

Pesticide Registration Criteria: On what basis do we decide which pesticide to authorise and which one not?

One of the main tasks of pesticide regulators is to authorize the use of a pesticide in their country, or refuse its registration. This is done by “evaluating 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” (International Code of Conduct on Pesticide Management). But when does a pesticide not pose unacceptable risks to human health? When is a pesticide effective for its intended purposes? Do we have specific criteria against which we compare the outcome of an efficacy or risk assessment, to decide what is acceptable and what is not? It is important to have clear and transparent registration criteria so that applicants for registration, but also farmers and consumers know why a pesticide is approved or refused.

About the Presenter



Harold van der Valk is an independent consultant in pesticide management and environmental toxicology and runs a small consultancy, called Falconsult, based in the Netherlands. He worked as a staff member for FAO in Senegal and Mali in 1990s. Since then, he collaborates with FAO, WHO, UNEP and Wageningen Environmental Research on pesticide risk assessment, registration and management, in Africa, Asia, the Pacific and the Caribbean.

Question 1: Which concrete criterion is used in your country/region or the country/region you work in to decide whether the human health or environmental risks of a pesticide are “acceptable”? (Be as specific as possible). If you do not know, please also indicate this.

Zambia: Zambia criteria are based on the data associated with the chemical. This includes information from MSDS and risk assessment data.

Togo: I don't know which criterion is used in Togo related to human health or environmental risks. We do not have MRL or ADI therefore it is a little bit difficult and information is not available. However, I think that registration is more based on efficiency.

Nigeria: The criteria used for the approval of a pesticide are both risk and hazard-based. Any pesticide that is submitted by any industry or individual for registration will be assessed for their intended purpose, efficacy, health implications on human and non-target organisms as well as persistence and effects in the environment National Agency for Food and Drug Administration and Control.

Tanzania:When deciding whether the human or environmental risks of a pesticide are acceptable, the following criteria are used: Pesticides are not registered (1) If the pesticide has substances with high toxic levels that can harm human health and (2). Can cause ozone layer depletion, and persistent pesticides in the environment.

Eswatini: Eswatini has not started pesticide registration yet but has enacted the pesticide management act which states that the criterion will be hazard and risk based. We currently rely on the South African registration scheme for now.

Malawi: Applicant submits the required documents like the dossier to the board with the help of the technical committee then go through the submissions and if the information

presented is in accordance with the accepted standards then it given a green light. Where such data reveal high levels of toxicity to humans, livestock and wildlife and non-target organisms like bees, fish and birds, we normally reject.

Zimbabwe: Classification of pesticides is based on the level of toxicity (oral), on the basis of human health. To some extent, the impact of the pesticide is considered, but not necessary for classification purposes. Acceptable levels are based on toxicity in relation to human health.

South Africa: The DALRRD in South Africa uses the toxicology tests in line with the WHO criteria and environmental fate in the dossiers of the pesticides submitted to see if they conform to the MRL limits as set by the DALRRD and also internationally set criteria.

Uganda: Hazard based criteria where we rely on the technical information given in the dossier, literature review and comparison with other existing database sources like EU, EPA, OECD. General acceptability in some of the trusted countries/regions like EU, USA, OECD informs our decision.

Belize: Currently in Belize, we have not yet adapted a criteria. The registration committee looks at all parts of the dossier separately, i.e. the toxicological part, ecotox and agricultural.....and meet and provide their reviews and recommendations and/or objections. BUT there isn't a detailed criteria on what to approve and not. The only existent (not formalized) criteria is that it shouldn't be listed on any of the COPs.

Question 2: Which criteria in the EU Uniform Principles are hazard-based; which are risk-based? Which EU criteria can be most easily applied in your country/region or the country/region you work in to? Which criteria are more difficult? Provide a reason for your answer?

RISK BASED	COUNTRY
EU risk based Principles; PPE requirements, pesticide package requirements, pesticide formulations, fate and distribution in the environment, acute and chronic effects on human health, REI and MRLs.	UGANDA
We would like to commence risk assessments and develop risk reduction strategies for the pesticides currently classified as Restricted-Use, to determine mitigation measures including, phasing out of those considered to present unacceptable risk under local conditions of use.	BELIZE
EU Risk Based Principles: the conditions of use of a pesticide dependent on its formulation.	EU

