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Committee on Sanitary and Phytosanitary Measures

REPORT
WORKSHOP ON PESTICIDE MAXIMUM RESIDUE LEVELS (MRLS)
MONDAY, 24 OCTOBER – TUESDAY, 25 OCTOBER 2016
WTO, CENTRE WILLIAM RAPPARD, GENEVA

NOTE BY THE SECRETARIAT[1]

The Secretariat of the World Trade Organization held a workshop on pesticide maximum residue levels (MRLs) in Geneva, Switzerland, on 24 and 25 October 2016.

The WTO funded, through assistance from the Doha Development Agenda Global Trust Fund (DDAGTF), the participation of 27 governmental officials from developing country Members and Observers in the workshop.[2] Sponsored participants were selected from over 300 applications.

In addition, the WTO Global Trust Fund made it possible to cover the costs of travel for several of the speakers in the workshop. Total attendance was close to 180, and included Geneva- and capital-based delegates, participants from intergovernmental organizations, as well as speakers from non-governmental organizations.

Members were invited at several stages to make comments on the programme and also to put forward names of speakers, and their proposals and suggestions were taken into account in preparing the programme. The final programme for the workshop is contained in G/SPS/GEN/1514/Rev.1. The presentations from this workshop are available via the SPS Gateway at https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/wkshop_oct16_e.htm.

1 OBJECTIVE OF THE WORKSHOP

1.1. The objective of the workshop was to bring together officials responsible for participation in and implementation of the SPS Agreement, as well as the relevant international standard-setting organization and scientific bodies for an in depth discussion, at a technical level, on pesticide maximum residue levels. More specifically to:

- Review the SPS Agreement and MRLs, including the relevant provisions of the Agreement and jurisprudence;
- Review the Codex approach to establishing MRLs. This included relevant information on the respective work of Codex and scientific bodies, such as the Codex Committee on Pesticide Residues (CCPR) and the Joint FAO/WHO Meeting on Pesticide Residue (JMPR);
- Be exposed to the relevant international, regional and bilateral work being undertaken on pesticide residues; and
- Discuss experiences in complying with MRLs and establishing MRLs, including information on Members' domestic regulatory and legal infrastructures.

[1] This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights or obligations under the WTO.

[2] Unlike previous years, WTO-funded workshop participants were not sponsored to participate in the SPS Committee meetings, in addition to their attendance at the workshop.

2 OVERVIEW OF WORKSHOP

2.1. Throughout the two-day workshop, participants benefited from detailed presentations on the relevance of the SPS Agreement to pesticide MRLs, the Codex approach to establishing MRLs, as well as various regional and international initiatives focused on harmonizing MRLs and establishing MRLs for minor-use crops.[3] In addition, various WTO Members shared their national experiences on establishing MRLs and provided insights into the challenges of implementing and complying with Codex MRLs, as well as the impact of default MRLs and MRL expiration on international trade. Speakers from the private sector also contributed to the workshop, highlighting the various ways for the private sector to be involved in establishing MRLs, such as by providing the relevant technical data. Several follow-up actions were proposed during the workshop, with a view to addressing various concerns related to pesticide MRLs. A summary of the various sessions of the workshop is provided below.

3 WORKSHOP SESSIONS

3.1 The SPS Agreement and establishing MRLs (Session 1)

3.1. **Session 1** set the framework for the subsequent presentations, focusing on: the relevance of the SPS Agreement to pesticide MRLs; the relevant provisions of the Agreement; key highlights of lessons learned from MRL-related jurisprudence; and statistics on MRL-related notifications and specific trade concerns.

3.2. **Ms Anneke Hamilton**,[4] from the WTO Secretariat, reminded participants of the objective of the SPS Agreement, which is to strike a balance between Members' right to protect human, animal, plant life or health, while at the same time ensuring that these measures do not create unnecessary barriers to trade. In highlighting the relevance of the SPS Agreement to pesticide MRLs, Ms Hamilton focused on the definitions of a SPS measure, as stated in Annex A(1). In particular, the definition of a SPS measure in Annex A(1)(b) was of most relevance to pesticide MRLs, as it stated that a SPS measure was any measure applied *"…to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;…".*[5] In addition, footnote 4 of Annex A further clarified that *'…"contaminants" include pesticide and veterinary drug residues and extraneous matter.'* On this basis, Ms Hamilton underscored that pesticide MRLs are considered to be SPS measures and as such, are subject to the provisions of the SPS Agreement.

3.3. Ms Hamilton also outlined Article 8 and Annex C of the SPS Agreement and their relevance for pesticide MRLs. Firstly, Article 8 required Members to observe the provisions of Annex C in the operation of control, inspection and approval procedures, including among others, national systems for establishing tolerances for contaminants in foods, beverages or feedstuffs. Secondly, Annex C spelled out certain obligations with respect to control, inspection and approval procedures, including those procedures for sampling, testing and certification.[6] In particular, Annex C(1) made reference to a situation where an importing Member had a positive list system for the establishment of tolerances for contaminants, outlining that the importing Member was required to consider the Codex standard as the basis for access (where a Codex standard exists), until a final determination was made. In this regard, Ms Hamilton highlighted that the procedures to check and ensure the fulfilment of pesticide MRLs were also considered SPS measures.

3.4. Other provisions of the SPS Agreement of particular relevance to pesticide MRLs were underscored, such as: non-discrimination (Article 2.3); scientific justification (Articles 2, 3 and 5); transparency (Article 7 and Annex B); technical assistance (Article 9); and special and differential treatment (Article 10). In particular, Ms Hamilton highlighted the scientific principle as the heart of the SPS Agreement, which required that where SPS measures are implemented, they should either be based on international standards (i.e. Codex standards for food safety concerns), or on a risk assessment. In the case where an SPS measure or pesticide MRL was based on a risk assessment,

[3] Crops for which pesticide manufacturers do not find it commercially interesting to produce the data packages required for a risk assessment that would allow the establishment of a MRL.

[4] The Secretariat's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s1_anneke_hamilton.pdf.

[5] Annex A(1)(a) of the SPS Agreement.

[6] Footnote 7 of Annex C of the SPS Agreement.

there was still an obligation under the SPS Agreement to ensure that the risk assessment was appropriate to the circumstances of SPS risks and that the assessment took into account the techniques developed by relevant international organizations.

3.5. In examining some key lessons learned from jurisprudence, Ms Hamilton explained that although there had been no SPS dispute case to date which had specifically focused on pesticide MRLs, a previous dispute case had examined the issue of veterinary drug residues.[7] She presented the legal findings on harmonization, risk assessment, consistency and provisional measures, as they provided useful insights for the discussions on pesticide MRLs. Ms Hamilton highlighted that: the non-use of an international standard as a basis for a measure required a risk assessment; there was no need for each Member to carry out its own risk assessment, as SPS measures could be based on an appropriate risk assessment carried out by another party; a risk assessment did not need to be quantitative; and that risk assessments could consider divergent or minority scientific views. In addition, the term "based on" required a rational relationship between the measure and the risk assessment.

3.6. Ms Hamilton also noted that there were three cumulative elements which had to be met in order for a measure to be found in violation of Article 5.5.[8] With respect to Article 5.7, which dealt with the exception to the requirement that SPS measures must be based on a scientific justification, Ms Hamilton underscored that the Appellate Body had ruled that precaution "finds reflection in Article 5.7".

3.7. Some statistics on MRL-related notifications and specific trade concerns were also provided. Ms Hamilton also further clarified, in response to a query, that the statistics on MRL-related notifications had been sourced from the SPS-IMS, using the keyword "MRL". As such, the filtered search would not fully capture all of the MRL-related notifications that had been submitted by Members, if MRL-related measures had been notified under more general laws or regulations.

3.2 Codex approach to establishing pesticide MRLs (Session 2)

3.8. The moderator of the session, **Dr Kazuaki Miyagishima** (Director, Department of Food Safety and Zoonoses, WHO) in his introductory remarks provided some background to the Codex and JMPR[9] process for establishing pesticide MRLs. In particular, he highlighted that the management of pesticide residues in foods was coordinated in a manner to ensure the functional separation of risk management (Codex) from risk assessment (JMPR). The Codex mechanism had evolved to cater to the changing nature of the world, e.g. the process to adopt pesticide MRLs had been reduced from 5 or 6 years to just one year through the fast track process, although there still remained scope for the procedure to be improved. In addition, Codex faced a difficult task in selecting the pesticides to be evaluated by FAO and WHO.

3.9. **Mr Ian Reichstein**,[10] Chair of the Codex Committee on Pesticide Residues (CCPR) Electronic Working Group (eWG) on Priorities, provided an overview of the role and operation of the eWG in the standard-setting process. Mr Reichstein first explained that CCPR based its risk management recommendations to the Codex Alimentarius Commission on JMPR's risk assessments of the respective pesticides, considering, where appropriate, other legitimate factors relevant for health protection of consumers and for the promotion of fair practices in international food trade. Codex MRLs for pesticides used in crop protection were only established if they passed a scientific evaluation by FAO and WHO in the JMPR.

3.10. In this regard, Mr Reichstein highlighted the key role of the CCPR's eWG on Priorities in the preparation of a draft schedule of JMPR evaluations and maintenance of the four tables of

[7] European Communities - Measures Concerning Meat and Meat Products (Hormones), DS 26 and DS48. More information available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm and https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds48_e.htm.

[8] Article 5.5 addresses the objective of achieving consistency in the application of the appropriate level of protection and seeks to avoid arbitrary distinctions in the level of risk considered to be acceptable, if that distinction results in a disguised restriction to trade.

[9] The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an expert ad hoc body administered jointly by FAO and WHO. The JMPR comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment.

