significant uncertainties and error margins.

- Tier 3 evidence: these would be areas where significant health and environmental impacts are suspected but the science, data, or monetisation methodologies are too limited to even attempt determining broad estimate ranges. It would, essentially, be a qualitative discussion of science/data/evaluation gaps on suspected impacts.

The CuBA Study focussed on complex issues with very many contributing factors, with incomplete evidence and, in some instances, with large margins of uncertainty. Notwithstanding this, an attempt was made to draw out the evidence, and to present this in different ways, according to what is available. The assumptions are clearly stated in the CuBA Study report. The key uncertainties in the benefits estimates approach used are:

- The modelling to derive the physical effects (avoided damage to human health arising from reduced exposure to chemical substances).
- The approach to monetising some of the key benefits identified. The approach and associated uncertainties are explained in in the report, with more detail in the technical appendix).

The type of analysis possible is largely driven by scientific knowledge and data available on the impacts that chemicals have on the environment. The analysis is however further complicated by the fact that other pressures (e.g. changes in population, technology, consumer preferences and economic activity) will also have impacts (both positive and negative) on the natural environment. This is reflected in another "scorecard" indicator in the summary findings section of each chapter of the study report as 'regulatory attribution'.

In this study, a wide range of evidence was reviewed literature (much of this qualitative, rather than quantitative) in an attempt to establish the impacts of chemicals on the environment (and through the environment on human health). The CuBA study sought to identify and use studies that already assessed aggregate 'top-down' figures (at EU-28 level where possible) of the benefits from chemicals regulations or in general or at the level of individual chemical regulations. Studies that cover all regulations at the EU level were not identified. Equally studies that look at individual pieces of legislation are often only available focusing on particular substances and at Member State level (i.e. the impact of a particular substance for one Member State). It was rare that a study looked at the impact on an environmental end-point (e.g. water quality or specific species) from multiple substances.

As a consequence, estimates derived in the CuBA study are often 'bottom up', building an EU level aggregate estimate from individual chemicals, often based on site-specific or Member State level data. To extrapolate to generate an EU-28 level estimate requires there to be a significant number of similar studies so that there is at least more certainty that such site/country specific estimates are 'representative'. However such studies are rare, making it only possible in many instances to derive indicative EU level estimates to give a feel of the scale of likely impacts (e.g. benefit is likely to be in several billions euros per year rather than several millions euros per year).

The "chrysohedonistic illusion": finally, and critically relevant for the CuBA study, in those instances where it has been possible to understand what the identified "risks" mean in terms of actual physical impacts, these are only a minority, a small sub-set of environmental end-points. A consequence is that, when attempting to value (monetise) a sub-set of impacts, the resulting analysis can inadvertently create the (misleading) perception that actual benefits are modest, because it has only been possible to assign a quantitative or monetary value to some

of those benefits. This is particularly evident in the water quality chapter where it has only been possible to present estimates for a subset of impacts (and not at EU level) and the 'market' benefits presented are not the main benefits. The main benefits here are 'non-market' benefits, which could not practically be assessed in quantitative and monetary terms within the scope of the CuBA study.

It is important to note that this is the first time a study on this scale and scope has been attempted. The work is based on drawing together existing information, though a number of calculations/interpretations have been necessary to derive some of the quantitative figures in the report. In some cases the estimates provided are associated with significant uncertainties. These are discussed at length, but are provided as a starting point for additional research and discussion. Where benefits relate to productivity and/or healthcare treatment ("direct financial") costs, these are compared to GDP in national accounts to provide context on their significance; others reflect "personal valuation" (willingness to pay to avoid certain medical ailments or for ecosystem services, for example). These costs are no less real than those that are linked to GDP: society places a high value on having a long, healthy and fulfilled life. Where appropriate, they are expressed in monetary terms.

4 Annex 4 Information regarding the legal scope of the Fitness Check, its supporting studies and other relevant sources of information

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
1. Classification, labelling and packaging (Regulation No (EC) 1272/2008, 'CLP')	• High level of protection of human health and the environment • Free movement of substances, mixtures and articles	-	-	X		X	X
2. REACH, Annex XIII (Regulation (EC) No 1907/2006, 'PBT/vPvB criteria')	• High level of protection of human health and the environment • Promotion of alternative methods for assessment of hazards of substances • Free circulation of substances on the internal market • Enhancing competitiveness and innovation	No	Both	X		X (*covers entire REACH)*	X (*covers entire REACH*)

[58] Please note that the CCA1 Study also covers pieces of legislation that are not in the scope of this Fitness Check while also not covers entirely the scope of this Fitness Check

[59] Please note that the CuBA Study covers pieces of legislation that are not in the scope of this Fitness Check while also not covers entirely the scope of this Fitness Check. Moreover, it only provides examples of quantified benefits and does not provide an overall benefit estimate of the EU chemicals legislation.

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
3. Inland transport of dangerous goods (Directive 2008/68/EC)	• Ensure the uniform application of harmonised safety rules throughout the Community and a high level of safety in national and international transport operations	Indirectly	Both	X		X	X
4. Carcinogens and mutagens at work (Directive 2004/37/EC)	• Protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work.	Yes	Both	X		X	X
5. Young people at work (Directive 1994/33/EC)	• Prohibit work by children • Ensure that work by adolescents is strictly regulated and protected • Ensure in general that employers guarantee that young people have working conditions which suit their age • Ensure that young people are protected against economic exploitation and	Yes	Both	X		X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	against any work likely to harm their safety, health or physical, mental, moral or social development or to jeopardize their education						
6. Pregnant workers (Directive 1992/85/EEC)	• Encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or who are breastfeeding	Yes	Both	X		X	X
7. Signs at work (Directive 92/58/EEC)	• Encourage improvements in the safety and health of workers at work	No	Both	X		X	
8. Chemical Agents (Directive 98/24/EC)	• Protect workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents	Yes	Both	X		X	X
9. Asbestos (Directive 2009/148/EC)	• Protect workers against risks to their health, including the prevention of such	No	Both		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	risks, arising or likely to arise from exposure to asbestos at work						
10. Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)	• Prevent and control pollution arising from industrial activities • Prevent or, where that is not practicable, to reduce emissions into air, water and land and to prevent the generation of waste, in order to achieve a high level of protection of the environment taken as a whole	Yes	Both	X	X	X	X
11. Waste Framework (Directive 2008/98/EC) and List of Waste **(Commission Decision 2000/532/EC)**	• Protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use	Indirectly	Both	X		X	X
12. Waste shipments (Regulation (EC) No 1013/2006)	• Protect the environment • Establish procedures and control regimes	Indirectly	GRC	X	X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	for the shipment of waste						
13. Major-accident hazards involving dangerous substances ('Seveso') (Directive 2012/18/EU)	• Prevent 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	Yes	Both	X		X	X
14. Water Framework (Directive 2000/60/EC)	• Protect and prevent further deterioration of inland surface waters, transitional waters, coastal waters and groundwater and reduce pollution; achieve good surface water status • Promote sustainable, balanced and equitable water use including the provision of the sufficient supply of good quality	No	Both	X	X	X	X
15. Urban Waste Water Treatment (Directive 91/271/EEC)	• Protect the environment from the adverse effects of discharge of waste water from households and certain industrial sectors	No	GRC		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
16. Marine Strategy Framework (Directive 2008/56/EC)	• Achieve or maintain good environmental status in the marine environment by the year 2020 at the latest	No	GRC		X		X
17. Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)	• Protect human health and the environment, including the environmentally sound recovery and disposal of electrical and electronic equipment waste	Indirectly	GRC		X	X	X
18. End of life vehicles (Directive 2000/53/EC)	• Prevent waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of life vehicles and their components so as to reduce the disposal of waste, as well as at the improvement in the environmental performance of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-	Yes	GRC	X		X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	of life vehicles						
19. Batteries (Directive 2006/66/EC)	• Improve the environmental performance of batteries and accumulators and of the activities of all economic operators involved in the life cycle of batteries and accumulators	No	GRC		X	X	X
20. Packaging and Packaging Waste (Directive 94/62/EC)	• Harmonize national measures concerning the management of packaging and packaging waste in order, on the one hand, to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community	Indirectly	GRC		X	X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
21. Biocidal products (Regulation (EU) No 528/2012)	• Improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment	Yes	Both	X	X	X	X
22. Plant protection products (Regulation (EC) No 1107/2009)	• Ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production	Yes	Both	X	X	X	X
23. Residues of pesticides (Regulation (EC) No 396/2005)	• Ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of	Indirectly	Both		X		