Risk assessment requires that you have information or models to estimate the level of exposure to the pesticide in your country.	PRESENTER
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HAZARD BASED	COUNTRY
Hazard Identification principle is hazard based and it defines the chemical and biological properties of the pesticide , Precaution principle is risk based and it defines the PPE and controls needed for the pesticide, Substitution principle is risk based, Sustainability principle is hazard base and Mutual Recognition principle is hazard base.	ESTWATINI
The active substance evaluation at European level criteria can be most easily applied in your Zimbabwe. The formulation evaluation criteria is difficult as the industry does not easily disclose the formulations and the co-formulants. The Country does not have testing facilities for evaluation of the formulations and financial resources to buy reagents and the chemical technical grades.	ZIMBABWE
Hazard based criteria can best be applied for it requires less resources and we can easily base on evaluations and decisions taken elsewhere.	UGANDA
In Eswatini the hazard based criteria would be easier to apply because we do not have in place the required infrastructure and expertise to do the risk based criterion. The hazard based can be sourced from industry.	ESWATINI
The hazards are inherent of the pesticide and those cant be changed but the exposure can be which is the risk so changing the way the pesticide is applied or the PPE used can make a difference. In SA the exposure is the problem as most communities don't wear their PPE for various reasons (too expensive, don't have access, temperatues when applying i.e too hot).	SOUTH AFRICA
It is included in the legislation that hazard and risk assessment should always be carried out before approval of such products. Hazard-based criteria can easily be applied in Nigeria because Risk-based criteria require large capital to conduct, so the industry usually neglect it and the Registration board also does not bother sometimes to question the Data safety sheet submitted by the industry.	NIGERIA
Hazard-based criteria are only taking into account the properties of the pesticide (not the level exposure). Hazard assessment is relatively easy and can be based only on the dossier data. There is always discussion whether hazard based criteria should be applied for pesticide registration. Some are against it because exposure to the pesticide is not taken into consideration (and "the dose makes the poison"). Some are in favour because they consider that for certain adverse effects, any exposure is unacceptable and therefore an indication of the hazard level is sufficient. E.g. this is the case for cancer or reproduction toxicity in Europe.	PRESENTER

Question 3: In your country/region or the country you work in, is the general public informed about the decisions that the registration authority takes? If yes, how can they find this information? Can the public comment on draft registration decisions. If yes, how is this done? What can be done to make the registration decisions more transparent?

YES

EUROPE: the full evaluation report of a pesticide needs to be made public, with the exception of confidential business data. You and I can find this on the internet at EFSA (for active ingredients) and the national regulators.
USA/EUROPE: the regulator publishes an intention to register a pesticide and allows a period of comments. Often it is not just individual that comment, but research institutions, beekeepers organizations; farmer groups; drinking water companies, etc. etc

NO

UGANDA: Only the list of registered pesticides is published in the National Gazette. The public has no access and say on the draft registration decisions.

SOUTH AFRICA: The general public does not seem to be informed. I'm a member of the general public as well as a professional and information on decisions taken by the registration authority is one I also haven't accessed.

ZIMBABWE: The general public can not easily be informed about the decisions of the registration authority. The information is hidden on the legislation and only give guidelines on what they are supposed to do. However, they cannot influence any decision.

ZAMBIA: There is no formal procedure or process in which pesticides are registered. Only list of registered pesticides is availed to the public. The public is not informed when it comes to the registration pesticides.

TOGO: General public are not informed about the decisions that the registration authority takes. Any Informations are not available on website (list of approved pesticide, banned pesticides etc). You should ask the Ministry of Agriculture to obtain what you desire.

BELIZE: The Pesticides Control Board in theory should publish in the gazette the new registered fomulations but in practice it isn't done. At the moment, we do not have a mechanism that captures any public comment on any of the registrations

NIGERIA: The list of all approved products are also listed on the website for public perusal but they never allow anybody outside the Agency to participate in the decision making.

TANZANIA: The general public is not informed on the decision about the decision of registration by the regulatory authority. The Registrar of pesticides after receiving consultation of the pesticide approval committee makes decisions on the registration or refuse to register the pesticide.

Resources and Further Reading

1. COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0546>
2. International Code of Conduct on Pesticide Management: Guidelines on Pesticide Legislation : <http://www.fao.org/3/a-i5008e.pdf>

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The Division of Environmental Health (DEH) Pesticide Discussion Forum is a bi-monthly online seminar for pesticide regulators and resource persons, as well as students in the Post-Graduate Diploma in Pesticide Risk Management (DPRM). Our aim is to provide support for managing pesticide risks and implementing risk reduction strategies. DEH is based in the School of Public Health and Family Medicine at the University of Cape Town (UCT).
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