

REACH chemical dossiers? Yes, please!

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Abstract

Medical writing knowledge and skills can be applied relatively easily to other areas of technical regulatory writing, with a bit of home study. One such area is in the compilation and write-up of REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) chemical dossiers. A concise overview of the legislation, requirements, and dossier content is provided, with links to guidance documents available online for further study.

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In today's volatile economy, medical writers would be wise to consider diversifying their portfolio so that their client base is not limited to writing for the pharmaceutical industry. There are many other regulated sectors that require the same skills and, with a bit of effort, are within reach of an experienced medical writer. 'Registration Dossiers' for chemical substances in the European Union (EU) is one area with an increasing demand for skilled technical writers of the calibre of medical writers. The legislation governing these chemical substances is called REACH, which is short for Registration, Evaluation, Authorisation, and restriction of Chemicals.

What is a REACH dossier?

REACH legislation requires that EU manufacturers and importers submit a registration dossier on the chemical substances that they manufacture or import into the EU in quantities greater than 1 metric tonne per year. The REACH dossier consists of a technical dossier and, depending on the amount produced, may require, in addition, a Chemical Safety Report. The REACH regulation is complex; the legislation contains 17 annexes (Table 1).

The REACH dossier is evaluated by the European Chemicals Agency (ECHA), based in Helsinki, Finland. ECHA has published several guidance

documents, factsheets, practical guides, webinars, and user manuals that provide an explanation of the dossier format and guidelines for summarising data in the dossier.

When is a REACH dossier required?

A registration dossier is required for chemical substances that are not considered exempt from REACH legislation and that are manufactured or imported into the EU in quantities exceeding 1 metric tonne per year. Exemption criteria are defined in Article 2 of the REACH legislation, with some specific listings of exempted substances in Annexes IV and V. Confirmation of exemption of a substance is not always straightforward; typically a technical writer would be contacted to compile a REACH dossier after the decision of non-exemption is already made. Substances can be considered exempt if they are 'generally considered safe' or consist of natural-based materials (e.g. plant extracts, water, oxygen, some hydrates, and natural elements). Some substances can also be considered exempt because they are covered by other EU legislation, such as food, pesticides, medical devices, and pharmaceutical products.

REACH dossier content and format – general principles

Once the non-exemption of a chemical substance is confirmed, a REACH registration dossier is required, consisting of two parts:

- A technical dossier that is required for all non-exempt chemical substances regardless of the amounts produced or imported, and
- A Chemical Safety Report that is required for substances placed on the EU market in quantities at or exceeding 10 tonnes per year.

The registration dossier is extensive and contains all necessary information including Robust Study Summaries for all of the tests that are submitted.

Table 1: REACH legislation annexes

REACH legislation annex	Annex content*
I	General provisions for the Chemical Safety Report (chemical safety report)
II	Requirements for the compilation of Safety Data Sheets
III	Criteria for substances registered in quantities between 1 and 10 tonnes per year
IV	Exemptions from the obligation to register in accordance with Article 2(7)(a)
V	Exemptions from the obligation to register in accordance with Article 2(7)(b)
VI	Information referred to in Article 10 (the information required for registration)
VII	Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more
VIII	Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
IX	Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
X	Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more
XI	General rules for adaptation of the standard testing regime set out in Annexes VII–X
XII	General provisions for the downstream user Chemical Safety Report
XIII	Criteria for the identification of PBT and vPvB substances
XIV	List of substances subject to Authorisation
XV	Dossiers
XVI	Socioeconomic analysis
XVII	Restrictions on the manufacture, placing on the market and use of certain substances, mixtures, and articles

*Many of the annexes have been updated and adapted as legal positions are clarified by the Commission and as interpretations evolve, and of course to include new or amended legislative controls for chemicals of concern. The amending regulations are published online and have been conveniently compiled by the ReachReady consulting group on their website: http://www.reachready.co.uk/reach_faq_free.php#text.

The REACH legislation defines the format and content of the dossier. A useful reference is the unofficial consolidated version,¹ which incorporates the changes made up to 10 June 2013. The amount of substance placed on the market in the EU determines the amount of test data and subsequent hazard and use assessments; the higher the amount, the more data required in the registration dossier, as outlined in Annexes VI–X of the REACH legislation. Table 2 lists the legislation annexes that specify the data requirements according to tonnage produced, from 1 tonne per year to 1000 or more tonnes per year (see also Article 12 of the REACH legislation). ECHA has published detailed guidance documents describing the registration dossier content and format, the dossier submittal process, and the procedure for updating registration dossiers. This will be described briefly in the subsequent sections of this article.

The format of the technical dossier must be compliant with the requirements of the International Uniform Chemical Information Database (IUCLID), as stated in Article 111 of the REACH legislation. This software is used to capture, store, submit, and exchange data on chemical substances, according to the format of the Organisation for Economic Cooperation and Development

Harmonised Templates.² All the information required under Article 10(a) for the technical dossier and under Article 10(b) for the Chemical Safety Report must be documented in the recommended reporting formats specified in IUCLID. IUCLID 5 is the latest version of this software, which is available for free (at <http://www.iuclid.eu>). The dossier can be prepared with other software, as long as they produce the exact same format.

