AgroCare Position Paper

"New Procedure" FAO/WHO Pesticide Specifications

The generic crop-protection industry can meet the highest standards of quality and safety and satisfy the global demand with a diversified supply of competitively-priced products. This vital and strategic industry can significantly contribute to the reduction of agricultural production costs and increase agricultural output worldwide. In order to achieve this, however, technical standards and regulations applicable to the marketing approval and international regulation of generic pesticides must be formulated and applied in a transparent, objective and impartial manner, consistently with existing international agreements.

The role of technical standards and regulations is to facilitate the exchange of information and the diffusion of technologies, improve production efficiency (notably through economies of scale) and encourage a level playing field for competing undertakings. In the particular case of pesticides, such standards and regulations also serve the fundamental purpose of protecting the environment and human health. In this regard, FAO/WHO specifications are intended to serve the purpose of international quality standards to be used in technical regulations. The Manual on Development and Use of FAO and WHO Specifications for Pesticides states the role of specifications in the world market as follows: "*Harmonization of relevant national and/or international standards through the use of FAO and WHO specifications should facilitate world trade in pesticides*."[1]

The original (often referred to as "old procedure") specifications served their intended purpose well. These original specifications contained two vital pieces of information: a) the minimum standard to purity of the active ingredient found in the technical grade material; and b) the maximum tolerance (concentration) of any *relevant* impurities plus their analytical methods. This information was published in its entirety, making "old procedure" specifications completely transparent. Any third party, whether a second manufacturer or a regulator, could *independently* assess the conformity of a second manufacturer´s product with the published specification. In order to do this, the third party required the impurity profile (based on the "5-Batch Analysis") in order to determine whether the published quality standards were being met. No involvement by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) Panel was required to determine the conformity of a second manufacturer´s material with the specification.

However, the "new procedure" for defining FAO/WHO specifications, as applied by the JMPS since 1999, may hamper rather than promote the availability of competitive products in the global market. All references made to or implied uses of specifications stated in the FAO/WHO Manual on Development and Use of FAO and WHO Specifications for Pesticides, as well as the Draft Guideline of Quality Control of Pesticides, are incompatible with how specifications actually work under the "new procedure", and raise the question regarding the purpose specifications serve today. For specifications to truly serve as international standards they must be public, transparent, impartial

[1] Manual on Development and Use of FAO and WHO Specifications for Pesticides, Second revision of the first edition, Article 1.5.5., Rome, November 2010.

and practical to implement. "New procedure" specifications set out standards that, due to inherent flaws in their design and mode of application, can block or delay the timely introduction of generic competitive products in an unacceptable manner, as mentioned above. Moreover, these specifications induce WTO members who subject the marketing approval of pesticides or the definition of technical regulations to compliance with such a procedure, to violate binding multilateral agreements aimed at preventing the creation of unnecessary barriers to trade.

Under the "new procedure" for defining FAO/WHO specifications, the resulting specifications are linked to a single manufacturer and include non-relevant impurities which are not published. Since "new procedure" specifications include this secret information, it is impossible for any third party (second manufacturer or regulator) to *independently* assess whether a pesticide conforms to the specification defined for its active ingredient. "New procedure" specifications have in essence partially blinded the international quality standard.

Flaws in FAO/WHO specifications

The recent methodology of defining FAO/WHO specifications applied under the "new procedure" is not transparent: they contain secret information. AgroCare does not question the right of any company to develop and preserve trade secrets, as protected by the TRIPS Agreement (Article 39). However, AgroCare objects to the incorporation of secret information into international specifications. Three main aspects need careful consideration:

a) Compliance with the FAO/WHO specifications, as currently implemented, is encumbered by the inclusion of items (information) for which intellectual property rights are claimed and whose content, in addition, is undisclosed. This generates uncertainty about conformity of equivalent products, discourages the entry of generic products into the market, and undermines the very nature of technical specifications as framework for the smooth functioning of a competitive market.

The legitimacy of technical standards that incorporate items protected by intellectual property rights has been challenged in the context of the WTO. Significantly, Member States have requested the WTO Committee on Technical Barriers to Trade to examine how patents *and other intellectual property rights* might become technical barriers to trade.[2] The Standing Committee on Patents of the World Intellectual Property Organization (WIPO) has also been requested and has started to address these issues.[3]

b) The secret elements in the FAO/WHO specifications create unfair advantages for the first registrant of pesticide products who is usually the proponent of the specification. As noted by the WTO Secretariat, the standard-setting dynamic may affect competition between countries and companies: "To the extent that promoters of competing standards come from different countries and the winner can claim rents from the adoption of their standard, strategic trade

[2] WTO documents G/TBT/W/251 of 2005 and G/TBT/W/251 add1 of 2006.
[3] See, e.g. WIPO Secretariat, Standards and Patents, document SCP13/2, March 2009.

policy considerations come into play."[4] Moreover, an UNCTAD-ICTSD report warned about the anti-competitive behavior that may be promoted when a standard 'has become closed (or captured) by a limited number of producers with a high level of market control'.[5] In the case of FAO/WHO specifications, the standard is usually captured by a single manufacturer that proposed the standard. Further changes in the specification can only be requested by the manufacturer who proposed the standard.

