Preliminary Market Research – Questionnaire for Chemical Substances Data Service Providers

Introduction

The European Chemicals Agency (ECHA) is inviting you to reply to this questionnaire by **28 November 2022 by 18.00 Helsinki time (EET)**, via e-mail addressed to the functional mailbox procurement@echa.europa.eu.

This questionnaire is meant for market consultation conducted by the Agency prior to launching procurement around services and expertise your company may offer related to provision of chemical substances data services. The market consultation is part of the preparation of a call for tenders for a new Framework Contract for the Provision of chemical substances data services under EU legislation for the European Union Chemicals Legislation Finder (EUCLEF).

Important: Before answering the questions, please read carefully the background information provided below.

ECHA will preserve the confidentiality of the information provided in response to this questionnaire. Your data will be processed in accordance with ECHA's privacy rules.

1. General Information

- The information included in this questionnaire is only indicative; it is meant to give context for the respondents to provide their answers, but does not commit or bind ECHA, i.e., with regard to any procurement launched by the Agency in the future.
- The responses do not bind the respondents in any way. The information to be collected through this questionnaire will not be considered by ECHA in the evaluation of tenders submitted during an eventual procurement procedure launched by the Agency.
- The identity of the companies that will respond to this questionnaire will not be disclosed to any third party except the European Court of Auditors, the European Anti-Fraud Office or, for the processing of personal data, the European Data Protection Supervisor if requested for the performance of audits and checks.
- The responses to be provided in the free text fields of this questionnaire should be clear and standalone, i.e., without web links to documents or websites.
- No further interviews are planned to take place with the respondents. Therefore, we kindly invite you to provide as much information as you feel is relevant for ECHA to assess best the market situation.

2. Background Information

EUCLEF[1] is a search portal for regulatory information on chemicals funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (SMP COSME), and it is hosted, developed and maintained by ECHA. The aim of EUCLEF is to improve the business environment for EU companies, regarding access to information

[1] https://echa.europa.eu/legislation-finder

on legislation applicable to a given chemical substance.

Following this aim, EUCLEF is an easy-to-use tool that enables companies, especially small and medium-sized enterprises, to find out how their substances are being regulated in the EU and what legal obligations they have. EUCLEF is a free online service that gives a comprehensive overview of several EU chemical pieces of legislation in one place. This allows users to take business decisions based on regulatory activities across different pieces of legislation. In addition, EUCLEF is seamlessly integrated in ECHA's chemical database[2].

EUCLEF was first launched to the public in March 2020, and it covered the regulations and directives under ECHA's remit and 35 other pieces of EU legislation on chemicals. In March 2021, ECHA expanded EUCLEF's scope with 16 additional pieces of EU legislation, completing this way the mandate it was entrusted by the European Commission. A total of 56 pieces of legislation, including six under ECHA's remit, are now available on ECHA's website for identifying which one apply to each substance.

The extension of ECHA's current website capabilities with the new pieces of legislation under the scope of EUCLEF enables users to search for chemicals, view legislation data and obligations, and substance information. Thus, EUCLEF allows to search either by substance and how it is regulated by different pieces of EU legislation, or by piece of legislation, and provides related information for it such as scope, regulatory activities or lists of covered substances.

The data for the pieces of legislation that are not under ECHA's remit are delivered to ECHA via an outsourced agreement that covers chemical substances data services under EU legislation[3]. A new Framework Contract, replacing the afore mentioned agreement, is planned for 2023[4] in order to ensure the continuation of the services.

2.1. EUCLEF Data

The main goal of EUCLEF is to offer for free to the public comprehensive and up-to-date information on chemicals pieces of legislation that are applicable for a given substance within the European Union or individual member states.

As a general note, data that is made available in EUCLEF can be defined as:

- **EUCLEF Data**: This is the aggregation of the substance and regulatory information, as delivered in a usable format to ECHA.

- **EUCLEF Substance Data**: This data consists of information on substances such as EC numbers, CAS numbers, names and other substance characteristics that are used to globally identify a substance or used to identify a substance within the context of a legislation.

- **EUCLEF Regulatory Data**: This includes information on the legislations themselves such as where it is applicable (e.g., Legislation Profile data) and information on the obligations associated with the substances listed in them.

[2] Information on Chemicals - ECHA (europa.eu)
[3] Reference: Framework Service Contract ECHA/2018/398 for the Provision of chemical substances data services under EU legislation for the European Union Chemical Legislation Finder.
[4] APB.05_(3)_Annex2_Procurement_Plan_2022.xlsx (europa.eu)

The data mentioned above will be provisioned to ECHA. as outlined below.

Through the future Framework Contract, ECHA intends to have the possibility to receive regulatory data on chemicals (information on how a chemical substance is regulated at EU level, excluding REACH[5], CLP[6], PIC[7], BPR[8], POP[9]s and Seveso[10]), that the Contractor would be provisioning, implying undertaking of:

- Data collection from official legislation sources such as EUR-Lex.
- Data management: especially management of a database of chemical substances, with solid and established procedures for substance identification, so that the same substance regulated under two or more different legislations would be identified as one.
- Data processing where and if necessary, e.g., for normalisation of certain information across similar legislations, or for derivation of substance properties (such as carcinogenic) based on their Harmonised classification under the CLP Regulation.
- Data updates, e.g., when legislations in scope are amended or updated with new entries or corrections,
- Data quality: e.g., data cleansing, precautions against data tampering,
- Data governance on related areas, e.g., strategy on how to determine if a legislation can be covered or not by the Contractor in their own database (also referred to as Catalogue).