[10] Mr Reichstein is also Director of the National Residue Survey, Residues and Food, Exports Division, Department of Agriculture and Water Resources, Australia. Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s2_ian_reichstein.pdf.

priorities.[11] Mr Reichstein outlined the timeline for the Codex step procedure, specifically highlighting the role of the electronic working group in step 1 of the process. He also provided data to illustrate the increased number of adopted Codex pesticide MRLs over the past years, while highlighting the various enhancements that had been made to the operations of the working group. He further noted that the eWG operated throughout the year and was comprised of about 200 representatives from interested member countries and observers, and operated on the principles of openness, transparency and inclusivity, as well as on the basis of the provisions specified in the Codex Procedural Manual.

3.11. Mr Reichstein outlined the improvements that had been made over the years to the table of priorities, such as: the inclusion of commodity lists in the schedules and priority lists; the inclusion of manufacturer identity; and nomination with date stamping to support strict adherence to nomination and scheduling criteria. Mr Reichstein further explained the prioritization and scheduling criteria, highlighting that given the increased number of requests, a higher priority was given to those nominations meeting the requirements, as set out in the Codex Procedural Manual.

3.12. Mr Reichstein also provided an overview on the requirements for the periodic review of Codex pesticide MRLs, as well as the revocation of Codex pesticide MRLs. In conclusion, Mr Reichstein indicated that many more pesticides and uses had been added than revoked by members, while emphasizing the need for members and observers to adhere to the nomination and scheduling criteria, in order to support an effective Codex MRL setting process. Mr Reichstein indicated that further procedural improvements were being discussed by the eWG, but that there were limitations in addressing the existing capacity bottlenecks in the scientific evaluation process and the subsequent delays in the establishment of new MRLs.

3.13. **Dr Juerg Zarn**,[12] WHO JMPR Expert, provided an overview of the role of WHO JMPR in the establishment of Codex MRLs, highlighting that its main objective was to guarantee that proposed pesticide MRLs were safe, so that consumption of food commodities with residues at the MRL level did not pose an unacceptable risk to consumers. In this regard, JMPR's role was to evaluate a dossier provided by the member/observer nominating the pesticide. This dossier would normally include a standard toxicology package, laboratory animal and in vitro studies, as well as human data (e.g. epidemiology data).

3.14. Based on this evaluation, Dr Zarn explained that the WHO group identified a safe dose in all laboratory animal studies,[13] under the assumption that animals were valid models for humans and by using safety factors for extrapolation from animals to humans, following which a safe dose for humans was established. The main output of WHO JMPR were two health based guidance values: (i) the Acceptable Daily Intake (ADI) - for lifelong daily exposure; and (ii) the Acute Reference Dose (ARfD) - for single high exposures. Dr Zarn further explained that it was the responsibility of the joint group (FAO and WHO) to propose a MRL for the particular pesticide in food commodities. The most important requirement was that the MRL be set at a level to ensure exposures below the ADI and ARfD, even if consumptions patterns considerably varied.

3.15. Dr Zarn emphasized that the JMPR recommended MRLs for pesticides strictly on a risk-based approach and not on a hazard-based approach. As such, MRLs for pesticides could be derived, even if it was found to induce tumors or fetal abnormalities in laboratory animals, but where a safe dose in animals was clearly identified, and on the assumption that a safe dose for humans could also be established. In such a case, the JMPR would indicate that the pesticide in question had the potential to induce tumors or fetal abnormalities, but that the exposure at dietary levels would not pose a risk if the MRL was not exceeded.

3.16. Dr Zarn further explained how WHO JMPR undertook its work, detailing the process used to draft the monograph on toxicological data for each pesticide before the joint FAO and WHO JMPR meetings. He outlined the work undertaken during the meetings to discuss and finalize the monographs leading to the subsequent publication of a report. In conclusion, Dr Zarn highlighted that toxicology was a developing science and as such, new data or new views on old data could have an impact on risk assessment and thereby change previous conclusions on a pesticide.

[11] Additional information is available in the Codex Procedural Manual, available for download at: http://www.fao.org/fao-who-codexalimentarius/procedures-strategies/procedural-manual/en/.

[12] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s2_juerg_zarn.pdf.

[13] NOAEL - No Observed Adverse Effect Level.

3.17. In response to queries, Dr Zarn clarified the calculation process used in the extrapolation of the safe dose from animals to humans, and also addressed concerns regarding the role of uncertainty in the process. Dr Zarn also provided additional information on the differences between ADI and ARfD, including its impact on the establishment of MRLs, as well as the critical assumptions on exposure underlying each of these concepts. He also explained that there was no available guidance on cumulative risk assessment.

3.18. **Dr Yong Zhen Yang**,[14] FAO JMPR Secretary, provided an overview of the role and function of the FAO JMPR panel in the estimation of MRLs for pesticide residues. She highlighted that the FAO panel was responsible for: (i) reviewing pesticide use patterns (good agricultural practices - GAPs), data on the chemistry and environmental fate, metabolism in farm animals and crops, methods of analysis for pesticide residues and processing studies; (ii) defining residues for enforcement of MRLs and for dietary risk assessment purposes; (iii) estimating MRLs, supervised trials median residue values (STMRs) and highest residues (HRs) in food and feed commodities; and (iv) assessing dietary risk from short and long term intake of pesticides in collaboration with the WHO Panel.

3.19. Dr Yang further described the data requirements and general procedures for JMPR evaluation of pesticide residues and the estimation of MRLs. The JMPR procedure included undertaking a risk assessment on the basis of the data generated by FAO[15] and WHO to see whether the toxicology and dietary intake of residues were compatible, following which a recommendation was made for the establishment of a Codex MRL, for adoption by the Codex Alimentarius Commission (CAC). Dr Yang underscored that FAO JMPR recommendations were based on "supervised trials", selected by the FAO panel and designed to reflect pesticide use patterns and "critical GAP" that lead to the highest expectable residues. In addition, the procedure for estimating MRLs included the selection of appropriate residue data for calculation of MRLs, supported by statistical tests, as well as the use of the Organization of Economic Cooperation and Development (OECD) MRL calculator. Dr Yang underscored that JMPR recommended the estimated MRLs only if the risk assessment passed both the chronic and short-term intake hurdles.

3.20. Dr Yand also provided an overview of the JMPR FAO panel workflow, detailing the process used to evaluate the monographs for compounds, including the work undertaken internally within the FAO expert panel, as well as during the joint FAO and WHO JMPR meetings to discuss and finalize the monograph. Once the evaluation monograph was finalized, it was then published online. Some of the challenges faced by JMPR in establishing international MRLs for pesticides were also highlighted, such as: resource constraints; data generation for JMPR review; funding of the JMPR Secretariat and meetings; sustainability of JMPR expertise; principles on combining global residue data sets and on extrapolation; estimation of crop group MRLs; and harmonization of methodologies for risk assessment.

3.21. In response to several queries, Dr Yang provided further clarification on the approach employed by WHO JMPR and FAO JMPR in the establishment of pesticide MRLs, highlighting that both groups had the same priority of making a recommendation on pesticide MRLs to Codex, for adoption by CAC. However, she highlighted the different aspects focused on by the two groups: WHO undertook the toxicology assessment (human health); while FAO reviewed the residue trial to determine the residue level in crops. She underscored that both outcomes were used to compare whether the MRL would cover the acceptable human risk in order to make a recommendation. She also clarified that JMPR reevaluates compounds when new impurities are discovered.

3.22. **Ms Gracia Brisco**,[16] Food Standards Officer at the Codex Secretariat, presented the Codex procedures for the establishment of pesticide MRLs. She first reminded participants that the SPS Agreement recognized Codex as the international standard-setting body in the area of food safety. Ms Brisco further provided an overview of the role, structure and mandate of the Codex

[14] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s2_yong_zhen_yang.pdf.

[15] Available resources included the *FAO Manual on Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed* (http://www.fao.org/3/a-i5452e.pdf) and the *FAO Manual on Evaluation of Pesticide Residues* (http://www.fao.org/3/a-i5545e.pdf).

[16] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s2_gracia_brisco.pdf.

Alimentarius Commission, highlighting that it was an intergovernmental food standards-setting body established by FAO and WHO.

3.23. In particular, she underscored the role of the CCPR in managing issues dealing with MRLs in food and feed. The mandate of CCPR was to: (i) prepare priority lists of pesticides for evaluation by JMPR; (ii) establish pesticide MRLs in food and feed moving in international trade; (iii) consider methods of analysis and sampling for the determination of pesticide residues; (iv) establish EMRLs[17] for environmental and industrial contaminants in food and feed (associated with the former use of pesticides in agriculture); and (v) consider any matter related to the safety of food and feed containing pesticide residues.

3.24. Ms Brisco emphasized that Codex develops international food safety standards based on risk analysis principles, while highlighting the importance of the functional separation between risk assessment and risk management. She provided an overview of the procedure for developing Codex standards, underscoring that there were two ways to establish pesticide MRLs: (i) through the regular 8-step procedure - where adoption of the draft MRLs occur at Step 8 by CAC; or (ii) through the accelerated procedure - where adoption occurs at Step 5/8 by CAC. She also explained that one of the key conditions for using the accelerated procedure was that the JMPR did not identify an intake concern, i.e. that the proposed MRL did not exceed the ADI and ARfD.

3.25. The process for the revision of MRLs, as well as revocation of MRLs, was also explained. Some of the challenges faced by CCPR included the absence of Codex standards for some pesticides, the use of import tolerances at LOD/LOQ levels and revision of the international estimate of short-term intake (IESTI) equation, among others.

3.26. In the **question and answer session**, speakers provided clarification on various areas of Codex and JMPR work. Ms Brisco further explained the process for revocation of a pesticide MRL, highlighting that there was no strict lifespan for MRLs, but that there was a periodic review process which occurred in principle every 15 years. The two triggers to reevaluate the pesticide before 15 years were related to increased health concerns and usage pattern of the pesticide. In the ensuing discussions various MRL challenges were identified by developing countries, such as the lack of MRLs for products (e.g. sesame seeds). Group MRLs were indicated as a way to address some of the MRL gaps, however, the challenges faced in undertaking group MRLs at JMPR were highlighted, as there was currently no international agreement on the principles, criteria and procedure, although guidance was available in other fora.

