REQUEST FOR SERVICES

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DG Internal Market, Industry,

Entrepreneurship and SMEs

D2, Chemicals and Plastics Industries

REQUEST FOR SERVICES FOR

IMPACT ASSESSMENT STUDY

ON THE SIMPLIFICATION OF THE LABELLING REQUIREMENTS FOR CHEMICALS AND THE USE OF E-LABELLING WITH A VIEW TO IMPROVE THE COMMUNICATION OF HAZARD AND SAFETY INFORMATION AS WELL AS USE INSTRUCTIONS TO USERS.

856/PP/GRO/IMA/19/1131/10774

IMPLEMENTING FRAMEWORK CONTRACT 575/PP/2016/FC

1. BACKGROUND OF THE STUDY

(a) Overall purpose and justification

This study should provide input for the Impact Assessment (IA) accompanying a new initiative on the simplification of the labelling requirements for chemicals and the use of e-labelling with a view to improve the communication of hazard and safety information as well as use instructions to users.

During the course of 2019, the European Commission published two evaluations in the field of EU chemicals legislation, namely: the Fitness Check of the most relevant chemicals legislation (excluding REACH)[1] and the evaluation of the Detergents Regulation[2]. These two evaluations provide a comprehensive assessment regarding the performance of the EU chemicals legislation in light of its objectives of protecting human health and the environment, ensuring the efficient functioning of the single market and enhancing competitiveness and innovation.

The findings of these evaluations showed, among others, that:

1. there is room for simplification in the communication of hazard and safety information to consumers and for improvement in terms of its effectiveness and efficiency; and

[1] 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): https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN

[2] Commission Staff Working Document, Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents: https://ec.europa.eu/docsroom/documents/36289

2. the use of innovative digital tools for the communication of such information is currently suboptimal.

The main purpose of this study is therefore to identify suitable policy options and provide a set of reasoned and ready-to-use recommendations on how:

1. to simplify and streamline the existing labelling requirements in the Classification Labelling and Packaging Regulation[3] (hereafter "CLP") and the Detergents Regulation ; and
2. to make optimal use of digital tools to communicate hazard and safety information as well as use instructions to users.

In this context, the study shall focus specifically on the labelling requirements of the CLP Regulation, and the Detergents Regulation[4]. It shall look into how the labelling requirements of each of these pieces of legislation can better fulfil their objective of communicating hazard and safety information as well as use instructions to users. As a second step, the opportunities of simplifying the labels via the use of digital tools shall be explored.

(b) Policy context

As mentioned above, the Commission finalised in 2019 two ex-post evaluations in the chemicals sector, one of them being the Fitness Check of the most relevant chemicals legislation (excluding REACH)[5] (hereunder 'the Fitness Check') and the other being the evaluation of the Detergents Regulation (hereunder 'the Detergents Evaluation').

1) The Fitness Check

The Commission undertook the Fitness Check in 2015.[6] Unlike most evaluations carried out under the European Commission's Regulatory Fitness and Performance programme (REFIT)[7], this Fitness Check was not an evaluation of just one or two pieces of legislation. It assessed over 40 pieces of legislation[8] that cover a great part of the EU chemicals *acquis*. This Fitness Check focused on the chemical hazard and risk assessment and risk management requirements, procedures and processes within the legislation. The legislation within the scope of this Fitness Check regulates both the chemical sector as well as related downstream industries that use chemicals and thus covers the full lifecycle of products manufactured both

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
[4] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
[6] Roadmap is available here http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf
[7] COM(2012) 746 final
[8] See Annex 4 of the Commission's Staff Working Document on the Fitness Check of the most relevant chemicals legislation (excluding REACH) as well as related aspect of legislation applied to downstream industries: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530884012&uri=SWD:2019:199:FIN

in Europe and abroad. The REACH Regulation[9], the pharmaceutical and food additives legislation were excluded from the scope of this Fitness Check.[10] The assessment provided a first comprehensive presentation of how various pieces of the EU chemicals legislation all fit together and addressed a number of stakeholder concerns expressed during the consultation activities. Its main findings are presented in a Report[11].

One of the Fitness Check findings is that the overload of information on chemicals' labels (e.g. too much text or chemical names that consumers are not familiar with printed in multiple languages) and overlaps in legal requirements (e.g. between the CLP, the Detergents Regulation and/or the Cosmetic Products Regulation), make it difficult for downstream users and consumers to focus on the essential hazard information. This reduces the effectiveness of hazard communication for example by restricting the understandability of the information.[12] The communication of hazard and safety information to consumers/users can thus be improved and simplified, including by taking advantage of the opportunities offered by digital technologies such as Q-R codes. Currently, however, the legal (mandatory) requirements do not incentivise the use of more innovative techniques and digital tools and when it happens, industry is using digital tools on voluntary basis, in addition to the traditional physical labels required by law. While this may improve the understanding and management of hazards and risks, it can also lead to confusion between the CLP-required and the sector-initiated pictograms and labels.

For the purposes of the Fitness Check a Eurobarometer survey[13] was carried out as part of stakeholder consultation activites. It indicated that 70% of EU citizens find information on the hazards of chemicals on the label useful. It also showed that there are varying levels of awareness and comprehension of the four (out of a total of nine) chemical hazard pictograms that were examined by the survey. At a more general level however, another Eurobarometer survey[14] found that less than half of the respondents (45%) felt well informed about the potential dangers of the chemicals contained in consumer products. However, this proportion varies considerably between Member States.

[9] Except its Annex XIII laying out identification criteria for persistent, bioaccumulative, toxic and very persistent and very bioaccumulative substances. Under the REACH Regulation, there is a legal obligation to review the legislation every five years. Findings of the second REACH evaluation are presented in the 'Commission General Report on the operation of REACH and review of certain elements' (COM(2018) 116 final) and its accompanying Staff Working Documents (SWD(2018) 58 final). This second evaluation builds on the findings of its first evaluation in 2013 and focused on its developments and achievements since then.

[10] The fact that hazard and risk assessment under the pharmaceuticals and food additives legislation is based on different considerations and underpinning mechanisms explains their exclusion of the scope of this Fitness Check. For example, under the Medicinal Products for Human Use Directive (2001/83/EC) the primary objective is to safeguard public health i.e. treat or prevent disease in human beings, restore, correct or modify physiological functions or make a medical diagnosis.

[11] Report: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN; and Commission Staff Working Document: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530884012&uri=SWD:2019:199:FIN

[12] 1st Fitness Check Study p. 24 and p. 70; see also Annex III, Section 7.3; Case Study 5; see also1st Fitness Check Study workshop report p. 12-13; see also Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) p. 77-79, p.106

[13] Special Eurobarometer 456

[14] Special Eurobarometer 468

Respondents to SME Panel consultation[15] expressed the following views:

- 76% of respondents agreed or strongly agreed that the information currently required to be included on labels is necessary and appropriate.
- 78% of respondents agreed or strongly agreed that the CLP hazard pictograms are generally representative of the actual hazard.
- 63% of respondents agreed that consumers generally do not look beyond the label for hazard information and information on safe use.
- 29% of respondents agreed or strongly agreed that consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (against 41% disagreeing or strongly disagreeing and 31% neither agreeing nor disagreeing).
- 65% of respondents agreed or strongly agreed that employers and workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals.

The Fitness Check concludes that, in part, this is an issue of citizen education and awareness raising by Member States. Hazard communication to workers and professional users is considered to be more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers due to employee training.[16]

2) The Detergents Evaluation

The aim of this evaluation was to examine which elements of the Detergents Regulation work well and what needs to be improved, both in terms of meeting policy objectives and of reducing regulatory burden. The findings of the evaluation were recently published[17].

In particular, the evaluation of the Detergents Regulation concluded that certain overlaps and inconsistencies between the Detergents Regulation and other pieces of EU chemicals legislation (notably the CLP Regulation, the Biocidal Products Regulation and the REACH Regulation) exist. The major issue that ensues from these overlaps is duplications in the labelling requirements for detergents that, in turn, contribute to the overload of detergents labels.

