# GENERIC RISK ASSESSMENT MODEL FOR INSECTICIDES USED FOR LARVICIDING AND MOLLUSCICIDING



# Generic risk assessment model for insecticides used for larviciding and mollusciciding

### 2nd Edition



World Health Organization Communicable Diseases cluster Department of Control of Neglected Tropical Diseases Vector Ecology and Management

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ISBN 978-92-4-151504-7

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**Suggested citation**. Generic risk assessment model for insecticides used for larviciding and mollusciciding, second edition. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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WHO/CDS/NTD/VEM/2018.04

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#### Acknowledgements

The first edition of this document was published jointly by the World Health Organization (WHO) International Programme on Chemical Safety and the WHO Pesticide Evaluation Scheme (WHOPES) in 2010. The document was subsequently revised in 2011.

Based on experience accumulated and developments in exposure assessment methods, the document was revised by the WHO Secretariat and peer reviewed by its contact points in September 2016. Comments were received from the following: Jérémy De Saint-Jores, French agency for food, environmental and occupational health & safety (ANSES), France; Flore Cognat, European Chemical Industry Council (Cefic); Graham Matthews, Imperial College London, UK; Beyene Negatu Mormeta, Institute for Risk Assessment Sciences, University of Utrecht, Netherlands; Laurent Patty, Bayer CropScience, France; Teresa Rodríguez, Universidad Nacional Autónoma de Nicaragua, León, Nicaragua. Advice was also received from Amadou Garba Djirmay and Jiagang Guo of the WHO Department of Control of Neglected Tropical Diseases. The WHO Secretariat included Richard Brown, International Programme on Chemical Safety, WHO Department of Public Health, Environmental and Social Determinants of Health, and Rajpal Yadav and Anna Drexler, Vector Ecology and Management, WHO Department of Control of Neglected Tropical Diseases. The WHO Secretariat was assisted by Antero Aitio, consultant, Helsinki, Finland.

The Secretariat revised the document based on these comments; advice was then sought on open questions during an expert consultation from Health Canada of the Government of Canada, the British Health and Safety Executive, the Finnish Institute of Occupational Health and the Dutch National Institute for Public Health and the Environment (RIVM). The document was then finalized by the Secretariat as the second edition. Comments received during peer review and the views of experts consulted during the expert consultation were advisory in nature, and the contents of the document are the responsibility of the Secretariat.

#### Terminology, abbreviations and acronyms

ADI acceptable daily intake
a.i. active ingredient
ARfD acute reference dose
AUC area under curve
BCF bioconcentration factor
BMD benchmark dose

CICAD Concise International Chemical Assessment Document

C<sub>max</sub> peak plasma concentration

DDD daily dietary dose
DFI daily food intake
EC European Commission

EC50 concentration having a 50% effect on test populations against a

specific end-point

EFSA European Food Safety Authority

EPPO European and Mediterranean Plant Protection Organization

ETR exposure—toxicity ratio
EU European Union

EUROPOEM European Predictive Operator Exposure Model

GHS Globally Harmonized System of Classification and Labelling of

Chemicals (United Nations, 2015)

GLP good laboratory practice

guideline scenario exposure scenario which assumes that the product is used

according to the instructions given on the product label and in

WHO guideline information

IARC International Agency for Research on Cancer IPCS International Programme on Chemical Safety JMPM Joint Meeting on Pesticide Management

JECFA Joint FAO/WHO Expert Committee on Food Additives

JMPR Joint Meeting on Pesticide Residues

lax standard scenario exposure scenario in which no personal protective equipment other

than light clothing covering the trunk is assumed concentration killing 50% of the test organisms

LC50 concentration killing 50% of the test of LOAEL lowest-observed-adverse-effect-level LOEC lowest-observed-effect concentration

NOAEL no-observed-effect concentration

NOEC no-observed effect concentration

NOED no-observed effect dose (terminology used in environmental risk

assessment (EPPO, 2003)

OECD Organisation for Economic Co-operation and Development

OEL occupational exposure level

PEC predicted environmental concentration
PNEC predicted no-observed-effect concentration

PPE personal protective equipment RfC reference concentration

RfD reference dose

RPE respiratory protective equipment

TSD tolerable systemic dose

TSD<sub>AC</sub> tolerable systemic dose, acute exposure

TWA time-weighted average

TWAC time-weighted average concentration

UF uncertainty factor

UKPOEM UK Predictive Operator Exposure Model

USEPA United States Environmental Protection Agency

WHO World Health Organization

WHOPES World Health Organization Pesticide Evaluation Scheme WP wettable powder formulation, diluted in water before use

#### 1. Introduction

This generic risk assessment model can be applied for both larviciding and mollusciciding products. The terms "insecticide" or "pesticide" are used in this document as generic terms and should be understood to refer also to chemical products used to control larvae, snails and relevant life-cycle stages as appropriate. A risk assessment model for vector traps which use larvicides or adulticides is annexed to this document.

Immature stages of vectors living in permanent or semipermanent water bodies can be controlled by applying a larvicide. This is usually done in urban and other densely populated areas, including refugee camps, but may also take place in extensively irrigated farms or other wetlands close to residential areas. Larviciding is a part of larval source management and should be applied within an integrated vector management approach involving use of other vector control methods and approaches. It can be applied to control vectors of malaria, dengue and other mosquito-borne diseases, as well as nuisance mosquitoes, but is most effective in ecological situations where mosquito breeding habits are few, fixed and findable (WHO, 2005b; WHO, 2006).

A number of products can be used in larviciding. These are chemical insecticides, including insect growth regulators and juvenile hormone mimics; biological/microbial formulations (e.g. bacterial larvicides); petroleum and other types of oils; and monomolecular surface films. The WHO-recommended larvicide classes are: bacterial larvicides; benzoylureas; juvenile hormone mimics; organophosphates; and spinosyns. The end-use larvicide products include liquid formulations (emulsifiable concentrates and suspension concentrates) as well as solid formulations (tablets for direct application; granules; matrix release formulations; water-dispersible granules; and wettable powders). The solid formulations are designed either for immediate release of their active ingredients into water, or their solid matrix provides a slow and prolonged release of the active ingredients giving a prolonged residual action of weeks or months, and applied in certain habitats, e.g. water-storage containers.

Larvicide products may be applied to water used for irrigation of food crops, or to treat drinking-water supplies. Pyrethroids are not recommended by WHO for larviciding since they are considered to have too wide an impact spectrum on non-target aquatic species.

Schistosomiasis is an acute and chronic neglected tropical disease caused by infection with the larval forms of parasitic worms. Fresh-water snails are an intermediate host of the causative agent, the trematode worms of the genus *Schistosoma*. Mollusciciding, i.e. decreasing the populations of the host snails by application of molluscicides, is a component

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