

Pesticide dossiers, an opportunity for medical writers

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Abstract

Pesticides, also known as crop protection products, are approved for sale through a process similar to that for authorising human medicines. For example, the toxicology data submitted are nearly identical to the nonclinical data generated for a drug, and the environmental risk assessment is similar in many ways to the risk assessment for human medicines. Consequently, an experienced medical writer could prepare a pesticide dossier. This article briefly describes the regulatory requirements for preparing a pesticide dossier and where to find detailed guidance and examples to help a medical writer with this type of regulatory document.

Keywords: Regulatory dossier, Pesticides, Chemicals, Non-medical

Pesticides, or crop protection products, ensure acceptable quality and yield for the farmer at an affordable price for the consumer. Even organic agriculture uses certain authorised pesticides, as long as they are obtained from natural sources.¹ Pesticides are evaluated and approved through a process similar to that used for the evaluation and approval of human drugs. Consequently, an experienced medical writer with access to the appropriate resources can compile and prepare pesticide dossiers.

Regulatory authorisation of pesticides

In the EU, pesticides are approved according to Regulation (EC) No 1107/2009 of the European Parliament and the Council. The approval process can take place at three levels:

1. The pesticide active substance is evaluated for approval at the EU level. This includes at least one pesticide product for one representative

agricultural use. The evaluation is conducted by one EU member state, referred to as the Rapporteur Member State. A subsequent peer review is carried out by the European Food Safety Agency.

2. If the active substance is approved, additional formulations containing the pesticide active substance (plant protection products) are approved at the national (member state) level.
3. The plant protection product dossier evaluations can be coordinated by one member state on behalf of a group of member states belonging to the same agricultural zone. This is called a zonal assessment. The agricultural zones are defined in legislation guidance documents and consist of the North, Central, and South zones (Figure 1).

Plant protection products and the active substances they contain can only be approved in the EU if the data demonstrate under the proposed conditions of use:

- sufficient efficacy against the targeted disease or pest;
- an acceptable risk to human health; and
- an acceptable risk to the environment.

The procedure is therefore similar to that for human drugs; however, the agencies involved and the format and content of the dossier differ.

Elements of a pesticide dossier

Countries belonging to the Organisation for Economic Co-operation and Development (OECD) adhere to a harmonised content and format for pesticide dossiers.² The pesticide dossier consists of a Summary Dossier and a Complete Dossier (Figure 2).

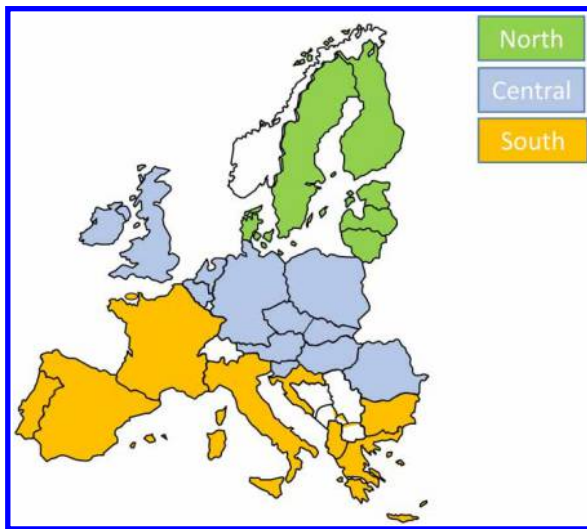


Figure 1: European Union pesticide product dossier approval zones.

The Summary Dossier is presented in tiers of increasingly high-level summaries and evaluations:

- Tier 1: Reference lists of submitted studies
- Tier 2: Summary and evaluation of the active substance and formulation data
- Tier 3: An overall assessment of the application and conclusions.

The Complete Dossier includes the Summary Dossier, the individual study reports, and