3.27. The role of the CCPR versus the role of national registration authorities was also discussed. Several comments and queries were also raised regarding the resource constraints faced by Codex and JMPR, in relation to data generation, lengthy waiting lists for establishment of pesticide MRLs, and members' capacity to apply and implement Codex standards. Participants were encouraged to identify solutions to address these challenges. In this regard, a suggestion was made to simplify JMPR procedures, especially if there was consensus by members that the uses of particular pesticides were safe. The query was raised whether in these situations it would be necessary for JMPR to conduct a full evaluation, especially in light of the capacity constraints.

3.3 Relevant bilateral, regional and international work on pesticide residues (Session 3)

3.28. Speakers in **Session 3** provided information on relevant bilateral, regional or international work in the area of pesticide MRLs. Part 1 of the session focused on ongoing regional MRL work being undertaken by the OECD, the Asia-Pacific Economic Cooperation (APEC) and the East African Community (EAC). In Part 2, speakers addressed issues related to establishing MRLs for minor-use crops (i.e. crops of low pesticide usage on a global scale). In particular, focus was placed on the ongoing work being carried out through projects (supported by the STDF, USDA, IDB, JMPR and/or other bodies) in Africa, Asia, Latin America and North America, including the experiences in identifying MRL needs for developing country exports and the implementation of legislation for setting MRLs for minor-use crops.

[17] Extraneous maximum residue levels (EMRLs).

3.3.1 Part 1: Regional Initiatives on MRLs – Ongoing work in OECD, APEC and EAC

3.29. **Ms Donna Davis**,[18] from the Office of Pesticide Programs, US Environmental Protection Agency (EPA), provided an update on several regional initiatives. She highlighted the importance of MRL harmonization in achieving national and international goals, as well as its role in supporting food safety, public health and environmental protection. She also noted that international collaboration improved the scientific basis of decisions and enhanced regulatory efficiency, while conserving resources and minimizing barriers to international trade. In providing an overview of the legislative statutes[19] of the US EPA regulatory framework, Ms Davis highlighted the "risk-based" approach to the tolerance (MRL) setting process and underscored the legislated mandate to make a finding of "reasonable certainty of no harm" to support establishment of a tolerance.

3.30. Ms Davis outlined the US EPA's active participation in the work of several international and regional bodies, such as Codex, OECD, JMPR, NAFTA and APEC. She highlighted several ongoing OECD initiatives, which included the MRL calculator tool, harmonized residue chemistry test guidelines and global joint reviews. Ongoing initiatives under APEC included the import MRL guideline for pesticides and an import tolerance pilot project to determine the feasibility of accepting other national authority or JMPR reviews to support the establishment of import tolerances.

3.31. Ms Davis underscored the importance of the use of crop groups in promoting harmonization and addressing the minor use issue. She highlighted the need to agree on a common crop group definition, recognized some of the harmonization challenges, and noted the ongoing work being undertaken by OECD and Codex to harmonize regulatory practices. Ms Davis provided information on OPP's work with industry and international partners to analyze field trial data from various global zoning projects, which entailed comparing residue data across a variety of geographic, environmental and climatic conditions to determine the impact on residue levels. Some of the preliminary work had suggested that geographic diversity could have a far smaller impact on residue values. She indicated that issues like application rate and application pattern could create more variability than geographic differences, which meant that field trial data could support tolerances in a variety of locations.

3.32. Several queries were raised in relation to the process for OECD global joint reviews, as well as the impact of geographic diversity on residue data from the APEC region and the impact of climate change on the effectiveness of pesticide MRLs. Ms Davis clarified the process for OECD global joint reviews, highlighting the advantages of this approach, such as the pooling of resources and encouragement of common scientific review, while noting that these reviews had also identified areas of inconsistencies with JMPR's work, mainly in relation to hazard assessment. Ms Davis indicated that the global exchangeability of residue data was being addressed in multiple fora and that the statistical evaluation of these datasets was still at an initial stage. She also explained that the United States had a re-evaluation programme, as well as the OECD, to reassess pesticide uses, in order to consider issues such as the potential impact of climate change.

3.33. **Dr Trevor Webb**,[20] General Manager of Food Standards Australia New Zealand – Australia, provided an overview of the APEC Import MRL Guideline for Pesticides, which included a background on the development of this guideline, the scope and issues covered, as well as the implementation plan. In 2007, APEC member economies had agreed to create the Food Safety Cooperation Forum (FSCF) in order to build robust food safety systems; accelerate harmonization with international standards to improve public health and facilitate trade; and strengthen capacity building activities and information sharing. As part of this process, FSCF had developed an APEC

[18] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_1_donna_davis.pdf.

[19] The four main legislative statutes are: (i) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – which deals with pesticide labels with worker and ecological risk issues; (ii) Federal Food Drug and Cosmetic Act (FFDCA) – which deals with risk from residues of pesticides on food and MRLs (or tolerances); (iii) Food Quality Protection Act (FQPA) – which amended both FIFRA and FFDCA, as well as codified the mandate to make a finding of "reasonable certainty of no harm" to support the establishment of MRLs; and (iv) Pesticide Registration Improvement Act (PRIA).

[20] This presentation was delivered on behalf of Mr Steve J. Crossley, Manager, Scientific Strategy, International and Surveillance, Food Standards Australia New Zealand — Australia. Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_1_trevor_webb.pdf.

MRL Roadmap which focused on greater regulatory convergence of MRLs across the APEC region on the basis of several broad principles.

3.34. In this regard, the development of an APEC Import MRL Guideline for Pesticides had been agreed through a three-year FSCF project led and funded by Australia, and cosponsored by China, Philippines, Chinese Taipei, Thailand and the United States, as well as with the participation of the APEC Wine Regulatory Forum. The language and content of the guideline had been developed in expert workshops, leading to the publication of the final document in 2016.[21] Dr Webb provided some examples to illustrate the different policies and processes for adopting MRLs across the APEC region, while underscoring that the guideline provided a "framework within which science-based standards could be developed and applied uniformly and transparently across APEC economies."[22]

3.35. The guideline specified the data set required by exporting economies to support their request, and referenced Codex MRLs and JMPR assessments, where available. The guideline also identified a minimum data set on which to assess a request for an import pesticide MRL, where health-based guidance values had been established either through a JMPR process or by an exporting country. Dr Webb further outlined the scope and issues covered in the three sections of the guideline and the accompanying three attachments, and highlighted the decision trees for different scenarios, e.g. scenarios where Codex MRLs and national dietary exposure assessments exist or scenarios where Codex MRLs do not exist.

3.36. Upcoming implementation activities included: further dissemination of the guideline; conducting pilot testing on mangoes; ongoing work on laboratory capacity by China; further in-country training to be funded by Australia; and a technical implementation workshop to be held in Australia in early 2017. To facilitate its implementation, the guideline was also being translated into Chinese, Spanish and Vietnamese.

3.37. **Mr Geoffrey Onen**,[23] Government Chemist Laboratory, Uganda provided an overview of the East African Community's regional initiative to harmonize pesticide MRLs, in order to facilitate regional and international trade in products of plant origin. In his overview, Mr Onen first noted that most of the pesticide residue data needed to establish Codex MRLs had been generated in developed countries. As a result, few Codex MRLs had been established for specialty crops,[24] which were key crops for EAC countries. He highlighted that the need to reduce divergences across national pesticide regulatory regimes and domestic legislation had led EAC partner States to focus on the harmonization of pesticide MRLs.

3.38. In particular, the objective of the EAC initiative was to expedite reviews and registration timeframe; support regional moves to ensure availability of safe and efficacious pesticides; facilitate mutual recognition and enhance work sharing; and establish EAC MRLs. Mr Onen provided an overview of the roles of the relevant bodies involved in the development of MRL guidelines for the region and the various steps taken by each in the process. Mr Onen also outlined the purpose and scope of issues covered in the Crop Residue Trial Protocol which was targeted at those parties intending to register a pesticide product or to establish a MRL for a pesticide product in a specific commodity in the EAC, as well as authorities responsible for regulating such substances and commodities. He explained that the Protocol provided a harmonized approach to planning, conducting and reporting crop field and laboratory trials in EAC partner States. In addition, the protocol served to generate data of sufficient quality to quantify the expected magnitude of residue(s), determine the rate of decline of the residue(s) of pesticide and promulgate EAC MRLs.

3.39. Some of the challenges faced in the harmonization work included crop differences; GAP use directions; and regulatory issues. Mr Onen also highlighted various lessons learnt in the process, such as the importance of harmonization in simplifying the development of regional MRLs, and the role of mutual trust and communication in the process. In relation to next steps, he indicated the

[21] This document is available at: http://publications.apec.org/publication-detail.php?pub_id=1750.
[22] Page 9 of the APEC Import MRL Guideline.
[23] This presentation was delivered on behalf of Mr Michael Odong, Assistant Commissioner, Head Agricultural Chemicals Control Division, Department of Crop Inspection and Certification, Ministry of Agriculture Animal Industry and Fisheries. Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_1_mike_odong.pdf.
[24] Crops of low pesticide usage on a global scale.

following: continued development of the guideline on crop field trials; finalization of the document for establishment of EAC MRLs; development of standard operating procedures to support accreditation of institutions conducting residue trials; and approval and endorsement by the Council of Ministers.

3.40. In the **question and answer session**, the level of cooperative efforts across various regional and international bodies was noted, including the use of the OECD calculator in regional work. Within this context, the query was raised whether there were other types of cooperative activities that could further facilitate MRL harmonization. Some of the speakers' responses included: a broader dissemination of the existing tools such as the APEC Guideline; providing capacity training workshops, including training for registrants on data submission; improving data generation; working on single submissions; adapting residue chemistry templates; expanding global joint reviews; and improving communication between different governments.