The labelling requirements of the Detergents Regulation are the primary means by which the Regulation aims to achieve its objective of ensuring the protection of human health. This is because the information included in detergents labels serves as a means of communicating information on the content of detergents (e.g. fragrance allergens) and use instructions to consumers thus allowing them to make more informed choices.

The labelling of detergents falls *by default* under two pieces of legislation, i.e. the CLP Regulation and the Detergents Regulation. As a result, detergents labels contain also *by default* two sections i.e. one section dedicated to the CLP labelling requirements and one section for the additional labelling requirements of the Detergents Regulation. The overlaps that exist between these two pieces of legislation result in duplications in the mentioning of

[15] 1st FC Study, Annex V, p. 39 and onwards, question 11, table 2-19
[16] 1st FC Study p. 70; see also1st FC Study workshop report p. 12-13
[17] https://ec.europa.eu/docsroom/documents/36289

certain substances on the label (e.g. allergenic fragrances). This means that the same substance is indicated twice or sometimes thrice on the same label and most of the time under different names. Similar duplications and overlaps exist between the Detergents Regulation and the Biocidal Products Regulation, for detergents that contain an active substance and claim to have a biocidal function.

Considering that detergents' labels also include other information, additional to the above, it becomes apparent that detergents labels end up overloaded with information. Overloading of labels with information is a factor that may reduce the effectiveness of the Regulation in terms of achieving its objectives in relation to protecting human health. Detergents labels become hard to read and it is not easy for consumers to detect the information that they are looking for, which could be crucial in case for example of an allergic reaction or a poisoning incident.

During the consultation for this evaluation, a number of stakeholders also argued that some irrelevant information is being presented to consumers on product labels, and that this distracts them from more pertinent information. For example, one consumer organisation noted that the surfactant content of the product must be listed on the label in terms of weight percentage ranges. This organisation explained that consumers would not know what to do with this information and that removing this unnecessary information would provide more space on the label for information that is important and of greater value to the consumer (e.g. allergenic fragrances and instructions for use). Apart from not being effective, many companies and industry associations indicated that the labelling requirements also pose an unnecessary regulatory burden for the detergents industry.

In line with the findings of the Fitness Check, it appears that there is room for simplification of hazard and safety communication on chemicals to consumers and improvement in terms of its effectiveness and efficiency.

Both the Detergents Evaluation and the Fitness Check also conclude that the use of innovative digital tools is currently suboptimal. During the consultation for the Detergents Evaluation, stakeholders pointed out that Q-R codes are already used voluntarily on some detergents available on the EU market and some others also suggested that innovative communication technologies could be used to convey other relevant information, such as sustainable consumption tips.

c) Legal background: communication of hazard information to consumers

1) General overview of the EU chemicals legislation

The EU chemicals legislation comprises a wide range of legal acts, ranging from horizontal legislation concerning chemical substances and mixtures to product-specific and sectoral legislation concerning particular uses of chemicals. This also includes many pieces of legislation the main purpose of which is not chemicals management but in which certain provisions on chemicals management are incorporated.

The first step in chemicals management is hazard identification and classification. A first step in hazard identification is appropriate gathering of information to identify relevant hazards (done mainly through testing, read-across, models or epidemiological studies). In EU legislation, this process is to a large extent covered by REACH, except for specific chemicals and uses, such as cosmetics, food, medicines etc. Typically, the next step in chemicals

management is hazard classification which allows an easier communication about the types and degrees of hazards linked to a particular chemical substance or mixture. This is mainly done through Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the 'CLP Regulation')[18]. In this context, the CLP also sets rules for hazard communication in the form of labelling. The CLP provisions are aligned with the UN Global Harmonised System (GHS)[19]. This means that any changes agreed to at the GHS level (e.g. refinements to the wording of the hazard statements required on labels) are transposed into EU law via the CLP Regulation.

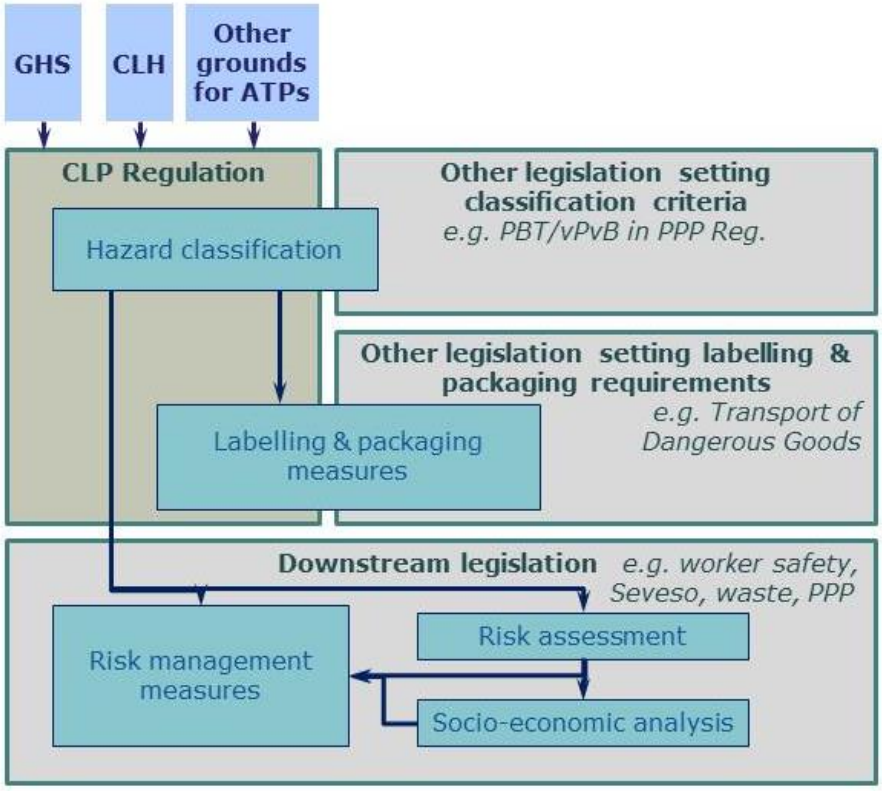

Figure 1: The interplay of the CLP Regulation with other chemicals legislation: other legislation related to the scope of CLP (classification, labelling and packaging) (top right/middle right) and downstream legislation (bottom).[20]

Complementing product labelling, Safety Data Sheets (SDS) are a key communication tool for downstream industry users of hazardous substances and mixtures towards workers. Even though the CLP criteria are used to trigger the obligation to develop a SDS, provisions are in REACH. A SDS must provide information on all hazards covered by the CLP Regulation, as well as on whether a substance or mixture meets the criteria of persistent, bioaccumulative,

[18] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. By June 2015, CLP fully replaces the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD).
[19] http://www.unece.org/?id=3623
[20] Abbreviations: GHS: Globally Harmonized System of Classification and Labelling of Chemicals; CLH: Harmonised Classification and Labelling; ATP: Adaptations to Technical Progress; PPP: Plant Protection Products.

toxic or very persistent and very bioaccumulative (PBT/vPvB) substances or on substances included in the Candidate List of substances of very high concern (SVHCs). Labelling - while being the only tool for communication to consumers - may also serve to draw the attention of workers to the more comprehensive information on substances or mixtures provided in SDS.

There are also a number of additional sector-specific labelling requirements (e.g. for fertilising products, cosmetics, toys, detergents, biocidal and plant protection products). In addition, the EU Ecolabel Regulation[21] sets out rules for a voluntary labelling scheme.

2) Labelling requirements

a) CLP labelling requirements

The purpose of the CLP Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles. The aim is to ensure that the same hazards are described and labelled in the same way in all EU countries.

The CLP Regulation applies to virtually all chemicals (chemical substances and mixtures). The products falling under its scope can therefore vary from fertilisers and detergents to biocides and paints.

