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FOREWORD

A survey on how countries set Pesticide Maximum Residue Limits (MRLs) was conducted in 2008. Responses were received from: Australia, Austria, Canada, the Czech Republic, Ireland, Japan, Korea, Mexico, New Zealand, Norway, Portugal, Switzerland, the United Kingdom, the United States and the European Commission.

A first analysis of the survey results prepared by the United States Environmental Protection Agency (US EPA) was presented at the 23rd Meeting of the Working Group on Pesticides (WGP) in November 2008. At that meeting, Delegates asked the Expert Group on Residue chemistry (RCEG) to develop summary matrices.

This document contains the survey results. It includes:

(1) a summary of the issues raised in the responses;

(2) matrices based on the responses, which list the national authorities responsible for establishing MRLs and approving pesticide products, describe the types of MRLs established, and assess the impact on MRL harmonisation; and

(3) the individual responses from countries.

The 24th WGP Meeting in June 2009 approved the draft report and recommended that it be forwarded to the Joint Meeting of the Chemical Committee and Working Party on Chemicals, Pesticides and Biotechnology, for consideration as an OECD publication.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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INTRODUCTION

1. A survey on how countries set Maximum Residues Limits (MRLs) was conducted in April-May 2008.

2. The objective of the survey was to identify technical/scientific barriers to greater harmonization and possible ways to remove such barriers. The results could be used by the OECD Registration Steering Group (RSG), the OECD Residue Chemistry Expert Group (RCEG) (see questions 12 – 23 except 17) and/or the WHO/FAO Joint Meeting on Pesticide Residues (JMPR).

3. At the June 2008 RSG meeting, it was stressed that neither the survey nor any work contemplated by the RCEG was aimed at actual setting of MRLs, as that remained an activity within the purview of national governments or conducted via the Codex Alimentarius process. Some participants noted that the survey was a valuable source of information, but cautioned that countries may set MRLs at different levels for a number of reasons, based on conditions specific to the country and its pesticide use patterns.

4. Following the compilation of the responding countries' responses by the US delegation and the Secretariat, the RCEG was requested to (1) conduct a more thorough analysis of the results and identify possible areas of work it could carry out to facilitate harmonization of approaches for setting MRLs, and (2) compare MRLs that have been established following a joint review with those that were set in Codex, and analyze any differences.

5. Note: Representatives of the RCEG have observed that MRLs involve a great many considerations other than residue study results, e.g., risk to vulnerable populations, efficacy issues, and a number of policy preferences. They suggested that it may be more appropriate for the RCEG to focus its efforts earlier on the MRL-setting process, rather than compare final MRLs. For example, in a joint review, the RCEG could examine whether all countries followed harmonized OECD guidance.

6. This survey report is divided into three sections:

(1) Summary of Issues Raised in Responses

(2) Key Responses in Matrix Format

(3) Individual Country Responses.

SECTION I

SUMMARY OF ISSUES RAISED IN RESPONSES

Part I: Establishment of MRLs

Question 1: Legal Requirement for MRLs

- All responses indicated that there are legal requirements for MRLs. Some responses included the standard or basis for approval of MRLs, but most did not.

- The European Commission (EC) response stated that, as of 1 September 2008, all MRLs would be fully harmonized and applicable in all European Union (EU) Member States.

Question 2: Organization(s) Responsible for MRL-Setting

- A variety of health, agricultural and environmental agencies are involved in MRL setting. (See compilation in Matrices 1A and 1B)

- Under the newly harmonized EC MRL regime, it is unclear how a Member State is "selected" to evaluate an MRL application under the new regime. Is the choice of reviewing rapporteur Member State left to the applicant proposing the MRL?

Question 3: Organization(s) Responsible for Pesticide Product Approval

- In some OECD countries, the organizations responsible for approving pesticide products are not the same organizations that set MRLs.

- For example, once the EC approves the active substances used in plant protection products, Member States are responsible for approving the actual products/formulations containing the approved active substances. Is it possible that formulations and directions for use may differ among Member States? Is there any centralized approach to address potential toxicity concerns related to ingredients other than the active (pesticidal) substances? In the U.S., these "inert ingredients" (non-pesticidal other ingredients, e.g. propellants, solvents, etc.) must also be reviewed, and an MRL (tolerance) or exemption established for any residues in food.

Question 4: Timing of MRLs and Pesticide Product Approvals

- Most countries responded that MRLs are established at the same time or before a pesticide product is approved for use.

- Australia stated that the process is sequential, but did not specify that the MRL always comes first.

- Canada issues registration certifications before MRLs are posted for consultation, but the proposed MRLs are published for comment "shortly" after the registrations are granted and no enforcement action is taken against residues at or below the proposed MRLs.

Are there any other countries that approve pesticide products before an MRL is in place? If so, how do they deal with residues in (domestically produced or imported) food during the interim period before an applicable MRL is in place?