3.3.2 Part 2: Establishing MRLs for Minor-Use Crops

3.41. **Mr Dan Kunkel**,[25] Associate Director, Food and International Programs, IR-4 Project Headquarters, Rutgers State University of New Jersey, presented the experience of IR-4 in addressing grower needs, and fostering international cooperation in support of international harmonization. Mr Kunkel explained that the IR-4 Project (IR-4), funded by the US Department of Agriculture, was the primary entity in the United States that worked to facilitate registrations of conventional and bio-pesticides on specialty (minor use) food crops, such as fruits, vegetables, nuts, herbs. Mr Kunkel outlined the challenges in defining minor uses and highlighted the two prominent, and often opposing approaches, to defining minor uses: (i) the "risk assessment" approach; and (ii) the "economic return" approach. Specifically, the IR-4 project focused on the economic return approach, where a grower had a pest control issue that was not being addressed and did not have a tool to address that situation.

3.42. Mr Kunkel observed that many countries were either creating or modifying systems for establishing and enforcing MRLs for imports and domestic use, which increased the complexity of moving commodities through global markets and led to a greater need for data generation. In this regard, IR-4's work provided minor use crop growers with crop protection tools, given the limited industry investment in this area, by developing research data (mostly pesticide residue data), through residues studies and field trials undertaken every year. This resulted in the submission of a final report and research data to US EPA for review and establishment of MRLs. This data was often repackaged and submitted for the establishment of Codex MRLs.

3.43. Mr Kunkel highlighted IR-4's vision to establish a global network of minor use programmes working together to solve minor use grower needs. Key factors in addressing the minor use issue included global collaboration and cooperation. In this regard, IR-4 had co-sponsored Global Minor Use Summits and had begun to build a platform of cooperation, which served to help harmonize standards and to promote sustainable newer, lower risk products critical to modern integrated pest management systems. Other activities included the development of a Global Minor Use Foundation (GMUF) to leverage resources.

3.44. Mr Kunkel shared IR-4's experiences in partnering with Canada, highlighting the joint residue studies undertaken, as well as the field trials and sample analyses conducted by Canada. Mr Kunkel underscored the importance of working with other countries to leverage resources, highlighting the direct cost savings to the IR-4 project. Several tools which could promote the harmonization process were highlighted, such as crop grouping; global zoning (exchangeability of field trials); incentives for industry to support minor uses; MRL calculator; crop group calculator; and global joint reviews. Finally, Mr Kunkel drew participants' attention to the Third Global Minor Use Summit which would take place in Montreal, Canada in October 2017.[26]

3.45. **Mr Jason Sandahl**,[27] Senior Program Manager, Trade and Scientific Capacity Building Division, Office of Capacity Building and Development, US Department of Agriculture (USDA),

[25] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_2_dan_kunkel.pdf.

[26] http://www.gmup.org/.

[27] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_2_jason_sandahl.pdf.

provided information on the collaborative approach in addressing global MRL needs for minor-use crops. Mr Sandahl first identified some of the reasons for the absence of Codex MRLs, such as the expensive and difficult nature of residue trials; lack of support for a minor use crop by the pesticide industry; and lack of interested groups willing to conduct the work. He also explained the reasons for differences in MRLs and underscored the lack of coordination in the data generation process.

3.46. Mr Sandahl provided an overview of the Global Residue Project for Tropical Fruits which was initiated to develop global capacity for generating residue data to establish Codex MRLs, particularly for high-value specialty export crops. This project had been undertaken by the USDA and the US IR-4 Project, in close partnership with the Association of South East Asian Nations, the African Union, and the Inter-American Institute for Cooperation on Agriculture (IICA). The Standards and Trade Development Facility (STDF) had provided funding for this project, with leveraged contributions by USDA, US State Department, US Agency for International Development, the Inter-American Development Bank, and in-kind contributions from IR-4, Dow, Sumitomo, Syngenta, and participating national governments. The project, which had started in 2012, consisted of three regional initiatives undertaken in Asia, Latin America and Africa, spanning a representative range of tropical crops. Project activities had included the identification of project crops and pesticides, field and laboratory training on conducting residue research, undertaking actual research, data review and preparation of data package for JMPR submission. The project was due to be completed at the end of 2017.

3.47. The long-term vision of the project was to establish a global network of residue research teams to collaborate in generating data for MRLs and to coordinate minor use programmes. To meet this goal, and to build upon gains accomplished under the STDF-funded project, USDA and IR-4 had created the Global Minor Use Foundation (GMUF), with the aim of identifying and prioritizing global MRL needs, encouraging exchange of data, and coordinating residue research across multiple countries. Mr Sandahl provided a practical example of how the Foundation could be used to implement projects in the future, in order to generate data for joint submission to JMPR. He underscored the importance of communication, coordination and collaboration in addressing the MRL issue for minor crops, as well as the role of various stakeholders. Mr Sandahl invited the participation of other partners and experts in phase 2 of the project.

3.48. Several queries were raised in relation to the project's budgetary scope, the submission of data packages to Codex and the selection process for products. Mr Sandahl clarified that capacity building and consumables had been included in the STDF project budget and highlighted the training activities undertaken to facilitate the project work, as well as indicated the future goal of implementing a cost-sharing approach with GMUF. Mr Sandahl explained that although the project's primary purpose was to generate data packages for submission to Codex, this data could also be submitted to export markets where an import tolerance was needed. He outlined the process for selecting products, which included the review of FAO and CCPR's work to determine the compounds which could be added to the nomination schedule, as well as other criteria related to identifying compounds with no challenges to toxicity concerns. He also highlighted future projects and welcomed countries to participate, as well as to attend the Global Minor Use Summit in October 2017.

3.49. **Ms Ana Carolina Lamy**,[28] Federal Inspector, Secretariat of Agribusiness International Regulations, Ministry of Agriculture, Livestock and Food Supply of Brazil, presented information on the Brazilian legislation for setting MRLs for minor-use crops. Ms Lamy first highlighted the process for registration of pesticides in Brazil, explaining the role of the three federal agencies involved in the process: Ministry of Agriculture (MAPA), Ministry of Health (ANVISA), and Ministry of Environment (IBAMA). The aim of the legislation was to address several issues identified by the fruit and vegetable sector in relation to the non-existent or insufficient supply of pesticides for minor crops. This supply issue had arisen as a result of the lack of interest from the pesticide industry, due to the limited revenue and sale of pesticides for minor crops, compared to the substantial costs to obtain and maintain registration. She explained that for the approval of new uses of existing pesticides, it was necessary to conduct crop field trials in order to determine the magnitude of the pesticide residue in or on raw agricultural commodities, and finally to derive

[28] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s3_2_ana_lamy.pdf.

MRLs. The challenge faced was to create a fair system of pesticide registration for minor crops in Brazil.

3.50. Ms Lamy indicated that the Brazilian regulation for minor crops had first been published in 2010 and subsequently reviewed in 2014. In developing the regulation, inputs had been received from various stakeholders, such as universities, farmers' associations, international references (IR-4, US EPA, Codex), and through official research. The goal of the regulation was to encourage pesticide registration for minor crops by adopting the principles of crop grouping and representative crop commodities for extrapolation of results from residue trials, so that data would not be required for each crop. This had resulted in reducing pesticide registration costs without increasing the risks to consumers and field workers.

3.51. Through the use of a specific example, Ms Lamy outlined the parameters used in defining crop groupings and representative crop commodities, as well as the legislative steps to allow registered pesticide MRLs used in a representative crop group (e.g. apples), to be extrapolated to minor crop groups (e.g. blackberry). She further explained that the MRL extrapolation was temporary, until the residue studies on a representative crop of the subgroup were concluded. The industry had two years to undertake the residue trials and present its data to the regulatory authorities. According to the results of the residue studies, a definitive MRL would then be established for all of the minor use crops in that group. If a minor crop was not included in any group, interested parties could apply for its inclusion and submit a scientific and technical justification.

3.52. Ms Lamy also provided statistics on pesticide registrations for minor uses in Brazil, highlighting that since 2010, almost 500 minor crops had been covered, with more than 1,000 target pests addressed. The challenges for minor-use crops in Brazil included increasing registration of minor use pesticides, in order to strengthen the integrated pest management approach and minimize pest resistance; and promoting global MRL harmonization, in order to facilitate international trade through support to the JMPR/Codex reviews.

3.53. In the **question and answer session**, Ms Lamy further clarified that definitive MRLs could be established in 2.5 to 3 years, but that this depended on the particular situation and how quickly the industry undertook the residue trials. She also provided further information on the MRL extrapolation process from the representative crop to a minor crop and explained Brazil's approach to crop grouping, indicating that there could be some differences between its approach and the Codex system. However, she explained that once the parameters to define the crop groupings and representative commodities were established, revisions were always being made.

3.54. Mr Kunkel addressed the issue of comparability of dietary needs and MRL practices across regions, explaining the differences in use patterns, as well as the project's focus on the critical GAP which would give the most flexibility in pesticide use, based on the most conservative use pattern. Mr Kunkel acknowledged the expensive nature of field analyses due to the more stringent requirements for compounds and changing residue definitions, indicating the challenges faced in registering pesticides in multiple countries. He also underscored the need for regulatory bodies to align reviews on a lateral rather than linear basis, and to have discussions on residue definitions at the beginning of the process. In response to a query on the types of industry incentives that could be used to promote harmonization, Mr Kunkel provided information on an OECD survey which had identified various incentives to promote minor use registration, such as providing public funding for minor use programmes; and extending the exclusive use period for protection of data rights for minor use registrations. He also highlighted Brazil's approach to allow a temporary MRL, while the industry generated data, and he further encouraged industry initiative to generate data on minor uses.