The CLP amended and repealed the Directive 67/548/EEC on chemical substances (the Dangerous Substances Directive (DSD)) and Directive 1999/45/EC on mixtures (the Dangerous Preparations Directive (DPD)) in order to take up requirements for the classification, labelling and packaging of chemical substances and mixtures according to the United Nations' Globally Harmonized System (GHS).

While there is no explicit requirement to ensure that the information provided on labels is easy to read and to understand, the CLP Regulation in its recitals states the following:

- "(41) To ensure proper and comprehensive information provision to consumers on the hazards and safe use of chemicals and mixtures, the use and dissemination of Internet sites and free-phone numbers should be promoted, particularly in connection with information provision on specific types of packaging."
- "(50) Rules for the application of labels and the location of information on labels are necessary to ensure that the information on labels can be easily understood."

Further, the European Chemicals Agency (ECHA) has published a guidance document on labelling and packaging in accordance with the CLP Regulation[22]. Section 3.1 of the guidance states: "The CLP Regulation requires that the labels are firmly affixed to one or more surfaces of the immediate container of the substance or mixture and that they must be readable horizontally when the package is set down normally. The label elements themselves, in

[21] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel

[22] https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

particular the hazard pictograms, must stand out clearly from the background. Furthermore, all label elements must be of such size and spacing as to be easily read. They must be clearly and indelibly marked. A physical label is not required when the label elements are shown clearly on the packaging itself".

According to article 4 of the CLP "where a substance or mixture is classified as hazardous, suppliers shall ensure that the substance or mixture is labelled and packaged accordingly" before placing it on the market. A mixture that contains any substance classified as hazardous shall not be placed on the market, unless it is labelled accordingly. Certain articles shall also be classified, labelled and packaged in accordance with the rules for substances and mixtures before being placed on the market.

The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Suppliers may use more languages on their labels than those required by the Member States, provided that the same details appear in all languages used.

Title III of the CLP Regulation lays down the labelling requirements. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:

(a) the name, address and telephone number of the supplier(s);
(b) the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;
(c) product identifiers as specified in Article 18;
(d) where applicable, hazard pictograms relevant for each specific classification in accordance with Article 19, fulfilling the requirements laid down in section 1.2.1 of Annex I and in Annex V.
(e) where applicable, signal words in accordance with Article 20 relevant for each specific classification set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I.
(f) where applicable, hazard statements in accordance with Article 21 relevant for each classification set out in the tables indicating the label elements required for each hazard class in Parts 2 to 5 of Annex I. Where the substance has a harmonised classification, the hazard statement relevant for each specific classification covered by the entry in that Part shall be used on the label, together with the hazard statements referred to in paragraph 2 for any other classification not covered by that entry.
(g) where applicable, the appropriate precautionary statements in accordance with Article 22, selected from those set out in the tables in Parts 2 to 5 of Annex I indicating the label elements for each hazard class. Where a substance has a harmonised classification, the precautionary statements shall be selected in accordance with the criteria laid down in Part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture. The precautionary statements shall be worded in accordance with Part 2 of Annex IV.
(h) where applicable, a section for supplemental information in accordance with Article 25 here a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex II.

According to Article 29 of the CLP where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the above described

requirements for a label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements shall be provided in fold-out labels, on tie-on tags or on an outer packaging. The label on any inner packaging, as well as when the full label information cannot be provided as specified, shall contain at least hazard pictograms, the product identifier and name and telephone number of the supplier of the substance or mixture.

b) Detergents labelling requirements

The labelling requirements of the Detergents Regulation are the primary means by which the Regulation aims to achieve its objective of ensuring the protection of human health. This is because the information included in detergents' labels serves as a means of communicating information on the content of detergents (e.g. fragrance allergens) and use instructions to consumers thus allowing them to make more informed choices.

The labelling of detergents falls *by default* under two pieces of legislation, i.e. the CLP Regulation and the Detergents Regulation. As a result, detergents labels contain also *by default* two sections i.e. one section dedicated to the CLP labelling requirements and one section for the additional labelling requirements of the Detergents Regulation.

Article 11 and Annex VII to the Detergents Regulation lay down the specific labelling requirements for consumer detergents. According to them detergents' labels must include:

- the contents of the detergent;
- the name and trade name of the product;
- the name or trade name or trademark and full address and telephone number of the party responsible for placing the product on the market;
- the address, email address, where available, and telephone number from which the ingredient datasheet can be obtained;
- the indication of instructions for use and special precautions; and
- dosage instructions.

3) User categories

Apart from few exceptions, the labelling requirements of the CLP and the Detergents Regulation apply to all products falling under their scope. Specifically for CLP, it should be noted that it applies to virtually all chemicals. The products covered can therefore vary from fertilisers and detergents to biocides to paints. The user categories of these products usually vary from (industrial) workers and professional users to consumers. For the purposes of this study, the needs of all user categories shall be taken into account.

However, it should also be noted that:

a. The labelling requirements of the Detergents Regulation are only compulsory for detergents that are put up for sale to consumers. According to Annex VII A, last paragraph, to the Regulation "for detergents intended to be used in the industrial and institutional sector, and not made available to members of the general public, the above-mentioned (labelling) requirements do not have to be fulfilled if the equivalent information is provided by means of technical data sheets, safety data sheets, or in a similar appropriate manner".

b. The CLP Regulation does not make a similar distinction. Labelling requirements apply irrespective of the user type. However, several differences exist between the various users of products subject to CLP labelling in terms of access to and understanding of hazard and safety information. First, apart from the information listed on the label workers and professional users also have access to Safety Data Sheets (hereafter SDS) under REACH[23]. SDS provide detailed information on the hazards related to the product at hand. Second, workers and professional users have undergone specific training that provides them with a better understanding of the hazard and safety information as well as use instructions included on the product label compared to consumers. Third, workers and professionals are also protected by the workers safety legislation[24] for risks and hazards arising in the workplace, while consumers' safety and protection is entirely based on the CLP communication of hazard and safety information through the product labels.
c. The findings of both the Fitness Check and the Detergents Evaluation showed that the legislation was least effective at communicating hazard and safety information as well as use instructions to consumers. Hazard communication to workers and professional users was considered to be more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers due to employee training.[25]

Taking into consideration the above, the study shall primarily focus on the communication of hazard and safety information as well as use instructions to consumers without however excluding the other user categories. In case differences arise in the information considered as essential per user category, these differences should be analysed and explained, and recommendations on essential information most useful to each user category should be made.

2. TASKS OF THE ASSIGNMENT

TASK 1 LEGAL FRAMEWORK ANALYSIS

Task 1 shall provide a comprehensive analysis of the legal provisions concerning the communication of hazard and safety information as well as use instructions to users falling under the scope of the study i.e. the CLP Regulation and the Detergents Regulation. The analysis conducted under this task should also take into account the interlinks between the above-mentioned pieces of legislation as detailed below. The results of this analysis shall

[23] Complementing product labelling, Safety Data Sheets (SDS) are a key communication tool for downstream industry users of hazardous substances and mixtures towards workers. Even though the CLP criteria are used to trigger the obligation to develop a SDS, provisions are in REACH. A SDS must provide information on all hazards covered by the CLP Regulation, as well as on whether a substance or mixture meets the criteria of persistent, bioaccumulative, toxic or very persistent and very bioaccumulative (PBT/vPvB) substances or on substances included in the Candidate List of substances of very high concern (SVHCs).
[24] Occupational health and safety (OHS) legislation
[25] 1st FC Study p. 70; see also1st FC Study workshop report p. 12-13

build on the evidence gathered for the purposes of the Fitness Check[26] and the evaluation of the Detergents Regulation[27] and deepen the analysis provided therein.

Recommendations on hazard and safety information as well as use instructions most useful to each/all user category(ies) should be made, where applicable, per piece of legislation.

