International Code of Conduct on the Distribution and Use of Pesticides

Guidelines on data requirements for the registration of pesticides

World Health Organization

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The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase international coordination in the field of chemical safety. The participating organizations are the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Organisation for Economic Co-operation and Development (OECD), the United Nations Environment Programme (UNEP), the United Nations Industrial Development Organization (UNIDO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organization (WHO). The World Bank and the United Nations Development Programme (UNDP) are observers. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the participating organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC participating organizations.

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Table of Contents

Abbreviations

CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council
FAO	Food and Agriculture Organization of the United Nations
GLP	Good Laboratory Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LD_{50}	median lethal dose
MRL	maximum residue limit
OECD	Organisation for Economic Co-operation and Development
TGAI	technical-grade active ingredient
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

Definitions

Active ingredient: the part of the product that provides the pesticidal action

Applicant: the party (producer, importer or their representative) that makes an application for registration of a pesticide to the responsible authority

Biochemical pesticide: a substance or mixture of substances that occurs naturally and has a mode of action other than direct toxicity to the target pest (e.g. growth regulation, mating disruption, attraction). If the substance is synthesized, it should be structurally identical to a naturally occurring chemical.

Co-formulant: a non-active ingredient component of a formulated product

Equivalence: the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk

Formulated product: any formulation containing one or more active ingredients

Formulation: the combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application

Good laboratory practice (GLP): a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported

Hazard: the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property)

Maximum residue limit (MRL): the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff

Pest: any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials or environments, and includes vectors of parasites or pathogens of human and animal disease and animals causing public health nuisance

Pesticide: any substance or mixture of substances of chemical or biological ingredients, intended for repelling, destroying or controlling any pest, or regulating plant growth

Pesticide industry: all organizations and individuals engaged in manufacturing, formulating or marketing pesticides and pesticide products

Pesticide registration: the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of scientific data aimed at demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region

Product (or **pesticide product**): the formulated product (pesticide active ingredient(s) and co-formulants) in the form in which it is packaged and sold

Public health uses of pesticides: pesticides that are used in the control of pests of public health significance. They include disease vector control pesticides, household pesticide products and professional pest control pesticides (used by pest control operators in homes and public areas)

Registration dossier: the set of data that is submitted by applicants, in a structured manner, in support of their application for registration

Responsible authority: the government agency or agencies responsible for regulating pesticides and more generally for implementing pesticide legislation

Risk: the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide

Semiochemicals: chemicals emitted by a plant or animal that evoke a behavioural or physiological response in another organism. When the semiochemical affects an individual of the same species, it is called a 'pheromone'. When it affects an individual of a different species, it is called an 'allelochemical'

Technical material: technical-grade materials and technical concentrates; also known as technical-grade active ingredient (TGAI)

1. Introduction

Registration of pesticides is the process by which authorities (e.g. national governments or regional authorities) approve the sale and use of a pesticide after evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. Registration also involves regular or unscheduled review of previously registered pesticides to determine whether they still meet the requirements. A re-evaluation may be made after relevant new information has become available, when criteria are being adjusted or after a predetermined interval has passed since initial registration.

Governments should introduce the necessary legislation for the registration of pesticides. This should include establishment of a registration procedure, on the principle that the sale and use of pesticides that have not been registered are prohibited. Furthermore, governments should make provision for effective monitoring and enforcement of pesticide regulations, including the establishment of licensing and inspection schemes for importers and retailers. Governments should establish procedures suited to their requirements and not necessarily adopt all the elements of comprehensive regulatory schemes in place in countries with more extensive resources. For example, the registration criteria should take full account of local circumstances and needs, social and economic conditions, literacy, climatic conditions and the availability of appropriate and affordable pesticide application and protective equipment.

Certain data requirements may also differ if the conditions of use of a product are likely to be different among registering countries or regions because of the effect of climatic conditions on pest species, pest life-cycles, possible application methods or likely exposure. Although the requirements should be tailored to the conditions of the registering country, many data requirements for registration will be the same, irrespective of the country or situation. This is the case, for instance, for many toxicity data, as outlined below.

These guidelines generally focus on the scientific data and other information that may be required to determine what products can be permitted for use and for what purposes. The data and other information described can be used to register all types of pesticides, including public health pesticides. Section 4.1 describes the types of data and information required and why; section 4.2 shows how the data may be used in decision-making; and section 4.3 explains factors that affect data requirements. The guidelines also address some special situations (section 5): biological pest control agents, emergency approvals and experimental use. The annexes provide comprehensive lists of recommended data requirements.

The data requirements presented in this document and its annexes are based on those required by advanced regulatory authorities, such as those of Canada, the European Union and the United States of America [*1–6*]. The requirements are extensive, and Member States may find it impractical to require and review all the data listed in the annexes. Nevertheless, as described in the 2010 FAO/WHO *Guidelines for the*

registration of pesticides [*1*], transparency and exchanges of information among responsible authorities in the pesticide registration process and during collection and review of data should be promoted to avoid duplication of efforts and to minimize the use of test animals, among other efficiency measures.

Governments and responsible authorities should facilitate such exchanges of information and should, when possible, use data that are in the public domain and, preferably, have been peer-reviewed, when considering an application for registration. Further, when possible and appropriate, mutual acceptance of data and mutual recognition of registrations within regional harmonized systems should be encouraged. Registration in the country of origin should not, however, be a requirement when mutual recognition of registration is not sought. The concept of work-sharing and data-sharing is discussed further in section 4.3.5.

These guidelines were prepared in accordance with Article 6 of the *International code of conduct on pesticides management* (Regulatory and technical requirements) [*7*] and under the umbrella pesticide registration guidelines, the FAO/WHO *Guidelines for the registration of pesticides* [*1*].

2. Scope and objectives

These guidelines are intended to:

- describe the scientific data and information that may be needed to allow governments to evaluate pesticides for the purpose of their registration. This information will help countries to ensure that all pesticides used in any sector, including agriculture and public health, are effective for their intended purpose and do not pose an unacceptable risk to human or animal health or the environment;

- facilitate the generation of data and submission of applications for pesticide registration in Member States;