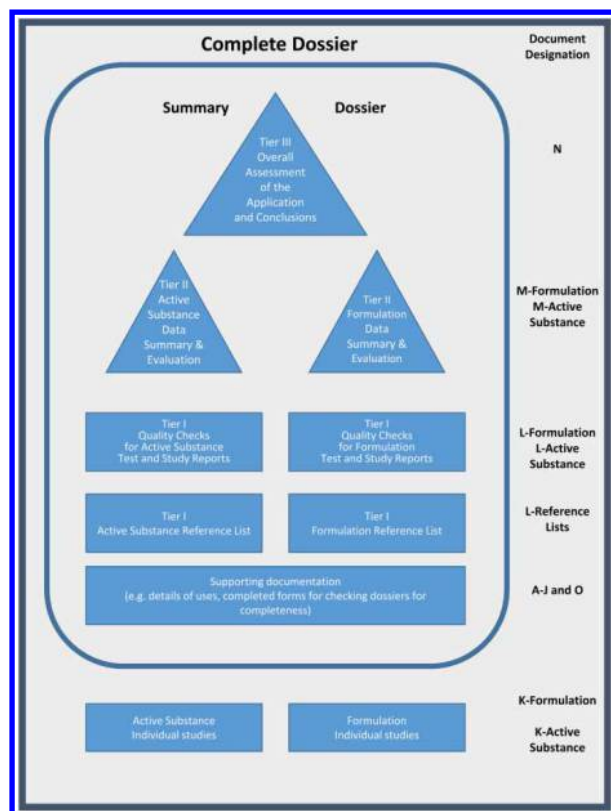


Figure 2: OECD dossier structure and format.

supporting documentation (administrative forms, completeness checks, details of agricultural uses). Each dossier section is assigned a letter A to O. The OECD provides extensive guidance for the preparation and presentation of Plant Protection Product dossiers and the active substances they contain on their website.³

Pesticide dossier content and format

The Pesticide Active Substance Dossier

A Complete Dossier will resemble the diagram presented in Figure 2. It will therefore contain an Active Substance Dossier, and a Formulation Dossier for products containing the active substance. A detailed guidance document that includes templates to prepare several dossier sections is available for download on the European Commission’s Directorate General for Health & Consumers website.⁴ Examples (with confidential information removed) of Active Substance Dossiers that have been submitted and are undergoing evaluation can be consulted on the European Food Safety Agency website.⁵ These examples provide useful insight into the content and format of actual Pesticide Active Substance and Formulation Dossiers.

Pesticide Active Substance Dossiers are submitted in an electronic XML format called Computer Aided Dossier and Data Supply (CADDY), which allows for the exchange, archiving, and evaluation of complex dossiers. The software is available for free online⁶ and includes an XML conformity checker and ‘demo dossiers’ to illustrate the CADDY-XML mechanism. The submission procedure and technical explanations for the preparation of an Active Substance Dossier are available on the European Commission Directorate General for Health & Consumers website.⁷

The Pesticide Product Dossier

The Pesticide Product Dossier is a stand-alone dossier that is submitted at the member state level to obtain authorisation to sell a pesticide product containing active substances that are already approved at the EU level. The templates and guidance for preparing Pesticide Product Dossiers are the same as those for preparing Pesticide Active Substance Dossiers.

The format of a Pesticide Product Dossier may be slightly different if a zonal assessment of the dossier is considered. In this situation, the Pesticide Product Dossier contains two separate sections:

- A Product Core Dossier section, which is identical to the sections pertinent to a pesticide product dossier

- A National Addendum Product Dossier, which has the same format but contains country-specific requirements that are not covered in the Product Core Dossier. It is important to verify the country of submission and to identify the nature and status of any country-specific requirements. For example, Scandinavian countries have a specific approach to the assessment of environmental metabolites specified in their North zone-specific guidance document.⁸

The general tendency in the EU is evolving towards a more harmonised approach to dossier content and format. Still, because of the diversity of the EU, country-specific national addenda may still remain in addition to the Core Product Dossier. Consequently, 6–12 months before submitting a Pesticide Product Dossier, be sure to contact the member state about whether national addenda are needed and whether there are any country-specific procedures. The European Commission publishes and regularly updates a list of member state representatives that can be contacted about this.⁹

Resources for developing competency in pesticide dossier writing

Many resources are available for developing competency in pesticide dossier writing, from online examples to training courses. Regular conferences provide updates and discussions on the evolution of dossier formats, guidelines, and data requirements. Four sources seem to be the most frequently consulted or attended: training events taught by the official experts of the United Kingdom Chemicals Regulation Directorate, who evaluate pesticide dossiers in the UK;¹⁰ the biannual AgChemForum Conferences, which are organized by Informa;¹¹ the European Crop Protection Association's annual Regulatory Conference;¹² and the European Food Safety Agency online database of guidance documents and pesticide dossiers.¹³

Conclusion

Pesticide dossiers are an interesting and valuable opportunity for medical writers. Despite the different formats and procedures, there are many similarities with pharmaceutical dossiers. Perusing the available resources and attending training sessions specific to the topic may take time, but medical writers possess the skills and knowledge that can allow them to become proficient in pesticide dossier writing.

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Conflicts of interest

The listing of any sources of information or training courses does not imply any endorsement by the author.

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