Submission of the dossier to ECHA in the IUCLID 5 format is done through the ECHA electronic portal, REACH iT.³ Within 3 weeks after submission, the ECHA will conduct a completeness check, consisting of two parts:

- A Technical Completeness Check to check if all the elements required by REACH have been provided, and
- A Financial Completeness Check to check the payment of the fee.

ECHA has developed software so that registrants can check the dossier completeness before submission. This software is available as an IUCLID 5 plug-in, called Validation Assistant, at the IUCLID 5 website.⁴ ECHA strongly recommends that applicants verify the validity of the dataset and the final

Table 2: Legislation annexes that apply for a given amount produced or imported per annum

Tonnage per year	Annex VI	Annex VII	Annex VIII	Annex IX	Annex X	Annex XI
1–10	X	X + Annex III				X
10–100	X	X	X			X
100–1000	X	X	X	X		X
≥1000	X	X	X	X	X	X

dossier with the Validation Assistant tool before submitting to ECHA. Chapter 5, *Technical Completeness Check (TCC)*, of the *ECHA Data Submission Manual Part 05 – How to complete a technical dossier for registrations and PPORD notifications*⁵ provides details on the installation and use of the Validation Assistant.

Contents of the technical dossier

The first part of the registration dossier is the technical dossier. The technical dossier contains the following information:

- The identity of the manufacturer/importer.
- The identity of the substance and information on the manufacture and use of the substance.
- The classification and labelling of the substance.
- Guidance on its safe use.
- (Robust) study summaries of the information on the intrinsic properties of the substance derived from applying Annexes VII–XI.
- An indication as to whether the information on manufacture and use, the classification and labelling, the (robust) study summaries, and/or, if relevant, the Chemical Safety Report has been reviewed by an assessor.
- Proposals for further testing, if relevant.

For substances registered in quantities between 1 and 10 tonnes, the technical dossier shall also contain exposure-related information for the substance (main use categories, type of uses, significant routes of exposure).

In their *Guidance on Registration* document,⁶ ECHA provides detailed guidance on the IUCLID templates, the selection of information, the level of detail of the data to include, and the type of summary to prepare in the technical dossier.

Contents of the Chemical Safety Report

The second part of a REACH registration dossier, for chemical substances manufactured or imported in quantities of 10 tonnes or more per year, is the Chemical Safety Report. Annex I, Section 7 of the REACH legislation describes the general provisions for assessing substances and preparing Chemical Safety Reports.

The Chemical Safety Report is used to document:

- The intrinsic properties and hazards of a chemical substance.
- The conditions of manufacture and use which are needed to control the risks to human

health and the environment throughout the life cycle of the substance.

- The expected emission/exposure of man and environment resulting from manufacture and use throughout the life cycle of the substance.
- The characterisation of risks following such emission/exposure.

The Chemical Safety Assessment is part of the Chemical Safety Report. It is a detailed summary of all the available information on the environmental and human health hazard properties of the substance, together with an assessment of exposure and risk (where such an assessment is required) to demonstrate that the risks from the exposure to a substance during its manufacture and its use are controlled when specific operational conditions and risk management measures are applied.

The Chemical Safety Report should be a readily understandable, stand-alone document, with the principles, assumptions, and conclusions applied to the hazard and exposure assessments clearly documented; it should include the key data used to conduct the assessment, so that there is no need to revert to the underlying substance dataset in IUCLID.

The Chemical Safety Report can be submitted separately or as part of a joint submission with other applicants covering all uses associated with the chemical substance.

General advice and detailed guidance on preparing a Chemical Safety Report, with recommendations to avoid common deficiencies, can be downloaded from the ECHA website.⁷

Resources to develop competency in REACH dossier writing

Many resources are available online to learn about the content and format of REACH registration dossiers, including actual sample dossiers that were created by ECHA to aid applicants in preparing an acceptable dossier. ECHA has prepared 15 different Practical Guides that cover everything from how to report robust study summaries to how to report weight of evidence and how to communicate with ECHA in a dossier evaluation. All of these guides are accessible online on the ECHA website.⁸ An example of a Chemical Safety Report prepared with a fictitious chemical substance that covers most of the required topics has also been developed by ECHA and is available on their website.⁹

Conclusion

While the breadth and depth of REACH legislation and dossier requirements can seem daunting at first

glimpse, the overall structure, content, and requirements do not differ all that much from those of a pharmaceutical dossier. Consequently, an experienced medical writer, with a bit of home study and perhaps a course or two on the topic, can add REACH dossier compilation and write-up skills without too much effort. There are many courses available in Europe that can provide the basics in REACH dossier compilation and write-up. For example, CEHTRA¹⁰ is an organisation that provides training on the collection of data and write-up of REACH dossiers. ECHA also provides a series of webinars on the topic.¹¹ Some of these courses are taught by the national officials who evaluate REACH dossiers. Attending one of these courses can thus provide a good initial introduction, hands-on practice in writing portions of the REACH dossier, and valuable personal contacts that can be a further source of information after the course.

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