European Chemicals Agency

External review of EUCLEF

Final report - August 2021

FWC ECHA/2018/452 SC02

pwc

Table of contents

Executive Summary

The European Union Chemical Legislation Finder (hereinafter EUCLEF) is a tool developed and operated by the European Chemicals Agency (ECHA) on behalf of the European Commission (EC) which aims to improve the business environment for EU companies, in particular Small and medium-sized enterprises (SMEs), with regard to access to information on legislation applicable to a given chemical substance.

Required as part of the agreement between the European Commission and ECHA which entrusted the Agency with the implementation of EUCLEF under the COSME Programme, the present externally run review focuses on **4 key objectives**, combining a forward-looking approach and a stock-taking/evaluation exercise.

1. ***Key objective 1****: Is EUCLEF meeting its original objectives as set in the Agreement between ECHA and the European Commission?*
2. ***Key objective 2****: What is the potential for increasing its scope including the identification of additional sources of legislation of relevance for EUCLEF?*
3. ***Key objective 3****: Is the current approach to outsourcing services, such as the data provision and the helpdesk, appropriate?*
4. ***Key objective 4****: What can be done to further develop EUCLEF and maintain it at its best? (recommendations for the future development and maintenance of EUCLEF)*

The evaluation has been based on a mixed-methods approach, combining different types of data sources and analytical methods: desk research, survey, interviews and data analysis, therefore ensuring to obtain robust evidence of the current performance of EUCLEF and possible areas for improvement.

Key Objective 1

Concerning Key objective 1, the evaluation objectives have been operationalised through evaluation criteria: relevance, effectiveness, utility, use and EU added, in line with ECHA's framework for ex-post and ex-ante evaluations. In terms of **relevance**, EUCLEF's objectives remain in line with stakeholders' needs and are perceived as relevant across countries and stakeholders despite some room for improvement in the relevance of EUCLEF in terms of the comprehensiveness of information provided. Concerning the **effectiveness** of EUCLEF, the final EUCLEF product is in line with the actions set out in the contribution agreement with the European Commission. An average of 59% of the survey respondents consider that EUCLEF fulfils all of them fully or to a high extent across all objectives. When it comes to its **utility and use**, the number of users of EUCLEF has been steadily increasing since its launch in 2020 and the tool can be considered to provide a high degree of utility based on stakeholders' willingness to recommend EUCLEF to their network. Survey and interview respondents also pointed out to the **added value** of EUCLEF, stressing out the negative consequences they would experience in case of discontinuation of the tool.

Based on those evaluation criteria, the present evaluation notably highlighted that there is room for raising further awareness of EUCLEF and planning more communication activities. Given the lower added value of the helpdesk function, due to the low level of awareness and utilisation of it so far, it is recommended to consider a discontinuation or reduction of the scope of the EUCLEF helpdesk function and to explore alternative means of addressing potential questions.

Key Objective 2

Concerning **the potential for increasing the scope of EUCLEF**, there is a strong support among stakeholders for the inclusion of additional pieces of EU legislation in the scope of EUCLEF, as it would strengthen its role as a one-stop shop for SMEs in need of information on chemicals regulation. There has also been support and arguments in favour of the inclusion of national-level legislation, but acknowledgement by stakeholders that this would be very resource-demanding.

In the light of those observations, the external review therefore suggests an expansion of the scope of EUCLEF. In case of limited resources for expansion, further targeted stakeholder feedback activities and scientific analysis should be considered to determine the prioritisation of the legal acts to add. National legislations could be potentially included in a limited way, such as simply alerting that a given substance is regulated at the national level and, possibly, linking the specific piece of national legislation.

Key Objective 3

Concerning the **current approach to outsourcing activities**, the external review found that the complexity of the project (developing and operating EUCLEF services) has been carefully managed in terms of feasibility study and procurement approach. The renewal of the contract will give the opportunity to ECHA to review the procurement arrangements notably taking into consideration the following elements: the possible modification of the scope of work (e.g. adjustment of the helpdesk services, extension of the EU legislation in the scope of EUCLEF); the renewal of the contract with a possible handover to another Data Service Provider ; and further analysis of the IP provisions.

Key Objective 4

Stakeholders have also raised several **recommendations for the future development and maintenance of EUCLEF** such as exploring ways of integrating hyperlinks of EU legislation and/or relevant policy website as part of the search results, possibilities to include information on regulatory changes or to improve the EUCLEF search engine. Suggestions have also been made to revisit the EUCLEF layout and language and to promote EUCLEF and its features further.

1 Introduction

1.1 Context

The European Union Chemical Legislation Finder (hereinafter EUCLEF) is a tool developed and operated by the European Chemicals Agency (ECHA) on behalf of the European Commission (EC) which aims to improve the business environment for EU companies, in particular Small and medium-sized enterprises (SMEs), with regard to access to information on legislation applicable to a given chemical substance. The tool is meant to be particularly user-friendly for SMEs, as they can check the legislation that applies to them for each chemical substance, helping them at navigating a fairly complex regulatory environment.

EUCLEF was launched in March 2020, starting with 40 pieces of legislation available, which increased to 56 as of March 2021. Of those, 51 pieces of legislation are out of ECHA's remit.

1.2 Objectives of the external review

An externally run review of EUCLEF is required by the delegation agreement between the EC and ECHA concluded for the purpose of setting up EUCLEF. The review combines elements of an evaluation and a forward-looking assessment, summarised in the following set of objectives / questions.

Key Objective 1

Is EUCLEF meeting its original objectives as set in the Agreement between ECHA and the European Commission?

Key Objective 2

What is the potential for increasing its scope including the identification of additional sources of legislation of relevance for EUCLEF?

Key Objective 3

Is the current approach to outsourcing services, such as the data provision and the helpdesk, appropriate?

Key Objective 4

What can be done to further develop EUCLEF and maintain it at its best? (recommendations for the future development and maintenance of EUCLEF)

These objectives have been operationalised through evaluation criteria (relevance, effectiveness, utility, use and EU added value) and questions, which were addressed on the basis of both primary and secondary data collection in order to formulate findings and recommendations.

The temporal scope of the review covers the period since the set-up of EUCLEF until June 2021.

1.3 Methodological approach

The evaluation is based on a mixed-methods approach, combining different types of data sources and analytical methods to obtain robust evidence of the current performance of EUCLEF and possible areas for improvement.

1.3.1 Desk research

The review took account of information and documentation provided by ECHA, including:

- The EUCLEF feasibility study conducted in 2017;
- The EUCLEF delegation agreement between the EC and ECHA;
- Procurement and contractual documentation related to the development of EUCLEF;
- Operational documents and data such as the EUCLEF communication plan, website statistics, etc.;
- EU policy documentation of relevance (strategies, communications, etc.).

As part of the desk research task, the evaluation team also considered other EU-level databases run by EU agencies and an international one – run by the OECD[1], in order to gain a better understanding of the context in which such databases are used and get a reference point for some of the performance indicators used to assess EUCLEF.[2]

1.3.2 Survey

A dedicated survey was developed for the purpose of the review and run on ECHA's website between 04 June 2021 and 27 June 2021. The survey questionnaire was developed objectively, in cooperation between ECHA and PwC, with the former facilitating its implementation and promotion among EUCELF stakeholders.

In order to ensure that a proper analysis could be carried out, the gathered survey data was extracted, cleaned, rearranged and, where this was relevant, coded. After the data was processed, a qualitative analysis was performed, observing visible trends, as well as patterns and correlations between responses to a given question and factors such as occupation, country of residence or responses to other survey questions.

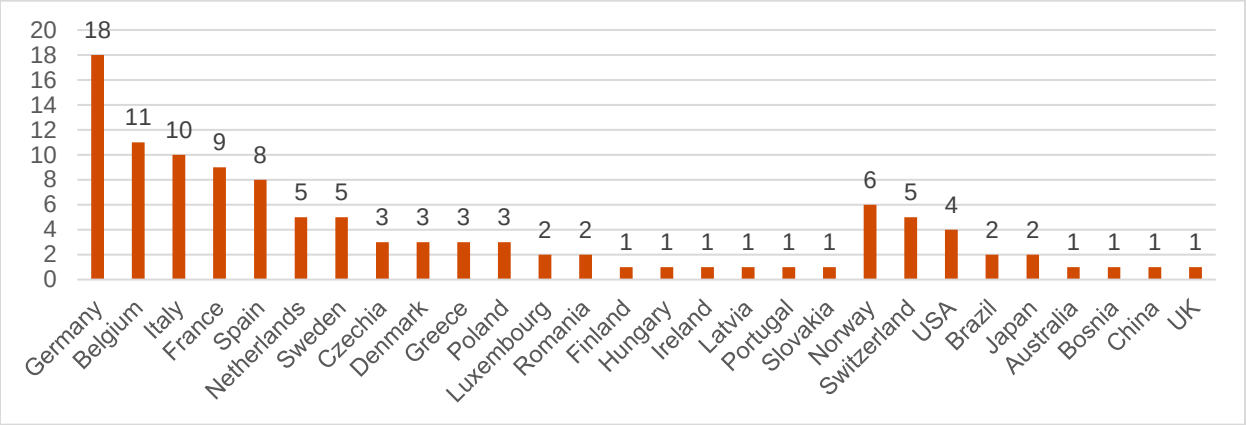
The survey was completed by 112 respondents representing a mix of stakeholder types and different EU and non-EU geographies. As such, the survey results can be considered to provide a relevant representation of the views of EUCLEF users in general, even if it's not possible to guarantee statistical representativeness of the results as the sample size is limited and the different groups of stakeholders are not equally represented. It should be noted that 147 individuals accessed the survey. Of those, 26 did not consent to ECHA processing their personal data (question 1) and a further 9 did not wish to familiarise themselves with the EUCLEF website in order to continue the questionnaire (question 9), leaving 112 respondents who completed the whole survey and whose input was considered for the analysis.

Overall, 111 respondents provided data on where the headquarters of their company were based or, alternatively, what their country of residence is. For the purposes of this analysis, both types of answers have been merged into a single category, based on the fact that they were counted as alternatives for each other in the survey. Of the 111 respondents, 88 were based in EU member states, while 23 – outside of the EU. In total, 19 Member States were represented, while 8 were missing, namely, Austria, Bulgaria, Croatia, Malta, Cyprus, Lithuania, Estonia and Slovenia. A further 8 member states could be considered to have been underrepresented, in terms of population relative to the EU, as Finland, Hungary, Ireland, Latvia, Portugal and Slovakia only accounted for one respondent each, while for Romania it was 2 and for Poland – 3. In these cases of underrepresentation, an additional effort was made to collect relevant feedback and

[1] OpenFoodTox (EFSA), Medicines database (EMA) and eChemPortal (OECD)
[2] See Annex 3 for more details.

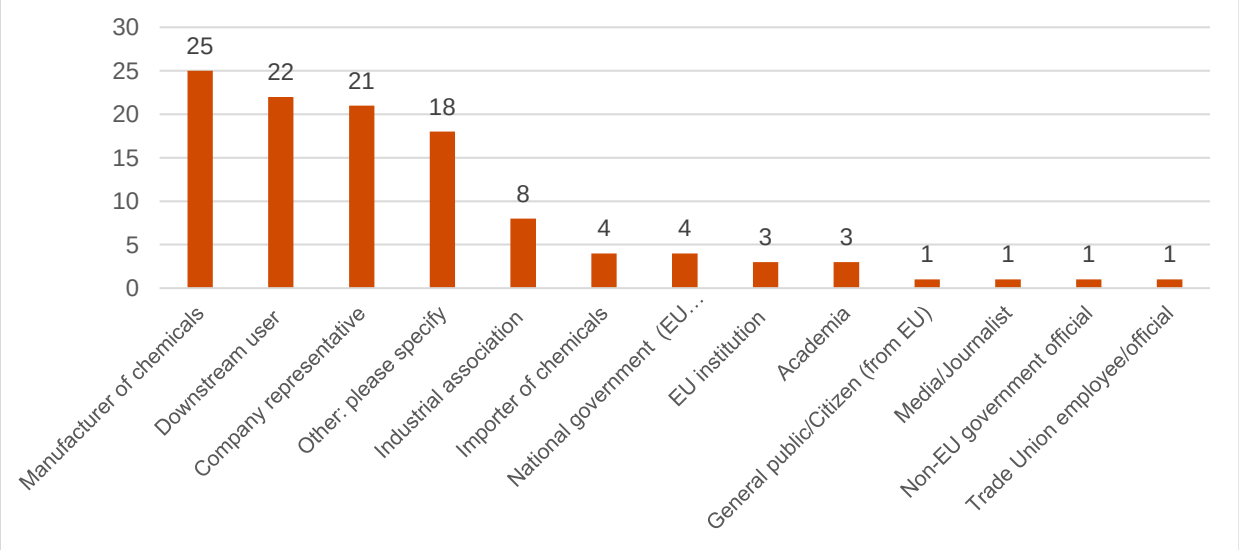
insights, by reaching out to their respective national helpdesks (i.e., Finland, Malta and Austria). One state could be considered as overrepresented – Belgium, which accounted for 11 respondents. More than half of the 23 responses from non-EU member states came from Norway (6), Switzerland (5) and the USA (4), while Brazil and Japan accounted for 2 respondents each and Australia, Bosnia and Herzegovina, China and the UK – for 1 each.

