

## Coalition for an Enhanced Codex Supporting Codex Alimentarius to enhance food safety and food security

### Introduction

As the most important international standard setting body in food safety, the Codex Alimentarius plays a crucial role in protecting the health of the consumers while enabling fair trade of agricultural products to the benefit of farmers and consumers. One of its most important responsibilities is Codex's role in setting international Maximum Residue Limits (MRLs) for trace levels of pesticides. Given the importance of global trade and the significance of MRLs in facilitating trade, the Codex Committee on Pesticide Residues (CCPR) plays a critical trade enabling role.

Empowering Codex to perform its role more effectively and efficiently by addressing current capacity challenges, embracing new scientific and administrative methods of evaluation, and ensuring adequate resources are available, is essential to supporting global food safety, security and international trade of food products. Delays or failure to establish MRLs and the resulting lack of national and international harmonization causes an unpredictable international trade environment with avoidable risks for traders of food and agricultural commodities. This has important consequences for market access, productivity and farmer livelihoods.

This paper highlights the importance of a global harmonized process for MRL setting. The Coalition for an Enhanced Codex ('Coalition') proposes six recommendations to enhance Codex processes to achieve greater food safety, facilitate global trade, and contribute to improving farmers' livelihoods, in particular smallholder farmers around the world.

### Background

Food has travelled around the world since ancient times. With the evolution of production and transport methods, the speed and quantity of food trade has increased, especially over the last few decades. The global consumers' demand for a safe, plentiful, affordable food has substantially increased.<sup>1</sup>

In the 1960s, Codex Alimentarius was established to set standards, guidelines and codes of practice for food safety and trade. Consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications. Codex works through more than 20 committees and working groups, exercising the core codex risk-management function. Codex committees are supported by independent expert scientific panels that are jointly administered by WHO and FAO. These panels also provide technical and scientific expertise to member states and the World Trade Organization.

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<sup>1</sup> <http://www.fao.org/fao-who-codexalimentarius/home/en/>

One of the most important functions of the Codex Alimentarius is its role as a standard setter of international MRLs or Codex Limits (CXLs). The Codex Committee on Pesticide Residues (CCPR) is the committee that establishes MRLs for pesticide residues. Its role is to advance MRLs through the elaboration process, which allows all member states to work to establish uniform standards. Once approved by the CCPR, the standard(s) are forwarded for adoption by the Codex Alimentarius Commission (CAC).

CCPR and CAC are the risk managers and are supported by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), the risk assessment body, an independent expert scientific panel administered jointly by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). At the request of Codex and others, it conducts scientific evaluations and provides advice on acceptable international pesticide residue limits.

- The WHO experts evaluate the toxicology of pesticides and estimate the Acceptable Daily Intake (ADIs).
- The FAO experts review and evaluate the registered use patterns, fate of residues, animal and plant metabolism, analytical methodology and residue data derived from supervised residue trials to propose residue definitions and MRLs for the pesticide in food and feed.
- Both groups play a role in determining global dietary risk assessment based on the proposed MRLs, the recommended ADI, and global diet data.

The JMPR risk assessment includes the estimation of both short-term (single day) and long-term dietary exposures and their comparison with the relevant toxicological benchmarks. This is to ensure that proposed MRLs are intended to be toxicologically acceptable.<sup>2</sup>

## The farmer perspective

Crop protection products – such as herbicides, fungicides and insecticides – contribute to improvements in agricultural productivity by protecting crops from disease, weed and insect pressures. It is possible that traces of pesticides can remain on the food; this is why MRLs are established. However, in some cases the lack of globally harmonized MRLs for registered products creates significant economic risk for farmers who rely on international trade and impedes farmers' access to important crop input tools.

Due to capacity limitations within Codex and the JMPR, it can take years to establish MRLs. When no national or Codex MRL has been established, some importing countries do not set any standards and apply zero or near-zero default tolerances for residues of pesticides. The application of a zero or near zero default MRL elevates the commercial risk and uncertainty in the global market place, accentuating the importance of global standards.