The presence in the FAO/WHO specifications of secret elements indirectly allows a small group of companies to keep the rate of new entries into the pesticides market artificially low and thereby maintain high profit margins, to the detriment of farmers and consumers. The market power conferred to those companies can be exercised well beyond the expiry of any relevant product or process patents, that is, when the technology is in the public domain. Hence, farmers and consumers are deprived of the benefits that would normally accrue to them through more intense competition, once technologies have become freely available for use and production.

c) If the secret information assessed in the context of the 'new procedure' includes data considered relevant to the safety and efficacy of the products, that information would enjoy, *de facto*, an indefinite protection. Test data protection, as implemented in the European Union, the USA, Japan and other countries provides for the exclusive use of such data for a *limited period of time,* starting from the date of the marketing approval of the product. The purpose of the limitation of that period is to ensure that, after its expiry, anyone is free to use or rely on the relevant test data for the marketing approval of an equivalent product. The system implemented under the FAO/WHO specifications, on the contrary, may prevent the competitive use of the information relied upon by the JMPS *sine die*. The over-protection thus conferred creates an unjustified obstacle to legitimate production and trade.

The JMPS Panel, which meets once a year, is the only entity capable of determining whether a second manufacturer´s product conforms with the international quality standard since the JMPS is the only body that has access to the secret information in the FAO/WHO specification. JMPS has thus become the exclusive conformity assessment provider in the world. The 2005 World Trade Report considers such a limitation in the options for conformity assessment to a product standard a critical trade barrier, by stating: "*The degree to which the assessment of conformity with a regulation may act as a trade barrier hinges critically upon the flexibility provided to exporters in choosing conformity assessment providers, activities and procedures*."[6] The "new procedure" specifications monopolize conformity assessment in the JMPS.

[4] See WTO Secretariat, World Trade Report 2005 – Exploring Links Between Trade, Standards and the WTO, 75 (2005), http://www.wto.org/english/res_e/booksp_e/anrep_e/wtr05-0_e.pdf.

[5] UNCTAD-ICTSD, Addressing the Interface between Patents and Technical Standards, Policy Brief No. 3, http://www.unctad.org/en/docs/iprs_pb20093_en.pdf, p. 5.

[6] World Trade Report 2005 "Exploring the links between trade, standards and the WTO (WTO) http://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report05_e.pdf.

Given that today´s "new" specifications are partially secret and now tied to a single manufacturer, any second manufacturer that wishes to assess whether their product meets the international standard for quality must submit its product´s dossier to the JMPS for an evaluation of "equivalence" to the specification developed by the first manufacturer. This creates a serious bottleneck due to the time it takes to evaluate each submission and the limited human and economic resources of the JMPS. This bottleneck is not a trivial problem since each active ingredient can have dozens of generic manufacturers around the world. Therefore, regulators are likely to have to review or assess the quality of hundreds of generic pesticides per year. Such a herculean task is not something the JMPS was designed or equipped to do. The JMPS cannot serve as the quality control authority or conformity assessment provider for the world since its response time would be in the order of years or decades. To get an idea of the bottleneck that the "new procedure" creates one only has to look at the rate at which "new" specifications are being defined per year (see Fig. 1 below). At the current annual rate, it would take approximately sixty (60) years for the JMPS just to replace all "old" specifications with "new" ones.[7] To this significant workload we must also add the conformity assessment work of generic products and the supposed periodic 10-year review of specifications by the JMPS.