Figure 1: Survey respondents by country N=111



Data on their type of occupation/stakeholder role was provided by all 112 respondents, with three categories accounting for close to two thirds of the survey participants. Those were manufacturers of chemicals (25), downstream users of chemicals (22) and company representatives (21). Other occupations which accounted for a multitude of responses included industrial association employees and officials (8), importers of chemicals (4), EU institution employees and officials (3) and individuals in academia (3). Eighteen respondents belonged to an "other" occupational category, with half of those working in consultancy (9). Other non-specified roles included respondents who were both importers and downstream users (3), certification experts (2) and software providers, inventors, security officers and laboratory analysts which all accounted for 1 respondent each.

Figure 2: Survey respondents by type N=112



1.3.3 Interviews

An extensive interview programme was implemented in the context of the review with the goal of obtaining more detailed information about the performance of EUCLEF and to collect suggestions for further improvements.

A total of 129 stakeholders were approached for an interview and 59, or 48% accepted the invitation, with interviews taking place over phone or video conference over the course of June and July 2021.[3] A significant number of the interviewed stakeholders were also survey respondents who expressed interest in being interviewed in order to provide further feedback. Additionally, contacts for the interview programme were provided by ECHA as well as the European Commission concerning the responsible contact for a given piece of legislation under the scope of EUCLEF proposed as an alternative when declining. A summary of the interviewed stakeholders is provided in the following table.

Type of stakeholders	Total number of interviewees
European Commission and Agencies	20
Businesses (including importers, manufacturers and downstream users of chemicals)	25
Private sector representatives	8
Non-Governmental organisations	2
Member States authorities	4
Total	59

1.3.4 Data analysis

The analytical approach reflected the different types of data utilised in the review. The survey results were analysed through both descriptive statistics and qualitative data coding for open text answers. The interview data was also subject to qualitative data coding, facilitated by the Nvivo® software.

Nvivo® is a qualitative data coding software which allows for the structured coding of large amounts of qualitative data, allowing the analyst team to transparently and robustly classify qualitative responses under different categories and obtain a more accurate understanding of magnitude of trends in the obtained responses.

Where possible, data has been triangulated – i.e. evidence from different sources has been compared to ensure the consistency and robustness of the analysis.

[3] Reasons for the declined interviews included lack of familiarity with EUCLEF (among non-users) and lack of availability.

2 Is EUCLEF meeting its original objectives as set in the Agreement between ECHA and the European Commission?

2.1 Relevance

The analysis of relevance considered how well the objectives of EUCLEF still correspond to stakeholders' needs based on stakeholder feedback.

EUCLEF was launched in March 2020 with a view to improve the business environment for EU companies, in particular Small and medium-sized enterprises (SMEs), with regard to access to information on legislation applicable to a given chemical substance. In this context, the results of the evaluation show that EUCLEF objectives are strongly aligned with stakeholders' needs in terms of access to relevant information on the legislation applicable to the chemical substances of interest.

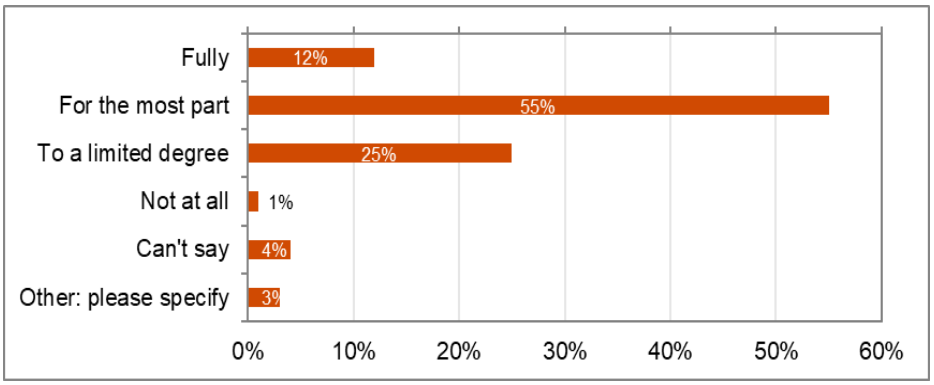
EUCLEF was developed in order to address the challenges faced by companies when it comes to accessing reliable and complete information about chemicals legislation. The feasibility study carried out for EUCLEF established a number of obstacles faced by companies, ranging from the issue of fragmented, incomplete and unreliable data sources to the burdensome and costly process of obtaining the relevant data.[4] EUCLEF was set up in order to address this gap, i.e. providing to companies and especially SMEs a tool allowing them to look for specific substances, and providing them with an overview of the applicable EU regulations – thus helping them saving significant time and financial resources. In doing so, it aimed to facilitate access to markets for SMEs.

The evaluation results show that EUCLEF's objectives remain in line with stakeholders' needs. Two thirds (67%) of survey respondents answered that the objectives of EUCLEF fully or mostly correspond to their individual needs. These results are corroborated in the interviews, which confirm that EUCLEF helps companies get an overview of the EU legislation applicable in the context of specific chemical substances (70%). In doing so, companies have a better understanding of what regulations they should comply with, and can get further information from the regulations themselves when need be. In addition, the tool is free of charge, which addresses some of the financial constraints SMEs may face (see more information in 2.3.2). In this sense, stakeholders tend to use EUCLEF as a first step before going through the regulation itself or other sources of information.

Importantly, EUCLEF's objectives are perceived as relevant across countries and stakeholders. The qualitative data points add a bit more nuance, specifying that EUCLEF is particularly in line with SMEs' needs, which often feature more limited capacities to address regulatory compliance issues than large companies. In that sense, EUCLEF was also found to be levelling the playing field for these actors.

[4] Feasibility study on a European Chemicals Legislation Finder (EUCLEF), Final Report No.4

Figure 3: How well do the objectives of EUCLEF correspond to your needs? N=112



The qualitative inputs from interviews and the survey indicate that, while EUCLEF is helpful in providing an overview of EU legislation applicable to given substances, stakeholders perceive that more could be done in order to get relevant results.

While EUCLEF results are generally up to date (see more information in Section 2.2.1), a few stakeholders noticed some discrepancies, indicating they wish for more regular updates. As a result, they need to verify it against the latest versions of the legal texts on EUR-Lex or via other tools (the EC-managed COSING database for cosmetics; Chemical Watch, etc). One reported example concerns the changes generated by the Regulation (EU) 2017/745 (notably on Regulation 1223/2009, Council Directives 90/385/EEC and 93/42/EEC) which at the point of the interview were not reflected in EUCLEF. This is relatively important as changes in chemicals regulations – in terms of the limit values or other requirements, are regular. In this context, stakeholders (two interviewees and seven survey respondents) also indicate that there is a lack of information on future versions of the laws and substance data contained in the legislations covered by the tool . At the same time, it is important to nuance this statement by highlighting that EUCLEF already covers some forward-looking elements such as if a law will be repealed.

There is some room for improvement of the relevance of EUCLEF in terms of the comprehensiveness of information provided. While the survey and interview data show that stakeholders generally find the results provided by EUCLEF comprehensive enough, several (two interviewees and six survey respondents) have pointed out the need of information on the implications and requirements stemming from the regulations. While stakeholders know where to find information, they have to go through the regulation itself to understand e.g. limit values for given substances and other requirements they may need to comply with. In light of these suggestions for improvements raised by the respondents, it is important to note that, while OELs are already to some extent covered by EUCLEF, the tool should not be perceived as a tool providing legal advice. In that sense, it seems that the objectives of EUCLEF and their scope are not always clear to its stakeholders.

Last, there is an interest in enlarging the scope of legislation under EUCLEF to improve its relevance, with a strong support for the inclusion of additional pieces of EU legislation in the scope of EUCLEF and some support and arguments in favour of the inclusion of national-level legislation (see Section 3).

2.2 Effectiveness in meeting objectives

This section aims to assess the extent to which EUCLEF fulfil its objectives. It does so by

i) comparing the EUCLEF as it is against what was initially envisaged;

ii) analysing its functionalities and characteristics; the benefits derived from its use; and

iii) the extent to which it helps stakeholders better understand and navigate the covered pieces of legislation.

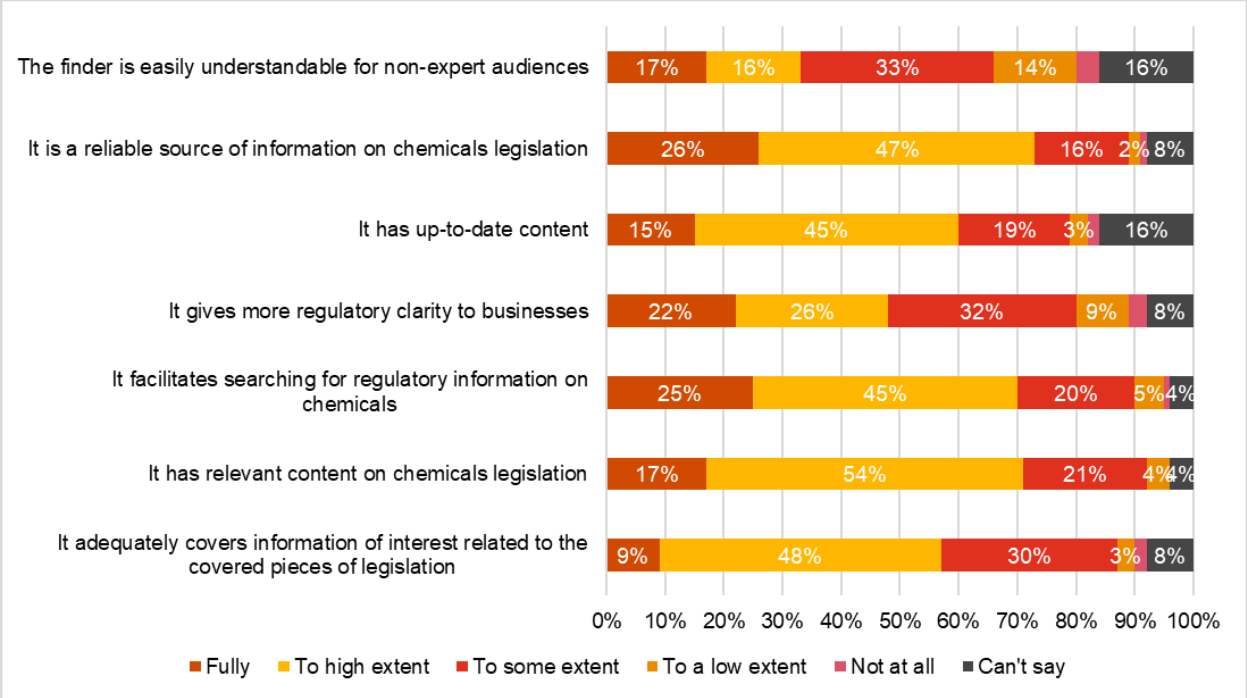
The evaluation finds that EUCLEF fulfils most of its objectives to a high extent, and that it could be rendered even more effective by improving the navigation / layout of the tool. A large share of the stakeholders hence finds that EUCLEF is effective in answering their needs.

2.2.1 To what extent does EUCLEF fulfil its objectives?

The final EUCLEF product is in line with the actions set out in the contribution agreement with the European Commission. All of these have been achieved in due time – from the data service provisioning, to the IT provisioning and communication activities. Based on the feedback of stakeholders (detailed in the sections below), EUCLEF awareness through e.g. communication activities could however benefit from further efforts.

EUCLEF fulfils partly its objectives with an average of 59% of the survey respondents considering that EUCLEF fulfils all of them fully or to a high extent across all objectives (see figure below). All categories of respondent types reported similar levels of satisfaction with how well EUCLEF fulfils its objectives. In addition, the share of stakeholders deeming that EUCLEF fulfils its objectives fully or to a high extent, goes up to 78% for all interviewees

Figure 4: To what extent does EUCLEF fulfil the following objectives? N=112



More specifically, over 70% of survey respondents consider that EUCLEF fulfil its objectives in terms of:

i) being a reliable source of information on chemicals legislation (73%);

ii) facilitating the search for regulatory information on chemicals (70%); and

iii) providing relevant content on chemicals legislation (71%).

These results were corroborated by interviewees, particularly those whose work focuses on compliance with the REACH regulation (Regulation EC No 1907/2006). First, EUCLEF is perceived as useful and

helpful in facilitating the search for relevant information – specifying that companies get a good overview of the EU legislation applicable in a quick and fairly easy way (according to 7 interviewees). This is explained by the fact that all the information they need is consolidated in one place, thus limiting the necessary time to go through several pieces of EU legislation. In that sense, EUCLEF is effective in providing relevant content on chemicals legislation, and is seen as a unique initiative in Europe, in that it is the only place where companies can find comprehensive, relevant and free content on chemical legislation. In addition, because EUCLEF is hosted on the ECHA website, its results are perceived as relevant and having some degree of authority, which contributes to making EUCLEF a reliable source of information.

What benefits have stakeholders experienced from using EUCLEF?