Taking into consideration the above, the contractor shall:

1. Map the current legal provisions that regulate the communication of hazard and safety information, as well as instructions for use to product users in the CLP Regulation and the Detergents Regulation.
2. Building on the findings of the Fitness Check and the Detergents evaluation, identify any overlaps or inconsistencies in the current legal provisions.
3. When mapping the legal provisions concerning the communication of hazard and safety information as well as use instructions, the contractor shall take into account the various user categories for each of the above-mentioned pieces of legislation. In case that differences in the information determined as essential per user category arise, such differences should be analysed and explained.

TASK 2 USER PERSPECTIVE ON LABELLING: UNDERSTANDING, RELEVANCE OF INFORMATION PROVIDED, NEEDS ETC.

As mentioned above, the Fitness Check and the Detergents Evaluation provided a first assessment of the issues related to users' understanding of hazard and safety information, as well as instructions for use.

In particular the Fitness Check concluded that: 1) hazard communication to workers and professional users was more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers due to employee training and 2) the relatively low level of understanding by consumers of certain CLP pictograms, labels and precautionary statements is partly due to the overload of information provided on labels.

This overload is either due to too much text or chemical names that consumers are not familiar with printed in multiple languages or to overlaps in the legal requirements e.g. between the CLP, the Detergents Regulation and/or the Biocidal Products Regulation, leading to duplication of the same information or to the listing of the same chemical ingredient multiple times on the label under different chemical names. This makes it difficult for consumers to focus on the essential hazard information, thus reducing the effectiveness of the legislation.

[26] 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) https://publications.europa.eu/en/publication-detail/-/publication/7e26e205-18f9-11e7-808e-01aa75ed71a1/language-en/format-PDF/source-search

[27] Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) https://ec.europa.eu/docsroom/documents/32561

Taking into consideration the above, the contractor shall:

1. Verify the level of understanding of chemicals and detergents labels by the various categories of product users (e.g. consumers, industrial workers, professional users).

2. Identify the importance of different information elements i.e. which information is essential and relevant for each user category.

3. Identify the factors affecting users' interpretation and understanding of hazard and safety information as well as instructions for use usually provided on labels e.g. users' familiarity with the product or the brand, consumers' perception of the hazard and safety of the product itself, emotional drivers and experience.

4. Assess how users' understanding of information provided on labels affects their purchase decisions, application behaviour, risk perception (i.e. how users rate the potential dangers of wrongly applying the product) and/or behavioural intentions (how they intend to use the product).

5. Assess how the current means/method of providing information affect, positively or negatively, users' understanding of the hazard and safety information, as well as instructions for use.

6. Explore how different means/methods of providing labelling information (e.g. e-labelling) could affect positively or negatively user's understanding of chemicals and detergents labels. Specifically for consumers the basic assumption of the assessment shall be that consumers with varying levels of education or training should be able to understand essential information on hazards and safe use.

The contractor shall use all available information sources (e.g. consultation, results of evaluations, Eurobarometer survey results) and in addition:

- For consumers: conduct the behavioural experiment described in section 3.3.6 below; and
- For workers, professional and/or other users: conduct a targeted consultation (including targeted interviews, surveys etc.) as described in section 3 below.

TASK 3 ASSESSMENT OF LABELLING REQUIREMENTS AND NEEDS OF USERS

The analysis provided under this task shall allow assessing whether the labelling information provided to users is the most useful to them and whether this information needs to be simplified and/or strengthened/ modified (e.g. by providing different or additional, more relevant, information) to better achieve the purpose sought.

Based on the information already available (consultation, results of previous evaluations and Fitness Checks, Eurobarometer survey results etc.) and the analysis and desk research conducted under Task 1 and Task 2, the contractor shall:

1. Assess whether the information that is currently provided on the label is the most useful to their users (i.e. relevant, sufficient, understandable and not redundant/overwhelming, and on the other hand; informative, practical and motivating to take appropriate preventive measures) and whether some of the requirements could

be exchanged, removed as redundant, or if information could be provided via an e-label instead (e.g. as secondary information non-essential for the physical label). When assessing the need and relevance of amending the CLP labelling requirements, the link and need for consistency between the CLP and the UN GHS shall be taken into account.

2. Assess if and which other information should be provided to users in order to allow them to be properly informed about the use of the product and the potential safety or hazard concerns associated with it. The assumption of the assessment shall be that users' education, training or experience shall vary in terms of being able to understand the information presented on the label. Different degrees of information granularity shall be specified, from a set of minimum information to a more detailed information, possibly including 'nice to know' information.

TASK 4 ANALYSIS OF IT SOLUTIONS

Under Task 4, the contractor shall:

1. Map different IT solutions and digital tools that are or could be used to communicate hazard and safety information as well as instructions for use to product users (e.g. Q-R codes, barcodes, websites providing full list of ingredients, voice recognition systems etc.).

2. Map the current practice of companies based on voluntary approaches as well as innovative approaches put in place both in Member States and outside the EU.

3. The assessment shall include a comparative analysis of the costs involved with the use and maintenance of the identified digital tools and IT solutions. The aim being to avoid unnecessary regulatory burden, the contractor shall further examine whether the use of these tools and IT solutions could reduce labelling costs for companies (especially SMEs) compared to the current situation.

4. The needs and understanding of different demographics of product users with respect to hazard and safety information and use instructions shall also be assessed taking into account, to the extent possible, the varying readiness to shift to an increased use of IT solutions and digital tools and associated risks such as creating a digital divide.

TASK 5 IDENTIFICATION OF INFORMATION FOR THE PHYSICAL LABEL AND THE E-LABEL

Under Task 5, the contractor shall:

1. Assess which information should be provided to users and via which of the identified IT solutions and digital tools in order to allow them to be properly informed about hazards and safe use, thus improving the effectiveness and efficiency of the current approach to chemicals labelling.

2. Assess which information should remain on the physical label (also based on comparisons or differences of the results in the outcomes of the assessment carried out under Tasks 1, 2, 3 and 4). Different degrees of information granularity shall be specified, from a set of minimum information to a more detailed approach, taking into account specific needs of different demographics of users, as well as the objectives and different categories of users of the CLP Regulation and the Detergents Regulation.

TASK 6 IDENTIFICATION OF POLICY OPTIONS

The contractor is expected to identify a reasoned set of policy options, based on the information gathered and the analysis made in tasks 1 – 5, to simplify the labelling requirements to make the communication of hazard and safety information, as well as use instructions to users more effective, efficient and innovative.

TASK 7 ASSESSMENT OF POLICY OPTIONS (INCLUDING IN PARTICULAR COSTS), COMPARISON OF OPTIONS

Under Task 7, the contractor is expected to compare against the baseline (no change of the status quo) the policy options that were identified under the previous Task (Task 6) of the study.

In his assessment, the contractor shall reflect on the advantages/disadvantages, costs-benefits as well as on the feasibility and/or complexity of each of the options considered. This assessment shall be substantiated by an analysis of the technological, practical, legal and economic limitations associated with each policy option, as well as by the conclusions regarding consumer needs and those of companies, SMEs in particular, identified throughout the study.

The study should analyse the following aspects:

(i) the environmental, social and economic impacts and an explicit statement if any of these are not considered significant;

(ii) a clear description of who will be affected by the initiative and how;

(iii) impacts on SMEs following the "SME test" in the Toolbox of the Better Regulation Guidelines;

(iv) impacts on the competitiveness of companies (see tool 20 of the Toolbox); and

(v) impacts on research and innovation and the application of the R&I Toolbox.

(vi) impacts on consumers and users

The contractor shall in particular provide a detailed assessment of costs and benefits of each policy options for different stakeholders groups.

It should further develop a comparison of policy options against coherence, effectiveness and efficiency (benefits to cost analysis) criteria.

The recommendations shall be provided in line with the outcome of Tasks 1, 2, 3 and 4.

3. APPROACH AND METHODOLOGY

The choice and a detailed description of the methodology must form part of the offer submitted. Advantages, limitations and risks involved in using the proposed tools and techniques should be explained.

