Division of Environmental Health
School of Public Health and Family Medicine
Isikolo Sempilo Yoluntu kunye Namayeza Osapho
Departement Openbare Gesondheid en Huisartskunde
UNIVERSITY OF CAPE TOWN

Division of Environmental Health | UCT

Sweden
Sverige

Pesticide Discussion Forum Summary Digest

Issue 05 of 2022
Forum Date: 19 May 2022

Impurities

FAO and WHO specifications for pesticides used in agriculture and public health aim at quality assurance and management of risks associated with the use of these products ("The International Code of Conduct on Pesticide Management" Article 4, Testing of pesticides). These specifications are published on the internet and currently cover over 150 active ingredients and many more formulated products for agricultural uses. The specifications reflect hazards and risks of a particular compound expressed as purity/impurity profile and limits for purity/impurities applied in normal manufacturing production for technical materials. They include acceptable physical-chemical properties for formulations. Certain impurities present in technical materials may clearly increase the hazard (or toxicity) of an active ingredient and of its formulated products. The criteria used to distinguish between impurities without particular concern and those that must be controlled and limited are presented and discussed here. The published specifications of two pesticides (an organophosphorus insecticide, malathion, and impurities) and a modern fungicide (prothioconazole and its impurity -desthio) are presented here. They are used to further illustrate the potential impact of these impurities on the overall hazard (toxicity) of end-user products and how technically achievable, yet safe levels of impurities, are evaluated. Then, corresponding limits are set in the FAO specifications for these two compounds.

This document is a summary of the University of Cape Town's Division of Environmental Health's Pesticide Community of Practice held on the 19 May 2022 titled: "Impurities". This digest presents the issues and points raised, and the information shared by participants in response to three questions prepared by the presenter, Dr Markus Mueller A total of 46 participants joined the live discussion and 1 individual blogged his responses. From the members who attended, 87% were from Africa, 4% were from Latin America and the Caribbean with 2% coming from Europe, Eastern Mediterranean, South-East Asia, and Western Pacific separately. Sector distribution amongst participants were as follows; 54% were from the Government sector followed by Academia with 20%, 17% from Non-Governmental Organisations, 7% Industrial and lastly 2% from Intergovernmental Organisations.

About the Presenter

Dr. Markus D. Mueller studied organic chemistry and worked with the Swiss Office for Agriculture in the field of pesticide registration - environmental safety, residues, and product chemistry for more than 30 years. He served as CIPAC Chairman and as an expert and chair in the JMPS Panel. He is author and co-author of more than 120 peer-reviewed research articles, dealing mainly with environmental behaviour of pesticides and associated analytical methodologies. He was a lecturer teaching pesticide science at his home university, the Federal Institute of Technology in Zurich, for 25 years.

DISCLAIMER: The information below represents the opinions of members participating from different countries expressed during the discussion and shall not necessarily be taken to reflect the official opinion of the DEH, UCT, FAO, or KemI.

PRESENTED BELOW ARE THE THREE QUESTIONS AND RESULTING DISCUSSION INPUTS FROM PARTICIPANTS:

Question 1: Please indicate to what extent, according to your knowledge, FAO specifications are a point of reference for stakeholders in pesticide management in your country (provide the name of your country).

REGION	EXTENT TO WHICH FAO SPECIFICATIONS ARE USED AS A POINT OF REFERENCE FOR STAKEHOLDERS
	AFRICA
Ethiopia	➢ It is not used as a reference in the country.
Kenya	➢ There is uncertainty as to whether it is used, however, the assumption is that it is.
Nigeria	➢ There is uncertainty as to whether there are agencies in charge of pesticide management in the country, however, FAO specifications are likely used by agencies. ➢ Phytosanitary law likely refers to FAO as there is a well-established and functional quarantine service that oversees this responsibility.
South Africa	➢ Sample reports are required on new registrations and registration renewals.
Sudan	➢ The FAO registration is used by the pesticide registration office, specifically, the Ministry of Agriculture.

Tanzania	➢ FAO specifications are used as a reference for laboratory verification of formulated pesticide content before registration, importation, and market sampling. The Pesticide Regulatory authority in Tanzania uses the FAO specifications for decision making. ➢ Testing for impurities is not done. ➢ The FAO specifications are not specified in legislation but rather in laboratory quality manuals and operational manuals.
Zambia	➢ Testing is mostly required during registration.
Zimbabwe	➢ FAO specifications are mainly used for the registration of pesticides. ➢ Stakeholders are sensitized to FAO specifications in the management of pesticides.
MIDDLE EAST	
Iran	➢ Many LMICs possess their pesticide formulator system and factories. Therefore, there is no guarantee about what is in the final pesticide products and whether smuggling in the system occurs. In recent years, many complaints about pesticide technical products are from new pesticide corporations in Asian countries.
Presenter comments	➢ As many participants indicated that there is no reference to FAO specifications, there is a need for FAO to do advocacy for countries to have a better understanding of the benefits of having FAO specifications as a global standard and for registration of pesticides, especially in LMICs. ➢ The FAO specifications are benchmarks for pesticides that are mostly off patent. It is a benchmark of what quality can be achieved and the reasonable quality evaluated in terms of minimum impurities, relevant impurities, and acceptable physical-chemical properties of the formulations. A benefit is that the benchmark comes free of charge and is easily accessible. It can prevent sub-standard pesticides from being manufactured and sold in LMICs.