3.55. Workshop participants highlighted several challenges in implementing MRLs in Africa, such as various capacity needs, including GLP compliance. In this regard, it was suggested that the next phase of the global residue project could target capacity building focused on laboratories, as well as the inclusion of additional countries in the data generation process. In response, Mr Spreij (STDF) indicated that laboratory capacity and other infrastructure could be reviewed in the next project phase, including the mobilization of other organizations, such as the African Development Bank, while underscoring STDF's demand-driven approach. Mr Sandahl encouraged countries interested in the project to come forward and further noted that training needs would be better addressed in the next phase. The role of regional economic communities, such as AU-IAPSC,

in supporting collaborative approaches was also highlighted, specifically in the dissemination of good practices from the various projects, as well as in addressing the challenges faced in encouraging data registration in Africa.

3.4 Domestic frameworks and approaches for establishing MRLs and import tolerances (Session 4)

3.56. In **Session 4**, speakers explained their domestic regulatory and legal infrastructures for establishing MRLs. In addition, through the use of case studies, speakers provided insights into their domestic frameworks for establishing MRLs and import tolerances. In particular, they highlighted their approaches to risk assessment and risk management where no international standard existed or where an existing international standard was not used. The session also explored concerns related to specific commodity and pesticide combinations.

3.4.1 Part 1: Domestic Policy, Regulatory and Legal Infrastructures for Establishing MRLs

3.57. **Mr Volker Wachtler**,[29] Policy Officer, Directorate-General for Health and Food Safety, European Commission, provided an overview of the EU policy for setting pesticide MRLs. Mr Wachtler explained the core types of EU legislation[30] which covered all stages of the lifecycle of a Plant Protection Product (PPP), regulating the placing on the market and use of PPPs, and pesticide residues in food and feed, as well as the General Food Law (Regulation (EC) No 178/2002). Specifically, Mr Wachtler provided an overview of the general principles of Regulation No 396/2005 on pesticide MRLs, which aims to protect consumers through the establishment and enforcement of MRLs, while facilitating trade.

3.58. Mr Wachtler explained the EU MRL setting process, highlighting that a consumer risk assessment was undertaken, based on a comparison of the exposure to toxicological reference values, similar to the process presented by WHO JMPR. In addition, the ALARA principle (as low as reasonably achievable) was followed in the EU MRL setting process, and the OECD calculator was used. For substance/commodity combinations without data, the MRL was either set at the analytical limit of quantification,[31] or at the default value of 0.01 mg/kg if there was no information on the analytical methods. In this regard, predictability was provided in the process, as opposed to a zero-tolerance approach.

3.59. Mr Wachtler indicated that EU MRLs were established either on the basis of GAPs in EU member States, GAPs in third countries, or on Codex Alimentarius standards. He provided additional details on the data requirements to accompany requests by third countries applying for MRLs and referred to the information available in the Guidance Document on the MRL Setting Procedure.[32] He underscored that MRLs, once established, applied to all food and feed on the EU market, whether from EU member States or third countries. Additional MRL information could be found in the EU Pesticides Database,[33] and detailed technical and procedural guidance was available on the website of the European Commission.[34]

3.60. Mr Wachtler further described the procedural framework, timelines and actors involved in the MRL setting process, both for EU uses and import tolerance requests. He highlighted that applications could be submitted by any party with a legitimate health or commercial interest and explained the information to be submitted in the dossier and the subsequent review process. Mr Wachtler also outlined key features of the ongoing review programme of existing MRLs in the European Union, highlighting that additional information on the programme, as well as the process for third countries to contribute information, could be found in document G/SPS/GEN/1494.

[29] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s4_1_volker_wachtler.pdf.

[30] The relevant EU legislation is as follows: Regulation (EC) No 1107/2009 on placing of PPP on the market; Directive 2009/128/EC on sustainable use of pesticides; and Regulation (EC) No 396/2005 on MRLs of pesticides. Legal texts available at: http://eur-lex.europa.eu/homepage.html.

[31] The EU has four reference laboratories responsible for pesticide residues, which provide advice on the appropriate LOQ which is taken into account during the decision-making process.

[32] SANTE/2015/10595 Rev.4, available at: http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc.pdf.

[33] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public.

[34] http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm.

Some of the MRL challenges faced by the European Union were highlighted, such as the interplay between different pieces of EU legislation, in relation to procedures and timelines; minor use crops; and negative public perception of the use of pesticides. Mr Wachtler further provided information on the EU Minor Uses Coordination Facility,[35] which had been established in 2015 to coordinate the work carried out in EU member States and to liaise with international actors.

3.61. Questions were raised on the procedure for third countries to provide comments on new MRLs and on the review programme, including submission of inputs on the criteria for endocrine disruptors. Mr Wachtler clarified the process for providing feedback on the review of existing MRLs, highlighting that draft acts were notified to the WTO for submission of comments by third parties and that third countries could also provide inputs at the beginning of the evaluation process. He referred to the information note (G/SPS/GEN/1494) which set out the steps for submission of information and further encouraged the circulation of this document to industry. He also clarified the procedure for the establishment of new MRLs. Mr Wachtler distinguished between the review programme for existing MRLs and the ongoing discussions on endocrine disrupting compounds, explaining that a decision had not yet been taken on endocrine disrupting compounds. He further invited participants to attend the information session that would be held by the European Union on the margins of the SPS Committee meeting.

3.62. In response to a query, Mr Wachtler indicated some of the scenarios in which the European Union had increased the MRL of a pesticide, and responded to the concern raised regarding European Union's reservations on certain compounds in CCPR. In relation to private standards and EU market access, Mr Wachtler clarified that EU MRLs were based on evaluation procedures outlined in the legislation. He acknowledged the presence of private standards, but highlighted that the European Union was not involved in this area and did not operate private standards schemes.

3.63. **Mr Takuya Kondo**,[36] Assistant Director, Standard and Evaluation Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan, provided an overview of pesticide MRLs in Japan. He highlighted the importance of ensuring food safety in the trade of goods and the critical role of MRLs in that regard. He also outlined Japan's risk analysis approach and the role of three government institutions in activities related to risk assessment, risk management and risk communication.

3.64. Mr Kondo explained that pesticide MRLs were regulated under the Japanese Food Sanitation Law and that they were established on the basis of an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) as estimated by the Japanese Food Safety Commission. He outlined the risk analysis principles used in establishing pesticide MRLs in food, such as ensuring that the theoretical maximum daily intake did not exceed 80% of the ADI, and that the chemical intake from each food commodity did not exceed the ARfD. Vulnerable groups, such as infants, children, pregnant women and elderly people were also considered in the evaluation process.

3.65. Mr Kondo indicated that since May 2006, the Ministry of Health, Labour and Welfare (MHLW) had introduced a "positive list system" for pesticides, where all food items were regulated for pesticide residues and where substances without specific MRLs could not exceed the uniform standard of 0.01 ppm. Through the positive list system, all agricultural chemicals were now targeted and MHLW had been accepting an import tolerance requirement for pesticides as approved by the foreign country. He further explained that the import tolerance system enabled the Japanese government to set MRLs for pesticides in imported food products. Applicants could request the MHLW to set new MRLs or set MRLs higher than the corresponding MRL in Japan, and were required to submit documents supporting the safety of target pesticides. Some examples of the required documents to accompany the application were provided. Additional information on the process for import tolerance applications could be found on MHLW's website: http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html.

[35] https://www.minoruses.eu/.

[36] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s4_1_takuya_kondo.pdf.

3.4.2 Part 2: Domestic Frameworks for Risk Assessment and Risk Management

3.66. **Dr Peter Chan**,[37] Director General, Health Evaluation Directorate, Pest Management regulatory Agency, Health Canada, provided information on the Canadian regulatory approach for establishing MRLs. He highlighted that under the Pest Control Products Act (PCPA), the Pest Management Regulatory Agency of Health Canada took a risk-based approach to specify MRLs for pesticide residues in food, where risk assessments considered both the hazard and exposure. In addition, MRLs were enforced under the Food and Drugs Act. Dr Chan outlined the Canadian MRL setting process, highlighting that Canadian MRLs were set only after an extensive review of the scientific information and after a thorough risk assessment confirmed that there were no health concerns to all segments of the population, when all possible food sources were eaten every day, over a lifetime. When established, the MRLs applied to all foods, regardless of whether they were from Canada or imported, and were set at levels well below the amount that could pose a health concern.

3.67. Dr Chan provided information on Canada's approach to risk assessment and risk management where international standards are not used, such as in the case where international MRLs are not aligned with Canadian MRLs for the same pesticide/commodity combination. Examples of this scenario included cases where there were differences in data packages; residue definitions; environmental conditions and pest pressures leading to different application rates and different GAPs; methodologies for calculating MRLs (e.g. NAFTA vs OECD calculator); criteria or legislative authorities for setting MRLs; and dietary and cultural preferences. Dr Chan also explained that where a tiered approach[38] was used for the dietary risk assessments and there remained risks of concern, MRLs were set at the limit of quantification (LOQ) of the enforcement method. He further indicated that Canada took into consideration Codex MRLs, where available.

3.68. Dr Chan highlighted several suggestions to minimize trade disruptions, from various perspectives. He underscored the responsibility of growers to communicate their needs to registrants regarding crops and export markets, as well as being aware of MRLs in other countries. For the industry, he underlined the benefits of globally harmonized GAPs, undertaking global joint review submissions, considering domestic registrations in key export markets and submission of the same data package globally. For regulatory authorities, he encouraged participation in global joint reviews, contributing to Codex (JMPR/CCPR) activities and development of policies based on science.

3.69. In the **question and answer session**, queries were raised on several areas related to the procedure for setting default MRLs and LOQs; the use of MRL calculators; and the MRL setting process to facilitate imports of raw or semi-processed products for use in domestic production. Dr Chan indicated that the default MRL of 0.1ppm applied to pesticides that were not registered in Canada and explained the process for the establishment of LOQs. Dr Chan also indicated that Canada had been using the OECD calculator since 2006, prior to which it had used the NAFTA calculator. Mr Wachtler explained that the MRL decision-making process for establishing MRLs did not factor in the trade costs, but instead focused on the evaluation of submitted data packages meeting the application requirements, as well as robust risk assessments. He further explained that while EU legislation provided for the possibility of setting MRLs for semi-processed foods, in practice MRLs were only set for agricultural products. Dr Chan indicated that the Canadian legislation provided for the establishment of MRLs for processed commodities, explaining that in most cases, MRLs for the raw commodities captured residue issues, however, MRLs could be set for processed commodities, as necessary.

