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**Agenda Item 8** **CX/CAC 10/33/7-Add.2**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

**33rd Session**

**Geneva, Switzerland, 5-9 July 2010**

# PROPOSALS FOR THE ELABORATION OF NEW STANDARDS AND RELATED TEXTS AND FOR THE DISCONTINUATION OF WORK

**Proposals arising after 1 April 2010**

Presentation of project documents arising from proposals for new work from the Committees on Pesticide Residues (CCPR) and Contaminants in Foods (CCCF) (listed in CX/CAC 10/33/7-Add.1).

**CODEX COMMITTEE ON PESTICIDE RESIDUES**

**PROPOSAL FOR NEW WORK:**

# PILOT PROJECT FOR JMPR RECOMMENDATION OF MRLS BEFORE NATIONAL GOVERNMENTS OR OTHER REGIONAL REGISTRATION AUTHORITIES FOR A GLOBAL JOINT REVIEW CHEMICAL

## BACKGROUND

The 42nd Session of the Codex Committee on Pesticide Residues agreed to request the Commission to allow initiating a pilot project in which JMPR would conduct an independent, parallel review along with a global joint review team and recommend MRLs before national governments or other regional registration authorities establish MRLs. It was proposed that the new chemical sulfoxaflor would be used as the pilot chemical and would be reviewed at the 2011 JMPR. A global joint review is an evaluation of a new chemical conducted by multiple national governments or authorities at the same time and working together where the chemical company submits applications to all participants at the same time; the work is divided among participants; and independent regulatory decisions are made with an effort to harmonize the outcomes, where possible. In conformance with the understanding among the governments and other authorities participating in global joint reviews, no government or other authority gives up its independent rights and its responsibilities to meet its governing requirements, in the same way, JMPR remains an independent scientific body following its governing requirements and meeting its responsibilities. The challenge is one of timing and organization to coordinate the review in such a way that the JMPR and global joint review processes can proceed in parallel.

## 1. PURPOSES AND THE SCOPE OF THE STANDARD

This proposal is not for the creation of a new standard although new MRLs would be proposed for the pilot chemical. Rather the proposal is to *pilot* a new process that involves a slightly altered way of JMPR and CCPR doing their usual work. This proposal, for JMPR to recommend MRLs before national governments or other regional registration authorities, is expected to further the harmonization of endpoint selection and MRL setting on a global basis. The global joint review process seeks to harmonize endpoint selection and MRL setting, to the extent possible, among national and regional authorities. Extending this process to Codex would involve bringing all of the globally available expertise together into the international standard setting process so that endpoint selection and MRLs are as fully harmonized globally as possible. This would allow technical issues to be resolved quickly and effectively.

The objectives of the pilot are to:

(1) Determine whether and how various procedural/process issues associated with the proposal (e.g. availability of sufficient data/timing of submissions, inconsistencies with existing Codex and JMPR policies and procedures, necessity to maintain the independent status of the JMPR, resource implications for the JMPR, handling of differing interpretations of the same data, late changes of proposed GAP, etc.) can be addressed *in practice.*

(2) Assess the outcomes (successes and failures, costs and benefits) of the proposal *in practice*.

## 2. ITS RELEVANCE AND TIMELINESS

The CCPR has discussed, for the last two years, the *possible* issues, costs, and benefits of the proposal for JMPR to recommend MRLs before governments or other regional registration authorities establish national or regional MRLs for global joint review chemicals. Conducting a pilot of the process will provide *actual information* which will allow the Committee to:

- Evaluate the feasibility and value of the proposed new process;
- Determine whether such a process should be implemented for new active ingredients reviewed by 3 or more national authorities as a joint review; and,
- Recommend a plan for future implementation (if that were the decision of the Committee).

## 3. THE MAIN ASPECTS TO BE COVERED

Below are the main aspects of the project plan. The work to be done by the JMPR is no different from the work currently being done, rather the issues are ones of timing and coordination with the joint review team.

- Nomination and placement of Pilot Chemical on Priority List;
- Submission of complete (and identical) data packages to national authorities participating in the joint review and JMPR by required timeframes;
- Incorporate the JMPR review into the joint review project plan;
- Provide JMPR with any reviews completed by the joint review national authorities for their information as is currently done;
- JMPR recommendation for ADI and MRLs will be considered by the national authorities involved in the joint review prior to finalizing their registration decisions and MRLs;
- National authorities on the joint review project team will prepare a report on utility of having the JMPR recommendations (WHO and FAO) prior to finalizing their registration (including the establishment of MRLs) decisions;
- Joint review project team will prepare a report for consideration at the CCPR meeting. Included in this review will be a confirmation of the GAP associated with the registration decisions;
- MRLs will be considered by the CCPR for elaboration.