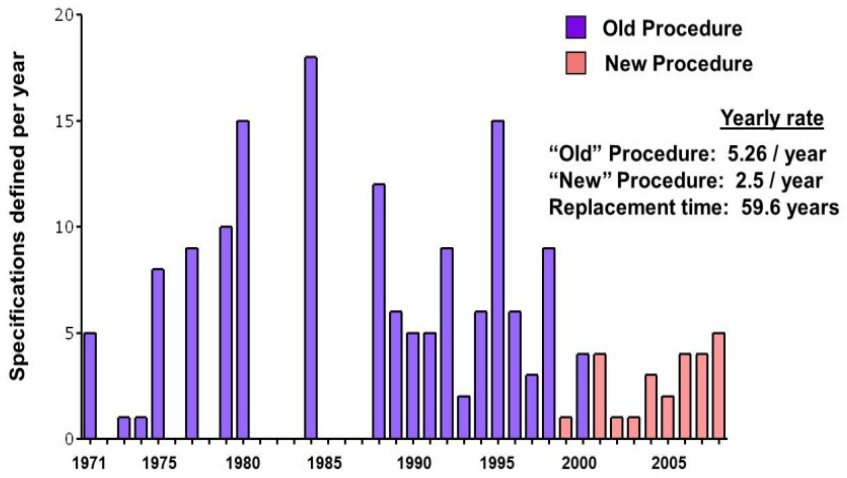

Fig. 1 FAO/WHO Specifications established between 1971-2008

The current workload of the JMPS has no slack in available capacity, even though less than ten (10) new specifications or conformity assessments are reviewed per year. Marginal increases in conformity assessments overwhelm the JMPS Panel. Recent requests by generic pesticide

[7] "International Regulation of Pesticide Quality", AgroCare Presentation given at the 7th Joint CIPAC/FAO/WHO Open Meeting in Ljubljana, Slovenia. Primary data obtained at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/ps-old/it.

companies for the inclusion of product evaluations in the schedule of the JMPS Panel have been rejected due to the inability of handling a moderately increased yearly workload. CropLife, the lobby of the large corporations, is very aware of this insurmountable bottleneck at the JMPS, and yet still recommends that all registration requests by equivalence in countries where a "reference profile" is not available be sent to the JMPS for evaluation.[8] This absurd position intends to assign the role of "registration authority of the world" to the JMPS Panel, well aware that such a role paralyzes generic registrations in those countries and consequently reducing competition in the market.

Violation of WTO disciplines

The FAO/WHO "new procedure", as currently implemented, may induce governments to directly or indirectly rely on such procedure in developing their technical regulations, and thus, to violate multilateral rules applicable in the context of the WTO. The Agreement on Technical Barriers to Trade ('TBT Agreement') and the Agreement on Sanitary and Phytosanitary Measures ('SPS Agreement') of the WTO, seek to prevent the establishment of non-tariff barriers via standards, technical regulations and other measures. Under these agreements, WTO member countries are bound to comply with a number of principles and ensure that the procedures they apply do not create unjustified trade barriers. Although FAO and WHO, as international organizations, are not subject to WTO disciplines, they have similar member countries as WTO and must contribute in a coherent manner to the realization of the principles enshrined in the WTO system, namely transparency and impartiality.[9]

The "new procedure" FAO/WHO specifications fail to meet the WTO disciplines in this area. Article 2.2 of the TBT Agreement provides that 'Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create…'.

The assessment of non-relevant impurities under the FAO/WHO "new procedure" on the basis of secret information puts an unnecessary burden on applicants seeking to demonstrate compliance with the FAO/WHO specification. Such impurities result from discretional decisions made by pesticide producers in the manufacturing process, namely regarding the raw materials, solvents and catalysts used. The Committee on Technical Barriers to Trade, which makes decisions on how the TBT Agreement should operate, places a high importance on transparency. In their decisions regarding transparency published on May, 23, 2002 they state that in providing the essential information on standards, the transparency procedures should at a minimum include: "the

[8] CropLife International Position Paper "The Use of FAO/WHO Equivalence Assessment in the Registration Process" July 06, 2010.
[9] See the Decision of the TBT Committee on principles for the development of international standards, guides and recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement.

prompt publication of a standard upon adoption".[10] The inclusion of undisclosed non-relevant impurities in the "new procedure" FAO/WHO specifications clearly fails this requirement.

In accordance with the quoted Article 2.2 of the TBT Agreement , the legitimate objectives that can be taken into account in conformity assessments are, *inter alia,* 'national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment'. Further, in accordance with Article 2 of the SPS Agreement, Members 'have the right to take sanitary and phytosanitary measures *necessary* for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement' (para 1) and 'shall ensure that any sanitary or phytosanitary measure is applied only to the extent *necessary* to protect human, animal or plant life or health' and that it 'is based on scientific principles' (para 2) (emphasis added).

The evaluation of non-relevant impurities, as implemented under the FAO/WHO 'new procedure', is not necessary to fulfill a legitimate objective under the TBT or SPS agreements. As elaborated by the WTO jurisprudence, 'necessary' is a concept close to 'indispensable'; 'the more vital or important' the common interests or values protected by a measure are, 'the easier it would be to accept as "necessary" a measure designed as an enforcement instrument'.[11] The assessment of non-relevant impurities, as implemented by the FAO/WHO 'new procedure' is unlikely to successfully pass the 'necessity test' as elaborated under WTO law.