The benefits pointed out by stakeholders can be divided into four categories. The first one relates to the fact that EUCLEF offers a one stop shop to get information on chemical substances and regulations (mentioned by 14 interviewees). In turn, this allows centralising all the necessary information stakeholders may want to access. Derived from the first benefit is the fact that EUCLEF offers a comprehensive overview of the EU legislation applicable to the substances, which is another of EUCLEF benefits (11 interviewees).

Having a search engine acting as a one stop shop and including a wide array of EU legislation in turn allows stakeholders to save time and financial resources in order to get an overview of the legislation applicable for the substances they deal with (11 interviewees). For instance, one stakeholder is considering discontinuing its subscription to another (expensive) database to rely only on EUCLEF for the future.

The last benefit refers to the access to regularly updated information on EU legislation (seven interviewees). Importantly, because the EUCLEF is hosted on the ECHA website, the information provided is considered credible and legitimate.

Though below the 70% threshold, the following objectives:

i) provide up-to-date content (60%);

ii) gives more regulatory clarity to businesses (48%);

iii) adequately covers information of interest related to the covered pieces of legislation (57%) are fulfilled to a high or very high extent for about 50% of survey respondents.

Importantly, the share of survey respondents considering these first six objectives fulfilled to some extent or better stood at over 80%. A number of interviewees also indicated that they only use EUCLEF, as the information supplied fully match their needs. While the feedback was positive, some stakeholders noted some points that could be improved over time to support the effectiveness of EUCLEF.

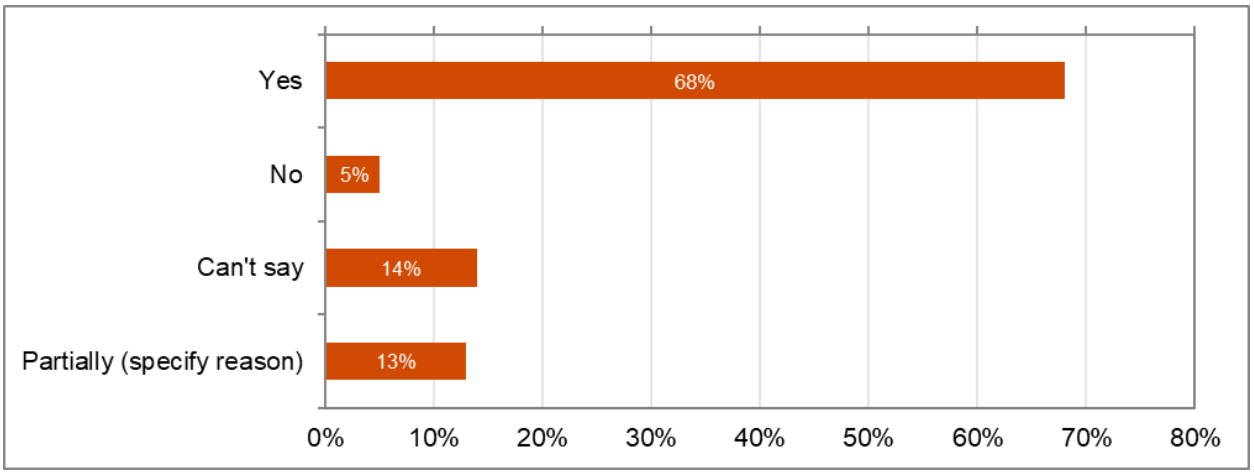
EUCLEF does not always provide complete or sufficiently in-depth information on a given substance according to six survey respondents and interviewees. The examples collected refer to regulations beyond the scope of REACH such as Food Contact Materials or Plastic Materials and Articles for which two public sector interviewees deemed the information incomplete. Likewise, when one searches for a substance contained in a given restricted chemical family or group in EUCLEF, it does not always show the REACH entry and restriction, according to three interviewees. This is explained by the fact that in some cases, regulations refer to a chemical group or family but not to the substance per se. Last, in cases where e.g. a company would manufacture products which may target or are reachable by children, the compliance requirement differ between e.g. REACH and the Toy Safety Directive. However, as the product manufactured is not a toy, the company would not be able to get the limits right by using EUCLEF.

As for the last objective on the "ease of usability by non-expert users" category, it scored the lowest with a mere 33% of survey respondents considering that it is fully fulfilled or to a high extent. This lower score is partially caused by the large part of "Can't say" answers, which stand at 16%. Among those providing qualitative data points relating to this issue, 12 survey respondents pointed out that they faced difficulties in navigating EUCLEF, which is not necessarily intuitive enough to allow stakeholders to understand where to find the information they are looking for. This refers particularly to stakeholders who do not use EUCLEF on a regular basis (more information provided in the section below).

2.2.2 Does EUCLEF help stakeholders better understand and navigate the covered pieces of legislation?

A large majority of the survey respondents (68%) stated that EUCLEF helps them in understanding and navigating the included legislation, with a further 13% agreeing "partially".

Figure 5: Does EUCLEF help you better understand and navigate the covered pieces of legislation? N=112



While this result shows that EUCLEF does help stakeholder in better understanding and navigating EU legislations, some improvements could be made to support the effectiveness of EUCLEF, according to six stakeholders:

1. Streamlining the search function
2. Making the interface more user-friendly and;
3. Simplifying the language used

Some of these aspects are further elaborated in the Section 5.1.

2.3 Utility & Use

The aim of this section is to evaluate the utility and use of EUCLEF, by examining how often respondents used it, to what extent they value its key features and how likely they are to recommend it.

Utilisation of the EUCLEF tool has increased over time and there is a high degree of user satisfaction, with most consulted users recommending it to their network. However, there is also room for improvement in raising awareness of EUCLEF throughout the EU, which can facilitate the utilisation of the tool by SMEs. A key feature for EUCLEF's usefulness is that it's free-of-charge and integrated into ECHA's database, while

the presence of a helpdesk is relatively less prominent and beneficial for users.

2.3.1 To what extent has EUCLEF been used?

Since the launch of EUCLEF in 2020, the number of users has been steadily increasing. The 2017 feasibility study for EUCLEF did not set targets for the number of users of the tool. As such, it is not possible to establish whether the tool's performance in terms of number of users is satisfactory or not, but the available website statistics show that the number of average page views for EUCLEF has increased substantially. While the average number of page views in 2020 stood at 955, in 2021 it had increased to 1371 (44% YoY growth).[5] In the same period, the average page views for the ECHA website had increased by 7% from 2019 to 2021. In terms of the overall number of users who visited the landing page of EUCLEF in EU member states in 2020 and 2021 shows a clear growth, as the number of visitors for the recorded period of 2021 was already at 77% of the number for 2020[6], despite the significantly shorter timeframe.

Data on the geographical location of users shows that most users are EU-based, but there is substantial interest in users located in third countries. Specifically, the numbers stood at 37,000 and 28,500 unique visitors from EU member states for 2020 and 2021 respectively[7]. These numbers represent 68% of the overall visitors globally in 2020 and 66% of them in 2021, signifying that EUCLEF is expanding slightly faster in non-EU states than it is in EU ones. Looking at the difference in number of users from each Member State between 2020 and 2021, there appears to be an expected correlation between this and the number of SMEs established in the country – when comparing data on the share of SMEs at regional level (Western, Southern and Central and Eastern Europe) compared to the total for the EU, the share of EUCLEF follows a similar distribution (34%, 45% and 21% respectively)[8].

Table 1: Top 10 countries by share of EUCLEF users 2020 and 2021 (page views of landing page)[9]

2020				2021			
Country	**Page Views**	**Users**	**Share of total users**	**Country**	**Page Views**	**Users**	**Share of total users**
Germany	12161	5891	11%	**Italy**	9347	3896	9%
Italy	11957	5716	11%	**United Kingdom**	6008	3847	9%
France	9245	4316	8%	**Germany**	7137	3061	7%
Spain	6649	3704	7%	**Romania**	7595	2979	7%
United States	5016	3266	6%	**Greece**	8398	2603	6%
Belgium	4025	2362	4%	**Spain**	4763	2357	5%
Netherlands	5454	2246	4%	**India**	3241	2275	5%
Japan	5045	2158	4%	**France**	4829	2095	5%
United Kingdom	3791	2071	4%	**United States**	2914	1899	4%
Portugal	2537	1721	3%	**Ireland**	2799	1866	4%

In order to put these results into perspective, the evaluation looked for information on the geographical

[5] Data provided by ECHA as part of the statistics on the usage of EUCLEF.
[6] Data provided by ECHA as part of the statistics on the usage of EUCLEF.
[7] Data provided by ECHA as part of the statistics on the usage of EUCLEF.
[8] PwC estimates based on Eurostat data on number of SMEs per EU MS in 2018 (last year available at the time of preparing this report)
[9] Data provided by ECHA as part of the statistics on the usage of EUCLEF.

trends in the use of two other databases maintained by EU Agencies – OpenFoodTox (run by EFSA) and the medicines database run by EMA. Website statistics by country of the user are not available in either of the two cases and the agency experts in charge of these databases consulted for the purpose of this review were not aware of any geographical trends in the use of their tools.

The evaluation also considered the experience with the OECD-hosted eChemPortal, which has an international focus and provides information/links to chemical hazard and risk information. eChemPortal was first launched as a prototype in 2007 and since then has been steadily growing its user base – by 2020, there were approximately 15,000 monthly users and 700,000 searches for the whole year[10]. The geographical trends mainly reflect the degree of industrialisation of the economy, with the top countries where users are based including the US, Germany, Japan, France, Italy, China, India and Canada. The OECD carries out dedicated communication activities to raise awareness of the portal – via the OECD Chemicals Programme newsletter and via dedicated webinars (sometimes in cooperation with stakeholder organisation) which target a global audience or selected countries.

While the number of users is growing, there is room for raising further awareness of EUCLEF. The question of whether there is sufficient awareness of EUCLEF was explored with some of the stakeholders consulted via interview. Respondents from different countries (Belgium (3), Germany (3), Italy (2), Spain (1), Ireland (1), Hungary (1) and Romania (1)) considered that there is room for increasing awareness among SMEs and there were concrete suggestions on how to do that. The most common one (3 respondents) was to make EUCLEF more visible on the ECHA website itself. These individuals pointed out that the homepage of the website has no mention of EUCLEF and recommended that some information about it, and possibly a logo, banner or icon, be included in a central and visible space on the homepage. Two other suggestions, expressed by 2 separate interviewees each, were to promote EUCLEF through national authorities or through company channels. Suggestions for the latter, in particular, included messaging companies directly to familiarise them with EUCLEF and ask them to promote it internally, as well as distributing short leaflets in the local language in physical form which give key information on EUCLEF, its uses and its benefits, specifically in order to reach companies which do not follow the ECHA newsletter regularly and in details. Another recommendation expressed by two respondents was to target promotion better and aim it at those who would benefit the most from it and who are least likely to find it be other means. Here, ECHA could consider the experience from the OECD eCHEM portal described above, which suggests that direct communication through webinars promoted among target users and leveraging on stakeholder organisations' contacts could be relevant means of raising awareness. One interviewee also suggested more promotion on social networks. They felt that ECHA is very active, for example, on Twitter but rarely if ever tweets about EUCLEF.

Box 1: EUCLEF communication activities 2018-2021

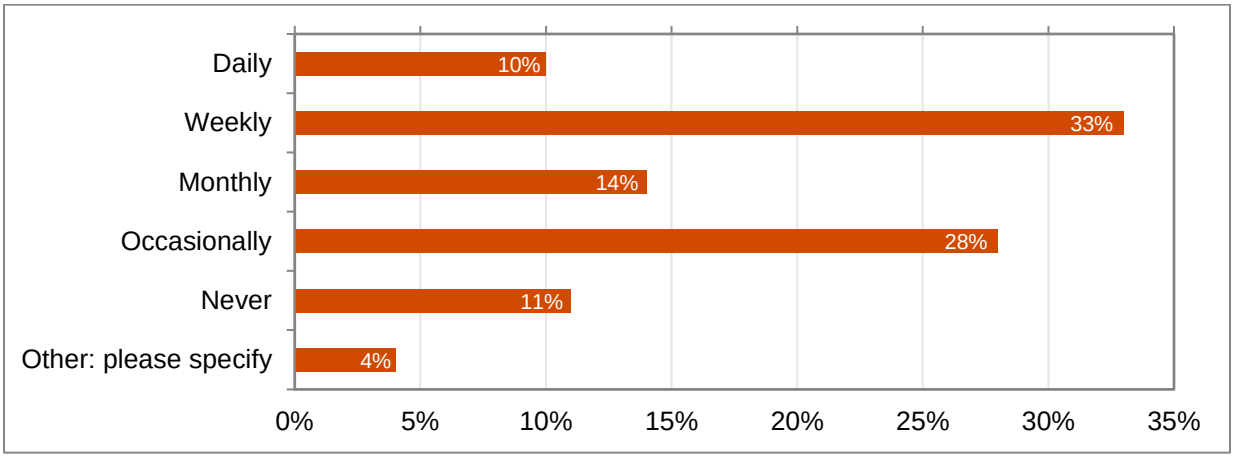
An analysis of the communication plan for EUCLEF shows that ECHA has implemented a number of communication activities aiming to raise awareness among the different stakeholder groups for the tool, with most scheduled for 2020 (dedicated events, presentation at conferences, social media promotion, etc.) and only one dedicated activity planned for 2021 – in the context of ECHA's conference.