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	pesticide residues in or on food and feed of plant and animal origin						
24. Export and import of hazardous chemicals (Regulation No 649/2012)	• Implement the Rotterdam Convention Promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment from potential harm • Contribute to the environmentally sound use of hazardous chemicals	Yes	GRC		X	X	X
25. Persistent organic pollutants (Regulation (EC) 850/2004)	• Protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants and and by	Yes	GRC		X	X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances						
26. Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)	• Ensure agricultural productivity and sustainability and to make it possible to ensure public and animal health, animal welfare and the environment • Ensure the free movement of goods, persons, services and capital	No	Both		X		X
27. EU Ecolabel (Regulation (EC) 66/2010)	• Establish a voluntary ecolabel award scheme intended to promote products with a reduced environmental impact during their entire life cycle and to provide consumers with accurate, non-deceptive, science-based information on	Yes	Both	X	X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	the environmental impact of products						
28. Toy Safety (Directive 2009/48/EC)	• Lay down rules to ensure the safety of toys and their free movement in the Community	Yes	Both	X	X	X	X
29. Cosmetic products (Regulation (EC) No 1223/2009)	• Establish rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health	Yes	Both	X	X	X	X
30. Detergents (Regulation (EC) No 648/2004)	• Achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health	Yes	Both	X	X	X	X
31. Drinking Water (Directive 98/83/EC)	• Protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean	No	Both		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
32. Fertilisers (Regulation (EC) No 2003/2003)[60]	• Ensure the internal market in fertilisers	No	GRC	X		X	X
33. Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, which have undergone a revision)[61]	• Harmonise the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices in order to guarantee the free movement of such devices within the internal market	Yes	Both		X		X
34. Aerosol dispensers (Directive 75/324/EEC)	• Remove barriers to the establishment and functioning of the common market	Yes	GRC	X			

[60] Currently undergoing a revision

[61] To be repealed (subject to exceptions) on 26 May 2020 and 26 May 2022 respectively by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 which entered into force on 25 May 2017

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
35. Explosives (Directive 93/15/EEC)[62]	• Ensure the protection of end-users and the safety of the public	No	Both		X	X	X
36. Pressure equipment (Directive 2014/68/EU)	• Harmonise national provisions on risks due to pressure • Remove obstacles to free movement of pressure equipment within the Union	Yes	Both	X	X		X
37. Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)	• Ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of	Yes	Both	X	X	X	X

[62] Repealed by Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	human health and the interests of consumers						
38. General Product Safety (Directive 2001/95/EC)	• Improve the functioning of the internal market • Ensure a high level of consumer protection and safety by introducing a general product safety requirement, and containing provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and on rapid exchange of information and action at Community level in certain cases	Both	GRC		X	X	X
39. Test methods (Regulation (EC) No 440/2008)	• Set out the test methods to be applied for the purposes of Regulation 1907/2006/EC • Review, where appropriate, the test methods contained in this Regulation	Yes	Not triggering RMMs	X			

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	with a view to replacing, reducing or refining testing on vertebrate animals						
40. Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)	• Provide for a harmonised system for study audit and inspection of laboratories to ensure that that they are working under GLP conditions and that test data generated by laboratories in one Member State are also recognised by other Member States	No	Not triggering RMMs	X			
41. Protection of animals used for scientific purposes (Directive 2010/63/EU)	• Establish measures for the protection of animals used for scientific or educational purposes	No	Not triggering RMMs		X		