The contractor shall ensure robustness of information by trying to acquire it from more than one source. In particular findings from consultations should be complemented when possible by official statistics and studies.

The contractor must support findings and recommendations by explaining the degree to which these are based on opinions, analysis and objectively verifiable evidence. Where opinions are the main source, the degree of consensus and the steps taken to test the opinions should be given.

The contractor will have a free choice as to the methods used to gather and analyse information and for making the assessment, but must take account of the following:

In parallel to launching the call for this study, the European Commission will launch another call for a study to support the impact assessment accompanying a new initiative 'on the making available and placing on the market of detergents'. This study is expected to measure the possible impacts of addressing the weaknesses and shortcomings that were identified in the evaluation of the Detergents Regulation[28]. As both studies may lead to the modification of the Detergents Regulation, the assumptions, and subsequent results of the findings would need to be consistent, enabling the integration of the data and findings of the two sources (studies) in an Impact Assessment. Any inconsistencies between the two studies should therefore be avoided. Good cooperation and communication between the studies (or contractors) shall be guaranteed. The data collection tools and data analysis the contractor shall use shall therefore be coordinated and compatible between both studies, ensuring cohesion and compatibility.

The contractor shall further take account of the following tools for data collection and data analysis:

The study shall systematically ensure that the suggested policy options and recommendations are compatible with the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). When identifying options and providing recommendations, the study shall also bear in mind the work on digitisation that has started recently at the UN GHS level[29]. It should also take into consideration the on-going work regarding development of tools to track and link information on substances of concern in products[30], in particular articles as well as the on-going work on the digitisation of safety data sheets (SDS) under REACH.

The different user categories (consumers, professional users, waste operators, etc.) of products falling under the scope of the study shall be taken into account in the proposed policy

[28] Commission Staff Working Document, Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents: https://ec.europa.eu/docsroom/documents/36289
[29] https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c4/UN-SCEGHS-36-INF14e.pdf
[30] https://op.europa.eu/en/publication-detail/-/publication/59d9b462-a9f6-11ea-bb7a-01aa75ed71a1/language-en

options[31]. In case that differences arise in the information considered as essential per user category, these differences should be analysed and explained, and recommendations on essential information most useful to each user type of the product should be made.

The needs and understanding of different demographics of product users with respect to hazard and safety information and use instructions shall also be assessed taking into account, to the extent possible, varying readiness to shift to an increased use of IT solutions and digital tools and associated risks such as creating a digital divide.

The study shall systematically look into the user-friendliness of potential solutions, and shall explore whether a "one-size fits all" solution is appropriate or whether differentiated solutions are needed. In the second case, the proposed alternatives should be presented in the study.

The needs of companies, SMEs in particular, in terms of reducing costs and administrative burden shall also be taken into account and reflected in recommendations. In support of this, the study shall also collect information regarding (voluntary) use of tools and best practices (sector or product type specific) to ensure that the tools and approaches proposed are implementable and fit for purpose.

The findings of the study shall be based mainly on evidence gathered through extensive desk and online research and literature review. In addition to this, the contractor shall also use a combination of approaches to reach out to relevant stakeholders and Member States and obtain the information required to successfully complete his/her tasks. For this purpose, the contractor may for example make use of questionnaires and targeted surveys, interviews with selected stakeholders (by telephone or face-to-face meetings) etc. All stakeholder groups shall be covered in a balanced way. The tenderer shall clearly describe the proposed investigation strategy.

3.3 DATA COLLECTION TOOLS

3.3.1 *Desk research/ literature review*

The contractor shall collect data and information from a wide range of publicly available sources, including, among other:

- *relevant academic research*
- *Structured analysis of the provisions of the legislation and of its implementation*
- *studies and other reports from MS, national Authorities, Notified bodies*
- *other relevant consultations reports/studies on the fields*
- *National/international official statistics (Eurostat, OECD, Etc.)*
- *Qualitative and quantitative analysis of existing data (e.g. market data)*
- *Analysis of existing documents*

[31] It should be noted that the CLP Regulation applies to virtually all chemicals (chemical substances and mixtures). The products falling under its scope can therefore vary from fertilisers and detergents to biocides and paints.

3.3.2 *Stakeholder consultation*

On the basis of the consultation strategy endorsed by the Interservice Steering Group, the contractor shall design a detailed implementation plan that will allow all stakeholders to be duly consulted. Stakeholders can be consulted either to collect evidence or to test/validate already existing analysis or evidence coming from different sources.

Particular attention should be paid to balance coverage of stakeholders consulted [companies (including all sizes), authorities, consumer organisations, etc.], geographical coverage, product coverage, etc. The relevant parts of the Commission Better regulation guidelines and Toolbox concerning stakeholder consultation should be followed.

The consultation strategy must include a 12-week internet-based public consultation, but should be complemented by other approaches and tools in order to engage all relevant stakeholders and to target potential information gaps.

For each proposed consultation tool and for each category of stakeholder the contractor shall analyse the potential gaps and propose a mitigation strategy. An analysis of possible overlap between the different tools shall also be put forward (in particular between the public and targeted consultation).

The contractor shall ensure capabilities in the 24 EU languages.

3.3.3 Public consultation

The Commission shall prepare a questionnaire for the mandatory internet-based Public Consultation which has to be agreed with the Steering Group. Public consultation is open to all – anyone interested to provide input - and so it is able to reach a broad range and large number of stakeholders.

The questionnaire will be available in 24 EU languages. The translation of the questionnaire will be provided by the Commission. Questionnaires shall be customised to different stakeholder categories such as companies (including SMEs), consumers, etc. taking into account their different level of engagement and experience with the measure.

The consultation will be encoded in a Commission tool, EUSurvey, hosted on a Commission web-site and the answers received (in the original language) will be forwarded to the contractor for analysis. The contractor shall analyse and summarise the responses. The contractor shall also prepare the Synopsis Report that sums up the results of all consultation activities conducted under this study.

The minimum time period for public consultation is 12 weeks (additional time should be given in case they run during major holiday periods or exceptional circumstances).

The contractor shall respect the European Commission standards for data protection when analysing responses.[32]

3.3.4 Targeted consultation

The targeted consultations will collect the specialist view of the different categories of stakeholders. It can take place at any time point during the study. There is no minimum

[32] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:EN:PDF

mandatory period for targeted consultation, but sufficient time should be given in order to collect as many replies as possible.

Questionnaires shall be customised to different stakeholder categories such as companies (including SMEs), workers and professional users, enforcement authorities, consumer associations etc., taking into account their different level of engagement and experience with the measure. The contractor shall propose mitigation strategies in case of low number of replies.

Targeted stakeholders can be organized using the Commission tool EUSurvey or any other tool proposed by the contractor and agreed upon by the Steering Group.

Any other operational works related to the survey itself will be the responsibility of the contractor. The contractor remains solely responsible for the analysis. The contractor shall respect the European Commission standards for data protection when analysing responses.

The responses to the targeted consultation (raw data) shall be provided to the Commission, and in particular Unit GROW/D2 that is responsible for this study.

3.3.5 Interviews

The contractor shall carry out a number of structured/semi-structured interviews. Whereas most interviews could be done via phone or video conference, face to face interviews may be needed at an early stage to get a better understanding of the sector. Further interviews may be needed when analysing the information received via the targeted and public consultation.

The Commission may issue a Recommendation Letter that the Contractor will be able to present to approached stakeholders.

In conducting the interviews the Contractor shall respect data protection and privacy standards of the Commission. The responses and transcripts of interviews shall be given to the Commission and in particular Unit GROW/D2 that is responsible for this study.

The selection of interviewees should be based on their knowledge of the subject and should be agreed with the Commission service.

Interviews should be conducted with:

- Relevant International/ National Administration, notification bodies, Authorities, Agencies, etc.
- Selected representatives from organisation of stakeholder's categories (Industry and SMEs, workers, consumers, etc.)
- Selected number of Enterprises
- NGOs, civil society

The approximate overall number of interviews that the contractor is expected to conduct is around fifty (50), either as face-to-face or as remote interviews.