	2018	2019	2020	2021
Number of communication activities	2	1	19	4

[10] Data provided by the OECD in the context of an interview carried out on August 27, 2021.

Another relevant indicator of the use of EUCLEF is the frequency with which users access it. According to the qualitative data gathered through the survey, the majority of users visit the EUCLEF website once per month or more often, with 33% identifying as weekly users and 10% as daily. The percentage of respondents who were aware of EUCLEF but did not use it is very low, signifying that the platform is indeed useful.

Figure 6: On average, how often do you visit EUCLEF? N=121[11]



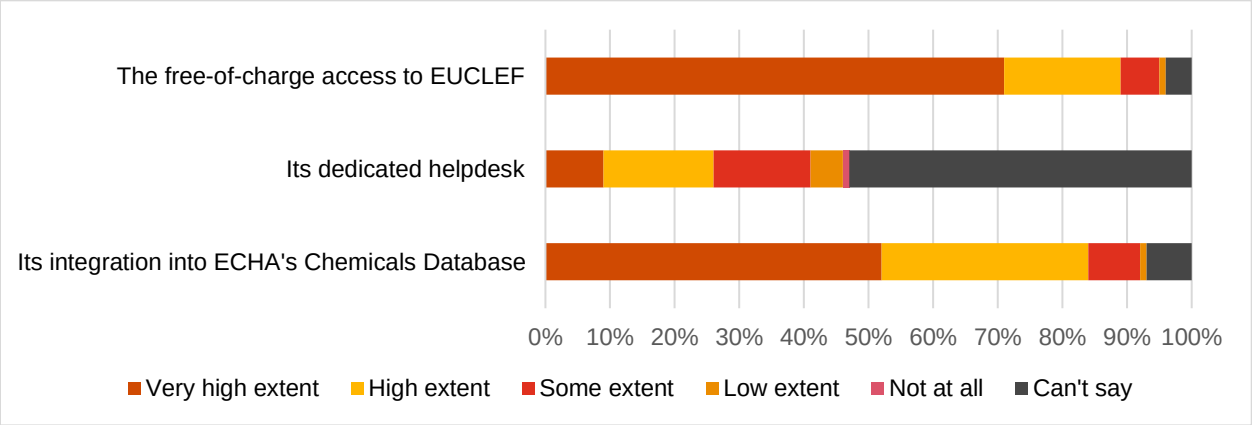
2.3.2 To what extent are EUCLEF's features useful to users?

The evaluation also considered the utility of some of the key features of EUCLEF – its free-of-charge access model, its dedicated helpdesk and the fact that it's integrated into the ECHA Chemical Database.

The free-of-charge access to EUCLEF is a key factor for its usefulness for the targeted users. The survey results unquestionably show that users greatly appreciate EUCLEF being free of charge, with more than 70% of respondents stating that this feature makes EUCLEF useful "to a very high extent" and an additional 18% answering "to a high extent". The integration into ECHA's chemical database was also scored highly, with 52% appreciating it to "very high extent" and 32% - to a "high extent". Respondents views on the dedicated helpdesk were substantially different. The majority (53%) did not have any opinion on the usefulness of this feature, while the other responses were much more evenly distributed between the "very high", "high", "some" and "low" extent answers. Only one user responded that the dedicated helpdesk was "not at all" useful.

[11] 121 respondents began the survey but only 112 completed it. 9 decided to leave after question 9, which was: *EUCLEF is an online service that gives you information on how your chemicals are regulated across the EU. It is funded by COSME (Europe's Programme for Small and Medium-sized Enterprises). Please familiarise yourself with EUCLEF by exploring it here before proceeding with the survey.*

Figure 7: To what extent do the following features of EUCLEF make it useful for you? N=112



The interviews confirmed the positive outlook of respondents towards the free-to-use model of EUCLEF and provided more insight into their reasoning. This feature of EUCLEF was universally praised, as virtually every respondent underlined that the free access is of great benefit to all users. Two interviewees specifically mentioned its importance within the context of EUCLEF's main target audience, SMEs, which often have more difficulties affording additional consultancy services.

There is also strong appreciation of EUCLEF's integration in ECHA website. The majority of interviewees valued the efficiency provided by having a single source of information for their questions regarding regulation of chemicals. In addition to that, two respondents expressed that integrating EUCLEF within the ECHA platform gives the former more credibility. At the same time, this integration in ECHA website should not be done at the expense of EUCLEF visibility, according to two interviewees, who wish to have EUCLEF displayed more prominently on ECHA website.

The usefulness of the helpdesk function is lower compared to the other defining features of EUCLEF. Based on the collected data, its lower scoring can be linked to lack of awareness/familiarity with it. The vast majority of users interviewed for the purpose of the review were not aware that the dedicated helpdesk exists. Throughout all user interviews, including users who reported spending a significant amount of time daily using EUCLEF, there was only a single individual who was familiar with and had used the dedicated helpdesk. Four users reported having heard of the helpdesk but never having used it. Usage statistics reflect the same trend, as the number of help requests made towards the helpdesk stood at just 50 in 2020 and 19 in 2021 for the period captured by the available data, as depicted in Table 2. As such, the number of requests is significantly below the estimate of an average of 100 requests per day provided in the EUCLEF Feasibility study. That being said, the interviewees were generally interested in the feature upon hearing about it, with multiple respondents saying that they would explore and potentially use it in the future. A single interviewee, from the European Commission, had a negative opinion on the need for a dedicated helpdesk. Their justification was that a complete database shouldn't need a helpdesk and that keeping a helpdesk operation is more resource-intensive than improving the completeness of the database and the ease of searching within it.

Table 2: Helpdesk requests submitted in 2020-2021[12]

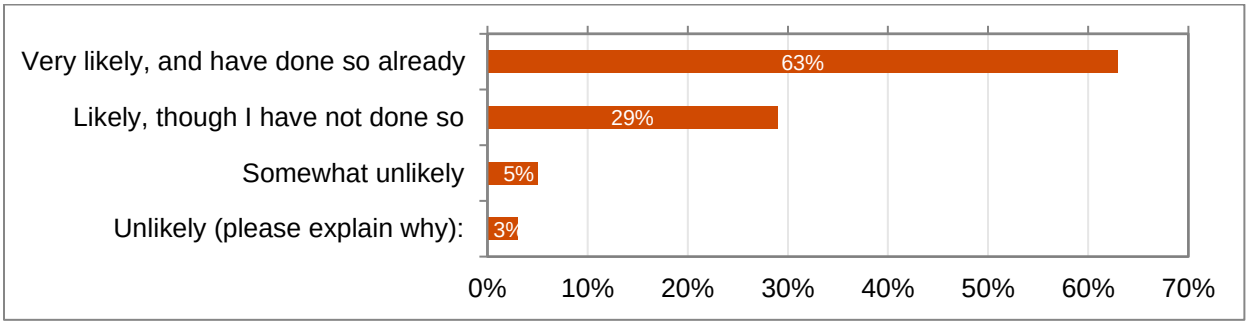
Year	Request type			Total
	Chemical information published on ECHA	Regulatory advice	Technical support	
2020	32	10	8	50
2021	11	3	5	19

These features of EUCLEF were also considered in the context of other EU-level tools provided by EU Agencies – OpenFoodTox (EFSA) and the EMA Medicines Database.[13] Both are free of charge, but can be considered as standalone tools run by the Agencies. An important difference is the absence of a dedicated helpdesk. Since those tools are related to specific legislations under both Agencies' remit, questions from users are handled by the agencies through their general channels for receiving queries from stakeholders and if of scientific nature – by the agencies inhouse experts. According to consulted representatives of the two agencies, the number of questions received is fairly limited and does not represent a substantial burden.

2.3.3 How likely are stakeholders to recommend EUCLEF?

Based on stakeholders' willingness to recommend EUCLEF to their network, the tool can be considered to provide a high degree of utility. According to the survey results, stakeholders are overall extremely likely (92%) to recommend EUCLEF and a large majority of them (62.5%) have already done so. Of the 3 individuals who stated that they are unlikely to recommend EUCLEF, all 3 noted that this is because they were not familiar with the service at the time of answering the survey; their responses did not represent a discontent with EUCLEF. Of the 6 respondents who reported they were "somewhat unlikely" to recommend the service, none provided any explanation for their reasoning. Their common characteristic was that they were all infrequent users of EUCLEF, with all but one stating that they use the service less than once per month.

Figure 8: How likely are you to recommend EUCLEF? N=112



[12] PwC based on data provided by ECHA

[13] See Annex 2 for more details. The analysis will include information about the OECD eCHEM portal should it be possible to arrange an interview with a representative before the finalisation of this report.

2.4 EU Added Value

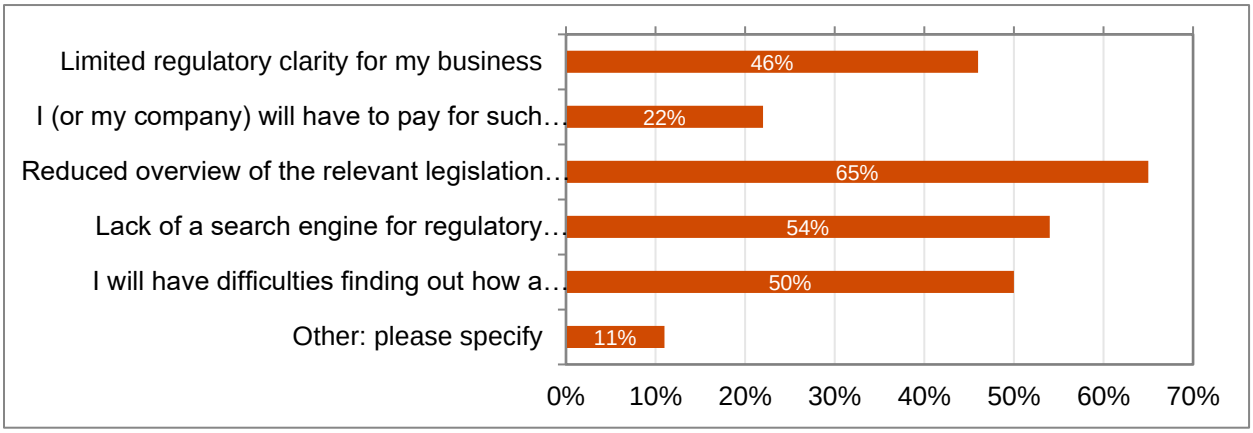
This section aims to assess the added value of EUCLEF by looking at what impacts its discontinuation, or that of its helpdesk, would have on users.

EUCLEF can be considered to deliver high EU Added Value, with the consensus among consulted stakeholders being that its hypothetical discontinuation would have significant negative consequences. While most would be able to obtain information from other sources, this will be less time and resource efficient and entail increased financial costs for paid services. The impact of discontinuing the helpdesk would be much smaller, mostly due to lack of awareness of its existence and therefore low number of current users.

2.4.1 What would be the most likely consequences if EUCLEF was discontinued?

The potential negative consequences for users should EUCLEF be discontinued are high, indicating the added value of the tool. To assess the added value of EUCLEF, we consider the hypothetical alternative of stakeholder experience in its absence. According to the survey results, virtually every single respondent would experience negative consequences if the EUCLEF service was discontinued, with the majority reporting more than one probable issue. By far the most commonly reported drawback of a potential discontinuation was a reduced overview of the relevant legislation for a given substance, expressed by two thirds of the respondents. Three other negative consequences were also frequently expressed, by around half of the respondents each. Namely, these were the lack of a search engine for regulatory information on chemicals (54%), having difficulties finding out how a substance is regulated in the EU (50%), and ensuing consequence of limited regulatory clarity for the business in question (46%). The final given answer, having to pay for similar services, was markedly less frequent – only 22% of respondents expressed such a fear. The open answers added two additional concerns, namely - loss of time or efficiency (4 respondents) and loss of certainty in the found information (2 respondents).

Figure 9: What would be the most likely consequences if the EUCLEF was discontinued? N=112



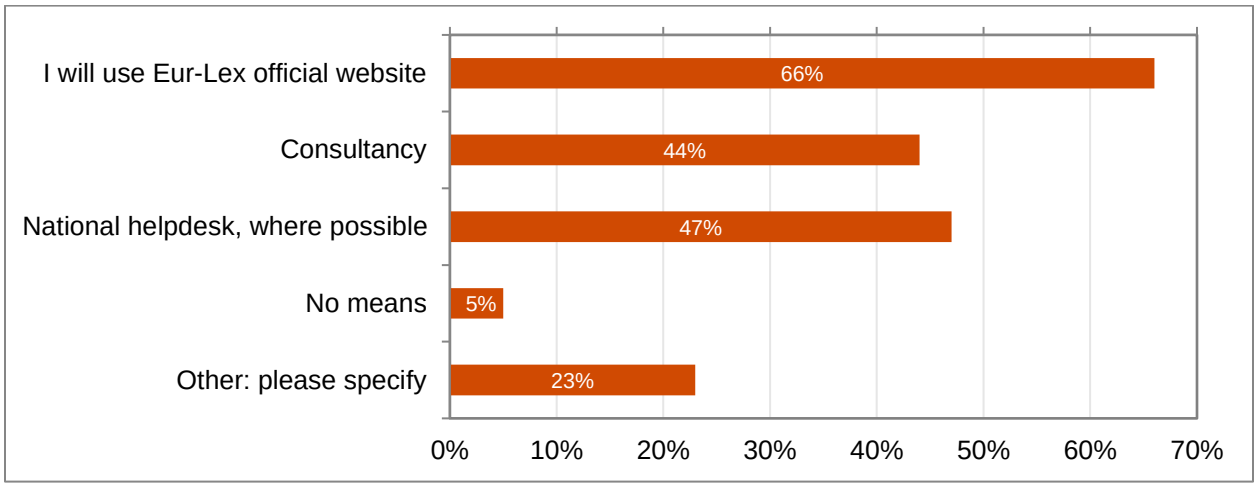
Qualitative data from the interviews shows a similar picture in terms of the overall discontent with the possibility of discontinuing the EUCLEF service, with practically every respondent expressing some kind of negative impact that this would have on their work. The most common concern expressed by the interviewees was that searching for the same information would require a lot more effort without EUCLEF (18 respondents) and that it would become more time consuming due to having to look at different sources (10). The other major concern, expressed by 8 individuals, was that without this platform they would have

to turn to paid services. This was specifically underlined by some respondents as problematic for SMEs, which might have more difficulties affording such services.