TABLE 2 Evolution of the EU chemicals legislation

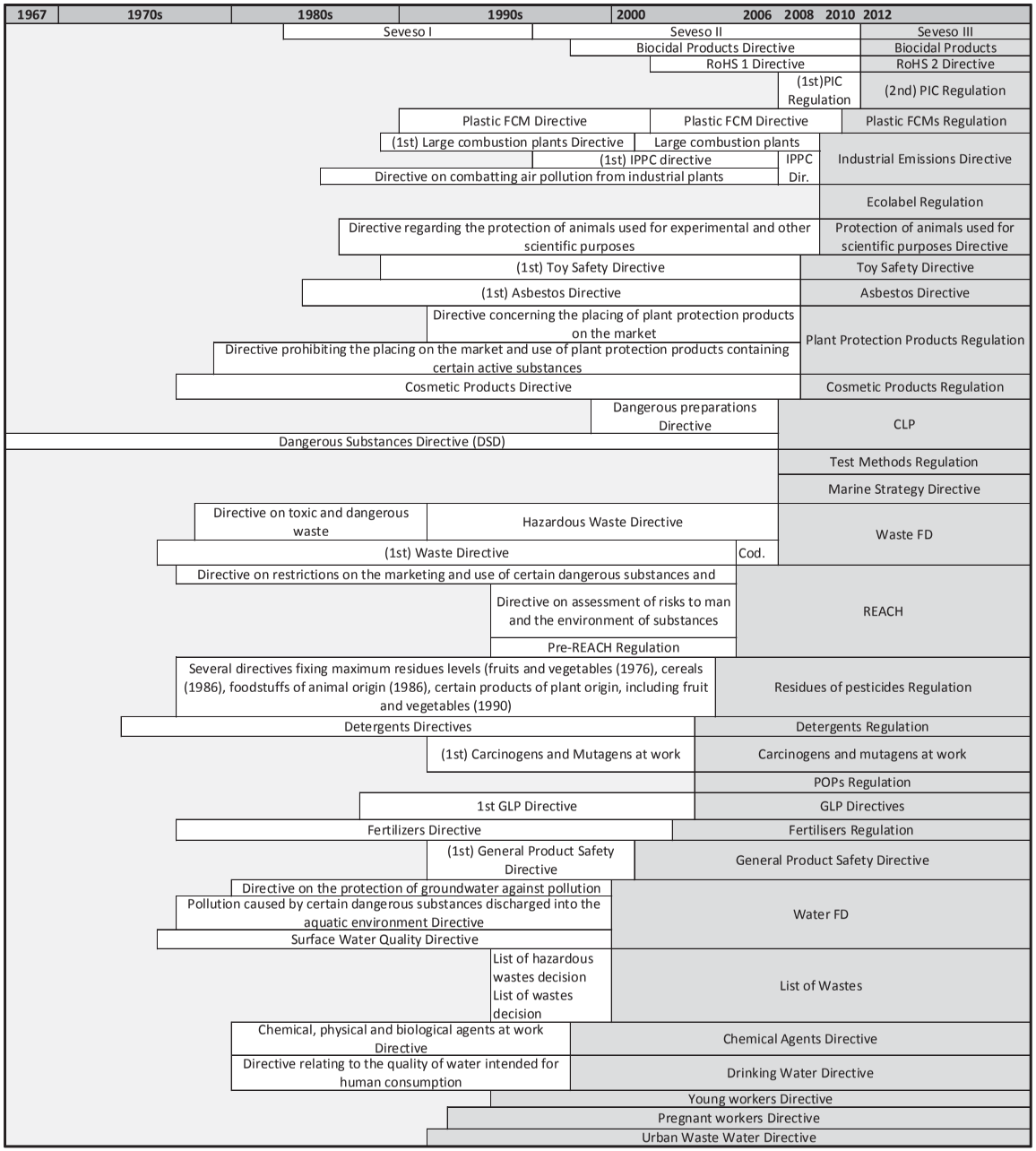


TABLE 3 Evidence and source of Fitness Check Chemicals findings

EFFECTIVENESS **1st evaluation question: to what extent does the EU legislative framework for the risk management of chemicals meet its objectives?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Substitution of hazardous substances by less hazardous substances has not yet occurred to any notable extent	**Main source**: Eurostat Chemical product and consumption statistics (December 2017)	Open public consultation (question 23)
Human and environmental exposures to hazardous chemicals: meaningful and successful reductions, concerns about ongoing exposures	**Main source**: CuBA Study **Additional sources**: reports from EU-OSHA, EEA and EFSA	Open public consultation (question 24)
Human health and environmental impact evidence and indicators	**Main source**: CuBA Study	
Internal market, competitiveness and innovation	**Main sources**: 1st FC Study; CCA1 Study; CEFIC reports (facts and figures) **Additional sources**: REACH REFIT (SWD(2018) 58 final)	Open public consultation (question 10) SME Panel
EFFECTIVENESS **2nd 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?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Data, knowledge and information	**Main source**: FC+ Study **Additional sources**: KEMI Market survey report; DG GROWTH and DG ENV websites; EMA; 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)	1st FC Study workshop
Hazard and risk assessment	**Main source**: FC+ Study **Additional source**: ECHA	Open public consultation (question 17)
Hazard classification	**Main source**: 1st FC Study **Additional source**: ECHA	Open public consultation (question 34)

Communication of hazards and risks	**Main source**: 1st FC Study **Additional source**: FC+ Study; the Commission's proposal with the 'Goods Package' ((COM(2017)795); RAPEX and RASFF annual reports	Eurobarometer Surveys (456 and 468) SME Panel 1st FC Study workshop
Precautionary principle	**Main source**: FC+ Study **Additional sources**: 1st Fc Study; the Commission's communication (COM/2000/0001 final); DG ENV Study 'The precautionary principle in EU environmental policies' (2017);	Open public consultation (questions 14, 15 and 30) FC+ Study workshop Position papers and targeted interviews (FC+ Study)
Balance between GRC and SRA	**Main sources**: 1st FC Study; FC+ Study	Open public consultation (question 14) 1st FC Study and FC+ Study workshop
EFFICENCY **1st evaluation question: what are the costs and benefits associated with the implementation of the legislative framework for chemicals? What are the key drivers for those costs and benefits? To what extent are the costs proportionate to the benefits**?		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Costs and cost drivers	**Main sources**: 1st FC Study; CCA1 Study **Additional sources**: FC+ Study; Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (interim report; June 2018); Fitness Check of Reporting and Monitoring of EU Environment Policy (SWD(2017)230); EFSA and ECHA websites; Better Regulation Guidelines, Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation)	Open public consultation (question 20) SME Panel 1st FC Study workshop
Benefits	**Main source**: CuBA Study **Additional sources**: EFSA; the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); UN Sustainable Development Goals website	Open public consultation (question 19) SME Panel
Proportionality of costs and benefits	**Main source**: 1st FC Study; FC+ Study **Additional sources**: DEFRA (2015)	
EFFICENCY **2nd evaluation question: Evaluation question: what aspects of the functioning of the framework are the most efficient and what are the least efficient?**		

TOPIC	EVIDENCE/SOURCE	STAKEHOLDER VIEWS
Reliance on the CLP Regulation	**Main source**: 1st FC Study	1st FC Study workshop FC+ Study workshop Eurobarometer Survey (456)
Use and access to data	**Main source**: FC+ Study **Additional source**: 1st FC Study	FC+ Study workshop
Grouping approach vs. substance-by-substance approach	**Main source**: FC+ Study **Additional sources**: 1st FC study; OECD website and guidelines	FC+ Study workshop
Organisational efficiency of the EU Agencies	**Main sources**: 1st FC Study; FC+ Study; ECHA, EFSA, SCHEER, SCOEL and SCCS websites (legal documents, rules of procedure; opinions; Second Intermediate Evaluation of the functioning of the SANTE non-food Scientific Committees report) **Additional sources**: REACH REFIT (SWD(2018) 58 final)	FC+ Study workshop

COHERENCE
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?

TOPIC	EVIDENCE/SOURCE	STAKEHOLDER VIEWS
Coherence of data and testing requirements	**Main source**: 1st FC Study; FC+ Study **Addition sources**: OECD website and guidance documents	
Coherence of hazard assessment and classification	**Main sources**: 1st FC Study; FC+ Study **Additional sources**: Regulations setting out scientific criteria for the determination of endocrine disrupting properties (plant protection and biocidal products; 2018); DG ENV website; the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)	Open public consultation (question 29)
Coherence of risk assessment	**Main source**: 1st FC Study; FC+ Study **Additional sources**: EMA guidance documents; Report from the Commission to the European Parliament and the Council 'Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on	

	cosmetic products with regard to substances with endocrine-disrupting properties (COM(2018) 739 final)	
Coherence of risk management measures	**Main source**: 1st FC Study; FC+ Study **Additional sources**: Council conclusions on the protection of human health and the environment through the sound management of chemicals (15046/16); 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final); 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)	

RELEVANCE **1st evaluation question: to what extent do the objectives of the legislative framework for chemicals meet the current needs?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Ensuring a high level of protection of human health and the environment	**Main source**: CuBA Study **Additional sources**: Eurostat	Open public consultation (question 15)
Internal market, competitiveness and innovation	**Main sources**: 1st FC Study; CCA1 Study; CEFIC reports (facts and figures) **Additional sources**: CuBA Study	Open public consultation (question 10) SME Panel
Combination effects	**Main sources**: FC+ Study **Additional sources**: 1st FC study; publications in scientific journals; Commission's communication (COM/2012/0252 final); EFSA website	Open public consultation (question 15)
Impacts on environment, biodiversity and eco-system resilience	**Main source**: CuBA Study	
Substances in articles and circular economy aspects	**Main source**: FC+ Study **Addition sources**: 1st FC Study; Circular Economy Action Plant (2015) and its deliverables (the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); the EU Plastics Strategy (COM(2018) 28 final)); ECHA report on enforcement and market surveillance (2018)	FC+ Study workshop

RELEVANCE **2nd evaluation question: 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?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**