Even if, hypothetically, such an assessment could be considered 'necessary' in the light of WTO law, the procedures, as applied, would fail to comply with Article 5.2.1 of the TBT Agreement. In accordance with this provision, when implementing conformity assessment procedures Members shall ensure that they 'are undertaken and completed as expeditiously as possible and in a no less favorable order for products originating in the territories of other Members than for like domestic products' (emphasis added). Similarly, Article 1(a), Annex C of the SPS Agreement requires Members to ensure, 'with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures' that 'such procedures are undertaken and completed without undue delay and in no less favorable manner for imported products than for like domestic products' (emphasis added). As noted above in this document, the conformity assessment implemented by the 'new procedure' leads to unacceptable delays that, in practice, amount to an exclusion of competitors from the market.

Further, the use of *individual* companies' product profiles as the basis of applicable standards runs counter to the adoption of harmonized standards that are essential to facilitate trade and legitimate competition. Harmonization is a key target in both the TBT and the SPS Agreements. There are no fundamental technological problems that would impede the development of a fully transparent international quality standard for pesticides. It will be impossible to reach this target, however, if the JMPS continues to base its assessment on profiles that contain secret information

[10] WTO TBT Decisions and Recommendations Adopted by the Committee Since 01 January 1995, G/TBT/1/Rev.8, 23 May 2002.
[11] Korea — Various Measures on Beef, paragraphs 161 and 162, WT/DS161/AB/R, WT/DS169/AB/R

the content of which, in addition, *may change at any time at the sole discretion* of the specification proposer of a product.

In summary, the incorporation of secret elements, protected by intellectual property rights, into the FAO/WHO specifications creates an unjustifiable barrier to market entry and violates the principles of TRIPS Article 39, the transparency and impartiality norm that any international standard should comply with. In addition, WTO members that follow the FAO/WHO recommendations regarding 'new procedure' specifications may be liable to challenges under existing multilateral trade agreements as consistently interpreted by WTO case law. The burdensome and disproportionately time-consuming conformity assessment of non-relevant impurities based on secret information is unlikely to survive such challenges. FAO and WHO should urgently review this and other aspects of the procedure and develop standards that are coherent with international agreements while at the same time ensuring a high level of quality and safety. The JMPS should be the standard-setting organization (SSO), not the exclusive conformity assessment provider of the world. The problems with the "new procedure" FAO/WHO specifications raise one simple question: What are new specifications used for? This question does not appear to have a very clear answer, despite the significant resources of running the JMPS program. This program achieved a much broader impact under the more efficient and effective "old procedure" system.

A possible solution

A true solution to the problem of applying FAO/WHO specifications must entail full transparency of the specification in order for third parties to be able to independently verify whether a product meets the international quality standard set by the specification. This solution is already being applied by WHO in its standard-setting practice for the quality of human pharmaceuticals. Human therapeutics are chemical substances that are intentionally ingested or injected into the human body, so "exposure" to the substance is guaranteed. Given the certainty of human exposure to pharmaceutical substances, WHO recommendations on quality and safety of such substances are obviously conservative recommendations with broad safety margins to ensure human health is not adversely affected. WHO issues such quality standards in the form of monographs, published in "The International Pharmacopoeia". Work on "The International Pharmacopoeia" is carried out in collaboration with members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. Pharmacopoeial standards are publicly-available compliance specifications and provide the means for an independent conformity assessment of the quality of a product at any time during its shelf-live.[12]

WHO monographs are the pharmaceutical equivalents of pesticide specifications. However, they are much more practical to develop and use than "new procedure" FAO/WHO pesticide specifications since they are completely transparent and not tied to a single manufacturer. Pharmaceutical monographs consist of the minimum concentration of the active ingredient and a list of relevant impurities which should be accounted for, such as heavy metals or certain organic

[12] The International Pharmacopoeia, Fourth edition, Volume 1, World Health Organization, Geneva 2006, p. vii.

impurities, although specific tolerances for the concentration of such relevant impurities are usually not given. In addition, the methods for assessing adherence to a pharmaceutical specification are made publicly available in such monographs.

The interesting characteristics of the pharmaceutical pharmacopoeia are the following:

1. They consist of completely transparent information (no secret information forms part of the specification).
2. They are not tied to a single manufacturer.
3. They usually set limits for general classes of impurities, not specific impurities.
4. Any third party, including the second manufacturer, can determine conformity with the published pharmacopoeia.

None of these characteristics are found in “new procedure” pesticide specifications. Drug monographs are developed by a very extensive list of experts and are based on solid scientific rationale. There is no reason why pesticide specifications cannot follow the same rationale and format as drug monographs, thereby making them relevant again as practical and useful international standards of quality.

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