2.4.2 If EUCLEF is discontinued, how do stakeholders plan to obtain information about the EU chemicals pieces of legislation, how substances are being regulated and/or their legal obligations?

The stakeholders consulted were also prompted to identify alternatives sources of information should EUCLEF be discontinued. While both the survey and interview respondents generally agree that discontinuing the EUCLEF service would make obtaining their necessary information more difficult, almost all of them also had back-up sources to rely on with only 5% not being able to identify alternative means of obtaining information.

Figure 10: If the EUCLEF service is discontinued, how do you plan to obtain information about the EU chemicals pieces of legislation, how your substances are being regulated and/or your legal obligations? N=112



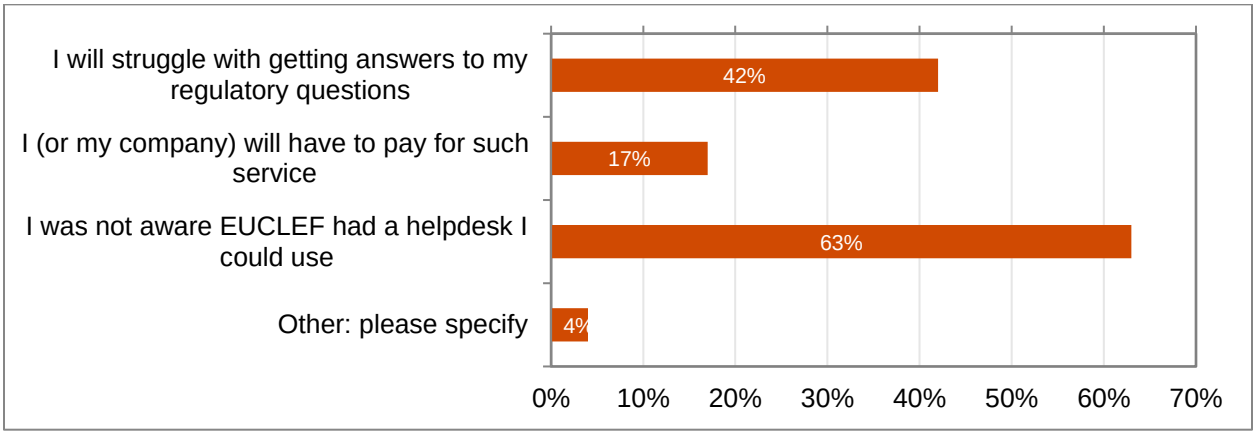
The most popular one, both in the survey (66%) and the interviews (13 respondents) was EUR-Lex. While many stakeholders would rely on it as a source of information, some interviewees underlined its drawbacks in terms of increased time and effort necessary to find the relevant information, when compared to the EUCLEF service. Another major source of information, expressed frequently by respondents in both the survey (44%) and interviews (7) as a potential alternative to EUCLEF, was that of paid consultancy services. Once again, while stakeholders acknowledged this option, during the interviews they expressed their dissatisfaction with the potential related costs. The third alternative channel included in the survey responses – national helpdesks – was expressed as a possible alternative by almost half (47%) of the respondents, although, it was not very often mentioned by the interviewees (3 respondents). Survey participants also frequently stated that they would use non-listed alternatives, most notably simply searching the web, expressed by 10 survey respondents. This type of alternative was also mentioned by interviewees – 3 of them stated that they would incorporate simple Google searches into their routine for finding information, while 4 would rely on a combination of alternative search engines, websites and services. Three interviewees would also rely on the ECHA website and database.

The absence of fully comparable sources of data was also confirmed by an interviewed representative of the OECD who noted that the organisation identified the absence of free regulatory data tool in the process of developing the eChemPortal and noted the added value of EUCLEF in addressing such a gap.

2.4.3 What would be the most likely consequences if the EUCLEF helpdesk was discontinued?

The added value of the helpdesk function is lower, due to the low level of awareness and utilisation of it so far. The helpdesk was envisioned in the feasibility study as a service which would address an average of around 100 requests, business and technical, per day[14]. However, the qualitative data points from both the survey and the interviews point towards a considerable majority of the users not knowing about this feature. Close to two thirds of survey respondents were not aware of the helpdesk's existence, alongside a large number of the interviewed individuals (22). A significant number of interviewees (9) were indifferent towards this feature, stating that a helpdesk is not necessary for EUCLEF. What is more, two interviewees stated that they found out about the helpdesk from the survey and wanted to explore it. However, they were not able to find the helpdesk on the website, signifying the presence of a potential issue with the visibility of the service.

Figure 11: What would be the most likely consequences if the EUCLEF helpdesk was discontinued? N=112



In terms of consequences of the potential discontinuation of the helpdesk, a significant group of survey respondents (42%) expressed a concern for having their regulatory questions answered while a smaller group (17%) feared they would have to pay for similar services. The interviewees reported much lower levels of concern over the discontinuation of the helpdesk. Two interviewees also responded that while they appreciate the existence of a helpdesk in principle, they don't see it as vital for the platform. Overall, interviewees were not particularly concerned about the possibility of discontinuing the EUCLEF helpdesk, although this may be linked to their lack of knowledge and experience with the feature. A potential promotional campaign and increase of the helpdesk's visibility on the website (through a change of its placement and/or sizing) could result in a much more used and useful helpdesk, more similar to the one outlined in EUCLEF's original feasibility study.

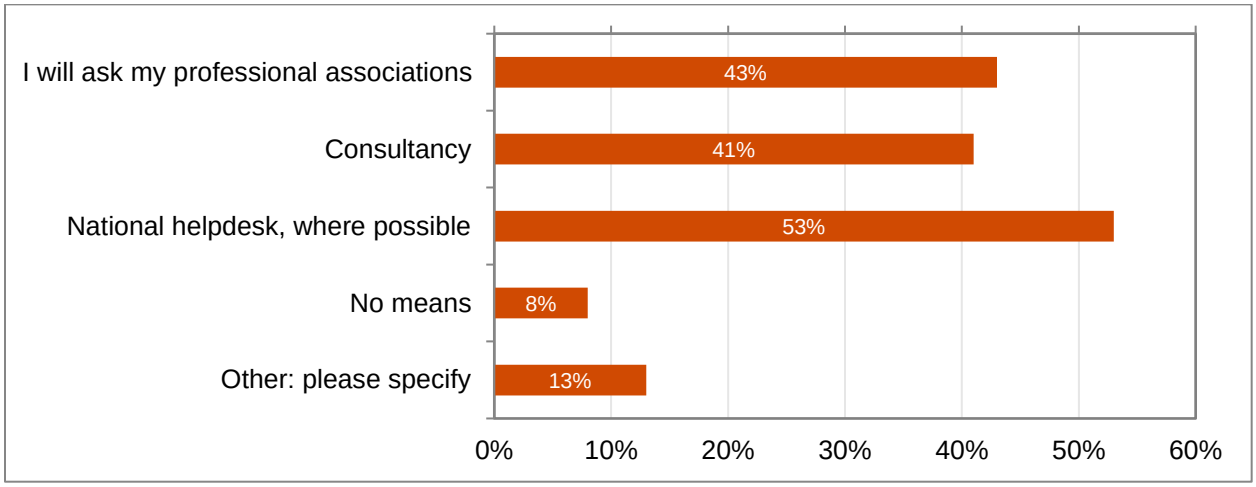
2.4.4 If the EUCLEF helpdesk is discontinued, how do stakeholders plan to get answers to their regulatory questions?

While a majority of both the survey and interview respondents were not aware of the existence of the EUCLEF helpdesk, several potential alternative sources of support can be considered. The three possible

[14] *Feasibility study on a European Chemicals Legislation Finder (EUCLEF) Final Report No.4*, 6.Nov.2017, p.25

alternatives given in the surveys had similar levels of popularity, with national helpdesks being the most widely chosen one (53%), while professional associations and consultant services were favoured by slightly fewer respondents, at 43% and 41% respectively. A small group (13%) also expressed that they would use other solutions, most notably simply performing web searches to answer their questions, or consulting colleagues within their company or organisation. Interviewees did not offer many alternatives to the EUCLEF helpdesk, mostly because they were largely unaware of the service itself. Still, two of them stated that they would use the ECHA service as a substitute, while one interviewee suggested that the EUCLEF helpdesk could be integrated within the Europe Direct Contact Centre.

Figure 12: If the EUCLEF helpdesk is discontinued, how do you plan to get answers to your regulatory questions? N=112



3 What is the potential for increasing EUCLEF's scope?

There is strong support for the inclusion of additional pieces of EU legislation in the scope of EUCLEF, which would strengthen its role as a one-stop shop for SMEs in need of information on chemicals regulation. Examples of relevant legal acts to include have been identified, but there was not overwhelming support for any particular one due to the limitations of the method of data collection, more specifically due to the fact that, in order to ensure the objectivity of the feedback, respondents were asked to suggest relevant acts based on their own individual interests and not to assess the need for including specific legislations based on a list of legislations provided to them. There is also support and arguments in favour of the inclusion of national-level legislation, but stakeholders acknowledge that this would be very resource-demanding.

3.1 What are the pieces of EU legislation that EUCLEF is missing and that can bring value for its comprehensiveness and usefulness?

Many legal acts from different subject areas could be considered for inclusion in EUCLEF. The tool currently includes information about substances from 56 pieces of EU legislation which focus on industry obligations. Defined in the feasibility study, these pieces of legislation were selected among 266 pieces of legislation considered and reflect the feedback from consulted stakeholders. Further legal acts have emerged from the consultations carried out for this report as well as through research on recent policy developments at EU level.

The majority of stakeholders consulted for the purpose of this review are in favour of the expansion of the scope of EUCLEF with additional pieces of EU legislation. The survey results showed that 75% of all respondents would like EUCLEF to include as many pieces of legislation as possible (see Figure 14). As for the interviews, 59% of all interviewed stakeholders were also in favour.

The additional legislation suggested by stakeholders covers a wide variety of areas and different categories of legislation. A total of 24 specific legislative acts were suggested by stakeholders, with multiple respondents referring specifically to the Regulation on explosive precursors[15] (7 respondents), the Drinking water Directive[16] (5), the F-gases regulation[17] (3) and the Regulation on drug precursors[18] (3), to name a few. A complete list of the specific legislative acts suggested by stakeholders is available in Annex 1.

The legislation (sub-)areas mentioned by respondents reflect also the strongest interest for

[15] Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

[16] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast)

[17] Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006

[18] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors

inclusion of specific legislative acts in EUCLEF. The mentioned areas of EU legislation of potential relevance for EUCLEF include: transport, customs, exports, food and food contacts legislations as well as environment and medical related legislation. Interest was indicated also around legislation related to cosmetics, toys, detergents, feed, packaging, pyrotechnics, construction and others.

Half of the specific legislative acts (12) suggested by the consulted stakeholders for inclusion in EUCLEF are actually already in the scope of the tool. The REACH regulation[19] has been mentioned by 2 respondents to be included in the tool while it is already in the scope of the later. For the 11 other legislative acts, their inclusion has only been raised by a single respondent. A similar trend can be found among the (sub-)areas mentioned by stakeholders as being of interest for inclusion, where more than half (19 out of 32) are already in the scope of the tool[20]. These results could be explained by lack of familiarity among some stakeholders of the full scope of legislation already covered or by possible difficulties some users are experiencing in finding/accessing an overview of the legislation currently in scope.

Recent EU-level strategic documents also provide an indication of which additional legislation can be included in the scope of EUCLEF, such as the EC's Chemicals Strategy for Sustainability Towards a ToxicFree Environment and Action Plan[21], the Commission Communications "A new industrial strategy for Europe"[22] and "A new Circular Economy Action Plan For a cleaner and more competitive Europe"[23]. From the analysis of 2 strategies[24], 2 communications[25], 1 database[26] and 1 Handbook[27], 66 legal acts could be considered for inclusion in EUCLEF – see Annex 1 for more details. Among the 12 legislative acts mentioned by respondents and already in the scope of EUCLEF, 6 of them[28] are also mentioned in the reviewed EU strategic documents.