**Criteria for Selection of Pilot Chemical:** New pesticide active ingredients that are being jointly reviewed by 3 or more national authorities are potential candidates for the pilot project. The timing of the submission of the registration application and the joint project plan would need to be considered to allow for the work of the JMPR to occur prior to the national authorities issuing registration decisions and establishing MRLs. The broadness of the use pattern would also be considered in selecting a chemical for the pilot project.

**How will JMPR/CCPR consider MRL recommendations when registered product labels become available?**

The proposed process, by definition, would not include having registered labels available at the time of the JMPR meeting. It must be recognized that there may be cases in which there are differences in the proposed GAP that was used by the JMPR assessors and the GAP that is ultimately registered. The process must include steps to ensure that the GAP evaluated by the JMPR is the GAP that is on the registered label and to deal with those cases in which the GAP has changed. The following steps have been proposed to address this important issue. It is also certainly possible that the pilot process would provide other proposals for addressing this central issue.

- The designated global joint review lead must keep the JMPR Secretariat informed of any changes that are made to the proposed labels
- As a final step in the process, a report must be submitted by the nominating country to the CCPR meeting documenting that the registrations that were the basis of the JMPR recommendations have actually occurred and the registered GAP is the same as what was considered at the JMPR meeting
- Only those MRL recommendations that are covered by the report would be eligible for advancement at the CCPR meeting

**The main purpose of the pilot is to provide information on the feasibility and value of the proposed new process. The following questions were agreed to by the 42nd Session of the CCPR to be used to guide the assessment of the outcomes of the pilot project:**

- Was it possible to set up a viable process that allowed for effective parallel work while maintaining the independence of the JMPR decision making process?
- Did the process effectively address JMPR/CCPR procedural/process issues, or what procedural/process changes would be necessary to effectively implement the proposed process?
- What were the added costs of the process (to the JMPR panel, the JMPR joint secretaries, the CCPR, the national authorities involved in the joint review, the manufacturers)?
- What were the added benefits (to the JMPR panel, the JMPR joint secretaries, the CCPR, the national authorities involved in the joint review, the manufacturers, member countries)?
- To what extent were harmonized endpoint selection and harmonized MRL recommendations achieved?

- The evaluation of the results of this project should be compared to other work sharing projects without participation of JMPR (e.g. fluopyram, chlorantriniliprole), in particular attention should be paid to:
    1. The speed by which MRLs are set at Codex and in the member countries,
    2. The level of MRL harmonization achieved at the final stage of the project, when all member countries have set national MRLs,
    3. The amount of duplication of work (E.g. when the risk assessment has to be redone or the residues re-evaluated),
    4. The burden on the budget of JMPR,
    5. The benefits for developing countries and minor uses.

**4. AN ASSESSMENT AGAINST THE *CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES*:**

As noted above, the proposed pilot process involves doing the same work, in the same timeframe as is currently done. Thus, there is no issue of completing the work within a reasonable period of time or of the proposal falling in an area outside the Committee's terms of reference. The following assesses the proposal against the criteria for establishment of work priorities.

**4.1 General criterion**--Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

This proposal is expected to provide benefits from all of the points of view noted. Production of agricultural products is a globalized industry. The advent of global joint reviews is an outgrowth of this reality as well as a response to it and it is revolutionizing the way that pesticides are regulated. Codex, *the international standard setting body for MRLs*, needs to be a part of this global process. Involving Codex in the global joint review process up-front provides the additional benefit of having all of the globally available scientific expertise applied at the beginning-- reducing rework and providing the final link in ensuring that results are globally harmonized *to the extent possible*.

These global efforts are essential to the quick transition to the *actual use as opposed to just registration* of newer, safer chemicals because it facilitates the establishment of harmonized MRLs in export markets at essentially the same time as these MRLs are established domestically. Thus, consumers are the major beneficiaries of these global efforts because the quick establishment of harmonized international standards allows agricultural producers to actually transition to newer, safer pesticides –resulting in a safer food supply. This pilot project has received strong support at the CCPR from developing countries because they rely on Codex MRLs and benefit greatly when these are harmonized with the other MRLs established though out the world.