Taking into account the concerns of citizens and other stakeholders	**Main source**: 1st FC Study **Additional sources**: the Commission's website (e.g. expert groups, Better Regulation Guidelines), the OECD Regulatory Policy Outlook 2018 report	Open public consultation (question 15)
Transparency of procedures	**Main source**: 1st FC Study **Additional sources**: the General Food Law REFIT (SWD(2018) 37 final); the Commission's proposal on the transparency and sustainability of the EU risk assessment in the food chain	Open public consultation (question 16) 1st FC Study Workshop
Robustness of procedures	**Main source**: 1st FC Study	
EU ADDED VALUE **Evaluation question: what is the added value of regulating the risk management of chemicals at an EU level rather than at national level?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
EU added value	**Main sources**: 1st FC Study; FC+ Study	Open public consultation (question 9) Eurobarometer Survey (456)

TABLE 4 Related and targeted evaluations of individual pieces of legislation with the scope of this Fitness Check

LEGISLATION	EVALUATION .	PROVIDES INFORMATION ON
Plant protection products (Regulation (EC) No 1107/2009) **Residues of pesticides (Regulation (EC) No 396/2005)**	***ONGOING***	Costs and cost drivers (industry, public authorities, the Commission, EFSA)
REACH (Regulation (EC) No 1907/2006)	***FINISHED***	Coherence SCOEL/ECHA Testing and alternatives to animal testing Coherence (hazard/risk assessment and risk management measures; derogation mechanisms)
Occupational Safety and Hygiene (OSH) Legislation[63]	***FINISHED***	State of play and implementation Cost drivers
Waste legislation (Five Waste Stream Directives: sludge, PPWD, PCB/PCT, ELV, Batteries)	***FINISHED***	State of play and implementation
Waste shipments (Regulation (EC) No 1013/2006)	***ONGOING***	-
Urban Waste Water (Directive 91/271/EEC)	***ONGOING***	-
EU Ecolabel (Regulation (EC) 66/2010) (EMAS and Ecolabel)	***FINISHED***	-
Safety of toys (Directive 2009/48/EC)	***ONGOING***	State of play and implementation
Detergents (Regulation (EC) No 648/2004)	***ONGOING***	State of play and implementation Costs and cost drivers Coherence

[63] Including Carcinogens and mutagens at work, Safety signs at work, Pregnant workers, Chemical agents at work, Young people at work, Asbestos at work Directives but also covers many pieces of OSH legislation, including the OSH framework Directive that are not in the scope of this Fitness Check

Drinking Water (Directive 98/83/EC)	***FINISHED***	-
Fertilisers (Regulation (EC) No 2003/2003)	***FINISHED*** *external*	-
Aerosol dispensers (Directive 75/324/EEC)	***FINISHED*** *external*	-
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)	***ONGOING***	-
EU Water Legislation (Water Framework Directive (2000/60/EC), Groundwater Directive (2006/118/EC), Environmental Quality Standards Directive (2008/105/EC), Floods Directive (2007/60/EC))	***ONGOING***	-

4.1.1 Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation (1st FC Study)

A. Objectives

The 1st FC Study's objective is to evaluate the CLP Regulation and the interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. The evaluation carried out by the study is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value in accordance with the Commission's Better Regulation guidelines.

B. Scope

The 1st FC Study covers the legislation that has horizontal linkages with the CLP Regulation in terms of hazard identification, classification and communication and/or that has vertical linkages in terms of risk management measures and risk assessment procedures triggered by the CLP classification.

<table>
<tr><th>Legislation with horizontal linkages with the CLP Regulation</th><th>Legislation with vertical linkages with the CLP Regulation</th></tr>
<tr><td>The REACH Regulation (Regulation (EC) No 1907/2006) (limited to Annex XIII on PBTs and vPvBs)</td><td></td></tr>
<tr><td colspan="2">Plant Protection Products Regulation (Regulation (EC) No 1107/2009)
Biocidal Products Regulation (Regulation (EU) No 528/2012)
Cosmetic Products Regulation (Regulation (EC) No 1223/2009)</td></tr>
<tr><td>Detergents Regulation (Regulation (EC) No 648/2004)</td><td></td></tr>
<tr><td colspan="2">Toy Safety Directive (Directive 2009/48/EC)</td></tr>
<tr><td>The Water Framework Directive (Directive 2000/60/EC)</td><td></td></tr>
<tr><td>Fertilisers Regulation (Regulation (EC) No 2003/2003)</td><td></td></tr>
<tr><td colspan="2">OSH legislation (Directive 92/85/EEC pregnant workers; Directive 94/33/EC young people at work; Directive 98/24/EC chemical agents at work; Directive 2004/37/EC carcinogens or mutagens at work)</td></tr>
<tr><td rowspan="7"></td><td>Directive 2014/40/EU on manufacture, presentation and sale of tobacco</td></tr>
<tr><td>Regulation (EC) No 66/2010 on the EU Ecolabel</td></tr>
<tr><td>Regulation (EC) No 450/2009 on active and intelligent materials</td></tr>
<tr><td>Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food</td></tr>
<tr><td>Directive 2014/68/EU pressure equipment</td></tr>
<tr><td>Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals</td></tr>
<tr><td>Directive 2012/18/EU on the control of major-</td></tr>
</table>

	accident hazards involving dangerous substances (Seveso III)
	Directive 2010/75/EU on industrial emissions
	Directive 2008/98/EC on waste
	Directive 1999/31/EC on the landfill of waste
	Directive 2000/53/EC on end-of life vehicles
	Regulation (EC) No 1013/2006 shipments of waste
	Directive 2004/35/CE on environmental liability

In addition, the 1st FC Study also covered:

- The Test methods Regulation (Regulation (EC) No 440/2008))
- The Aerosol dispensers Directive (Directive 75/324/EEC)
- The Inland Transport of dangerous goods Directive (Directive 2008/68/EC
- The GLP Directives (Directives 2004/9/EC and 2004/10/EC)
- The Signs at work Directive (Directive 92/58/EEC)

C. Time period covered

As the 1st FC Study covers legislation that has links with the CLP Regulation, the reference in time is aligned to the adoption of the CLP (2008) and goes until 2016 approximately (the 1st FC Study was competed an published in January 2017). Cost-benefit assessment covers:

- Transition costs: comparison to cost estimated done in 2006 (impact assessment for the implementation of the UN GHS via the adoption of the CLP Regulation).
- Ongoing costs: comparison to no legislation in place (2008-2016).
- Benefits: annual benefits of the DSD and the DPD (2000-2008) and of the CLP (since 2008).

D. Deliverables

The work required for the 1st FC Study was organised into a series of main tasks and sub-tasks. The Evaluation report provides evidence on the following aspects:

- An analysis of the different pieces and provisions of legislation, which make up the framework of chemicals regulation;
- The identification of areas where the cost of implementation is high compared to the benefits for health and the environment, as well as positive examples where the implementation is particularly efficient;
- The identification of gaps in health and environmental protection as well as gaps, overlaps, inconsistencies and other issues affecting the performance of the legislation;
- The identification of areas where potential for improvement, modernisation and simplification have not yet been harnessed; and
- The identification of existing mechanisms and procedures that work well and that could be considered as best practice.

The Evaluation report is organised as follows:

- The main document sets out the higher level conclusions of the evaluation for each of the main evaluation criteria (Section 3 to 7).

- Annexes II to V provide more detailed analysis that supports the higher-level conclusions presented in the main document. Annex VI provides separate reports on individual case studies.