The comparison of acts in the scope of strategic documents and those mentioned by stakeholders

---

[19] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

[20] See Annex 2.

[21] Communication from the Commission to the European Parliament, the Council, the European Economic And Social Committee And the Committee Of the Regions Chemicals Strategy For Sustainability Towards A Toxic-Free Environment, COM(2020) 667, 14.10.2020.

[22] Communication From The Commission, A New Industrial Strategy for Europe, COM(2020) 102, 10.3.2020

[23] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan. For a cleaner and more competitive Europe, COM(2020) 98, 11.3.2020

[24] EC's Chemicals Strategy for Sustainability Towards a ToxicFree Environment and Action Plan;
European Digital Strategy

[25] Communication From The Commission, A New Industrial Strategy for Europe, COM(2020) 102, 10.3.2020; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan. For a cleaner and more competitive Europe, COM(2020) 98, 11.3.2020

[26] Risctox database, available here: https://risctox.istas.net/en/

[27] Export Control Handbook for Chemicals (2021 edition)

[28] The legislative acts mentioned are:

- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Text with EEA relevance)
- Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste
- Regulation (EU) No 649/2012 of the European Parliament and the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast)
- 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
- 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
- Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast)

provides a preliminary indication of the legal acts to consider as priority for inclusion in the scope of EUCLEF. The evaluation team cross checked which legal acts are mentioned by both stakeholders and EU policy makers in the context of the documents reviewed. It appeared that 4 have been mentioned by both stakeholders through the survey and interviews and the EU strategic documents, therefore taking them into account as candidate for insertion. The legal acts covered by both are summarised in the following table:

Table 3: EU legal acts suggested for inclusion in EUCLEF and which are also included in to consider for inclusion in EUCLEF

EU legal act	EU strategic document in which it is mentioned
Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013	Export Control Handbook for Chemicals; also references to 1907/2006, i.e. REACH
Annex I of Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011	EC's Chemicals Strategy for Sustainability Towards a ToxicFree Environment and Action Plan (reference to 2019/1020); Commission Communication: A new Circular Economy Action Plan For a cleaner and more competitive Europe (reference to 305/2011)
Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003[29]	EC's Chemicals Strategy for Sustainability Towards a ToxicFree Environment and Action Plan (reference to 1107/2009)

Building upon these first observations, a prioritisation of the legal acts to be inserted in the tool has been conducted based on several criteria associated with a point system. This analysis focused solely on the legal acts that have been proposed for insertion in the tool by stakeholders through the interview and/or the survey and which are not yet included into EUCLEF.

Table 4: Criteria and point system used for prioritisation of the legal acts to be inserted in EUCLEF

Criteria	Sub-criteria	Point attributed to that legal act
Inclusion in the scope of EU strategic documents	Included in one document	1 point
	Included in 2 documents	2 points
Number of time respondents have mentioned a specific legislation through the interview and/or survey as well	Mentioned by 1 respondent	1 point
	Mentioned by 2 respondents	2 points
	Mentioned by 3 or more respondents	3 points

[29] On EUCLEF's landing page, on Regulation (EC) No 2003/2003 (i.e., Fertilisers Regulation), an informative message is included highlighting that such Regulation has been repealed by Regulation 2019/1009, that will enter into force on 16 July 2022.

Number of time users have suggested the area of the legislation for inclusion	Mentioned by 1 respondent	1 point
	Mentioned by 2 respondents	2 points
	Mentioned by 3 respondents	3 points

Besides these criteria, an analysis has been conducted based on the number of SMEs which could have a potential interest in the insertion of those legal acts. It has been observed that the legal acts suggested for inclusion impacted 3 groups of SMEs: the accommodation and food services sector, the manufacturing sector or all sectors (in case of cross-sectoral legal acts). A point system has then been developed based on the number of SMEs possibly concerned by those legal acts, the highest the number of SMEs being possibly impacted, the more point being attributed.

Table 5: Criteria and point system used for prioritisation of the legal acts to be inserted in EUCLEF

Sector	Number of SMEs (EU27, 2020)[30]	Point attributed to that legal act
The accommodation and food services sector	1682509 SMEs	1 point
The manufacturing sector	1963336 SMEs	2 points
All sectors	22526457 SMEs	3 points

The results of this prioritisation exercise are presented in the following table.

[30] Numbers are from the SME Performance Review (available here https://ec.europa.eu/growth/smes/sme-strategy/performance-review_en#sba-fact-sheets) and more specifically from the Country SME key figures (see tab 3 – sectoral distribution)

Table 6 : Prioritisation of the legal acts to be included in EUCLEF

EU legislative acts		Presence in strategic EU documents	User suggestions for inclusion		Area for inclusion suggested by the user under which this legal act is falling	Sector that would be concerned by this legislation (numbers taken from SME performance review - see next tab)		Total count
1.	Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013	**1**	**3**	Chemical weapons	**2**	Manufacturing	**2**	**8**
2.	Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006		**3**	Ozone depleting substances	**1**	All sectors	**3**	**7**
2	Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors		**3**	Drugs	**2**	Manufacturing	**2**	**7**
2.	Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast)		**3**	Food	**3**	Accommodation and food services	**1**	**7**
3.	Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC		**2**	Hazardous substances	**1**	All sectors	**3**	**6**
3.	Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer		**2**	Ozone depleting substances	**1**	All sectors	**3**	**6**

	EU legislative acts	Presence in strategic EU documents	User suggestions for inclusion		Area for inclusion suggested by the user under which this legal act is falling	Sector that would be concerned by this legislation (numbers taken from SME performance review - see next tab)		Total count
4.	Directive 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC		**2**			All sectors	**3**	**5**
4.	Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast)		**2**	Exports	**1**	Manufacturing	**2**	**5**
4.	Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003	**1**	**1**	Fertilisers	**1**	Manufacturing	**2**	**5**
4.	Commission Implementing Regulation (EU) 2020/1771 of 26 November 2020 approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4		**1**	Environment	**2**	Manufacturing	**2**	**5**
5.	Annex I of Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011	**2**	**1**			All sectors	**3**	**4**

The limitations of this analysis should be taken into account for any further steps to expand EUCLEF. The analysis does not reflect any scientific judgement on the relevance of including the legal acts highlighted by stakeholders. A limitation of the evaluation is that it has not been possible to establish a more detailed comparison of the relevance, added value or impact of including these particular legal acts in the scope of EUCLEF – the data collected did not point to overwhelming support for any particular legal act, which can partly be explained by the fact that the consulted stakeholders were left to suggest relevant acts based on their own individual interests and not to assess the need for including specific legislations based on a pre-selected list of legislative acts they can comprehensively assess/rank in terms of relevance and impact.[31] Additionally, the distribution by sectors used for evaluating the potential reach of the inclusion of a specific legal act in the scope of the tool is rather broad and does not provide a more specific classification by sector. Therefore, only 2 groups encompassing a large variety of SMEs could be potentially interested by the insertion of some of the legal acts mentioned: the accommodation and food sector and the manufacturing sector, while the rest would be cross-sectoral in scope. For example, while the regulation on explosive precursors might only be of interest for the defence industry, the later falls under the broader category of manufacturing sector and therefore the legal act in that regards collects 2 points in the prioritisation exercise while it is a rather specific industry with potentially low concentration of SMEs and therefore a legal act of potentially lower interest many users of the tool.

Building upon the suggestions provided by the respondents through the survey and interviews, further consultations with stakeholders at EU and national level, including with the Commission and scientific experts, may be needed to establish more robustly the priorities in including other areas of legislation or specific acts in EUCLEF. Introducing sound governance arrangements around the expansion will be beneficial for the relevance of the prioritisation of resources and support buy-in from key stakeholders.

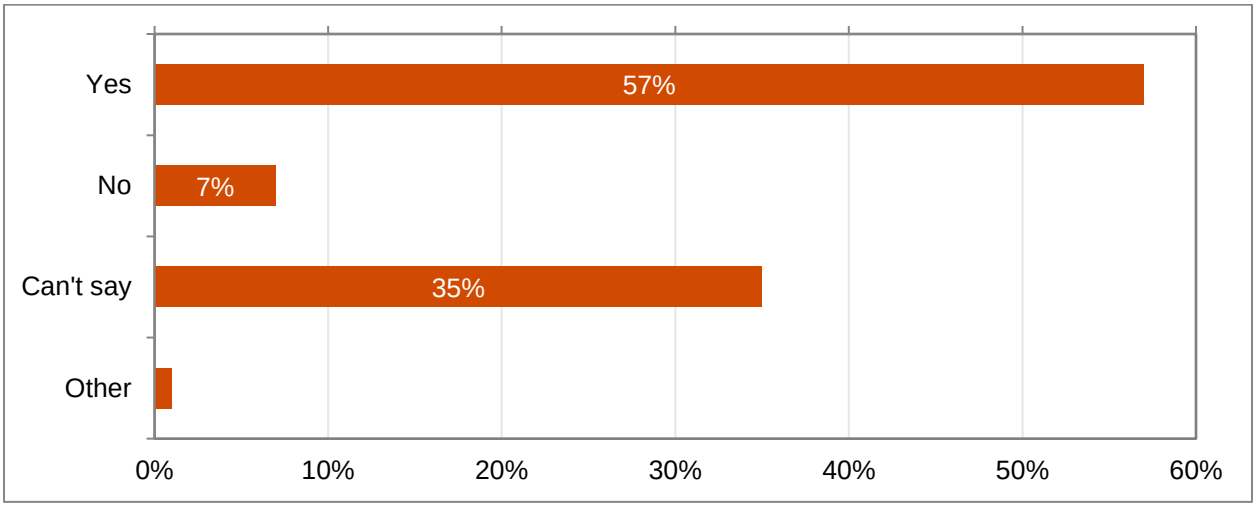
3.2 Should EUCLEF be expanded to cover relevant EU Member States (national) pieces of legislation?

The inclusion of national legislation in EUCLEF has been considered in the initial feasibility study prepared by TRASYS International for ECHA. The EUCLEF feasibility study found that companies are faced with a number of challenges when looking for/accessing comprehensive and reliable information on the latest legislation developments at national level. The study found that access to important national chemical legislation is inconsistent and cannot be retrieved with one identifier such as the CAS number, making it difficult for companies to find national chemical legislation. The feasibility study also noted that while the first priority for EUCLEF is EU legislation of industry relevance, the second should be national occupational health and safety legislation of industry relevance and then legislation of national relevance (reporting and monitoring).

[31] This was done in order to avoid introducing bias in the options put forward.

The stakeholder consultation carried out for the purpose of this report shows that there is support for the expansion of EUCLEF to legislation at EU Member States' national level, especially among industry stakeholders. The survey results show that a majority of the 112 respondents state that they would like them to be added to the EUCLEF platform, at 57%. It should be noted that those who strictly oppose such an expansion are very few, 7%, while there is a significant percentage of respondents who do not have a specific opinion on the topic - 35%. Looking at the 51 open text answers provided by respondents as elaboration for this question, a large majority of those who responded with "yes" (36 out of 44) talked around the benefits of having EUCLEF serve as a single source of information for all relevant legislation, both in terms of the substantial time saving from searching through alternative sources and also in terms of using a trustworthy channel to supply this information. Other benefits mentioned included that of overcoming language barriers which are typically a big issue when researching other national regulations. From the 6 open answers of individuals who don't view this expansion as necessary, 4 stated that alternative channels already exist for such information, such as national helpdesks or authorities, while 2 replied that including this information on EUCLEF would make the website too cluttered.

Figure 13: In your opinion, should EUCLEF be expanded to cover relevant legislation at national (EU Member State) level? N=112



Most of the interviewed stakeholders (70%) were also in favour of the expansion of EUCLEF to cover relevant EU Member States pieces of legislation. Indeed, as EU law is composed of many directives setting out goals that all EU countries must achieve, it remains in the hands of the countries themselves to set up their own laws on how to reach these goals, therefore leading to national specificities and sometimes stricter rules at national levels. Respondents therefore consider that expanding EUCLEF to national legislation would ensure consistency and comprehensiveness of the tool and provide a one-stop shop for EU businesses gathering all the legislative requirements applicable to their business, rendering internal trade easier. Some respondents (3) representing companies have more specifically raised the fact that it would provide them support for the preparation of safety data sheets, the authorisations and the fulfilment of necessary administrative requirements.

The specific examples of relevant national legislation to include cover several different areas which were also considered as part of the feasibility study. Respondents (8) have especially highlighted the added value of the insertion of national legal acts concerning occupational exposure limits. National legislations on food contact, packaging and cosmetics have also been mostly mentioned as categories of interest for inclusion in EUCLEF. Some specific national legislations have also been pointed out such as the German Technical Rules for Hazardous Substances (TRGS) and the French legislation on

Environmentally Protected Facility (ICPE). For some categories of legislation, respondents also indicated specific legislation at country level for which they would have an interest in having EUCLEF include additional legal acts, for example Italian legislation for food contact or French and Portuguese legislation for packaging.

There is also some support for inclusion of non-EU national legislation. This was suggested by 11 interviewees who saw a benefit in EUCLEF including information regarding non-EU jurisdictions like the US, UK, Switzerland, Korea and Japan as well as international treaties and conventions from which the EU legislation derives. For example, the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) is based on the United Nations' Globally Harmonised System (GHS).