The issue of missing and mis-aligned MRLs between producing and importing countries are illustrated in three case studies that the Coalition compiled in 2017. Two cases show the impact of missing and mis-aligned MRLs in the production and export of minor crops; the third demonstrates the impact on the animal sector of missing and delayed MRLs for veterinary drugs. The three case-studies outline the problems farmers across the world face when imports are rejected, how issues are solved, and the efforts undertaken to avoid those issues in the future. Such cases are more and more common with increasing global trade and improved testing and analysis. It is, therefore, increasingly important that trade-enabling, harmonized and

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<sup>2</sup> Codex Alimentarius Commission, Procedural Manual, Twenty-sixth edition, 2018

science- and risk-based MRLs are established in a timely manner to avoid misaligned MRLs between country of export and country of import.

The case studies are available under: <https://agrifood.net/documents/codex/275-case-studies-on-missing-mrls>

## Issues constraining the Codex MRL process

Codex members recognize the importance and value of Codex MRLs. This has led to process improvements. Since 2007, reforms have occurred in the CCPR decision-making process making the Codex process much more efficient, reducing the time for establishing Codex MRLs from over 10 years to approximately 2 years. The scheduling process has also improved and allows new active ingredients to be scheduled for the JMPR review before their first approval in member countries. Process improvements have led to steadily increasing output in recent years with JMPR taking up to eight new compound reviews and 20 new use and other evaluations, as well as several periodic reviews on a yearly basis.

In addition, Canada and the United States has sponsored an extraordinary JMPR meeting to evaluate substances that require follow-up or that have new uses. This additional expert meeting has eliminated the backlog for new uses.

The Codex Coalition is very pleased about the recent developments and sees further possibilities for enhancement to meet current and future needs. The following issues should be addressed:

### 1. Growing demands upon Codex Committee on Pesticide Residues

Codex has produced an admirable number of MRLs for crop protection products considering the number of expert reviewers available and their volunteer status. However, the recent improvements in evaluation and scheduling processes have led to even greater demand for evaluation resources.

Efforts must be taken to build on these process and scheduling successes and adopt changes to increase the JMPR efficiencies and review capacity to meet the ever-increasing demand for the review and recommendation of Codex MRLs for:

- New active ingredients, around the same time or shortly after their introduction into the marketplace,
- New uses, particularly for minor/specialty crops, and,
- The reevaluation of chemicals that have been on the market for 15 years or more.

Ideally Codex MRLs are established around the same time or soon after a new active ingredient or new use is approved by a national authority and in use on crops entering international commerce. If this does not occur, then farmers do not have access to new crop protection products and agricultural efficiencies cannot be realized by both farmers and consumers.

### 2. Funding for Codex scientific work

There is a widely recognized need for adequate and sustainable funding to support the scientific advice provided to Codex Committees and the secretariat services. Stable and predictable funding is necessary for this fundamental area of work.

### **3. Availability of experts to provide scientific advice**

While the demand for panel reviews has increased over the years, the number of experts on each panel has not increased substantially. The current rosters of JMPR Experts include just 45 toxicologists and 28 residues experts (status November 2018). The output of these experts is limited by the fact that they are working professionals who conduct reviews for JMPR on a volunteer basis, in addition to their normal professional workload (based on a survey in 2018, about half of the experts are allowed no time on the job to devote to JMPR work). JMPR Panels are similarly constrained in the number of evaluations and proposed MRLs that can be reviewed during an annual two-week joint meeting. The Canadian and US government have made funding available to train additional experts to serve in JMPR to respond to increased demands for Codex MRLs and to ensure a sufficient number of experts on the roster.

### **4. Communication during the JMPR review process**

During the review of dossiers, expert reviewers may reach out to data submitters for additional data or information. However, sometimes data needs or other issues are raised late in the process, leaving no time for the submitters to resolve them prior to the JMPR meeting. Where reviews are then postponed until the following JMPR, establishment of a Codex MRL is delayed by a full year and JMPR's backlog is exacerbated.

The FAO Manual provides a general timeline for Experts to communicate with their peer reviewer and the JMPR Panel, but does not provide the reviewers with any guidance regarding the timing of communication with submitters, which may be needed to complete the review and establishment of a Codex MRL during a single cycle.

Following each session, the recommendations of the JMPR are reported out with full explanations regarding the scientific rationale for each recommended MRL. However, a full explanation is not necessarily provided for decisions to not recommend an MRL that was sought or decisions to recommend single-commodity MRLs rather than a crop group MRL. These explanations are of significant importance to registrants, farmers and national governments that rely on Codex MRLs.