E. Engagement with stakeholders

The work required for the 1st FC Study included supporting the Commission in organising an online open public consultation, SME Panel Survey and a stakeholder workshop.

In addition to the formal consultation activities, targeted data collection from key stakeholder groups took place. This targeted consultation covered: Member State authorities, civil society (as represented by various non-governmental organisations), workers representatives, consumer representatives and industry (via the main EU industry associations).

F. Main conclusions

Effectiveness:

- CLP and its links to other legislation are an important contributor to health / environmental protection by providing a coherent system for the identification and communication of hazards and forming the basis for risk management under other legislation.
- Issues negatively affecting effectiveness include specific differences in implementation between Member States, inappropriateness of classification rules for certain mixtures and information overload on labels.
- Legal gaps include the lack of consideration of combination effects of different chemicals and multiple routes of exposure for a single chemical, as well as the lack of certain classification criteria under CLP and the delayed completion of criteria for endocrine disruptors.

Efficiency:

- It is not possible to provide full quantification of all the costs and benefits of the chemicals framework. The study does provide detailed cost estimates of the implementation of CLP, amounting to 1.3 billion euros in annual costs for industry. This is in the same price range as the recent estimate in the Cumulative Cost Assessment (CCA) for the chemicals industry.64 This is complemented by costs related to poison centre notifications (around €1.7 billion).
- In terms of benefits, classification, labelling and related risk management have generated significant health and environmental benefits, in particular due to reductions in poisoning incidents and occupational diseases.
- Costs for the transition to the CLP Regulation from the EU's system are estimated at 1.2 billion euros, which is significantly higher than the original estimate in the impact assessment in 2007.65 Anticipated benefits with respect to international trade have

64 The CCA study estimated 1.47 billion euros of annual costs for capital and operational expenditures (CAPEX/OPEX) generated by chemicals legislation and incurred by the chemicals industry. The estimate in the fitness check study only covers the CLP Regulation, yet comprises all sectors of industry.

65 The impact assessment (SEC(2007) 854) provided an estimate of 526 million euros transition costs (albeit based on a slightly different transitional period). Annual costs for CLP may decrease in the future, in particular after the REACH 2018 deadline.

been realised by only a small percentage of companies, as significant differences in GHS implementation around the world continue to exist.
- Revisions in harmonised classifications can generate significant costs, either due to the impacts of labelling on consumer perception or due to legal requirements (automatically triggered) in downstream legislation.

Coherence:
- The central position of CLP in the chemicals framework ensures a coherent approach to hazard classification.
- Incoherent scientific opinions can occur between ECHA and EFSA with regard to the hazardousness of active substances in plant protection products.
- There are inconsistencies within the framework, e.g. inconsistent legal definitions, overlaps and inconsistent requirements (e.g. GLP)
- There are inconsistent approaches to labelling, in particular between cosmetics and other chemicals (including detergents), e.g. for environmental hazards.

Relevance:
- There is agreement among stakeholders that the objectives of the legislative framework remain relevant.
- Some needs are not adequately addressed by the legislative framework, notably the minimisation of hazardous substances in consumer products.
- There is scope for the use of more innovative approaches, notably to convey safety information to consumers, in particular given the increasing interest of consumers in the ingredients of the products that they purchase (e.g. allergens).
- Development of opinions on harmonised classifications by ECHA's Committee for Risk Assessment is considered to be very transparent.

EU added value:

There is consensus that risk management of chemicals at an EU level is needed to ensure a high level of health / environmental protection while avoiding barriers to trade.

4.1.2 Study supporting the Fitness Check on the most relevant chemicals legislation (FC+ Study)

A. Objectives

The FC+ Study's objective is to gather, compile and analyse evidence to inform the Fitness Check and to complement the 1st FC Study that covers a substantial part of the FC scope (identified in the Roadmap) but not all aspects e.g. specific risk assessment procedures were not investigated in detail, particularly those that are not linked to the CLP. Similarly, a comparison of the various risk management approaches in the EU chemicals and chemicals related legislation needed to be performed.

B. Scope

The FC+ Study reviews those pieces of legislation that operate independently from the CLP for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process.

Independent of CLP	Utilises both CLP and other approaches for

	specific components.
Detergents Regulation (Regulation (EC) No 648/2004)	Safety of Toys directive (Directive 2009/48/EC)
Explosives Directive (Directive 93/15/EEC)66	Cosmetic products regulation (Regulation (EC) No 1223/2009)
Pyrotechnic articles Directive (not in the scope of the FC)	Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, which have undergone a revision)[67]
Asbestos Directive (Directive 2009/148/EC)	Pressure equipment directive (Directive 2014/68/EU)
Water Framework Directive (Directive 2000/60/EC)	Industrial emissions (integrated pollution prevention and control) Directive (Directive 2010/75/EU)
Urban Waste Water Directive (Directive 91/271/EEC)	Waste shipments Regulation (Regulation (EC) No 1013/2006)
Marine Strategy Framework Directive (Directive 2008/56/EC)	Export and import of hazardous chemicals (PIC) Regulation (Regulation No 649/2012)
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive (Directive 2011/65/EU)	EU Ecolabel Regulation (Regulation (EC) 66/2010)
Batteries Directive (Directive 2006/66/EC)	Biocidal products Regulation (Regulation (EU) No 528/2012)
Packaging and Packaging Waste (PPWD) Directive (Directive 94/62/EC)	Plant protection products Regulation (Regulation (EC) No 1107/2009)
Persistent organic pollutants (POPs) Regulation (Regulation (EC) 850/2004)	Food contact materials Regulations (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
Drinking Water Directive (Directive 98/83/EC)	General Product Safety Directive (Directive 2001/95/EC)
Protection of animals used for scientific purposes Directive (Directive 2010/63/EU)	
Contaminants in food and feed Regulation and Directive (Regulation (EEC) No 315/93 and Directive 2002/32/EC)	
Residues of pesticides Regulation (Regulation (EC) No 396/2005)	

The FC+ Study also looked at cross-cutting themes and asked the question ‘what works well?’ and ‘what works less well?’ covering:

- Science, data and knowledge,
- Risk management based on specific risk assessment,

66 Repealed by Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses

67 To be repealed (subject to exceptions) on 26 May 2020 and 26 May 2022 respectively by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 which entered into force on 25 May 2017

- The role and use of generic and specific risk management approaches within EU chemicals legislation,
- Coherence of data, science and risk management procedures are measures,
- Gaps in the EU chemicals acquis as regards achieving high level protection of human health and the environment, as well as for the functioning of the internal market and competitiveness.

C. Time period covered

The FC+ Study was launched in October 2015 and completed in November 2017. The focus of the Study was therefore on the state of play of the EU chemicals legislation by that time.

D. Deliverables

The report briefly sets out the history of and rationale for chemicals legislation, and in particular the approach to risk assessment and associated risk management. It includes a review of the use of specific risk assessment approaches, and their use as compared to the identification of risk management measures based on generic risk considerations. It also includes a review of the different types of risk management measures and the circumstances under which different measures are selected.