Question 2: At the best of your knowledge, does the national authority for pesticide registration in your country use the equivalence process as described in the FAO/WHO Pesticide Manual?

YES:

- **Tanzania, Zimbabwe**: the equivalence process as described in the FAO/WHO Pesticide Manual and other guidelines is used.
- **South Africa:**
  - Under the Agricultural remedies regulation.
  - If information about pesticides in SA, is required, Agri-Intel cab is used. What is published by the government is very difficult to find and the information is limited.
  - The SA agricultural department handed over information on pesticides registered in SA to CropLife and CropLife wants people to pay for this information, which is a violation of access to information and transparency.
  - Yes, and more information as per the Fertilizers, Farm Feeds, Seeds and Remedies Act 36 of 1947
  - An interesting point is that the public should have access to information on impurities. Not possible in SA

PARTLY:

- **Iran:** It is followed only in part and not completely.

NOT CERTAIN

- **Nigeria, Kenya, Zambia:** There is uncertainty as to whether an equivalence process, as described in the FAO/WHO Pesticide Manual, is used.

Question 3: In your country or region, do the pesticide registration bylaws adequately cover these aspects of relevant impurities and provide sufficient guidance so that the manufacturers and/or importers understand the importance of the issue?

REGION	
AFRICA	
Ethiopia	➢ No, all are not covered.
Malawi	➢ In Malawi, on registration specifically, the requirements are like the FAO label guidelines. Things like impurities are not covered in the country's laws. The challenge is that the information has not yet been demanded by the public or organisations. ➢ Lack of technical capacity and infrastructure is the major issue. Though policies might be in place, it is more theoretical than practically implementable.
South Africa	➢ Compliance monitoring is done in terms of efficacy, composition, and labelling. A batch report is sent to technical advisors for validation and the registrar can be asked for products to be sampled.
Sudan	➢ In Sudan, it is included in the guidelines for pesticide registration. Impurities are strictly monitored. ➢ Before the pesticide goes to the pesticide register, a sample of it is analysed in the laboratory.
Sierra Leone	➢ None for Sierra Leone, however, specific data or monitoring tools are used.

Tanzania	➢ As impurities are in biopesticides, they have been mistaken as "safe". However, they can still facilitate toxicity. Therefore, more research is needed and unfortunately, registration by law does not cover impurities as guidance to manufacturers. ➢ As impurities have health implications, there is a need to work on them. For example, Lambda Cyhalothrin formulation seems to be more toxic than technical material. ➢ The challenge is that impurities are kept as confidential business information (CBI) which is hidden by manufacturers. Therefore, the legislation would need to specify when impurities are not considered as CBI or else all will be classified as such by industry. ➢ Most pesticide specifications are covered by legislation and only water is mentioned as relevant. ➢ Manufacturers should provide impurity information.
Zambia	➢ In Zambia, it is not explicitly covered. ➢ There is a general monitoring scheme in place. However, it needs to be strengthened. ➢ In the case of Zambia, monitoring is not in place. However, we have had Adhoc programs which show the presence of pesticides in food and surface water.
Zimbabwe	➢ The laws on what is expected by pesticide registration are available however, there is uncertainty as to whether it is specific to impurities.
MIDDLE EAST	
Iran	➢ Like other LMICs, Iran only follows it partly. Pesticide structures are very complicated and when these compounds arrive in LMICs (particularly recently), there are lots of impurities and it is even more challenging.

PRESENTED BELOW ARE QUESTIONS FROM PARTICIPANTS AND AN ANSWER FROM THE PRESENTER'S PRESENTATION:

Question (Q) & Answer (A):

(Q): Is IsoMalathion an activated form that works to kill insects-like other OPs?
(A): No, not necessarily. IsoMalathion is an internal transesterification degradation product and has a higher likelihood to kill humans.

(Q): In the percentage description of the active ingredient, does the remaining percentage mean impurities?
(A): Yes, it does. It can however be different kinds of impurities. Companies analyse five batches out of production and do a mass balance. In that way, they show how many of the active ingredients they have and what are impurities.

(Q): How often is it required for ingredient testing in a particular pesticide? Is only one time enough at the reference lab?
(A): There are guidelines on how the market controls should be done and there are different strategies in countries. For example, some countries test everything before it goes to the storehouse.

(Q): Is it voluntary for countries to follow the FAO specifications or is it included in international agreements?
(A): It is voluntarily and must be under national legislation. It is not a convention, just a code of conduct that is voluntary**.**

Resources and Further Reading

1. FAO/WHO Code of Conduct on Pesticide Management: https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/en/
2. FAO/WHO Manual, Specifications: https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/pesticide-specifications-list/en/
3. CIPAC, Organisation and Publications: https://www.cipac.org/index.php

If you are not a member, we invite you to join UCT's Pesticide Discussion Forum: https://forms.gle/NzYH5REfUruL3jdm6

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 postgraduate 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). environmentalhealth@uct.ac.za

This Digest was produced by: Tatum Louw| Forum Administrator | tatum.louw@uct.ac.za.
Prof Andrea Rother | Forum Moderator | andrea.rother@uct.ac.za
Acknowledgement: *Financial assistance from the Swedish International Development Cooperation Agency* ***(SIDA)****, has been arranged by the* ***Swedish Chemicals Agency (KemI)***