

28 April 2000

Position Paper

Utilisation of FAO Specifications by National Authorities

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It is becoming increasingly apparent that certain governmental crop protection product regulatory authorities may be inappropriately utilizing the new FAO specification process. The purpose of this paper is to clarify the principles involved in establishing and using FAO specifications by country authorities.

Purpose and Intent of the New Procedure

The purpose and intent of the new FAO procedure, as defined in the Fifth Edition of the "Manual on the Development and Use of FAO Specifications for Plant Protection Products," adopted in 1999, are quite clear. The purpose of establishing specific FAO specifications under this new procedure is to ensure that technical materials from different manufacturers are equivalent, but not necessarily identical, from a toxicology and ecotoxicology point of view. Most importantly, the FAO specification is not meant to be a *de facto* registration. The specification is established by the FAO as a tool for local authorities to use to determine the suitability of the product for local use.

Provisions of the New Procedure

Under the new procedure, in addition to the package of formulations and analytical information submitted under the former procedure to FAO, the manufacturer submitting the initial FAO specifications now provides to FAO a greatly expanded data package for the active ingredient. This package is comprised of information on:

- the manufacturing process for the active ingredient,
- its complete impurity profile,
- its physical-chemical properties,
- a summary of its toxicological and ecotoxicological properties.

After evaluation and on acceptance of the data and the specification, FAO will publish a standard document specifying certain characteristics and physical properties of the technical material, including relevant impurities, and of its formulations. FAO will also publish the name of the sponsoring manufacturer. All other data and the data package itself are kept confidential within the FAO. Another supplier wishing to claim that its products meet these FAO specifications must present to FAO a reduced data package, including acute toxicity and manufacturing process, but most importantly, a full impurity profile of the active ingredient as manufactured by the subsequent applicant. FAO will then compare the new package with that from the original sponsor and, under strict standards of confidentiality, will judge the equivalence of the subsequent active to the original substance on which the FAO specification was based. This equivalence determination is carried out using carefully defined considerations detailed in the Fifth Edition of the Manual. If the active ingredient from the subsequent supplier is judged to be equivalent to the original, then products from the subsequent supplier will be deemed to be acceptable under FAO criteria, and the new supplier will be added to the published list as meeting FAO specifications for that active ingredient. If the equivalence criteria are not satisfied, then the subsequent applicant will not be "certified" as having met FAO specifications for that active.

Conditions for Effective Use of the New Procedure

The Global Crop Protection Federation strongly supports the new FAO procedure in its intent to ensure that only quality products are provided to users, especially in developing countries. Industry is committed to continuing participation in the FAO specification process, but emphatically recommends that the following principles be observed:

- It must be recognized that published specifications alone are inadequate for assessment of equivalence between two actives. The content of relevant impurities, while critically important from a safety point of view, is a necessary, but not sufficient, consideration in equivalency determinations. Only comparison with full impurity profiles, done on a confidential basis within FAO, can provide assurance of equivalence and the resultant comparability of physicochemical, toxicological, and ecotoxicological properties. Accordingly, the full process as required by FAO should be the primary mechanism for equivalency determination of active ingredients.
- Countries should be discouraged from granting country secondary registrations based only on the published information in a global FAO specification. A full equivalency assessment within FAO will ensure that the subsequent manufacturer is truly producing product of comparable quality and safety to that on which the FAO specification was based. Thereafter, since establishment of equivalency is only a first stage of an effective secondary registration process, authorities may then proceed to

review secondary registration applications using the full, formal process established for registration of products in their country. This process should include the submission of a supporting data set generated by the secondary applicant or evidence of agreement of access to data from the primary registrant.

- National authorities are to be commended and encouraged in their engagement of FAO to utilize FAO procedures to assess quality and equivalency of products under consideration for secondary registration. We believe, however, that countries should be encouraged to establish the following provisions before utilizing FAO procedures for internal decision-making:
 - Reliable data protection for owners of proprietary data,
 - Patent protection,
 - Competent technical and analytical personnel and processes to evaluate pertinent data,
 - Fair, efficient, and enforced processes for data compensation to original registrants, when appropriate,
 - Efficient processes to monitor the quality of products routinely in the marketplace.
- FAO specifications approved by the old procedure will remain in force until amended or cancelled by the FAO. These older specifications should continue to be used as they were originally intended, that is, for quality assessment based on analysis and comparison of physical properties among products from different sources.

Conclusions and Recommendations

Based on these points, it is strongly recommended that national registration authorities should adopt the above-mentioned principles in their recognition of, and utilisation of, FAO procedures by their countries. Applicants for secondary registration to be based on existing FAO specifications should apply to the FAO for assessment of equivalency under the established protocols. By following this procedure, national authorities will be able to conduct equivalency assessments and make certain that the process will yield the required safe products for sale and use in their countries. To further ensure that outcome in cases where no FAO specification under the new procedure yet exists, industry is committed to work together with country authorities to develop procedures that are acceptable both to government and to industry for the protection and evaluation of data for determinations of equivalency.