2.2. EUCLEF Use Cases

The following list provides a non-exhaustive description of the main use cases for EUCLEF as an extension of ECHA's current capabilities and services provided to the public. The common characteristic of these use cases is their extension to cover chemicals regulatory information not managed/maintained by ECHA and that is to be collected, maintained and

[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)
[6] 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 (Text with EEA relevance)
[7] 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 (recast) (Text with EEA relevance)
[8] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
[9] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast) (Text with EEA relevance)
[10] 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 (Text with EEA relevance).

provided by the Contractor.

1. Search for chemicals
2. View Legislation List data/obligations
3. View Legislation information (Legislation Profile and List of all EUCLEF pieces of legislation)
4. View Substance Information/Infocards
5. Export/Download Substance and Regulatory Data
6. Features for logged in users

The aims of this market survey, which is open to all possible interested tenderers, are to:

- Ensure that the future call for tenders is sufficiently attractive to the market players
- Help ECHA in
    - Ensuring the requirements are in line with the availability of offerings on the market
    - Further understanding the availability on the market to deliver for other use cases, as outlined below, such as providing the data to external third parties (e.g., EUCLEF public users) via web services and/or in the form of bulk export.

3. Questions

Exploitation of EUCLEF data

ECHA wishes to clarify whether there would be a willingness to assign (i.e., transfer) the possible intellectual property rights and other proprietary rights vested in the EUCLEF data to ECHA, or whether licensing would be the only agreeable contractual arrangement for exploiting the data.

1. In both instances, can you please exhaustively list the intellectual property rights and other proprietary rights vested in the EUCLEF data, if any?

2. In addition, we wish to understand whether any of these rights belong to third parties, and how your company would secure the necessary permissions or transfers from the rightsholders (e.g., CAS information)?

3. In case licensing is the only acceptable means of exploiting the EUCLEF data, it is important for ECHA to already understand the acceptable duration and scope of the licence, as well as the agreeable modes of exploitation of the EUCLEF data. ECHA requires a global license to the EUCLEF data, whose duration is, at least, the term of the intellectual property rights and other propriety rights. Is this possible?

4. The modes of exploitation required are fairly extensive, noting the intended use of the EUCLEF data, as described above, and include, but are not limited to, reproduction, creation of derivative works, distribution and communication to the public. Equally, ECHA wishes that the general public can freely exploit the EUCLEF data, other than for direct commercial sale. Would you be opposed to this? Please detail any conditions, if any, you would have to allow such modes of exploitation, e.g., imposition of a disclaimer.

5. ECHA also wants to be able to sublicence the EUCLEF data to our partners (e.g., EU institutions, other EU agencies and the Member States) so that they can exploit it under the same modes of exploitation as ECHA, including public dissemination. Would you be agreeable to this, and under what conditions (if any)?

Distribution and communication to the public

ECHA wishes to discuss the possible use of certain modalities for distribution of the EUCLEF data to the general public or other third parties. Specifically, ECHA is investigating, in the context of the new Framework Service Contract, the following use cases for EUCLEF data:

- Bulk exports, where a public user of the ECHA website or other database and/or solution could get an export of the full set of EUCLEF data for two and more substances at the same time.
- Web services (i.e., programmatic access to the data, for machine-to-machine interaction) that would re-distribute the EUCLEF data to external third parties (e.g., public EUCLEF users).

6. Would you as a Chemical Substances Data Service Provider have any concerns regarding the provision to external third parties (e.g., public EUCLEF users) of the data in such formats? Would your answer be different if these formats were only used for exchanging the EUCLEF Data with ECHA's partners (e.g., the European Commission) – and not the general public at large?
7. List any constraints and conditions you would have regarding the provision of the data? Please detail them separately for:
    a. bulk download
    b. web services
8. List any acceptable and excluded modes of exploitation (e.g., educational purposes) for:
    c. bulk download
    d. web services
9. Detail any concerns, constraints and conditions regarding the indirect use of the data provided in EUCLEF, e.g., via data mining performed in accordance with Article 4 of Directive (EU) 2019/790[11]?
10. Would you still be willing to offer chemical substances data provision services if ECHA would decide to proceed in making available bulk download and/or web

[11] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (Text with EEA relevance.): https://eur-lex.europa.eu/eli/dir/2019/790/oj.

services as defined hereabove to the general public and/or its partners?

11. We would like to bring to your attention that even in the case that ECHA would decide to restrict bulk downloads and web services) at the start of the new framework contract, the Agency may be required in some instances to make such data available in the above-mentioned modalities of distributions to comply with applicable EU law, such as Directive (EU) 2019/790. If your answer was negative under point 10), would you re-consider in such a case your position?