The contractor shall ensure capabilities in the 24 EU languages.

By the end of the consultation process the contractor shall prepare a summary of all consultation activities carried out under this study. This summary should follow the rules for Synopsis report as described in tool 55 “Synopsis Report” of the Better Regulation Toolbox

3.3.6 Other tools

Behavioural experiment

Under Task 2 the contractor shall conduct online, off-line *or* laboratory behavioural experiments, for example, in dedicated laboratories or other suitable areas, including field settings, *or* equivalent. Contractors should detail and justify in their tenders their proposed experiment type or combination of experiment types and methodologies. A pilot testing phase should be foreseen before full implementation.

The objective of this experiment is to test the hypotheses and complete the sub-tasks outlined in Task 2 in relation to consumers. The experiment shall also assess or identify additional or different factors that affect consumers' understanding of chemicals' labels and how the latter affects consumers' application behaviour, risk perception (i.e. how users rate the potential dangers of wrongly applying the product) or behavioural intentions (how they intend to use the product). The findings of this experiment should also feed into the mapping of the information that is essential and relevant to consumers and in that sense would need to stay on the physical labels as opposed to information that is secondary or not immediately understandable and that could therefore be provided via the digital label. It shall also help identify *when*, *why* and *if* some of the information provided on the label is incomprehensible/redundant and could therefore be completely removed. The behavioural experiment shall include questions measuring both spontaneous and aided associations and understanding.

The behavioural tests carried out shall be conducted in the form of Randomised Controlled Trials (RCTs) and coupled with questionnaires addressed to the participants coming from different cultural, educational and socio-economic backgrounds and different age groups; such a survey may also be launched separately and run after the behavioural experiments. The contractor shall analyse the results from the RCTs in parallel with the replies to the questionnaires, the content of which should be agreed with the contracting authority.

Behavioural experiments shall be carried out using appropriate incentives to avoid unreliable replies. Sample size and the level of incentives should be carefully calibrated to strike the best compromise between accuracy and the need to minimise unreliable replies and self-selection. The sample of participants should be representative of the general population of users for the issue at stake. Different factors such as age, gender, income and education shall be considered to this effect. The experiments shall foresee a sample size that will deliver results of sufficient accuracy and shall rely on reasonable assumptions based on past behavioural experiment results. The sample should cover consumers who are users of products labelled according to the legislation in question, from as many EU countries as possible belonging to different regions (i.e., Nordic countries, Eastern-European countries, Central- European countries, Mediterranean countries). The number of participants fulfilling these criteria in the sample shall to be large enough to allow meaningful statistical inferences. An online behavioural study shall have a minimum sample size of 1000 participants per country, and cover at least 4 Member States (i.e. at least 4000 participants in total. A laboratory experiment shall have a minimum sample size of 400 participants per Member State, and cover at least 3 Member States per policy option.

It will be the contractor's task to suggest a design of the experiment(s) and for the contracting authority to approve.

3.3.7 Purchase of commercial data/statistics

For the purpose of conducting the study the contractor may create or purchase access to external databases. The contractor should be able to assess the quality and completeness of data in such database.

Any database purchased for the purpose of this study will become property of the European Commission, together with all documentation and access rights.

Any database created for the purpose of this study will become property of the European Commission; the datasets should be accompanied by a clear documentation explaining all the variables and be presented in the following format: *xls files.*

All source-codes and/or spreadsheets used for the statistical/econometric analysis have to be shared and will become property of the European Commission.

3.3.8 Quality of the collected data

The data collection process as well as all data and statistics that are part of the study should be clearly and exhaustively described so that the users are able to (a) assess the quality of these data/statistics, (b) interpret them in a consistent way and (c) replicate their methodology in the future. For that purpose, each data collection process carried out by the contractor should include the following information as a minimum:

- Objective of the exercise
- Description of the target and sampled population; including measures taking to achieve representativeness (e.g., randomization procedure, stratification, etc.)
- Detailed description of data (variables) to be collected (incl. information on scales)
- Degree of precision i.e. are there some missing data or breaks in time series?
- Detailed ex-ante description of exclusion criteria (e.g., wrong answers to test-questions, attention checks, too fast response times, identical IP addresses, etc.)
- The planned statistical analyses of the hypotheses
- Collection mode, i.e. how will the data be collected (by email, web platforms, dedicated application)
- Periodicity/frequency of a process i.e. is it a one-off exercise or a regular one?
- Data validation
- Publication format i.e. in which electronic (open) format will the data be made accessible (plain text CSV files,. Excel, R, or Stata files)
- Metadata i.e. what background information about the data shall be disclosed:
    - Data collection methodology;
    - Target population;
    - Sampled population;
    - Glossary and definitions of indicators/variables and their respective measurement units (“Codebook”);
    - Codes, acronyms, flags used (those should normally be harmonised with Eurostat codes, e.g. two-letter country codes);
    - The timing and frequency of data collection;
    - The publication date;

- Limitations, confidentiality issues, disruptions of methodology etc.
- Contact point for potential questions and comments from the public.

3.4 DATA ANALYSIS

Considerable emphasis should be placed on the analysis of the information/data collected. The contractor will have a free choice as to the methods used to analyse information and for making the assessment, but must, at least, take account of the following:

3.4.1 Identification of the most relevant impacts (intended and unintended)

The contractor shall identify and assess the most relevant impacts of the proposed policy options. These include both direct and indirect impacts such as behavioural, economic, social, environmental impacts, etc.

The selection of the most relevant impacts should be done on the basis of the principle of proportionate analysis taking into account the following factors: 1) the relevance of the impact within the intervention logic e.g. options that will directly contribute to the achievement of the policy objectives; 2) the absolute magnitude of the expected impacts i.e. focus on the impacts with the greatest magnitude; 3) the relative size of expected impacts for specific stakeholders; and 4) the importance of impacts for Commission horizontal objectives and policies.

Significant impacts should be assessed qualitatively and, whenever possible, quantitatively. The contractor shall make significant efforts to quantify administrative costs and use the standard costs model, wherever possible. Further guidance on the identification and assessment of the relevant impacts can be found in Better Regulation Toolbox 19.

In line with the Green Deal communication, the industrial strategy package, in particular the new SME strategy, and the Commission's Better Regulation principles, the Commission shall carefully consider the consequences and socio-economic impacts of introducing new legal requirements. Therefore, when proposing measures creating new burdens, the contractor shall provide detailed analysis of costs and pay particular to the balance of cost and benefits of the policy option.

3.4.2 Cost-effectiveness, cost-benefit analysis

The contractor is asked to map regulatory and administrative costs and benefits stemming from the measure. Costs and benefits should be disaggregated to specific actions necessary. For the quantifications the contractor should follow as much as possible the logic of the cost-benefits analysis and more generally the methods described in the Better Regulation Toolbox[33].

The contractor shall try to estimate benefits of the initiative. The contractor shall try to estimate other benefits of the measure that will emerge during the course of analysis.

[33] [33] https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

3.4.3 Case studies

The contractor may use case studies in order to provide practical examples; these could also be used to present examples of costs and benefits for manufactures of specific products (success stories).

3.4.4 Other (optional):

- *Statistical analysis of data*
- *Econometric modelling*
- *Value chain analysis*
- *Input-output analysis*
- *Sensitivity analysis*
- *Risk assessment*
- *Standard cost model*
- *Non-market valuation techniques*
- *Multi-criteria analysis*

The analytical and reporting tasks to be delivered shall be fully in accordance with the Commission Better Regulation Guidelines and Better Regulation Toolbox.

4. AVAILABLE INFORMATION AND DATA SOURCES

Please find an indicative list of available information and data sources in Annex I to this document.

5. COMMISSIONING BODY AND PUBLICATION

The present study is commissioned by Unit D2 "Chemicals and Plastics Industries" of DG Internal Market, Industry, Entrepreneurship and SMEs.