The FC+ Study Evaluation report provides evidence on the following aspects:

- Science, data and knowledge:
  - Uptake and treatment of different scientific inputs;
  - Test methods for hazard determination;
  - Availability and suitability of occurrence and exposure data;
  - Data sharing and access.
- Risk Management Based on Specific Risk Assessment (SRA):
  - Risk assessment triggers;
  - Health and environmental end-point coverage;
  - Exposure assessment and reduction;
  - Transparency, access and stakeholder inputs;
  - Efficiency of specific risk assessment procedures;
  - Socio-economic assessment;
  - Uncertainty and the precautionary principle.
- The role and use of generic and specific risk management approaches within EU chemicals legislation:
  - Effectiveness, efficiency and balance: the application of the generic and specific risk management approaches under the EU chemicals acquis;
  - The use of specific risk assessment derogations within generic risk management approaches;
  - Consistency of application of each approach.
- Coherence of data, science, and risk management procedures and measures:
  - Coherence of use of science, data and knowledge across legislation;
  - Coherence of decisions to trigger a risk assessment / regulatory action;
  - Coherence of risk assessment procedures (hazard identification, exposure assessment, risk assessment);
  - Coherence of risk management measures.
- Gaps in the EU chemicals acquis:

- Combination effects of chemicals;
- Endocrine disruptors;
- Nanomaterials;
- Chemicals in products;
- Pharmaceuticals and the environment;
- Missing hazard classes;
- Vulnerable groups;
- Circular economy considerations.

E. Engagement with stakeholders

The FC+ Study included a significant amount of stakeholder engagement including interviews with Commission Services, Member State Competent Authorities, industry, NGO groups and academics. The study has also included a one day workshop.

F. Main conclusions

Effectiveness:

- Overall, the EU's chemicals legislation, including its risk assessment and associated risk management approaches, have been effective in meeting their objectives of protecting health and the environment, while improving the free movement of substances, mixtures and articles on the market and enhancing the EU's competitiveness and innovation.
- There are specific areas where the legislation could work better e.g. ongoing exposure to substances present in (imported) articles, how chemicals are managed in recycled materials in the context of the circular economy.
- There are some cases where the highest-hazard chemicals are given particular regulatory attention, but also cases where chemicals with arguably equally significant hazards are not managed in a comparable way (e.g. neurotixicity).
- The high resource requirements for specific risk assessments (and submissions for approval/authorisation) that are triggered by industry mean that, under some legislation, the submissions are dominated by larger companies, with SMEs finding the resource needs a barrier to applying.
- The fact that assessments of a chemical under one piece of legislation do not always trigger (re)assessment under other legislation has also been highlighted as an area where risks are not being adequately assessed/managed and hence benefits not being fully realised.
- There are also examples of unnecessary regulatory burden being placed on industry and authorities through the difficulties in sharing information on chemicals between different pieces of legislation, largely due to intellectual property issues.
- Overall the balance between the use of risk management based on specific risk assessment and that based on generic risk considerations seems to work well.
    - There are a few instances where it has been questioned whether the right balance between the two approaches is being struck, most notably in the case of whether the generic approach should be applied to a wider range of hazard classes (e.g. neurotoxicity, sensitisers, and environmental effects where currently only health impacts are covered), or should be applied to a more consistent list of hazard classes across legislation.

    - Likewise, however, there are cases where adverse socio-economic impacts are occurring through e.g. automatic bans under the generic approach, and these could perhaps have been mitigated if there was more potential for specific risk assessment (and socio-economic considerations) to be taken into account, allowing for derogations from automatic restrictions on substances.
    - Furthermore, there are cases where the resource burden of undertaking specific risk assessments means that insufficient progress is being made (e.g. for risk assessment of substances in food contact materials).
- Implementation and enforcement at Member State level is still a challenge.

Efficiency:

- Costs of the legislation, and in particular the specific risk assessment processes, vary significantly amongst the pieces of legislation.
- In general, specific risk assessments under legislation covering the most hazardous chemicals and most widespread uses are more costly and time-consuming (e.g. on biocides and plant protection products). Conversely assessments in clearly defined uses (e.g. cosmetics, toys) are generally less resource intensive.
- The requirement for approval of active substances and subsequent authorisation of the products (in two stages) and the need to apply for authorisation of products in multiple member states have been highlighted as areas where there are opportunities to streamline and reduce costs.
- While differences in approaches of the various scientific committees have been highlighted (sometimes with seemingly contradictory conclusions on the same substances), some actions are already being taken to improve consistency in approaches and decision making. One of the least efficient elements highlighted was the speed at which substances used in food contact materials are being assessed.

Coherence:

- In general, chemicals legislation is coherent in terms of the use of science, data and knowledge across legislation and their use in assessing and managing risks.
- There are different information requirements, different approaches and different levels of stringency in identifying/applying RMMs; however the different approaches are largely tailored to the specific circumstances of the legislation in question.

Relevance:

- Overall, the chemicals legislation in scope continues to meet current needs in terms of the risk assessment and associated risk management approaches. Changes in scientific knowledge are taken into account; product authorisations are largely reviewed regularly; and the legislation covers new substances and products as they are introduced to the market.
- A number of gaps in relation to relevance to current needs have been identified e.g. omission of environmental risks from consideration under some legislation; a number of emerging health/environmental endpoints that are seemingly not taken into account such as neurotoxins, immunotoxins, sensitisers and endocrine disrupting chemicals.
- A number of gaps in the current chemicals acquis are identified, including how legislation deals with the effects of chemicals in combination (or from multiple sources); endocrine disrupters; nanomaterials; chemicals present in products; pharmaceuticals in the environment; vulnerable groups; circular economy

considerations (hazardous chemicals in closed material loops); and the missing hazard classes identified above.

EU added value:

- The current approach to regulating the majority of chemicals through assessment and management of risks at EU level in general works well. It leads to good sharing of data and pooling of resources; it enables consistency of approach and predictability in terms of risk management; and helps to facilitate the internal market.
- Collectively, EU-level action on chemicals has helped to create a unified approach which in some cases has set the standard for managing health and environmental risks at a global level.

4.1.3 Cumulative cost assessment (CCA1 Study)

A. Objectives

The aim of the CCA1is to provide for quantification of the cumulative costs of the most relevant EU legislation with a bearing on the chemicals industry in the 28 EU Member States during the period 2004-2014 and quantify the cumulative costs in the subsectors of the chemical industry. The objective is also to demonstrate how the costs have changed over time and to compare the costs with relevant financial indicators for the chemical industry.

This study does not assess the benefits of EU legislation and does not aim to provide insights related to the proportionality of costs and benefits of legislation, nor its efficiency or effectiveness

B. Scope

The CCA1 Study analyses cumulative costs of EU legislation with a bearing on six subsectors of the chemicals industry during the period 2004-2014. The six subsectors concerned are inorganic basic chemicals, organic basic chemicals, plastics in primary forms, pesticides and other agrochemicals, specialty chemicals, soaps and detergents. The choice of the subsectors is based on the availability of reliable data (and therefore not on the volumes produced and placed on the market, market shares, etc.).