### **5. Delay between pesticide registration and establishment of a Codex MRL**

Some JMPR practices may unnecessarily delay the establishment of Codex MRLs. JMPR requires a registered label before recommending a Codex MRL and it is JMPR procedure that residue trials submitted for review must match the Good Agricultural Practices (GAP) of the registered label for the national authority where the trials were conducted (despite that labels often changing over time). We encourage the CCPR to develop a mechanism to allow the experts to work with draft labels. The JMPR is encouraged to provide CCPR with a recommendation while noting that the recommendation is based on a draft label only. In addition to causing delay, this precludes the use of trial data from countries without a national label, preventing Codex MRLs for minor crops and older substances that do not warrant manufacturer support for further field trials, and creating a paradoxical situation in some developing countries that require a Codex MRL before registering the compound.

At the same time, it is not standard procedure for JMPR residue reviewers to reference the existing reviews completed and MRLs set by competent national authorities. This is left up to

individual reviewer's discretion. Submitters are not required to and do not consistently supply this information, although individual reviewers may seek national evaluations on their own.

There is potential to better coordinate and leverage the work of national authorities to realize efficiency gains and reduce the burden of work for JMPR Experts without eroding the scientific independence of the Codex evaluation.

## **6. Trade impact and importance of Codex pesticide MRLs**

The World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement) references Codex as the relevant food safety standard setting body for harmonization and facilitation of international trade. It encourages Members States to harmonize SPS measures to the extent possible and to base these on international standards, guidelines and recommendations.

National governments, registrants, farmers and traders, and the development community all have a growing awareness of MRLs and growing concerns about trade disruptions that can be caused by missing, non-aligned MRLs or zero tolerance policies. While Codex MRLs must be science based, this does not preclude CCPR from considering the trade impact and implications for farmers, countries, the global market for food, and the global economy. Codex MRLs can help ensure consumer health and safety and address practical trade facilitation needs for importing and exporting countries without sacrificing safety and scientific rigor.

### **6 recommendations to enhance Codex MRL setting**

Enhancements to Codex are required to further ensure food security, to facilitate international trade and to ensure farmers have access to crop protection products. While no easy solution to address capacity constraints exists, high-level commitment to increase the capacity and efficiency of the JMPR from the leadership of FAO, WHO and the Codex Alimentarius Commission is a fundamental requirement.

Farmers, traders and official control bodies need more Codex MRLs, as well as Codex MRLs issued in conjunction with product registrations, or shortly thereafter, and certainly prior to treated commodities moving in international trade.

The Codex Coalition proposes the following initiatives that together could result in a significant increase of the JMPR's ability to meet the current and future demand for Codex MRLs. The Codex Coalition encourages FAO and WHO to consider the following recommendations:

#### **1. Increase availability of experts**

While the demand for panel reviews has increased over the years, the number of experts on each panel has not increased substantially. It would be important to expand the provision of experts and expert time by national governments, as well as re-assess whether the required qualifications are unduly limiting the number of eligible scientists. While it is important to increase the number of experts on the roster, this alone is insufficient to ensure timely scientific advice and reviews.

The Codex Coalition suggests:

- Member states to consider if they can provide experts with a reduced workload on a rotating basis to ensure adequate time for the volunteer to conduct the reviews.
- Reviewers could rotate amongst the member states so that there is always a critical mass of experts available.
- Allow experts to use part of their working hours maintaining their full salary entitlement (for those who are government employees at least)

## **2. Secure budgetary resources**

Sustainable and adequate funding by FAO/WHO and members is critical for Codex to fulfil its mandate and ensuring timely and high-quality scientific advice. There is a need for consistent and adequate funding from FAO, WHO, and national governments. Funding of Codex scientific advice needs to be predictable to ensure that regular work can be achieved (such as holding JMPR and secretariat support) and increased demands for outputs such as Codex MRLs are accomplished.

## **3. Reduce the delay between registration of a compound and establishment of a Codex MRL**

FAO experts do not routinely consider existing reviews completed or MRLs set by competent national authorities, instead conducting a de novo evaluation of the data.

We think that JMPR could consider maximizing the use of national reviews, focusing on areas where they disagree. Many of the FAO and WHO experts are drawn from countries that have already done detailed national reviews of the chemicals going through the JMPR process.

The Coalition encourages the JMPR to conduct a peer review instead of doing a full evaluation where recent national detailed evaluation reports are available, and the applicant can demonstrate that the information submitted for the national review met FAO's and WHO's data requirement.