***Question 5*: Transparency/Opportunity for Public Comment**

- Mexico and Switzerland responded that there were no opportunities for public comment before MRLs are put into force.

- The EC responded that there is an opportunity for public comment "through the WTO-SPS system."

- Most other countries indicated that they seek public comment before MRLs take effect.

- An opportunity for review and comment by trading partners would seem a minimum requirement for transparency and preventing unnecessary disharmony and trade irritants. Even then, it might take a while for the information to reach key stakeholders and regulators, if countries rely solely on WTO procedures.

***Question 6*: Organization(s) Responsible for MRL Enforcement**

- A number of countries responded that there are multiple organizations responsible for enforcing (or empowered to enforce) MRLs.

- New Zealand has only one organisation responsible for MRL enforcement.

- In the U.S., the responsibility is shared by FDA and USDA, depending on the type of food. In other countries (e.g., Australia, EC) it appears that multiple authorities are enforcing the same MRLs for the same types of foods, but this has not resulted in significant problems/disputes about the reliability of residue findings. Australia and the EC noted that quality control measures (methods validation and proficiency testing) are in place to help prevent such problems.

***Question 7*: Who Can Apply for an MRL to be Established?**

- Most responders indicated that anyone can apply for the establishment, modification or revocation of MRLs.

- The exceptions were Mexico ("industries can apply...when submitting for a new registry or a use addition") and Switzerland ("proposals have to be made by the applicant.")

- It is unclear if limitations on who can apply in these countries affect their ability to achieve harmonization; in practice, this may not be a significant problem.

***Question 8*: Requirements for Periodic Review and Reporting New Data**

- There are significant differences in requirements for reporting new data and periodic review of MRLs.

- Some countries reported no requirements (Australia, Korea). Although Australia does not have a formal periodic review process for MRLs, there is a requirement for reporting of new residues data under the AgVet Code Act 1994, s.161 Notification of New Data to the APVMA.

- The EC reported that MRLs must be reviewed within one year, and temporary MRLs within four years.

- Registrations in Mexico are valid for five years.

- Canada and the U.S. have a 15 year review cycle, unless concerns prompt earlier review.

- The scope/level of detail of reviews was not addressed. Coordination of review schedules could offer potential benefits in terms of work-sharing. Consistency in requirements for reporting new data could help ensure that countries have access to the same information in making regulatory decisions to modify or revoke MRLs.

***Question 9*: MRL Revocation Process**

- Most countries reported that the process for revoking MRLs parallels the process for establishing them, and noted that they may be revoked either because they are no longer needed or based on risk concerns.

- New Zealand noted that MRLs are usually revoked 5 years after cancellation or withdrawal of a pesticide use.

- In Mexico, "revocation of a MRL goes with revocation of the registry."

- The triggers for revocation in Switzerland are (1) a new toxicological evaluation or (2) loss of efficacy.

***Question 10*: Applicability to Domestically Produced and Imported Foods**

- In general, all responding countries indicated that the same MRLs apply equally to domestically produced and imported foods.

- New Zealand allows imported food to comply either with the New Zealand MRL standard, or the Codex MRL standard. Australia and New Zealand also have a separate mutual recognition agreement to allow exporters/ importers from either country to comply with either their domestic MRL standard when exporting/importing between each country.

Part II: Categories of MRLs Established

***Question 11*: "Import MRLs"**

- Korea and Mexico do not establish "import only" MRLs for pesticides not used domestically, to cover residues in imported foods.

- The Australian and Czech responses are not clear as to whether they set MRLs solely for imports. Food standards Australia – New Zealand is able to establish MRLs for imported food only.

- All others responded that they will establish import MRLs provided food safety standards are met.

***Question 12*: MRL Requirements for Processed Foods**

- The most common approach (cited by Australia, Canada, Korea and the U.S., and also used in the global context by the Joint Meeting on Pesticide Residues (JMPR)), is to set MRLs for processed foods only when residues are shown to concentrate as a result of processing.

- Mexico and New Zealand do not establish processed food MRLs.

- In Europe, the approach to residues in processed foods is based on MRLs for the raw agricultural commodities, corrected or adjusted based on application of a "processing factor accounting for the possible increase or decrease of pesticide residues" in processing. At the present time, no factors are specified and this is a matter for enforcement discretion, which could lead to inconsistencies in approaches. Processing factors may be generic (for common processes such as dehydration or desiccation processes) or chemical/commodity-specific.

- In Switzerland, MRLs for wine are based on the grape MRL adjusted by compound-specific processing factors.

The RCEG has established a harmonized guideline and guidance document for processing studies (OECD Test Guidelines No. 507 and 508 and guidance document ENV/JM/MONO(2008)23). These documents are designed to ensure that countries have compatible data for setting processing factors (PF) and that the data will be accepted by any OECD country. The EU appears to be considering enforcement of separate residue limits (the raw commodity MRL adjusted by a PF) in all processed foods, including those that dilute as well as concentrate residues. The WGP/RSG may wish to consider work to harmonize enforcement policies, for example, whether enforcement action would be taken only with respect to processes which concentrate residues or to all processes.

