



International Code of Conduct on the Distribution and Use of Pesticides

Guidelines for the Registration of Pesticides



**World Health
Organization**



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Abbreviations

CBI	Confidential Business Information
CILSS	Comité Permanent Inter Etats de Lutte contre la Sécheresse au Sahel (Permanent Interstate Committee for Drought Control in the Sahel)
CRA	Comparative Risk Assessment
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IPM	Integrated Pest Management
IVM	Integrated Vector Management
JMPR	Joint Meeting on Pesticide Residues
NAFTA	North American Free Trade Agreement
OECD	Organization for Economic Co-Operation and Development
PRD	Proprietary Rights Data
SAICM	Strategic Approach to International Chemicals Management
UN	United Nations
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

Definitions

Active ingredient means the biologically active part of the pesticide.

Applicant means the party (producer, importer or their representative) that makes an application for registration of a pesticide to the Responsible Authority.

Banned pesticide means a pesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term includes a pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Equivalence means 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 pesticide product means any formulation containing one or more active ingredients.

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users.

Hazard means 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 human and animal health, the environment or property).

Minor uses are those uses of plant protection products in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest is not important on a major crop (minor pest).

Pesticide¹ means any substance, or mixture of substances, or micro-organisms including viruses, intended for repelling, destroying or controlling any pest, including vectors of human or animal disease, nuisance pests, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feeding stuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as insect or plant growth regulators; defoliant; desiccant; agents for setting, thinning or preventing the premature fall of fruit; and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide.

Pesticide Board (sometimes referred to as Pesticide Registration Board, Pesticide Council or Pesticide Committee) is the officially or legally appointed body that takes the final decision on the request for registration.

¹ For the purpose of this guideline, the definition of pesticide provided in the Manual on development and use of FAO and WHO specifications for pesticides [11] is used, rather than the definition in the Code of Conduct, as the former better reflects all the different types of pesticides that a registration procedure should comprise.

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

Pesticide registration means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the 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.

Product (or pesticide product) means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

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

Responsible Authority means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and, more generally, for implementing pesticide legislation.

Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

Severely restricted pesticide means a pesticide for which virtually all use has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

1. Introduction

Registration of pesticides is the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the 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 to the environment.

Registration is an important step in management of pesticides as it enables authorities primarily to determine which products are permitted to be used and for what purposes, and also to exercise control over quality, use levels, claims, labelling, packaging and advertising of pesticides, thus ensuring that the interests of end-users as well as the environment are well protected.

It is emphasized that registration also involves regular or unscheduled review of already registered pesticides to determine whether they still meet the requirements, for instance after relevant new information has become available or when criteria are being adjusted. Registration criteria should take full account of local circumstances and needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate and affordable pesticide application and protective equipment.

Governments should introduce the necessary legislation for the regulation of pesticides. This should include the establishment of a registration procedure and 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.

The *International Code of Conduct on the Distribution and Use of Pesticides* [1]² (further referred to as the Code of Conduct) describes the shared responsibility of many segments of society, including governments, industry, trade and international institutions. The Code of Conduct, originally adopted in 1985 by the Food and Agriculture Organization of the United Nations (FAO) Conference and revised in 2002, promotes sound pesticide management practices that minimize potential risks to human health and the environment. The revised Code of Conduct includes the life-cycle approach to pesticide management and calls upon all private and public entities to support its implementation. The Code of Conduct provides a framework for management of all pesticides, including those intended for use in agriculture and public health.

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