The different pieces of legislation within its scope are divided in seven legislative packages:

Legislative package	Legislation covered by CCA1 Study
Emissions and industrial processes package	Emission Trading Scheme (ETS) legislation Industrial Emissions Directive (repealing IPPC and Large Combustion Plants Directives) National Emission Ceilings (NEC) Directive Waste Framework Directive and related (WEE, Landfill, ELV, Batteries, PPWD) Seveso Directives Water Framework Directive Air quality legislation
Energy package	Energy Taxation Directive Renewable Energy Directive Energy Efficiency Directive Promotion of COGENERATION Directive
Chemicals package	CLP (including the repealed anterior legislation) Plant Protection Products Regulation and related

	(including the repealed anterior legislation) Sustainable Use of Pesticides Directive Biocidal Products Regulation (including the repealed anterior legislation) REACH (including repealed pre-REACH legislation) POPs Regulation
Workers safety package	Occupational Safety and Health (OSH) framework Directive Carcinogens and mutagens at work Directive Young people at work Directive Pregnant workers Directive Signs at work Directive Chemical Agents Directive Directive on Personal Protective Equipment
Product specific, customs and trade and transport package	Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive Food Contact Materials (FCMs) Regulation General Product Safety Directive PIC Regulation RoHS Directive Inland transport of dangerous goods Directive Tyre Labelling Regulation Ethanol Denaturation Regulation and Directive Deco-Paints Directive Explosives Legislation

The CCA1 therefore covers several pieces of legislation that are not in the scope of this Fitness Check but also does not cover the full scope of the Fitness Check.

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

C. Time period covered

The CCA1 study covers legislation active during the period 2004-2014 even if repealed or amended within this period.

D. Deliverables

The final report briefly provides:

- a broad overview of the chemical sector;
- a short overview of each legislation package and focuses more on the types of cost incurred by legislation to the industry;

- a presentation of different types of costs per legislative package;
- an overall picture of the cost (as a total and for each legislation package and subsector); and
- estimates of the evolution of the costs over the period 2004-2014.

E. Engagement with stakeholders

The CCA1 Study engagement with stakeholders was done through its different preparation phases e.g. discussion of the legal scope with industry and during the data collection phase e.g. sending to a list of pre-identified companies a detailed questionnaire, interviews. While only an online survey was carried out was used to test and adjust the estimated legislation costs, a validation workshop with targeted companies and industrial associations took place. A second workshop was organised by the European Commission and gather a wider audience of stakeholders (industry, trade unions, NGOs and Commission services).

F. Main conclusions

When all legislation relevant to chemical companies is cumulated, the estimated average annual total direct cost borne by the subsectors covered by the study during the period 2004-2014 approaches €9.5 billion, representing around 2% of their turnover and 12% of the value added. In addition to the estimated cumulative cost, companies also bear indirect legislation costs, passed on to them through feedstock and other inputs (e.g. electricity or machinery). The opportunity costs due to the withdrawal of substances or the loss of markets may also be important. Although companies raised the issue of indirect cost during the interviews, no robust assumptions could be made for estimating the relevant costs based on the provided qualitative information.

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 package 29% (3.5% of value added) and workers' safety 24% (2.9% of value added). The contribution of the other legislation packages to the overall regulatory cost is much smaller. The share of the energy package is around 9% (1.1% of the value added), transport 3% (0.3% of value added), product-specific 1% (0.2% of value added) and customs and trade only 0.4% (0.05% of value added). Although the other reported figures do not include costs associated with national legislation, the estimation of the energy taxes cost, which represents 69% of the energy package, does contain the contribution of national legislation.

The variability of costs across the different subsectors is significant and reflects not only differences in product groups and their production chains but mainly differences in the anticipated impact of each subsector on health and safety (of both consumers and employees), and the environment. Thus, the higher cost as a percentage of value added is observed in pesticides and other agrochemicals, amounting to 23.2%, and the lowest in plastics, at 2.7%. The cost for specialty chemicals represents 16.7% of the subsectors' value added, for inorganic basic chemicals the cost amounts to 12.1%, for organic basic chemicals it is 11.3%, and for soaps and detergents 11.4%.

Within subsectors, variability reflects the size of companies and their organisational structure, efficiency, level of integration and product portfolio. SMEs in general incur higher costs compared to large organisations because the costs to comply with legislation are not linear and cannot be amortised on a large volume of chemicals.

Administrative burden is mainly related to the cost of the preparation and submission of information for registrations and the issue of permits, as well as for the information of product users (e.g. labelling), while it does not include the associated monetary obligations (e.g. fees for registration, permits or certification). Overall, it amounts to 10% of the total regulatory cost. Although administrative burden is the smallest cost category, it affects all subsectors. The highest administrative burden is observed in soaps and detergents, where it represents almost 28% of the legislation cost and 3.2% of the subsector's value added. Pesticides also bear a relatively high administrative burden, representing 14% of their regulatory costs and 3.2% of their value added. It is less significant, but with a share higher than average, for specialty chemicals, amounting to 12% of the regulatory cost, equivalent to 2% of the value added. This cost is mainly driven by the chemicals legislation package, which is responsible for 75% of the administrative burden, and more specifically by the legislation related to REACH, Plant Protection Products (PPPs), Biocides and Classification, Labelling and Packaging (CLP). However, a noticeable reduction of administrative burden is expected in the future, due to the final registration deadline for REACH in 2018.

Monetary obligations amount approximately to 20% of the regulatory cost. They include mainly taxes, levies, charges and registration fees. The latter contributes to the financial viability of the monitoring and enforcement system by covering part or all of their costs (for example, REACH registration fees cover the cost of maintaining the REACH registration and monitoring system). Out of all monetary obligations, those stemming from the chemicals legislation package, representing 7% of the total cost, are related to the sustainability of the enforcement and monitoring system. The remaining monetary obligations (representing 13% of this type of costs) are linked directly to energy and environmental policy objectives (taxes and allowances related to the Emission Trading System).

When restricting the focus to the chemicals package, the highest monetary obligations cost is observed in pesticides and other agrochemicals (25% of the cost), specialty chemicals (8% of cost) and inorganic basic chemicals (7% of cost). The pieces of legislation generating the highest monetary obligations are REACH, PPPs and biocides. Again, as in the case of administrative burden and monetary obligations, a reduction is expected after 2018 in the costs due to REACH.

Capital Expenditures (CAPEX) and Operating Expenditures (OPEX), representing the highest portion of the legislation cost (approximately 71%), affect all subsectors and are mainly driven by the emissions, chemicals and workers' safety legislation packages. CAPEX and OPEX generated by the emissions and industrial processes package aim at reducing emissions and at complying with the best available technique principle. They represent 3.2% of the value added and 27% of the total legislation cost. CAPEX and OPEX driven by the workers' safety and health package aim at increasing the safety conditions and protection of workers. They represent 2.9% of the value added and 24% of total cost. The CAPEX and OPEX generated by the chemicals legislation are mainly driven by CLP and represent 1.7% of the value added and 14% of the total legislation cost. However, similar to REACH registrations, a significant reduction in the costs related to CLP can be expected after the final deadline in 2017.

Changes in the classification of substances published in Adaptations to Technical Progress (ATP) affect the compliance of companies with several legislation packages, requiring additional investments or generating administrative burden. When frequent changes in classification affect the same family of products or the same subsector, the economic impact

on the value added can be significant. Classification changes are difficult to predict and, therefore, ex-ante impact assessments fail to consider them in their estimation of cost. CAPEX and OPEX are also often overlooked by impact assessments that mainly focus on administrative burden and monetary obligations that are easier to estimate.