The steering group contributes to the development of the impact assessment study and is part of its management structure. The steering Committee for the present study is composed of the following representatives:

SG, LS, DG ENV, DG SANTE, DG JUST, DG CNECT and the JRC

The results may be shared with other interested bodies inside and outside the European Commission.

6. REPORTING AND DELIVERABLES

6.3.1 General reporting requirements

The contractor shall provide the required reports and documents in accordance with the timetable below.

The contractor must ensure that all deliverables under this contract are clear, concise and focused on their purpose. All deliverables shall be written in English, reviewed and corrected by a native speaker before submission.

Electronic files must be provided in *Microsoft ® Word, PDF* or xls format. Additionally, besides Word, the Final Report must be delivered in pdf format and in 5 (five) hard copies.

All deliverables are presented as draft documents to be discussed with the Steering group and finalised based on the comments received from Commission services.

The Commission shall have 30 days to approve or reject the report. The contractor shall have 30 days in which submit additional information or a new report.

6.3.2 Deliverables

For the purpose of this specific contract, the following deliverables will need to be produced:

Deliverable 1 (DI)	**At the latest 1 month after signature of the contract by the last contracting party and no later than 1 week before the kick-off meeting**
An **inception report** will specify the detailed work programme and planning for the study and describe the methodological approaches and working assumptions to be used for the tasks defined. The report will also identify any additional needs. The steering group shall provide comments either at the kick-off meeting or in writing within 2 weeks after delivery of the inception paper. The comments shall be taken into account in a final revised version of the inception report within 2 weeks. The contractor shall provide a tabular response to comments, indicating how each comment has been addressed.	

Deliverable 2 (D2)	**At the latest 5 months after signature of the contract by the last contracting party**
A **first interim report** will summarise results reached until that moment and raise any problems encountered with sufficient information to permit reorientation if appropriate and required. It will demonstrate what preliminary conclusions have been drawn and give clear indications and detailed planning of the work to be carried out during the rest of the period of completion of the tasks. It is suggested that the first interim report presents some preliminary findings on Tasks 1 and 3 such as mapping of the legal provisions and available IT tools. The steering group shall provide comments on the reports, either orally at the interim meetings or in writing within 3 weeks. The contractor shall provide a revised version of the report within 2 weeks after receiving the comments. The revised report shall take into account the comments provided by the steering group. The contractor shall provide a tabular response to the comments, indicating how each comment has been addressed. The responsible Commission service shall either accept the revised report or provide further comments to the contractor within 2 weeks from the date of reception. In case of further comments, the above-mentioned deadlines shall apply mutatis mutandis.	

Deliverable 3 (D3)	**At the latest 9 months after signature of the contract by the last contracting party**
A **second interim report** will present the further progress made, preliminary conclusions that may be drawn, and how the contractor is proceeding. At this stage, the report is also expected to present the findings of the behavioural experiment for consumers and the targeted survey for workers and professional users. Further, this report shall include the proposed structure of the final report. The contractor shall present the second interim report to Member States and stakeholders in one of the meetings of the expert group CARACAL and one of the meetings of the expert group on detergents (Detergents Working Group). The timing of the meetings may be modified in agreement with the Commission. The steering group shall provide comments on the second interim report, either orally at the interim meetings or in writing within 3 weeks from its reception. The contractor shall provide a revised version of the report within 2 weeks after receiving the comments. The revised report shall take into account the comments provided by the steering group as well as the input received during the workshops. The contractor shall provide a tabular response to the comments, indicating how each comment has been addressed. The responsible Commission service shall either accept the revised report or provide further comments to the contractor within 2 weeks from the date of reception. In case of further comments, the above-mentioned deadlines shall apply mutatis mutandis. The acceptance of the 2nd interim report will be a pre-condition for the interim payment.	

Deliverable 4 (D4)	**At the latest 12 months after signature of the contract by the last contracting party**
A draft final report will be delivered to the Commission, taking account of the comments made earlier on in the process. It will cover all points of the work plan and shall include sound analysis of findings and factually based conclusions and recommendations, in line with the purpose and objectives described above. The Commission will accept the draft final report in the definitive form or comment on it within *30 days* of its reception. Should the Commission still not consider the final report acceptable, the Contractor will be invited to amend until the Commission is satisfied within 30 days. In cases of late delivery, the Commission reserves its right to apply the corresponding liquidated damages according to the provisions of Article II.15 of the Framework Contract. The Interservice Steering Group reserves the right to carry out a quality assessment of the final report and publish it along with the study. If the Commission does not react within the above mentioned 30-day period, the final study shall be deemed to have been approved.	

Deliverable 5 (D5)	**At the latest 15 months after signature of the contract by the last contracting party**
The **final report**: Annexes to the final report will include any graphical material, the main bibliographic and information sources, verbatim of interviews. The contractor shall present the findings of the final report to Member States and stakeholders in one of the meetings of the expert group CARACAL and one of the meetings of the expert group on detergents (Detergents Working Group). The timing of the meetings may be modified in agreement with the Commission.	

Deliverable 6 (D6)	**At the latest 15 months after signature of the contract by the last contracting party (submitted as annex to D5)**
An **executive summary** (around 6 pages) summarising the purpose, methods used, key findings and possible recommendations of the study.	

Deliverable 7 (D7)	**At the latest 15 months after signature of the contract by the last contracting party (submitted as annex to D5)**
All the data collected under this contract, as well as all the summaries, analyses, underlying calculations and findings, which will be the property of the Commission and must be handed over in the agreed format.	

The Commission shall have 30 days to approve or reject the reports. The contractor shall have 30 days to submit additional information or a new report.

The contractor must ensure that the inception, interim reports under this contract are clear, concise and focused on their purpose. Each report must clearly report on what is new, the status of any findings/conclusions (e.g. whether they are tentative or more final), any problems encountered and how they will be surmounted, and the next steps and timetable.

Graphic requirements

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at: http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.

The accuracy of the data produced and published will be under full responsibility of the contractor. The sources of the data must always be clearly identified. Assumptions and calculations should be made fully transparent. The data underpinning the assessment of costs and benefits shall be provided to Commission upon request.

7. PUBLICATIONS

The study (including executive summary, abstract, annexes) will be published on the DG Internal Market, Industry, Entrepreneurship and SMEs internet site, on the EU Bookshop website and on other web-sites in relation to the study.

In view of its publication, the final report must be of high editorial quality. In cases where the contractor does not manage to produce a final report of high editorial quality within the timeframe defined by the contract, the contracting authority can decide to have the final report professionally edited at the expense of the contractor (e.g. deduction of these costs from the final payment) according two Article II.16 of the framework contract.

8. WORK ORGANISATION

8.1 Meetings with the Commission

The contractor is expected to take part in maximum 5 meetings with the Commission services that will either take place on Commission premises in Brussels or online:

- a kick-off meeting at the beginning of the study;
- two interim meetings ;
- a final meeting to present the results of the study.

The 'kick-off' meeting will allow for the discussion of the draft outline approach and work programme elaborated by the contractor for the execution of the contract.

The 'interim' meetings will allow an in-depth discussion of the progress/interim draft reports.

The 'final' meeting will allow an in-depth discussion of the draft final report and requirements for the completion of the Final report.

The contractor is also expected to give a presentation to Member States and stakeholders in two meetings of the expert group CARACAL and two meetings of the expert group on detergents (Detergents Working Group). The contractor shall cover his/her own travel and subsistence costs. The timing of the meetings may be modified in agreement with the Commission. In addition, the contractor shall be available for interim telephone conferences with the responsible Commission service every 2-4 weeks, as appropriate, to monitor the progress of the work and to clarify any open questions.

8.2 Work Plan

The contract shall enter into force on the date on which it is signed by the last contracting party.

It is expected to be signed in December 2020. The provision of the services shall not exceed fifteen (15) months.