3.70. In relation to the required documentation for import application requests, Dr Chan explained that there had to be a registered use in order to apply for an import MRL. Mr Wachtler also indicated that there needed to be a label and established pesticide MRL in the requesting country, before submission to EFSA. Dr Chan also addressed the issue of the efficiency of joint reviews, highlighting the need for capacity building and increased participation of global partners, and further encouraged the involvement of non-OECD countries. The minimization of science-based interpretation differences was also underscored as a positive outcome of the joint review process, which had facilitated the establishment of MRLs in a more timely and aligned fashion. Mr Wachtler

[37] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s4_2_peter_chan.pdf.

[38] Tier I: MRLs; Tier II: field trial data and Tier III: food monitoring data.

noted that the EU regulatory timelines made it challenging for the participation of the European Union in such reviews. Participants also highlighted the various challenges related to the varying data requirements by trading partners, as well as prioritization issues related to the establishment of pesticide MRLs for domestic uses vs. import MRLs.

3.5 Experiences in implementing and complying with Codex MRLs (Session 5)

3.71. **Dr Olga Egorova**,[39] Senior Researcher at the F.F. Erisman Federal Scientific Centre of Hygiene (Rospotrebnadzor), presented the Russian Federation's experience in complying with Codex pesticide MRLs. Dr Egorova explained that the process of harmonization dated back to 2009 with the implementation of Decree No. 761 of 28 Septembe 2009 on *Harmonization of Russian Sanitary and Epidemiological Requirements, Veterinary and Sanitary and Phytosanitary Measures with International Standards*. She also highlighted other pieces of Russian legislation relevant to the harmonization process, while noting that the scientific principles used in establishing pesticide MRLs in the Russian Federation were the same as those used by Codex.

3.72. Dr Egorova outlined the process of MRL harmonization, both for pesticides authorized in the Russian Federation and for imported products not authorized in the Russian Federation. MRL setting in the Russian Federation included the toxicological assessment of pesticides and their hazardous metabolites, and the development of MRLs for each active ingredient intended for use in the Russian Federation, according to the complex hygienic regulation principles.[40] These principles were not applicable for any pesticide active ingredient in imported products that were not being registered in the Russian Federation. She further outlined the process by which pesticide residue data were generated, highlighting the importance of field trials across various soil-climatic zones and growing seasons at a maximum use rate. An example of a risk and exposure assessment of the non-carcinogenic effects of Chlorantraniliprole at food intake was also provided.

3.73. As a result of the harmonization of Russian pesticide MRLs with Codex standards, 1,500 MRLs of 162 active ingredients had been revised, 66 of which were new active ingredients.[41] Guidelines on MRL establishment and risk assessment had also been developed, along with eleven harmonized analytical methods of control for 66 individual commodities based on international approaches. Ms Egorova noted that the process of MRL harmonization was dependent on the submission of toxicological and residual data for the registration of pesticides. In addition, the periodic MRL review programme in the Russian Federation had resulted in two amendments to the list of pesticide MRLs in 2015 and 2016. Dr Egorova also highlighted the obligations under EurAsEC, emphasizing the shared responsibility of EurASeC members in the MRL setting process. In 2015, amendments had been made to the Custom Union Commission Decision No 299, which included the harmonization of pesticide MRLs with international MRLs and a list of validated analytical methods for the determination of pesticide residues.[42]

3.74. Some of the obstacles faced in the harmonization process were the significant divergence between the pesticide MRL values set by Codex and those used in the Russian Federation; and the frequent and significant reconsideration of standards approved by international and national bodies, on the basis of human risk data. Lastly, she highlighted that harmonization of Russian MRLs with Codex MRLs had led to a significant increase in the level of acceptance of Codex MRLs and that the harmonization process would continue.

3.75. **Mr Rául Peralta Girón**,[43] Director, Agrifood Safety Department, Ministry of Agriculture, Dominican Republic, provided information on the impact of the implementation of Codex MRLs on exports of fruits and fresh vegetables. Mr Peralta explained that the Dominican Republic exported

[39] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s5_olga_egorova.pdf.

[40] The complex hygienic regulation dictates that the total amount of a pesticide active ingredient (and products of its transformation), which can be absorbed into an organism from various media (food, water and atmospheric air), must not exceed an acceptable daily intake (ADI) for a human being.

[41] A list of MRLs is available in the Hygienic Standards of 2013 (HS-1.2.3111-13).

[42] Uniform sanitary and epidemiological and hygienic requirements for products subject to sanitary and epidemiological supervision (control); Section 15. Requirements for pesticides and agrochemicals, EurAsEC, 2015, Moscow. Decision of the Board of the Eurasian Economic Commission No 149 of 10 November 2015 "On Amendments to the Customs Union Commission Decision No 299 d.d. 28 May 2010."

[43] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s5_raul_peralto_giron.pdf.

a variety of fresh fruits and vegetables to the United States, Canada and the European Union, accounting for more than US$300 million. However, in recent years, exports of these products had been affected by rejection notifications and notices of non-conformity, linked to the detection of pesticide residues higher than those approved in the MRLs of the importing country. This situation had led national authorities to adopt Codex MRLs as official national MRLs in 2010, through Regulation 244-10. This regulation incorporated risk assessment principles for the registration and renewal of pesticide registrations.

3.76. In order to implement Codex MRLs, the authorities had undertaken the following actions: (i) established a baseline for pesticide residues under a monitoring plan carried out from 2011-2013; (ii) established a National Programme for the Monitoring of Pesticide Residues in 2014; (iii) developed a traceability system for rejection notifications due to pesticide residues; and (iv) created a publicly accessible database of pesticide MRLs. Mr Peralta also presented the results of the baseline study, highlighting that 93% of the products were in conformity with the adopted MRLs, according to Regulation 52-08. Mr Peralta further noted that only 21% of the pesticide MRLs notified by the destination market had established Codex MRLs. In addition, 89% of national pesticide MRLs identified as non-compliant in the destination market were within the Codex MRLs, highlighting that trading partners had established stricter legislation.

3.77. Mr Peralta provided two examples of MRLs for Carbendazim and Permethrin for use in pimentos, which had been notified as non-compliant by trading partners, and observed that the notified MRLs were actually more restrictive than the Codex MRLs. He noted the positive reaction to the implementation of Codex MRLs, as it had increased consumer trust. Some of the difficulties faced in the harmonization process included trading partners' use of MRLs more restrictive than Codex MRLs; lack of Codex MRLs for most of the pesticides; obtaining analytical standards; and the high accreditation costs for laboratory tests and maintaining laboratory teams.

3.78. In the **question and answer session**, Mr Peralta addressed the challenges faced in exporting certain products, when specific Codex pesticide MRLs were not established. He explained that in this situation, the MRLs of other trading partners were adopted, such as the United States and the European Union. In response to a query regarding the challenges in establishing GAPs after pesticide MRLs had been adopted, Mr Peralta highlighted that once MRLs were adopted, an assessment was undertaken of the level of compliance among producers. He noted the pressures from the domestic and international markets, but underscored the importance of consumer safety. Mr Peralta also acknowledged the various constraints faced in relation to the operational costs for laboratory machinery, underscoring the challenges faced in maintaining functional laboratories and meeting high accreditation costs.

3.79. In relation to the recognition of GMPs by various trading partners, Mr Peralta noted the importance of producing on the basis of the most demanding market, in order to ensure compliance with all markets. With respect to the frequency with which reviews were undertaken in order to harmonize the Russian Federation MRLs with Codex standards, Ms Egorova explained the review process and indicated that updated lists were published every two to three years. The first list had been published in 2013, followed by two subsequent amendments in 2015 and 2016.

3.6 Panel discussion on the role of the private sector in the establishment and implementation of MRLs (Session 6)

3.80. Through the use of specific examples, speakers in this session explored the various ways in which the private sector could be involved in the establishment of MRLs, their experiences in the implementation of MRLs and challenges faced. In particular, the session highlighted the role of the private sector in providing support for the scientific review process through data sharing, expert consultation and contribution of financial resources to support the review process.

3.81. **Mr Matt Lantz**,[44] Vice President, Global Access, Bryant Christie Inc. (BCI), United States, provided information on how commodity groups and the private sector could approach international MRL issues, the challenges faced and the possible areas for cooperation. Mr Lantz first provided background information on the work undertaken by Bryant Christie Inc., a US-based consulting firm specializing in international MRL issues and representing grower groups in a

[44] Speaker's summary is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s6_matt_lantz.pdf.

number of commodities. BCI also developed and maintained GlobalMRL.com, a database that housed up-to-date MRL information for over 115 markets.

3.82. Mr Lantz categorized BCI's work on international MRL issues into two broad areas: (i) dealing with major pesticide regulatory changes in key export markets; and (ii) undertaking day-to-day management of MRL issues. BCI's objective was to ensure that its clients' trade was not affected by major MRL regulatory changes in target markets, which included assessing which pesticides were used domestically and identifying any gaps in the new MRL lists of trading partners. BCI's work also included reviewing and monitoring notifications to determine regulatory changes and submitting comments, as well as cooperating with registrants on new products on offer to seek MRLs and assisting groups to address residue violations in foreign markets.

3.83. Several challenges faced by the private sector were highlighted, which included the timing of MRL establishment; differing data requirements; obtaining MRLs for older products; onerous violation sanctions; and limited time for submitting comments on proposed MRL changes or comments not being taken into consideration by trading partners. Mr Lantz also noted the recent positive developments in managing international MRL issues, such as cooperation between international grower groups, increased availability of MRL data, discussion of MRL issues in different fora and the increased number of MRL notifications to the WTO. He also indicated that the technical nature of MRLs provided opportunities for resolving issues through cooperation, whether among grower groups, collaboration among registrants on data submissions, or cooperation by governments on joint reviews.

