Data Contribution
Q&A

Version 1.0
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Legal Notice

The Data Contribution Q&A was prepared by the participating companies as a means of providing support on the Data Contribution initiative (https://iuclid6.echa.europa.eu/data-contribution), including on points of a general nature as well as answers to question from parties that might wish to join the initiative. The Data Contribution Q&A is not endorsed by the European Chemicals Agency (ECHA), whose platform is being used to host the data offered by the contributing companies.

The questions and answers contained in the Data Contribution Q&A are not intended to be exhaustive and do not constitute professional advice of any kind. Access and the right to use the data offered by the participating companies in the initiative is subject to the acceptance of an end-user licence.

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Version 1.0	First edition	30 March 2022
Version 1.1	Link to the Data Contribution section of the IUCLID website added	2 April 2022

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In case your questions are not addressed in the Data Contribution Q&A or you have any other queries regarding this document, we encourage you to contact the Data Contribution initiative's secretariat: chemical.legislation@roche.com.

Questions and Answers

Question: What is this initiative all about?
Answer: The research based pharmaceutical companies represented in the European Federation of Pharmaceutical Industries and Associations (EFPIA) are in possession of physicochemical, toxicological and ecotoxicological data on chemical substances which are no longer of economic value. For example, this data may have been generated on substances that were not pursued or intermediates that are no longer used.

The making available of this data is intended to extend the variety of publicly available high-quality hazard data on chemicals to, among other things, enhance the effectiveness of database-dependent property prediction tools. Through this, there would be an opportunity to improve the hazard characterization of structural analogues, optimize their safe use and can potentially lead to a reduction in animal testing.

As a voluntary non-profit industry initiative, the project is run under the patronage of EFPIA, which is also responsible for publicizing this initiative.

Question: How can this project be described?
Answer: To gradually reduce or to even avoid animal testing of chemical substances, theoretical models of "Structure Activity Relationship" (SAR) should be further improved. The opportunity for read-across and the performance of SAR models depend on the amount, diversity, and quality of data on which these considerations or calculations respectively are based.

Companies in the pharmaceutical industry possess physicochemical, toxicological and ecotoxicological data that are no longer of economic value for them. This is because the substances in question were not pursued into development, or are no longer used. This applies for instance to a variety of intermediates from syntheses, which have commercially never been or are no longer used.

Some companies generate data as part of internal voluntary safety requirements, such as the minimal data for safety instructions and safety data sheets, for substances, which have small annual volumes thus not triggering formal data generation regulatory requirements.

Question: In which form will the data be made available?
Answer: The data will - as with (REACH) registrations required by Regulation (EC) No 1907/2006 - be offered to the public in the format of structured summaries, i.e., in the electronic IUCLID format. With the contribution, the contributing company waives any financial compensation for the use of the data.

Question: What is the difference between this data contribution project and the iPIE (Intelligent Assessment of Pharmaceuticals in the Environment) project?
Answer: The data contribution project has some resemblance with the iPiE project that was successfully started under the participation of large pharmaceutical companies and EFPIA in 2015. The scope of iPiE, however, is clearly different: iPiE focuses on active ingredients of pharmaceuticals and on their long-term adverse effects on the environment, whereas the project proposed here focuses on other substances such as “industrial” chemicals and on a broader REACH-oriented spectrum of endpoints. The proposed project also does not aim to process any of the contributed data, but just to make them available to the public and especially to the scientific community.

Question: What is meant by contribution?
Answer: With the contribution, the data is offered free of charge, but its use is subject to an end-user licence.

Question: Is there any liability on the side of the participating companies?
Answer: The contributed data are made available to the public under the conditions laid down in an end-user licence. This includes the stipulation that the contributing companies are not to be held liable for any direct, special, indirect, incidental, punitive, exemplary, or consequential damages including, but not limited to, loss of time, revenues, profits, clients, data, for a decision made or action taken based on the data made available as part of a data contribution.

Question: What is the role of ECHA?
Answer: ECHA agreed to facilitate the project by allowing the data to be hosted on its platform. The data is intended to be published in different ways; for instance, on the ECHA Dissemination page and the OECD eChemPortal.

Question: What is in the scope of the project and what is out of scope?
Answer:
In scope is:

- The contribution of physicochemical, toxicological, or ecotoxicological data on chemical substances, such as intermediates or process aids from syntheses which have commercially never been or are no longer used;
- Physicochemical, toxicological, or ecotoxicological data related to chemical legislation end-points of the REACH annexes VII-X;
- Publication of the data in summary form to allow use;

Not in scope is:

- The contribution of physicochemical, toxicological, or ecotoxicological data on pharmaceutical active ingredients or excipients;
- The contribution of physicochemical, toxicological, or ecotoxicological data from chemical substances, such as intermediates or process aids, which occur in the commercial manufacturing processes of the pharmaceutical industry;
- Risk assessment;
- Data from clinical trials;
- Full publication of the test reports;
- Sale of physicochemical, toxicological, or ecotoxicological data or individual reports;
- Use, exposure or volume data related to the chemical substances, the data of which are contributed in the frame of this project;
- Processing of the data within IUCLID to form overall conclusions on the classification and labelling of the substance.

Question: How did this initiative come about?
Answer: This project started as a grassroots initiative of product safety experts of the participating companies. These experts are aware of quality data on chemicals in their companies' archives. They wondered how this data could be used for the benefit of society and how it could be made available to the public. They found support from their managements, which recognized the value for society.

One idea was also to open up a new section of the "chemical space" with unique substances which are not used in other sectors of the chemical industry.

Question: What is the role of EFPIA?
Answer: The initiative is formally under the auspices of EFPIA, which is responsible for compliance with anti-trust law and for public relations.

Question: How can other companies join the initiative?
Answer: The initiative is open to any EFPIA-member company, which signs up to the project charter elaborated by the founding companies. The project charter can be requested by any interested company from the initiatives' secretariat: chemical.legislation@roche.com. A Memorandum of Understanding with ECHA must also be signed.

The initiative's charter also provides interested companies with an observer role to learn more about the initiative and then decide whether to become a full member.

In case other companies, which are not members of EFPIA, would like to contribute data, they should get in touch with ECHA.

Question: Are there quality requirements for the data to be contributed?
Answer: Yes, there are. Ideally, only higher reliability data (Klimisch 1 or 2) should be used. In case, the available data are of good scientific quality also data could be used which do not fulfil the requirements of Klimisch categories 1 and 2.

Question: Who is responsible for the creation of the study summaries?
Answer: The individual companies are responsible for the generation and submission of their own data. They also carry all the costs thereof.

Glossary and Acronyms

Abbreviation or Acronym	Explanation
ECHA	The European Chemicals Agency
EFPIA	The European Federation of Pharmaceutical Industries and Associations
REACH	EU Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
IUCLID	International Uniform Chemical Information Database. IUCLID is a software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. ECHA co-develops the software with the OECD.
iPIE	Intelligent Assessment of Pharmaceuticals in the Environment
OECD	Organisation for Economic Co-operation and Development