**4.2 Criteria applicable to general subjects**

(a) ***Diversification of national legislations and apparent resultant or potential impediments to international trade***

The global joint review process helps to address the issue of international harmonization of MRLs. While it would *never be a requirement* that the expected outcome of this process is harmonized endpoints/MRLs just as it is not a requirement that the outcome of any particular joint review is harmonized endpoints/MRLs, the *goals* of the global joint review process include harmonization of endpoint selection and MRLs, *where possible*, thus:

- The process developed (that would now include a parallel JMPR review) should allow all participants to make every effort to harmonize;
- However, success should be defined as developing a workable process and not by the outcome of the process in any specific case;
- In practice, the goals of harmonized endpoint selection and MRLs have been achieved in some cases in the global joint reviews and have not been achieved in others;
- The benefit of the process, even in cases where harmonized endpoint selection and/or MRLs is not achieved, is that participating governments and other authorities (and now the JMPR) have tried to harmonize up-front to the extent possible and, where differences remain, these are thoroughly documented for all to see and understand.

(b) ***Scope of work and establishment of priorities between the various sections of the work***

The scope of the work is no different than in the current process of MRL recommendation. It is expected that the pilot will not involve any substantive change in terms of the initial resource costs of the JMPR review. The JMPR review will proceed as it always does except that the process will have the advantages of the JMPR evaluator having access to the relevant joint assessment documents and deliberations of participating national governments and the full data packages. These advantages may be associated with substantial resource *savings.* As in the case of the global joint reviews, the resource costs of doing the work jointly (or in this case in parallel) will be minimal for the evaluators actually doing the work and any additional costs will likely be associated with **management of the process**. These resource costs will likely be borne within JMPR by the secretariat and outside of JMPR by the joint review team-- all of whom will have to invest the resources necessary for effective and timely interaction.

(c) ***Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)***

As explained above, this is an extension of the global joint review process. Governments currently participating in global joint reviews include Canada, United States, Australia, New Zealand, EU Member States, Brazil, and Japan. It is expected that, in the near future, China and possibly Kenya will also be participating.

**5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES:**

This proposal is relevant to the key objective of setting *globally relevant* standards. As noted under Point 3 in the "Introduction" of the Strategic Plan for 2008-2013, "*The CAC needs to maintain its pre-eminent status as the internationally recognized body for food standard-setting and to call for the use of its standards to the widest extent possible…This will help members to be more aware of the importance on the international harmonization of food safety and quality standards, as well as the enhancement of food control systems for ensuring food safety and quality*."

This proposal is most relevant to Goals 2 and 4 of the Strategic Plan. Under paragraph 11 of Goal 2 it states that "The CAC has the goal of elaborating standards that cover the needs of its entire membership to ensure these standards are applicable globally." Perhaps the best way to ensure that MRLs are applicable globally is to harmonize up-front, to the extent possible, before any MRLs are set. This pilot process is expected to provide valuable information on the extent to which this is possible.

Goal 4 refers to promoting cooperation between Codex and relevant international organizations and under paragraph 16, specifically notes that, "*The CAC also has a responsibility to provide its technical input and expertise towards the building of international consensus on food standards and regulatory policy matters*." The proposed pilot has this as one of its specific goals, that is, to pilot a process in which the technical input and expertise of the JMPR can be used more effectively by changing the timing of that input. In this way the recommendations of the JMPR would be available to international regulatory authorities *before* decisions are made on new global joint review chemicals.

**6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX**

**Documents**

This proposal relates to the recommendation of MRLs for a new chemical which would not be significantly different from the usual process and would not be related to any existing standards or other documents.

**7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC**

**Advice**

The requirement for and availability of expert scientific advice would not be any different than for any other chemical for which JMPR is doing an evaluation for recommendation of MRLs.

**8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

The proposal involves JMPR working in parallel with a global joint review team. The pilot chemical would be a global joint review chemical, therefore, all of the elements would be in place to obtain the input needed to do the work. Thus, the technical input would not have to be "planned for", but would have to be organized, as described in Section 3. above.

**9. THE PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK, INCLUDING THE START DATE, THE PROPOSED DATE FOR ADOPTION AT STEP 5, AND THE PROPOSED DATE FOR ADOPTION BY THE COMMISSION**

A pilot chemical would be incorporated into the Codex Step Procedure in the same way that other chemicals are. Thus, the timeline for MRLs proposed in the pilot process would be exactly the same as for any other MRLs. The current proposal is for a pilot to be done at the 2011 JMPR. The associated MRLs would be proposed for adoption at Step 5 at the 2011 CCPR. If there were no safety concerns noted by the JMPR, and no other issues were brought up at the 2011 CCPR meeting then the MRLs would be advanced to step 5/8 for adoption by the Commission in July 2011.