Stakeholder acknowledge the challenge of integrating national level legislation in EUCLEF. Both survey and interview respondents reflected on the challenges of organising and updating a database containing all relevant national legislation. A suggestion proposed by several respondents was that national legislation be included in a more limited way, such as simply alerting that a given substance is regulated at the national level and, possibly, linking to the specific piece of national legislation.[32] Another suggestion made was to include a brief summary of the national legislation, to avoid difficulties in understanding of the legislation in case it would only be available in a national language and not in English.

Potential drawbacks of such an expansion should also be considered. Some respondents (3) have raised doubts as to whether this expansion to national legislations would be too ambitious, would generate confusion or whether it would be difficult for ECHA to include all this information in EUCLEF. Several respondents (3 users and 4 interviewees from the European Commission) consider that EUCLEF should not be expanded to national legislations but that priority should rather be given to ensuring the accuracy and regular update of the EU legislation in the tool.

The limitations of this analysis should be taken into account when deciding on next steps. As with the analysis of potential additional EU legislation to include in EUCLEF, this part of the study is subject to limitations regarding the absence of scientific judgement on the relevance of the suggested areas of national legislation to include and the limitations in terms of the amount of the collected data, given that users were invited to identify potential pieces of legislation to include rather than provide with options they could rank. Further analysis of the potential costs of expansion should be made in order to assess more robustly the efficiency/added value as well.

[32] A similar approach is applied by the OECD eChem database which is run with a small team of OECD staff.

4 Is the current approach to outsourcing external services appropriate?

This question relates to Objective 3, i.e. to assess the appropriateness of the current approach for procurement with external services for data provision and helpdesk: to assess to the extent possible if there is room for reassessing back those options or not, if this decision on outsourcing still holds, if the choice of the external provider is the most efficient way in terms of quality and exhaustivity of the data put in EUCLEF. The ultimate purpose is to find out if there is anything on the procurement side ECHA can do in another way and if the current approach is the right one.

The external review found that the complexity of the project (developing and operating EUCLEF services) has been carefully managed in terms of feasibility study and procurement approach. In addition, the procurement arrangements have proved to be appropriate and suitable for meeting EUCLEF's objectives. The renewal of the contract will give the opportunity to ECHA to review the procurement arrangements notably taking into consideration the scope of work (e.g. adjustment of the helpdesk services, extension of the EU legislation in the scope of EUCLEF).

4.1 What assumptions were made in the decision to outsource?

In 2017, the design and the development of EUCLEF database and the associated helpdesk service has been assessed as a rather complex project based on the following dimensions: scope of coverage (notably 56 EU legislations), expected level of quality, liability & intellectual property rights, complexity of the data processes to be implemented notably in terms of technology, expected timeline and constrained resources. It is worth noting that these considerations are still valid today.

ECHA has handled this complexity mainly by:

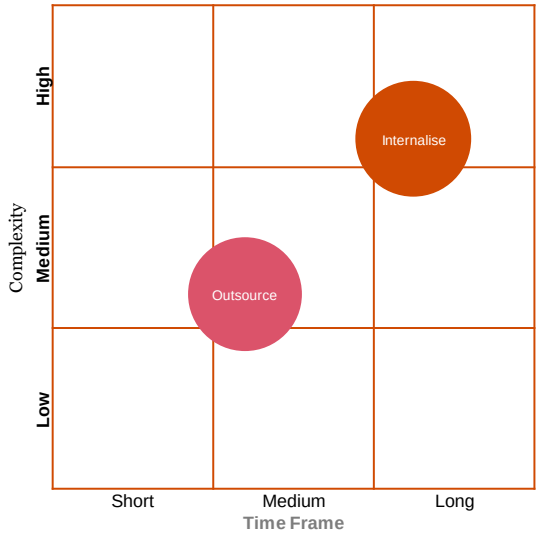
i) forming a multidisciplinary team involving the operational side (legislation), lawyers, etc.;

ii) performing a feasibility study; and by

iii) adapting its procurement process (with a preliminary market research – see next section).

Further to the feasibility study, two alternatives options have been identified and are briefly depicted in the following figure: “Internalise” or “Outsource” the development and the running of EUCLEF. In addition, the main elements of the assessment have been summarised in two dimensions: complexity and time frame.

	Complexity	Time frame
Internalise	• Capacity to identify/develop/recruit the necessary team (number of FTEs, skills set, budget visibility in a medium-term perspective) • IT requirements and capacity • Not directly linked to ECHA’s core mandate • No previous experiences	• Required time for recruitment and/or development • Required time for IT development
Outsource	• Mainly related to the procurement procedure (to be adapted to the scope of work)	• Constrained mainly by the procurement process • Better aligned with the timeline of the contribution agreement of the EC



Based on this analysis, it was decided to outsource this activity in November 2017. While no additional assumptions have been clearly identified for the different scenarios and the related estimated costs, the previously indicated considerations have not changed. Thus, outsourcing seems to be still relevant in the current conditions.

4.2 Are current procurement arrangements appropriate and suitable for meeting EUCLEF’s objectives?

Once the decision of outsourcing was confirmed, one of the challenges was to define the most adapted and relevant procurement arrangements. To this end, the procurement process consisted in two main phases:

i) Preliminary market research (Please refer to “Preliminary Market Research – Questionnaire for Data Service Providers); and

ii) Procurement process as such (call for tender).

This two-step approach was successful as the preliminary market research has enabled to confirm/generate the interest of potential candidates (market operators), as well as to provide ECHA with the necessary elements to define the technical requirements, as well as to the related budget. It has to be noted that the Preliminary market research outcomes were not formalised on a dedicated report as such, but rather directly included in the elaboration of the technical specifications.

These procurement arrangements have proved to be appropriate and suitable for meeting EUCLEF’s objectives, notably based on the following elements:

- The external review finds that EUCLEF is meeting the objectives set in the Agreement between ECHA and the European Commission EUCLEF's users (see Objective 1's conclusions);
- No major concerns related to the procurement arrangements have been identified. These arrangements enable to have smooth and efficient operations, as well as a worthy relationship between ECHA and the DSP (Data Service Provider).

While areas of improvement for the renewal of the contract are described in the next section, only the following element was identified during interviews:

- Refining the Service Level Agreement (SLA): Lessons learned show that the SLA related to the helpdesk could be refined on the definition of the accountability (accountability depending on the typology of the helpdesk requests) and the calculation of the related key performance indicator (measuring the processing time of the request) in order to have a smooth operation.

It has to be noted that the monitoring activities of the contract were not included in the scope of this evaluation.

4.3 What are the areas of improvement and the challenges ahead?

The following areas of improvement and/or points of attention have been identified through the desk review and the interviews with the main stakeholders.

Contract & Procurement

- **Ensuring a fair competition for the renewal of the contract:** The DSP had to build an adaptation layer to ensure the interoperability between ECHA and DSP. In case of a transition to another DSP, ECHA will have to support the handover costs (already including in the contract with the current DSP – sections I.17 & I.18 of the current Framework Contract) and the interoperability-related costs for the possible new DSP. Thus, there will be a financial saving not to change the DSP. This situation is common to any IT contracts. However, ECHA will have to ensure a fair competition for the renewal of the contract. These elements will have to be taken into account in the definition of the award criteria (notably for the financial criteria), i.e. not including the set-up budget in the financial evaluation of the tenders when renewing the contract, carefully reviewing the handover clause.
- **Analysing further the IP provisions:** The IP provisions have been carefully analysed when awarding the current contract (Section II.13. Intellectual property rights of the current framework contract). These provisions should be cautiously reviewed from a legal perspective in the context of the launch of a tendering procedure for the next service contract. The clarification of the intellectual property on the processed data will determine the access to the historical data, in case of the handover to another DSP.

Scope of work

The following elements could be considered when refining the technical specifications for the renewal of the DSP contract.

- **Refining some technical requirements:** Although the mapping of substance identity between the DSP and ECHA's own database of substances is partly automatised, some elements of the technical specifications could be possibly refined, to make the integration between the DSP data and ECHA as efficient as possible. For instance, all companies in the market use the CAS number for each chemical and ECHA uses the EC number - which is easier as ECHA is the owner for EC number). Therefore, it

would be valuable to specify in the technical requirements e.g. the format of the chemical number (in this case the EC number) to facilitate the integration between the DSP and the ECHA.

- **Refining the quality control data framework:** There has been a few instances where the data provided by the DSP did not pass the ECHA's scientific and/or IT validation – e.g. a substance provided by the DSP did not belong to any of the existing list that are in the EUCLEF scope; or a substance is marked as parent but does not have children. Therefore, ECHA had to require the DSP to review the data again, before its publication and display on EUCLEF. The data quality control plan of the DSP could possibly be reviewed in order to limit this situation.
- **Specifying the requirements related to simultaneous work:** The current DSP could face some issues when working simultaneously on adding a new list of legislation and on the monthly update (as the DSP has then to work on the testing environment as well as on the production environment). This situation should be analysed further and possibly be taken into account in the elaboration of the technical specifications.
- **Assessing the capacity of the possible providers to include additional pieces of legislation and the impact in terms of costs:** The effort required for adding legislation must be carefully assessed in terms of costs, time and expected benefits, whatever the decision to outsource or not the services. Adding new legislation was already done in the first quarter of 2020 without major issues. It turned out that it was not a complex process, rather a resource intensive process. Thus, this investment should be assessed against the expected impact and benefits for EUCELF's users, as well as the European Commission and ECHA. It could also be assessed against other changes, such as adding new features, that might have a greater impact and cost. Please refer to the next section.
- **Confirming the need of having a helpdesk** (Please refer to sections 2.4.3 and 2.4.4).

5 What can be done to further develop EUCLEF and maintain it at its best?

This evaluation, taking place a bit more than a year into the operation of EUCLEF, aims to provide inputs on how EUCLEF could be best maintained and further developed moving forward. The data points collected and analysed in this evaluation indicate several areas for possible improvements focusing on the content of EUCLEF, its layout and promotion. In turn, if implemented, these recommendations could increase the usefulness of EUCLEF.

5.1 What additional information, features or services would stakeholders like to see in the future in order to increase the usefulness of the EUCLEF?

While the extension of the scope generates a strong interest among stakeholders, the analysis here focuses on other aspects, as the expanded scope is addressed in depth in Section 3.

Featuring links to the relevant policy and legislation websites in the results of the search in EUCLEF would strengthen its usefulness and allow stakeholders to save time in getting the desired information (according to 10 interviewees). In particular, having the link of relevant policy websites (particularly in cases where the scope goes beyond REACH) would help EUCLEF stakeholders access reliable information directly without spending time doing further searches. For instance, for food contact materials, a hyperlink towards DG SANTE dedicated webpage could be featured, so as to allow users to get easily guidance on how to interpret the legislation. Likewise, for cosmetics, a hyperlink towards COSING (an EC managed database including all substances regulated and ingredients) could be provided to users. Other examples included an upcoming database on animal test substances named ALURES[33], which could be featured in EUCLEF results when relevant. From a policy perspective, this would also contribute to strengthening synergies and coherence within the EC and its agencies.

Another area where synergies could be built regards the envisaged implementation of a tool similar to EUCLEF but focusing not on the EU level but rather international level by the European Chemical Industry Council – CEFIC (thus tackling one of the gaps identified regarding the absence of international treaties and conventions in EUCLEF). In this context, it may be interesting for EUCLEF to try and exploit synergies would this tool come to life. For instance, ECHA could help ensure that the tool i) is complementary to the EUCLEF; ii) refers to EUCLEF for companies desiring to leverage on the single market specifically; and iii) features similar function and design to the EUCLEF, to allow companies to shift from one tool to another very easily. This would contribute to EUCLEF's objective to improve the business environment for EU SMEs.

Including past and proposed future versions of the laws and substance data contained was the

[33] https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm

second most common suggestion mentioned by seven survey respondents and 15 interviewees. Introducing this additional layer of information would enable users to trace the evolution of how a substance has been regulated and to prepare for future changes. Besides anticipating future regulatory changes, this would allow EUCLEF users to update their safety datasheets and identify the main regulatory changes affecting their activities without having to check back the full legislation. This is of particular importance as regulatory updates are frequent. In this context, having the ability to subscribe to notifications for changes in regulation would be of prime relevance according to five stakeholders. Through this notification system, users would select the CAS numbers for which they would like to be notified when changes occur and would receive regular updates based on the selected CAS numbers. **Improvement in the layout/language** was also a popular area for improvement mentioned by 18 interviewees**.** The layout could be modernised in a way that looks more attractive and user-friendly. Among the concrete recommendations made, a few (4) revolve around adding visuals and icons to illustrate e.g. restricted substances (thus limiting to the extent possible the use of text); aligning it to the latest EC communication standards (2); and including a (visual) disclaimer stating specifically what regulations are in the scope of EUCLEF, and the information provided is a summarised for informational purpose.

Another way to improve the users' experience is also to adapt the language. First, the fact that results are only accessible in English, which may limit its use among SMEs – which is a key target of EUCLEF. This complaint was specifically made by three survey respondents and interviewees. In addition, acronyms were perceived to be extensively used, which in turn impede the readability and understanding of stakeholders – especially those with limited knowledge of English.