3.84. **Mr Michael Kaethner**,[45] Global Regulatory Policy Manager, Bayer CropScience, Germany, provided information on the work of CropLife International, highlighting its role as the voice of the global plant science industry through its championing of agricultural innovations in crop protection and plant biotechnology, as well as advancing sustainable agriculture. Mr Kaethner outlined its activities geared at obtaining national MRLs, import MRLs and Codex standards for use of crop protection products. In relation to national and import MRLs, Mr Kaethner outlined the work undertaken on product authorization and submission of MRL data. He highlighted the various ways in which CropLife International contributed to the Codex process, through its support to the nomination process for active substances and uses, submission of detailed study reports and comprehensive summary dossiers for scientific evaluation by FAO and WHO JMPR, as well as involvement in electronic working groups. He underscored that most Codex MRLs were based on data submitted by the crop protection industry.

3.85. Mr Kaethner noted the importance of the APEC initiative to develop an Import MRL Guideline for Pesticides, since not all countries had provisions to set import tolerances. He also observed that not all countries deferred to or accepted Codex MRLs, and further encouraged countries to make their national policies publicly available in order to facilitate trade. With respect to harmonization of data, Mr Kaethner explained the support provided by CropLife International's experts in the development of improved tools and guidance for MRL setting through its contributions to the OECD's Residue Chemistry Expert Group. In addition, it had also provided data and expertise to the IR-4 project, as well as various government initiatives.

3.86. Mr Kaethner identified some of the MRL challenges faced by the private sector, such as improving the harmonization of data requirements and policies, as well as increasing transparency and predictability in the decision-making process, especially in relation to the acceptance of Codex MRLs by governments. He also underscored the uncertainties arising from the introduction of new national approaches for import MRL setting. In highlighting the capacity constraints faced by FAO and WHO in meeting the increasing demand for pesticide MRLs, Mr Kaethner suggested that members needed to have a fresh perspective in relation to the procedures and approaches that could be adapted. He further encouraged trade representatives to interact with their national regulators and ministries responsible for undertaking risk assessment and risk management activities, in order to ensure that MRLs were set to meet consumer safety goals, while enabling free trade.

[45] Mr Kaethner is also Chair of the Consumer Safety Team at CropLife International. Speaker's summary is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s6_michael_kaethner.pdf.

3.87. **Mr Gord Kurbis**,[46] Director of Market Access and Trade Policy, Pulse Canada, provided an overview of the work of Pulse Canada[47] and its role in addressing MRL-related issues. He highlighted that the Canadian pulse industry was the largest exporter of pulses, trading to over 150 countries from approximately 25,000 farmers. Following the experience of an MRL-related trade disruption in 2011, Pulse Canada had expanded its focus to include the challenges to export trade associated with MRLs. In this regard, the association was now executing a domestic framework of co-operation, information-sharing and management of trade risks associated with MRLs. This framework applied to both large and small exports of pulses, as well as to specialty products grown under contract by a small number of farms or other pulses grown on a commodity scale by individual farmers. A key component of the framework was information-sharing among farmers, government and the pesticide industry leading towards the establishment and implementation of key MRLs.

3.88. Mr Kurbis further explained that as part of the International Year of Pulses 2016, Pulse Canada was participating in the Global Pulse Confederation's advocacy efforts concerning the extent to which misaligned MRLs could disrupt trade and constrain growers' productive use of pesticides in pulse growing regions around the world. He underscored the increasing opportunity to expand positive examples of MRL collaboration between governments to manage ongoing challenges, such as the OECD global joint reviews.

3.89. Some of the challenges included: (a) establishment of national MRL lists without reference to Codex; (b) applying zero, near-zero or undefined default MRLs in the absence of established MRLs; and (c) applying testing with limits of detection much lower than were possible when MRL policies were established. He also highlighted the importance of ensuring that the Codex MRL-setting process was adequately resourced, given the greater need for a single, global MRL reference.

3.90. **Ms Morag Webb**,[48] Policy Adviser, COLEACP[49], highlighted the MRL work undertaken by COLEACP in representing the interests of EU importers, and ACP (Africa, Caribbean and Pacific) producers and exporters of fruit, vegetables, flowers and plants. The overall goal of COLEACP was to facilitate the flow of trade between ACP countries and the European Union, and within the ACP region. In this regard, she explained how COLEACP had extended its activities into the implementation of EU-funded technical assistance programmes, such as the Pesticides Initiative Programme (PIP - Phases 1 and 2), which ran from 2001 to 2015.

3.91. PIP was designed to provide producers and exporters with the necessary information, training and support so that they could meet the new EU food safety regulations and private industry standards. In particular, the EU MRL Harmonization programme had set new limits for pesticide residues in foodstuffs sold in Europe. Ms Webb detailed the various activities undertaken by COLEACP to allow producers to have effective and affordable methods of pest management. This included, among others, undertaking surveys to identify the most critical crop-pest combinations where ACP producers faced a real risk of losing market access; analyzing data to develop proposed MRLs; preparing import tolerance dossiers for submission; liaising with rapporteur member States; and applying for new and extrapolated MRLs. The importance of public-private partnerships was also highlighted, such as the collaboration with PPP manufacturers and COLEACP's role in identifying and coordinating the various stakeholders, orchestrating the complex series of activities required and securing the necessary investment.

3.92. Ms Webb highlighted the concrete results of COLEACP activities under the PIP programme, which included the granting of a total of 43 EU import tolerances between 2001 and 2015, and obtaining extrapolations for more than 10 substances on crops that included snow peas, yams and sweet potatoes. Ms Webb also explained that one additional EU import tolerance was pending and that data had also been submitted for several Codex MRLs, but progress was delayed pending registration extensions, and changes in residue definition. In addition, 140 crop-active ingredient

[46] Speaker's summary is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s6_gord_kurbis.pdf.

[47] Pulse Canada is a national association of farmers and exporters.

[48] Speaker's summary is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s6_morag_webb.pdf.

[49] The Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP) is a private sector association which provides a range of services to members in support of horticultural import and export activities, including communication, technical assistance, lobbying, and advocacy.

combinations had been tested in ACP fruit and vegetables to define the pre-harvest interval for compliance with EU and Codex MRLs, and to develop GAP recommendations for local conditions.

3.93. In the **question and answer session**, various questions were raised on the ways to increase private sector engagement in the establishment and implementation of MRLs and how support could be provided to the industry. Some suggestions from speakers included encouraging proactive dialogue and engagement between industry and regulatory authorities to identify growers' needs and priorities; notifying MRLs in advance and considering submitted comments; introducing new residue requirements at a pilot testing stage; governments taking the least trade restrictive measure and finding reasonable policy solutions or transitional measures in the face of changing residue requirements; public investment for generating public goods; fast tracking applications; capacity building for regulatory authorities; sharing of reviews among regulators; and standardization of data submission packages.

3.94. Questions and comments from participants also focused on the lack of MRLs for certain pesticides and the need for a more efficient Codex process. Speakers were encouraged to propose fresh ideas with respect to a more efficient Codex system. Some of these suggestions included submission of the same data packages to JMPR; consideration of whether new substances, which had already been evaluated by several authorities, needed to be reviewed again by JMPR; and use of crop groupings to allow for more commodities to be covered under a single MRL, as well as to address the issue of minor crops. Participants highlighted the lack of local registration for minor crops and the challenges in obtaining resources, as well as in meeting data requirements due to the associated costs and changes in data definitions. Speakers outlined the main reasons for the lack of support from the private sector in registering new pesticides, highlighting the various commercial considerations which did not warrant the investment of manufacturing companies, even if the crop was of great export value to a country. In this regard, the opportunity for increased collaboration was highlighted, e.g. through collaborative efforts among several countries to create a larger market. It was also underscored that the higher the degree of misalignment between MRLs in different countries, the greater the investment in major crops and the greater the disincentive to invest in minor crops.

3.95. Regarding consumers' demand for stricter MRLs than those set by regulators, speakers observed that consumer concerns primarily focused on residues in general, but not on whether residues were safe. Speakers noted the certification systems which worked on the basis of a list of allowed substances, as well as other types of private standards schemes which set different MRLs to those of national or Codex MRLs. Participants highlighted that the issue of private standards had been raised in CCPR and the SPS Committee, and some points for further reflection were shared. These included how to move forward in addressing private standards and consideration of whether a parallel system should exist, separate from the officially adopted standards. The importance of continued discussions was highlighted, as well as the need to separate commercial from regulatory interests. It was also acknowledged that some private standards could provide a framework for regulatory compliance.

3.96. Some of the main challenges concerning MRLs in the future were highlighted by speakers, such as compliance with MRLs not based on risk assessments, e.g. those that are set at zero or near zero thresholds, which occurred, in part, due to the growing number of missing MRLs, as countries moved to national lists. In addition, the proliferation of national lists was identified as creating more difficulties for exporters to keep pace, as well as leading to the lowering of MRLs. The varying MRL policies of different countries also posed challenges to trade, as well as issues related to data harmonization, and predictability in the MRL setting process (e.g. timeframes). In the ensuing discussions, it was suggested that there should be consideration of a fast track process for newer, low risk products, which could be safer than older products.

3.7 Impact of MRLs on International Trade (Session 7)

3.97. In **Session 7**, speakers explored the impact of the use of default MRLs, as well as MRL expiration, on agricultural trade. Through the use of case studies, speakers explained their experiences with addressing the use of default MRLs by trading partners and the subsequent impact on agricultural exports. In addition, speakers explored some of the possible approaches to address concerns that may be posed by older products, while maintaining safe trade.