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**PROJECT DOCUMENT**

**PROPOSAL FOR NEW WORK ON MAXIMUM LEVELS FOR DEOXYNIVALENOL IN CEREALS AND CEREAL-BASED PRODUCTS**

**1. The purpose and scope of the project**

This project aims to establish maximum levels for deoxynivalenol and its acetylated derivatives in cereals destined for food use and cereal-based products.

**2. Relevance and timeliness**

Deoxynivalenol occurs in cereal grains around the world as a result of *Fusarium* disease. Wheat, barley and corn, the cereals most susceptible to disease, account for two-thirds of the world production of cereals. Deoxynivalenol has also been found in rye, oats, rice and their products.

At its 72nd Meeting (February, 2010), JECFA concluded that at the national level, mean exposures to deoxynivalenol were below the provisional maximum tolerable daily intake (PMTDI) that the Committee reaffirmed and converted to a group PMTDI for DON and its acetylated derivatives (3-Ac-DON and 15-Ac-DON). However, some national studies showed dietary exposures above the PMTDI among children at upper percentiles.

Previous work on MLs for DON was discontinued by the Committee on Food Additives and Contaminants due to a lack of available occurrence data. However, the Committee on Contaminants in Foods considers that there is now sufficient data to resume this work.

Several governments have established maximum levels of deoxynivalenol in cereals and cereal-derived foods.

There is a need for an international regulatory level, based on scientific evidence, for cereals and cereal-based products, which are important staple foods, aiming at the protection of human health with a minimum impact on international trade.

**3. The main aspects to be covered**

It is proposed to discuss maximum levels for deoxynivalenol in food considering:

a) The results of the JECFA evaluation of deoxynivalenol conducted at its 72nd Meeting in 2010, including toxicological evaluation and exposure assessment;

b) The application of good practices to prevent deoxynivalenol contamination as much as reasonably achievable;

c) Analytical methods and decontamination/processing effects on occurrence levels in processed products.

d) This project will not include the establishment of maximum levels of deoxynivalenol in feed. The JECFA secretariat indicated that it was unlikely that animals would consume feed with high deoxynivalenol levels because it induces emesis.

**4. Assessment against the criteria for the establishment of work priorities**

*1. Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

The new work will provide maximum levels for deoxynivalenol in foods that are protective of human health without introducing unnecessary trade barriers.

*2. Diversification of national legislations and apparent resultant or potential impediments to international trade.*

Currently, there are existing guideline/maximum levels for deoxynivalenol in some countries for various cereal grains and their food products. Considering that cereal grains are staple foods and are major exporting commodities for some countries, there is a need for international harmonization of standards.

**5. Relevance to Codex Strategic Goals**

*Goal 1. Promoting sound regulatory frameworks*

With a view to promoting maximum application of Codex standards, this work will provide harmonized practices for developed and developing countries, based on the most up-to-date scientific information, and will support fair trade practices.

*Goal 2. Promoting widest and consistent application of scientific principles and risk analysis*

This work will help in establishing risk management options, based on scientific evaluation and risk assessment conducted by JECFA.

*Goal 3. Strengthening Codex work-management capabilities*

The establishment of maximum levels for deoxynivalenol in some cereal grains and their food products is a way to manage risks associated with the consumption of highly contaminated food.

*Goal 4. Promoting maximum application of Codex standards*

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by encouraging the participation of both developed and developing countries to conduct the work.

**6. Information on the relationship between the proposal and other existing Codex documents**

The Discussion Paper on Deoxynivalenol (CX/CF 07/01/17) which contained an update on toxicology, sampling, analysis, and occurrence of deoxynivalenol in cereals and in processed products was presented at the 1st Session of the Codex Committee on Contaminants in Foods.

**7. Identification of any requirement for any availability of expert scientific advice**

The 72nd JECFA meeting in 2010 provides the most up-to-date scientific guidance to support the development of this new work.

**8. Identification of any need for technical input to the standard from external bodies**

At this point, there is no need for additional technical input form external bodies.

**9. The proposed time line for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed date for adoption by the Commission**

Pending approval by the CAC at its 33rd session in 2010, the proposed draft maximum levels for deoxynivalenol will be considered by the Committee at its 5th Session (2011) for possible adoption as a draft standard at Step 5 and subsequently, for final adoption at Step 8 by the Commission (2012).