Three main recommendation were made by stakeholders regarding EUCLEF's offered functionalities. These can be split into the following categories: search engine; downloadable results; guidance. First, the search function could be improved by allowing

i) searching by topic and by group and;

ii) getting suggestions for keywords when searching according to nine stakeholders.

In addition, in order to get less (and more relevant) results, interviewees (2) suggested to use a question tree tool to tailor the results to their activities/needs. Last, in cases where EUCLEF does not present any results for a search, currently it does not specify it explicitly. Stakeholders (2) hence suggested putting forward a "no result" message in such instances may contribute to improving users' experience.

As for the download function, the main recommendations focused on providing EUCLEF users (4) with the possibility to extract the data provided under the template of the EU safety datasheet; and to be able to download the information on the website as PDF and not only under HTML format.

Besides the download feature, other suggestions include the development of a general guidance document about how to create an EU Safety Datasheet on the basis of the information provided by EUCLEF. This could be complemented by a training (which recording could be made available on the website) on how to use EUCLEF (in this regard, stakeholders did not necessarily seem to be aware of the existing guidance documents featured on EUCLEF).

A last recommendation highlighted by stakeholders (12) focused on promoting more extensively the EUCLEF webpage and its features (including the helpdesk) in order to increase its usefulness among companies and SMEs. This could be done in three ways:

i) better advertising the EUCLEF tool on the ECHA website – by clearly informing users visually that the search engine they are using is EUCLEF;

ii) organising events to present the tool not only to EU public and private sector (associations) actors but also NGOs, who can then spread the information and raise awareness of their

members at the national level;

iii) featuring a EUCLEF in other websites (youreurope portal), other EC agencies (in charge of e.g. food regulations), international organisations (OECD) or industry actors like ChemicalWatch;

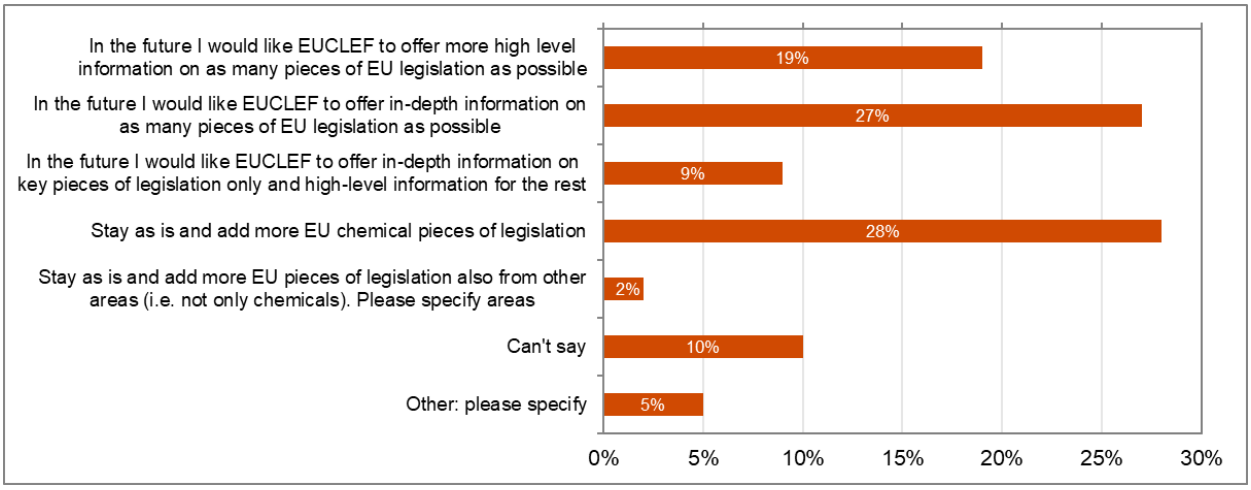
iv) regularly promoting EUCLEF through e.g. ECHA's newsletter, especially in case of updates.

5.2 If EUCLEF were to be expanded to additional legislation, which level of detail would be of more use to stakeholders?

The data collected by the survey show that while EUCLEF stakeholders are interested in having its scope extended, they are divided as to which level of details it should provide – with 19% opting for more high-level information and 27% opting for in depth information. Those wishing for high-level type of information would prefer to have hyperlinks available in case they need further information. For those requiring in-depth information, the qualitative data points analysed reveal that they relate to the implications behind the regulations (having e.g. limit values featured or if the substance is under evaluation).

This result was to some extent corroborated in the interviews where two interviewees suggested tailoring EUCLEF to the type of stakeholders and their needs (namely those experts requiring in depth information, and the non-expert demanding high level type of information). For the latter (non-experts), this would allow limiting the amount of information per search, which was perceived as too overwhelming for three interviewees.

Figure 14: If EUCLEF were to be expanded, what kind of information and level of detail would be of more use to you? N=112



Another way to limit the amount of information deemed relevant by 9% of survey respondents relates to providing in depth information only on key pieces of legislation, while providing high level information on other areas. This also matches to some extent the picture depicted above, where EUCLEF could focus on chemicals / REACH regulations, and provide hyperlinks to other regulation/policy website on other areas of legislations, thus exploiting synergies between EU agencies.

For 30% of interviewees, the level of detail provided by EUCLEF is fully relevant to their needs, while the scope of EUCLEF could be expanded (for 28%) – as reflected in the sections above.

6 Conclusions and recommendations

The conclusions and recommendations are structured in line with the objectives set for the evaluation.

Objective 1: Is EUCLEF meeting its original objectives as set in the Agreement between ECHA and the European Commission?

The external review finds that EUCLEF is meeting the objectives set in the Agreement between ECHA and the European Commission. These objectives remain relevant for stakeholder needs and EUCLEF meets them with a high degree of effectiveness. Utilisation of the EUCLEF tool has increased over time and there is a high degree of user satisfaction, with most consulted users recommending it to their network. However, there is also room for improvement in raising awareness of EUCLEF throughout the EU, which can facilitate the utilisation of the tool by SMEs. A key feature for EUCLEF's usefulness is that it is free-of-charge and integrated into ECHA's database, while the presence of a helpdesk is relatively less prominent and beneficial for users.

While the tool as a whole is considered to provide a high degree of EU added value and its hypothetical discontinuation will entail negative consequences for users across the EU such as cost, loss of time or inconvenience, the helpdesk function is utilised to a lesser extent, mostly due to lack of awareness of its existence.

Recommendation 1: ECHA should explore additional means of raising awareness of EUCLEF among relevant target users both through its direct communication channels and through multiplier organisations (public and private) at national level. The communication plan for 2021 and going forward should be strengthened and backed up with sufficient resources for reaching SMEs across the EU who could benefit from the information provided on EUCLEF.

Recommendation 2: It is recommended that ECHA consider a discontinuation or reduction of the scope of the EUCLEF helpdesk function in view of the low level of its utilisation. Alternative means of addressing potential questions should be explored (i.e. through other support functions provided by ECHA) with the freed-up resources directed towards the improvement of the content or functionalities of the tool.

Objective 2: What is the potential for increasing EUCLEF's scope?

The external review found strong support for the inclusion of additional pieces of EU legislation in the scope of EUCLEF, which would strengthen its role as a one-stop shop for SMEs in need of information on chemicals regulation. Examples of relevant legal acts to include have been identified, but there was not overwhelming support for any particular one due to the limitations of the method of data collection. There is also support and arguments in favour of the inclusion of national-level legislation, but stakeholders acknowledge that this would be very resource-demanding.

Recommendation 3: The European Commission and ECHA should explore the possibilities for expanding the scope of EUCLEF in order to enable it to function effectively as a one-stop shop for EU SMEs when it comes to up-do-date information about EU chemicals regulation and potentially national legislation. In the event that the resources for expanding the scope are limited, ECHA should consider a dedicated consultation activities aiming at the prioritisation of legal acts to be included in the scope of the tool on the basis of further targeted stakeholder feedback. In case of expansion of EUCLEF to national legislation, this should be included in a more limited way, such as simply alerting that a given substance is regulated at the national level and, possibly, linking the specific piece of national legislation.

Objective 3: Is the current approach to outsourcing external services appropriate?

The external review found that the complexity of the project (developing and operating EUCLEF services) has been carefully managed in terms of feasibility study and procurement approach. The challenging dimensions of these services remain the same, namely: scope of coverage (notably 56 EU legislations), expected level of quality, liability & intellectual property rights, complexity of the data processes to be implemented notably in terms of technology, expected timeline and constrained resources. In addition, the procurement arrangements have proved to be appropriate and suitable for meeting EUCLEF's objectives.

Recommendation 4: The renewal of the contract will give the opportunity to ECHA to review the procurement arrangements notably taking into consideration the following elements:

i) Possible modification of the scope of work (e.g. adjustment of the helpdesk services, extension of the EU legislation in the scope of EUCLEF);

ii) Renewal of the contract with a possible handover to another DSP (necessity to ensure a fair competition); and

iii) Cautious legal review of the IP provisions in the context of the launch of a tendering procedure for the next service contract

Objective 4: What can be done to further develop EUCLEF and maintain it at its best?

The external review identified five main recommendations which could contribute to the development of EUCLEF and increase its usefulness.

Recommendation 5: It is recommended that EUCLEF explore ways to include, as part of the results of the search provided to its stakeholders, the hyperlinks of relevant policy website – especially for legislation falling beyond the scope of REACH.

This would allow its stakeholders to access directly further relevant information and save time and resources while building synergies and ensuring coherence with existing initiatives.

Recommendation 6: ECHA should explore ways to include in EUCLEF past and proposed future versions of the laws and substance data contained (when available), allowing its stakeholders to identify and anticipate future regulatory changes affecting their activities without having to refer necessarily to the full legislation. This would be particularly relevant for stakeholders dealing with substances characterised by regular regulatory updates. In this context, ECHA could set up a notification system to which users could subscribe and that would provide them with the information on legislative changes relevant to them. To do so, users would select the CAS numbers for which they would like to be notified when changes occurs and would receive regular updates based on the selected CAS numbers.

Recommendation 7: It is recommended that the ECHA revisit the layout and language of EUCLEF to make it more visible; simplify its navigation; and make the tool more attractive and user-friendly for stakeholders. In addition, a more prominent and visual disclaimer specifying the scope of legislation covered by EUCLEF would help potential users know the potential limits of the tool.

Recommendation 8: ECHA should explore the possibility to improve EUCLEF search engine (having an option to search by topic or chemicals group); the options to download results (under the form of the EU Safety Datasheet); and the addition of guidance. This would contribute increasing the relevance of the EUCLEF to its stakeholders.

Recommendation 9: ECHA should further promote the EUCLEF webpage and its features (including the helpdesk) in order to increase its usefulness among companies and SMEs. This can be done by leveraging on the existing ECHA website, organising events/trainings; featuring EUCLEF in other websites and regularly promoting EUCLEF through e.g. ECHA's newsletter, especially in case of updates of legislation.

Annexes

Annex 1 – Additional legislation to be considered for inclusion in the scope of EUCLEF

This annex is provided as a separate file in Excel

Annex 2 – Covered areas of legislation mentioned by stakeholders

The following table lists areas of legislation or specific acts which were suggested by stakeholders for inclusion in EUCLEF but are in fact already covered by the tool.

Areas of legislation raising interest for insertion	Legal acts falling under this area and already in the scope of EUCLEF
Transport of dangerous goods / transport	Directive 2008/68/EC on the inland transport of dangerous goods
Exports of chemicals	- Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals
Food / Food contact	- Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food - Regulation (EC) No 1935/2004 on Food Contact Materials (FCM) - Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with food
Regenerated cellulose	Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
Protection of marine life	Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)
Environment	Directive 2008/105/EC on environmental quality standards in the field of water policy Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Fertilisers	Regulation (EC) 2003/2003 relating to fertilisers
Medical devices	Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices
Dangerous products and labelling	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
Packaging	Directive 94/62/EC on packaging and packaging waste
Chemical weapons	Directive 2014/28/EU 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
Feed	Regulation (EC) No 396/2005 on maximum residue levels (MRL) of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (MRL Regulation)
Cosmetics	Regulation (EC) No 1223/2009 on cosmetic products
Detergents	Regulation (EC) 648/2004 on detergents
Toys	Directive 2009/48/EC on the safety of toys
Building and construction	Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products
Hazardous Substances	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Annex 3 – Review of other database tools

The following table synthesises the main features of EUCLEF in comparison with other EU-level tools provided by EU Agencies or other international institutions.

Indicator / Database	EUCLEF	OpenFoodTox	Medicines database	eChem
Operator	ECHA	EFSA	EMA	OECD
Data type	EU Chemicals legislation	Chemical and toxicological information on chemicals assessed by EFSA	Information on medicines at various stages of their lifecycles	Information on chemical properties
Scope	EU	EU	EU	International
Operational model	Outsourcing of tool development, content development & maintenance, helpdesk	Outsourcing of data quality assurance	Outsourcing of data quality assurance	In-house data management, partner organisations are invited to provide links to relevant websites
Data source	Publicly available legislation	EFSA risk assessments	Data provided by medicine producers	Databases run by other entities (TBC)
Links/ed to other sources	Yes – EUR-lex	Yes – eChem	No	Yes – to all contributing databases
Helpdesk function	Yes	No	No	No
Search function	Yes	Yes	Yes	Yes
Subject to evaluation	Yes	No	No	No