3.7.1 Part 1: Impact of Compliance with Default MRLs on International Trade

3.98. **Ms Rebeka Tekle**,[50] Acting Deputy Director, Agriculture and Agrifood Canada, presented the impact of compliance with default MRLs on international trade. Ms Tekle underscored that managing trade risks associated with pesticide MRLs was a challenge, as it necessitated a balancing act between protecting public health, maintaining market access for agricultural products and practical access to plant protection tools. In this regard, she highlighted the importance of agricultural products in Canada's economy, both in terms of imports and exports.

3.99. Ms Tekle underscored Canada's participation in various domestic and international activities, aimed at reducing these trade risks associated with pesticide MRLs, while ensuring regulatory compliance, as well as promoting transparency and predictability in the process. The coordination and cooperation undertaken at all levelswas key, whether within the Canadian agriculture sector, between industry and government, or between the Canadian government and international partners. The activities included industry-led risk mitigation projects to ensure compliance with international regulations, called "keep it clean"; industry-government collaboration to increase understanding of challenges and priorities; and government to government cooperation to facilitate international standards development, adoption, and alignment.

3.100. She highlighted the benefits of collaborative work in order to better manage risks and facilitate trade in agriculture products. These included supporting risk-based analysis of pesticide residues; recognizing the role of the Codex scientific bodies; recognizing the obligations under the SPS Agreement; encouraging transparency and predictability of MRLs and pesticide regulations, including through the WTO notification process; and increased cooperation to minimize differences in regulatory approaches and facilitate market access, including at the OECD and other regional fora.

3.101. **Ms Lucy Namu**,[51] Senior Principal Analytical Chemist, Head Quality Assurance and Laboratory Accreditation, Kenya Plant Health Inspectorate Service, presented Kenya's experience with trade impacts of default MRLs. Ms Namu provided a background of Kenya's horticulture industry, highlighting that the sector had grown at an annual average rate of 15% between 2001 to 2013, accounting for 30% of agriculture (in GDP value) and with 45% of the country's exports destined to the European Union. Ms Namu explained that in January 2013, Kenyan beans and peas in pods had been listed for increased controls for pesticide residues, noting that many of the targeted pesticides had MRLs set at the limit of detection. This had a negative impact on exports from Kenya, leading to an approximate 50% decrease in value. In order to overcome the challenges, the authorities worked with the grower community and various risk management options were employed to improve compliance at production level. These included, among others, training of small holder producers in the supply chain; enhanced pesticide residue monitoring programme for beans and peas in pods; enhanced checks on pesticide labels; and controls for placement on the market. These actions resulted in the delisting of beans in pods in July 2015, but peas were still listed.

3.102. Ms Namu indicated several concerns in relation to the lack of replacement pesticides, the need for data generation to support the establishment of MRLs based on GAP principles and the matching of crop protection needs with research alternatives. In addition, she voiced the concern that default MRLs were not always linked to health concerns, but due to other reasons such as minor uses/specialty crops, lack of supporting data for the MRL setting process and limited support from agrochemical companies. She presented various suggestions on how to address these challenges, which included harmonization of procedures to increase plant protection product registration; joint data generation programmes; implementation of African data generation initiative; creation of regional minor use programmes; and enhanced capacities for developing countries to increase pesticide residue data generation in order to have more Codex MRLs which reflect the realities in developing countries.

3.103. Participants raised questions in relation to the level of engagement between regulatory authorities and growers, as well as engagement with the European Union. Ms Namu noted that the

[50] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s7_1_rebeka_tekle.pdf.

[51] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s7_1_lucy_namu.pdf.

MRL issues faced by the industry had increased the participation of grower groups in discussion forums. In particular, Kenya had a horticulture mechanism which facilitated the identification of challenges by growers and exporters in meeting market requirements, resulting in subsequent discussions with authorities in target markets. Ms Namu also indicated the various positive engagements, through diplomatic channels, with technical officers and DG SANTE, which included providing regular updates and responding to feedback from the rapid alert system. However, she noted exporters' concerns with the change in EU Regulation 669/2009 to undertake biannual reviews, instead of quarterly reviews, which implied a longer time-frame for the delisting of peas. The European Union explained the rationale for increased controls and the steps taken by EU member States in their review of trade issues and the resulting decision to delist a commodity. The European Union's collaboration with Kenya on the MRL review programme was also highlighted.

3.104. Ms Namu also addressed a query in relation to Kenya's reliance on GlobalGap standards, noting some constraints in Kenya's review of current registrations, in light of changing EU requirements. She highlighted that although data generation was ongoing, a commensurate change in GAPs had not taken place. In response to a query, Ms Namu also indicated that default MRLs continued to be one of the biggest challenges and that this was a barrier to trade when it was not supported by the actual use pattern in the country.

3.7.2 Part 2: Impact of MRL Expiration on Agricultural Trade

3.105. **Mr Daniel Mazzarella**,[52] Technical Supervisor, Directorate of Agrochemicals, SENASA presented the impact of MRL expiration on agricultural trade. He noted the increasing complexity of the food chain and increasing public concerns about food safety, while underscoring the MRLs challenges faced in trade, whether these limits were legitimate or not. Mr Mazzarella recalled that pesticide MRLs were SPS measures, and as such were bound by the provisions of the SPS Agreement, particularly the scientific principle. Similarly, he noted that the expiration of a MRL was also a SPS measure, which should be based on scientific evidence.

3.106. Mr Mazzarella explained the bases for establishing MRLs in Argentina, highlighting the toxicological parameters, such as ADI and ARfD, as well as the GAP practices, where supervised field trials were undertaken to establish critical dose and MRL. In addition, SAGPyA No 350/1999 on *Manual of Procedures, Criteria and Uses for the Registration of Phytosanitary Products in the Argentine Republic* established criteria for setting MRLs. This document was based on the 5th edition of the *Manual on the Development and Use of FAO Specifications for Plant Protection Products*.

3.107. Mr Mazzarella also noted the risk analysis principles applied by CCPR in establishing pesticide MRLs, but observed that some MRLs were re-evaluated after a period of time, which had led to the unnecessary elimination of MRLs where there was no specific evidence of any danger. He indicated that when a MRL was eliminated, other families of herbicides could be examined in order to identify alternatives, but noted that a range of uncertainty could be introduced, such as: the different toxicity levels of replacement products; impact on pest management; increased application of herbicides; and economic effects related to patented vs. generic products.

3.108. Mr Mazzarella used the specific example of glyphosate MRLs (established at a domestic level) in several crops to show how MRLs had been set, as well as the importance of the monitoring process. He highlighted the potential impact of the elimination of glyphosate MRLs and queried whether glyphosate had stopped being safe for food and opined that this was not the case.

3.109. In the **question and answer session**, participants raised queries on the scientific basis for revocation of MRLs, including concerns related to the available alternatives for developing countries. Ms Namu reiterated that the absence of MRLs for certain pesticides was due to a lack of support by manufacturers to generate toxicology and residue data to support the development and registration of MRLs. Mr Mazzarella similarly indicated several challenges in the data generation process, while emphasizing that where there was no scientific information demonstrating that the product had stopped being safe, MRLs should be maintained.

[52] Speaker's presentation is available at: https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/s7_2daniel_mazzarella.pdf.

3.8 CONCLUSIONS (Session 8)

3.110. In **Session 8**, speakers summarized the key outcomes of the various workshop sessions from a developing and developed country perspective. **Ms Lucy Namu** outlined the importance of the risk assessment principles used in the Codex process, but noted concerns with the limited participation of developing countries in the data generation process and its impact on Codex decisions. She suggested that data harmonization could be a way to encourage registration of plant protection products in developing countries, and that harmonization initiatives, such as those of APEC or NAFTA could serve as a learning platform for developing countries. Ms Namu underscored the need for increased cooperation between private sector and regulatory agencies, and the role of proactive engagement in identifying and addressing potential concerns, before a specific trade issue arose. Ms Namu referred to the use of default MRLs and the challenges they posed, especially where these were not based on scientific data. She also emphasized the importance of capacity building assistance from partners, noting the needs identified by some countries, such as laboratory and technical capacity for quality data generation. She welcomed continued discussions to address these concerns and the development of more regional approaches to deal with minor use issues.

3.111. **Dr Peter Chan** observed that there were similar approaches to data review by developed countries in relation to risk assessment, and that focus had been placed on harmonizing the underlying science, in order to resolve differences in scientific interpretation which could lead to different MRL outcomes. He noted that, based on the presentations, various countries had import MRL registration processes similar to the APEC initiative. He underscored the benefits of collaboration as demonstrated by the joint OECD work and indicated the need to engage other countries, e.g. through minor use programmes. Given scarce resources, Dr Chan highlighted the positive impact of collaborative initiatives in the efficient use of existing resources. He also underscored the importance of Codex MRLs, while noting the need to improve the Codex MRL setting process, as several concerns had been raised in relation to missing MRLs, by developed and developing countries, as well as by industry representatives. Other industry concerns were highlighted, such as transparency and predictability in the regulatory process and the role of private standards. Dr Chan further emphasized the need for collaboration, coordination and communication in the process.

3.112. In the **question and answer session**, speakers provided views on whether the discussions on MRL issues were heading in the right direction, from a developed and developing country perspective, and whether government ministries were sufficiently aware of the challenges faced in addressing MRL issues. In particular, Ms Namu noted the increased challenges faced by Kenya due to the more stringent regulatory changes in target markets, while observing that the difficulties in accessing markets had also led to the increased engagement of the private sector with regulatory agencies, and greater recognition of the role of science in supporting trade. However, Ms Namu underscored that MRL issues would continue to be a challenge, due to limited capacity and scarce resources. Dr Chan noted the positive direction of MRL discussions, highlighting several forums which provided opportunities for information sharing and underlined the need for more collaboration to address MRL issues, given their horizontal nature. He also indicated that certain EU regulatory proposals could have an impact on MRLs and underscored the importance of having channels for submission of comments. Lastly, he acknowledged that fundamental scientific principles could also have trade implications.