An attempt, presented in the following graph, was made to interpret the evolution of legislation burden by estimating the changes of cost as a percentage of turnover. However, this estimate has to be interpreted with caution, as this is an estimate of the trend based on the extrapolation of data from a limited number of typical companies and their recollections of past costs. Therefore, information about the most recent years is more accurate than about the earliest years of the examined period, as it is demonstrated by comparing collected data with Eurostat data for CAPEX and OPEX for environmental protection. However, direct comparison is difficult due to different definitions and assumptions about the costs. Comparing the data series of Eurostat with the evolution of cost of the emissions and industrial processes package, which is the most relevant to Eurostat data, there are clear differences in the period 2004-2007, where Eurostat data presents a declining of cost. However, for the period after 2008 both data sets demonstrate a similar trend, namely an increase during the period 2008-2010 followed by a period of stability.

The major milestones of the evolution of cost is the introduction of REACH and CLP in 2007 and 2008 respectively (affecting the cost of chemical legislation) and investment by companies after 2009, in anticipation of the enforcement of Seveso III in 2012 and ETS Phase 3 in 2013. Energy legislation also contributes to costs, especially after 2012. One can expect that CLP and REACH costs will decrease after 2017 and 2018 respectively, while cost of compliance with Biocides and PPPs will continue to expand. Costs of compliance with workers' safety and transport legislation should remain stable.

4.1.4 Cumulative health and environmental benefits of chemicals legislation (CuBA Study)

A. Objectives

The objective of the CuBA study is twofold:

- Evaluate the benefits – in terms of avoided damage to human health and to the environment from exposure to chemicals – of chemicals legislation that have been achieved since 1967.
- Evaluate the costs of on-going damage to human health and the environment that is caused by chemicals exposure today.

The assessment of benefits does not include the consideration of wider socio-economic benefits or impacts of chemicals legislation (in terms of accelerated or foregone innovation, loss of consumer surplus, for example). Similarly, health/environmental benefits of certain chemicals in facilitating efficiencies or technologies for example and potential negative impacts of removing these from the market due to EU chemicals legislation have not been taken into account.

B. Scope

The CuBA Study covers "chemicals and related legislation" ("chemicals" as defined in REACH):

- The chemicals legislation covered by Annex I to the study entitled "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps", published in the context of the 2013 Review of REACH (1967-September 2011).
- Relevant legislation implemented between September 2011 and August 2015 (the vast majority of these are amendments to the existing body of legislation rather than 'new' legislation).

The CuBA covers several pieces of legislation that are not in the scope of this Fitness Check but also does not cover the full scope of the Fitness Check. The legal scope can be presented as follows:

COVERED ONLY BY CuBA	COVERED BY CuBA AND FC CHEMICALS	COVERED ONLY BY FC CHEMICALS
REACH	CLP	Signs at Work Directive
Directive on the assessment of the effects of certain public and private projects on the environment	REACH Annex XIII	Residues of pesticides Regulations
Sewage Sludge Directive	Inland Transport of Dangerous Goods Directive	Aerosol Dispensers Directive
Dangerous Products Resembling Foodstuffs Directive	Carcinogens and Mutagens at Work Directive	Test Methods Regulation
Food Additives Legislation	Young People at Work Directive	Good Laboratory Practice Directives
Occupational Safety and Health Framework Directive and related	Pregnant Workers Directive	
Nitrates Directive	Chemical Agents Directive	
Regulation on Community Customs Code	Asbestos Directive	
Recovery of Petrol Vapors during Storage Directive	Industrial Emissions Directive	
PCB/PCT Directive	Waste Framework Directive and related (ELV, Batteries and PPWD)	
Directive on Certain Methods for the Quantitative Analysis of Binary Textile Fibre Mixtures	Waste Shipments Regulation	
Internal Combustion Engines for Non-road Mobile Machinery Directive	Seveso Directive	
Novel Foods legislation	Water Framework Directive	
Information Procedures legislation	Urban Waste Water Directive	
Fuels legislation	Marine Strategy Framework Directive	
Landfill Directive	RoHS directive	
GMOs legislation	Biocidal Products Regulation	
Tobacco Directive	Plant Protection Products Regulation	
Air Quality legislation	PIC (Import and Export of Dangerous Chemicals) Regulation	
WEEE Directive	POPs Regulation	
General Food Law	Contaminants in food and feed Regulation and Directive	
Recreational Craft Directive	Ecolabel Regulation	
ETS legislation	Toy Safety Directive	
Measuring Instruments Directive	Cosmetic Products Regulation	
Drug Precursors Regulation	Detergents Regulation	
Medicinal Products legislation	Drinking Water Directive	
Bathing Water Quality directive	Fertilisers Regulation	
Directive on Machinery	Medical Devices Directives	
Pyrotechnics directive	Explosives Directive	
Textiles Name Directive	Pressure Equipment Directive	
Market Surveillance legislation	Food Contact Materials Regulation	
Simple Pressure Vessels Directive	General Product Safety Directive	
EMAS Regulation	Protection of Animals used for Scientific Purposes Directive	

Figure 8 Comparison of pieces of legislation covered by the Fitness Check and by the CuBA Study

C. Time period covered

The CuBA Study covers pieces of legislation adopted and amended from 1967 to 2015.

D. Deliverables

The CuBA Study draws together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation on human health and on the environment, including in a cross-cutting manner.

E. Engagement with stakeholders

A two-day workshop took place in January 2018. The purpose of the workshop was to present the study findings and to gather stakeholder views on these.

F. Main conclusions

Since the late 1960s the body of chemicals legislation has delivered significant benefits in terms of avoided damage to human health and the environment. These benefits have included:

- Avoided health care costs; avoided lost productivity (from illness/disease and care); avoided damage to cognitive development, reflected in greater long term earnings potential and avoided suffering (assessed through willingness to pay methods).
- Reducing the risk of widespread release of hazardous substances – especially those that are persistent, bio-accumulative and/or toxic - and the associated health, environmental and clean-up costs. These can be most readily observed where action to restrict or ban the use of substances was taken some time after the risks became known, but there has more recently been a general shift toward more proactive risk-based management of chemicals in Europe.
- Avoided environmental damage (such as various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs) are harder to quantify and monetise. However, the available evidence suggests they are likely to be significant and in the order of tens of billions of Euros per year for the European Union.
- When individuals' personal valuations (based on "willingness to pay" to avoid environmental or health damage) are taken into account the values are greater still. For example, long term action taken to protect the ozone layer is cumulatively valued at several hundred billion Euro. The environmental benefits on nutrient recycling arising from tributyltin (TBT) regulations are estimated at upwards of tens of millions of Euro, whilst more general valuations of improved water quality are valued at several billion Euro per year.

Whilst there are many uncertainties, the overall conclusion is that the monetary value of all of these benefits over the last 50 years are likely in the high tens of billion Euro per year, perhaps more. It has only been possible to quantify and monetise a subset of benefits, largely due a lack of data available to quantify the physical impacts of chemical releases (especially on the environment). As methods to aggregate monetary values, particularly for some environmental end points, are improved and as more data becomes available, the balance of evidence indicates the known value of these benefits are likely to increase, perhaps significantly.

Whilst much lower than they otherwise would have been, significant health and environmental impacts from chemicals remain to be tackled. Nor is the situation static, new risks are emerging. Moreover, there is still much we do not know about the health and environmental hazards and risks of many existing chemicals in the EU.

Despite regulatory intervention (and other factors like consumer preferences) there remains an ongoing cost to the environment, from (i) continued use of substances that may be harmful to the environment, (ii) continued use of substances for certain applications that have been exempted from regulation to date, and (iii) residual concentrations of harmful chemicals in the natural environment.

There are several challenges associated with estimating the benefits of chemicals legislation on human health and the environment.