This would streamline the JMPR review process and allow for more chemicals to be reviewed each year. Alternatively, FAO and WHO experts could review the dossier of a new active ingredient concurrent with the national authorities and consult with them prior to finalizing a Codex MRL recommendation. This process has some parallels with the EU EFSA evaluation process.

The use of all available data developed on the same Good Agricultural Practice (GAP) use pattern or substantially similar GAP should be routine (global data sets). The establishment of an electronic working group to discuss the label requirement, its rationale, and possibilities for flexibility would lay the foundation to ultimately ensure that JMPR consider all scientifically robust trial data.

## **4. Increase use of Crop Grouping and Representative Commodities**

CCPR has formally established extrapolation principles that if data is adequate to establish an MRL for the representative commodities of a crop group, then that data is generally adequate to set an MRL for all commodities in that crop group. CCPR has revised and refined Codex crop group definitions and established processes and data requirements for the extrapolation of

residue data to major and minor crops. The number of crop group MRLs set by CCPR has steadily increased – from 8 in 2001 to an average of 66 per year in the last five sessions. However, further improvement is possible, as many Codex pesticide MRLs continue to be established for single commodities. Governments and submitters may not be explicitly requesting crop group MRLs and FAO and WHO experts do not consistently recommend crop group MRLs when appropriate representative commodity data is available.

The establishment of crop group MRLs is especially relevant for minor crops and therefore particularly important for least developed countries. Maximizing the establishment of crop group MRLs based on a review of representative and all other supporting commodity data will also expand the productivity and annual output of the JMPR and CCPR.

## **5. Strengthen implementation of JMPR and CCPR procedures and more efficient communication**

JMPR Experts evaluating the data work to a very tight schedule. The Codex Coalition encourages the FAO/WHO Joint Secretariats to support them with guidance to ensure that adopted CCPR procedures are followed consistently. Experts need to ensure that they are not acting independently of those procedures. An expert's objection serious enough to delay a recommendation of a MRL should be communicated to the whole panel well in advance of the meeting, such as the rationale for not pursuing a crop group or establishing an MRL. The Codex Coalition encourages experts to communicate with data providers, requesting additional data or raising issues earlier in the review process.

Full utilization of the electronic tools available would allow discussion of identified issues before the actual face-to-face JMPR meeting and to increase the number of active ingredients or additional uses reviewed at each annual meeting. We believe that teleconferences or videoconferences are excellent as means to assist early reviews among experts as soon as the dossier has been submitted and we encourage FAO and WHO to support their use. During the JMPR, experts could focus on complex scientific issues that could not be resolved prior to JMPR. If the review of a chemical is straightforward and no issues are raised, there is no need for discussion at an international meeting.

## **6. Elevate the trade perspective at Codex**

Greater attention and increased awareness of the trade facilitation role played by CCPR is required. The stated purpose is that "Codex standards ensure that food is safe and can be traded". Incorporating a trade perspective into a deliberation does not reduce its scientific validity or food safety and security mandate.

We encourage the JMPR and the CCPR to consider the use of MRLs established by national authorities to avoid creating unnecessary trade impediments that have no impact on food safety.

We further believe that risk management decisions taken by the CCPR need to take safety as well as trade aspects into account and therefore encourage national CCPR delegations to take decisions in agreement with their competent trade experts and to include delegation members that are trade and risk management experts (in addition to food safety experts). Analyses of trade flows, data on the number of countries that rely on Codex MRLs, and/or case studies regarding how countries use Codex MRLs could be produced.

The Coalition for an Enhanced Codex brings together organizations looking to enhance Codex Alimentarius processes for setting Maximum Residue Limits (MRLs) for pesticides and veterinary drugs. Coalition membership encompasses the global agriculture and food value chain. Members represent crop input suppliers, animal health products, agri-commodity traders, farmers, and the food and drink manufacturing sector. The Codex Coalition's mission is to help provide sufficient amounts of safe, healthy, high-quality and diverse food at affordable prices to consumers in an economically, environmentally and socially sustainable way. In doing so, the Codex Coalition contributes to increased food safety, food security, better nutrition and health, economic growth and development, and poverty reduction. Coalition members, therefore, seek effective and impactful Codex reforms to ensure the continued production and trade of safe, high-quality, and diverse food in an economically, environmentally, and socially sustainable way.

For more information see: [www.agrifood.net](http://www.agrifood.net)