Deliverables (D), Meetings (M), and Payments (P)	Deadline (Month)
M1: Kick-off meeting with the Commission in Brussels D1: Inception report	1
D2: First interim report M2: First interim meeting with the Commission in Brussels P1: 1st Interim payment	5
D3: Second interim report M3: Second interim meeting with the Commission in Brussels and presentation of the findings in CARACAL and Detergents Working Group P2: 2nd Interim payment	9
D4: Draft final report M4: Final meeting with the Commission in Brussels	12
D5: Final report and presentation of its findings in CARACAL and Detergents Working Group D6: Executive Summary of the final report D7: All data collected P3: Final payment	15

8.3 Proposed team

Total days	

Task	Name	Role in the team	Staff Category	Expertise	Languages	Unit price	Man days
			Cat. I - Team Leader				
			Cat. II - Senior Consultant				
			Cat. III - Junior Consultant				
			Cat. IV				

The tender must include a description of the proposed team, its composition, its expertise and the work effort planned for each member in terms of man/days for each task of the project.

9. PRICE

The maximum budget available for this project is € __200.000_____

The offer must include a detailed proposed budget. The tenderer should provide a quote of the total cost of the services to be provided (fixed price) in its financial tender following the table below:

Price component	*Staff category*	*Unit price* *(= daily rate for Human Resources including the travel and subsistence expenses linked to the five meetings with the Commission on its premises in Brussels)*	*Quantity* *(= number of man days devoted to the project by person XY for Human Resources)*	*Total*
Human resources				
Person X (name and a role)				
Person Y (name and a role)				
…..				
Subtotal (1)				
Other				
Item X				
Item Y				
…..				
Subtotal (2)				
TOTAL (1+2)				

10. PAYMENTS

The payment scheme will consist of

- **two interim payment(s),** corresponding to **a maximum of 30 %** (each) of the price specified in article 3.1 of the specific contract;

- a **balance payment** corresponding to **no less than 40 %** of the amount specified in article 3.1 of the specific contract;

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.6, II.21, II.22 and II.23 of the framework contract.

11. AWARD OF THE SPECIFIC CONTRACT

As specified in the tender specification for this FWC, the offers submitted within the re-opening of competition must contain:

a) **A technical part**, detailing the methodology, the composition and skills of the team and the responsible team leader for the specific agreement;

b) **A financial part** detailing the number of man-days to be multiplied by the man-day price as defined in the Framework Contract, and other cost items.

The Specific Contract will be awarded according:

- to the qualitative award criteria given below,

AND

to the price of the financial tenders.

The formula used to rank tenders and to calculate which tender is the most economically advantageous tender is displayed in section b) below.

A) TECHNICAL QUALITATIVE AWARD CRITERIA

No	Qualitative award criteria	Weighting (maximum points)
1	**Clarity, relevance and coherence** *This criterion will assess whether the offer is written in a clear language, whether it is well and logically structured, whether all the information requested in the specific contract is duly covered.*	**0-5**
2	**Quality of the proposed mechanisms for project management, including quality control, risk management and reporting** *This criterion will assess the quality control system proposed for the services foreseen in the offer concerning the quality of deliverables, the language quality check, continuity of the service in case of absence of a member of the team, as well as the overall project management (organisation of work, contacts with the contracting party etc.). This quality control system should be detailed. A generic quality control system will result in a low score.*	**0-15**
3	**Balance of profiles and breakdown of tasks** *This criterion will assess how the roles and responsibilities of the proposed team and of the different economic operators (in case of joint tenders, including subcontracting if applicable) are distributed for tasks specified in individual Terms of Reference for specific contracts. The tender should provide details on the rationale behind the choice of this allocation.*	**0-20**
4	**Relevance and quality of the methodologies to carry out data collection** *This criterion will assess how the tenderer will collect data.*	**0-25**
5	**Quality of the proposed methodology to carry out data analysis** *This criterion will assess how the tenderer will analyse the available and collected data.*	**0-35**
	Total number of points	**100**

The award criteria cannot be further supplemented during the evaluation procedure.

Only tenders that have reached a total score of a minimum of 60% and a minimum score of 50% for each criterion will be taken into consideration for awarding the specific contract.

B) AWARD METHOD

The contract will be awarded to the tender which is the most cost-effective (offers the best value for money) on the basis of the ratio between the total points scored and the price using the following formula:

Score for tender X	=	$\frac{\text{Lowest price*}}{\text{Price of tender X}}$	*	100	*	Price weighting (30%)	+	Total quality score (out of 100) for all award criteria of tender X	*	Quality criteria weighting (70%)

* Only tenders passing minimum quality levels are ranked. The lowest price refers to the lowest price among the tenders that have passed the minimum quality levels.

12. ANNEX I

A. Indicative list of relevant Stakeholders

I. **Detergents**

1. A.I.S.E. – International Association for Soaps, Detergents and Maintenance Products
2. Detergents companies like: Unilever, Henkel, P&G, Beckitt Renckiser etc.
3. Member States competent authorities such as:
   KEMI – Swedish Chemicals Agency
   TUKES – Finnish Chemicals Agency
   Danish Environmental Protection Agency
   THINK Chemicals - Danish Consumer Council
   UBA – The German Environment Agency

II. CLP

1. CEFIC – The European Chemical Industry Council
2. CLEEN - Chemical Legislation European Enforcement Network
3. BEUC - Bureau Européen des Unions de Consommateurs/The European Consumer Organisation
4. ECHA – European Chemicals Agency
5. Business Europe
6. Client Earth
7. Concawe
8. DUCC - Downstream Users of Chemicals Co-ordination Group
9. EuroCommerce
10. Eurogroup for Animals
11. Fecc - European Association of Chemical Distributors
12. ECEAE - European Coalition to End Animal Experiments
13. EEB - European Environmental Bureau
14. CheMI - European Platform for Chemicals Using Manufacturing Industries
15. ETUC - EUROPEAN TRADE UNION CONFEDERATION
16. Greenpeace European Unit
17. HEAL - Health & Environment Alliance
18. HSI/Europe - Humane Society International/Europe
19. industriAll European Trade Union
20. ChemSec - International Chemical Secretariat
21. PISC - PETA International Science Consortium Ltd.
22. REACH Alliance
23. SMEunited aisbl

B. List of relevant documents and online sources

I. Fitness Check:

- Report form 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: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN; and

- 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: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530884012&uri=SWD:2019:199:FIN

1. The Fitness Check supporting studies:
   - 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 1st Fitness Check study) https://ec.europa.eu/docsroom/documents/32561 (main report), http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/ (Annexes I – V) and http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/ (annex VI)
   - Study supporting the Fitness Check on the most relevant chemicals legislation (the Fitness Check+ Study) https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF
2. Other studies and useful sources of information:
   - Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals, Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals: *Proposal for a work item for biennium 2019-2020: digitalization and GHS hazard communication,* available at https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c4/UN-SCEGHS-36-INF14e.pdf
   - Commission impact assessment of the CLP Regulation: *Commission Staff Working Document accompanying document to the proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006*, SEC(2007) 854, 27 June 2007, available online: http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/ghs_ia_en.pdf
   - External impact assessment of the CLP Regulation: *Impact Assessment of Implementing the GHS*, RPA, London Economics & DTC, May 2006, available online: http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/ghs_sc_study_summary_final_en.pdf
   - *Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation*, Commission Services, August 2006, available online: http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/ghs_sc_study_final_and_addendum_101207_en.pdf
   - European Chemicals Agency, *Communication on the safe use of chemicals, Study on the Communication of Information to the General Public*, 20 January 2012, available online: https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf
   - *Report from the Commission to the European Parliament and the Council on communication on the safe use of chemicals,* COM/2012/0630

II. Detergents Evaluation

- Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents available at https://ec.europa.eu/docsroom/documents/36289
- Executive Summary of the Evaluation of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents available at https://ec.europa.eu/transparency/regdoc/rep/10102/2019/EN/SWD-2019-299-F1-EN-MAIN-PART-1.PDF
- Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) available at https://ec.europa.eu/docsroom/documents/32561