***Question 13*: MRLs for Animal Feed**

There appear to be significant differences in reported approaches to residues in livestock feeds.

- Some countries set separate MRLs (Australia, Czech Republic, Japan, Switzerland, U.S.), but not necessarily for all feed commodities.

- Some countries do not set MRLs for animal feed (Austria, Canada, Korea, Mexico, New Zealand.)

- Other systems apply the MRL for the corresponding human food when a commodity is also used in animal feed, but do not appear to set MRLs for feed-only commodities (EC).

- Whether or not they set separate feed MRLs, most responders indicated that they do set MRLs for livestock commodities that take into account residues in the feed consumed by the livestock. Australia noted that JMPR and FAO have well-developed principles for determining residues in livestock commodities.

- Mexico and Korea responded that they do not set feed MRLs but did not address the question of residues in food derived from animals as a result of feed consumption.

The RCEG has harmonized guidance for Magnitude of Residue studies in livestock (under preparation) and has completed a harmonized Crop Field Trial Test Guideline (OECD Test Guideline No. 509 published in 2009). These documents provide for uniform procedures to obtain residue data in livestock foodstuffs and feed commodities. The WGP/RSG may wish to consider if uniform policies should be developed through OECD for enforcement of residue limits in livestock foodstuffs or feed. Once this is done, the RCEG may consider if additional guidance for data development or assessment is warranted.

***Question 14*: Residues in Livestock Commodities/Food Derived from Animals**

- Except for Mexico and Switzerland, all responders indicated that they set MRLs for livestock commodities when measurable or finite residues are expected.

- If data show residues at or below the level of quantitation (LOQ), the responses were less consistent and not as clear.

- Australia and Austria indicated that they would set the MRL at the LOQ of a validated analytical method.

- Canada may set MRLs at the LOQ provided an acceptable enforcement method exists.

- The EC indicated that the MRL would be set at the LOQ but was silent on the requirement for a validated method.

- Japan does not always set the MRL at the LOQ "even if residues are below the LOQ."

- New Zealand sets the MRL at the LOQ "if the submitted residue data supports this limit."

- Responses from Mexico and Switzerland indicated that no MRLs would be set, although the Swiss may rely on a certain threshold of expected residues like the 0.1 ppm they use in establishing MRLs for animal feed commodities.

- The U.S. do not set MRLs when no residues are expected in livestock commodities, even if there are residues in the animals' feeds. (The feed would require an MRL.)

The RCEG has provided harmonized guidance for development of analytical methods for residues in livestock food commodities, even when residues are at the LOQ. The WGP/RSG may wish to consider whether it is desirable to harmonize enforcement and policies governing MRL-setting when residues in livestock commodities are at LOQ.

Question 15: Exemptions from MRL Requirements

- All responders appear to have the ability to establish exemptions from the requirement for setting an MRL, but the standards for establishing exemptions and the numbers of exemptions established appear to vary widely. The EC indicated that a guidance document is under development.

- Canada expressed support for development of more common criteria/guidance for establishing exemptions. This would seem appropriate for consideration as new work by the RSG.

Once the RSG develops comprehensive policies/guidance, the RCEG could evaluate whether data development guidance should be amended to provide for additional study waivers.

Question 16: Inadvertent Residues in Rotational Crops

- Countries appear to be at different stages of policy development in terms of how to handle inadvertent residues resulting from rotational crop situations.

- A number of countries/regions require rotational crop studies (Austria, Canada, Portugal, U.S., EC) but they make take different risk management approaches based on those studies (setting restrictions on rotations, denying registrations, establishing MRLs for the rotational crops).

- Japan and Mexico indicated that this issue is not considered in establishing MRLs.

- Ireland responded that the LOQ may be raised.

- New Zealand is developing policies to handle rotational crop residues.

The RCEG has harmonized guidelines for Confined and Limited Field Rotational Crops studies (OECD Test Guidelines No. 502 and 504). The RCEG noted, however, that OECD countries have different policies; had more explicit and unified policies for managing rotational cropping situations been available at the OECD-level, the two harmonized test guidelines would be more complete. Therefore, the RCEG has recommended that the WGP/RSG consider whether rotational crop management policies should be unified in OECD countries/regions. Subsequent to that, rotational crop testing guidelines could be amended to take the harmonized policies into account when data are developed for use by OECD countries.

Question 17: Emergency Pesticide Uses

- Most responding countries (except Japan and New Zealand) have some ability to permit pesticide use to deal with emergency pest outbreaks, but vary in terms of whether MRLs are set to cover resulting residues.

- New Zealand and Canada note that a default MRL of 0.1 mg/kg may cover some such situations.

- Austria, Korea and the U.S. require the establishment of an MRL in connection with the emergency use.

- Australia has the authority to establish MRLs "if required."

- In the EU, Member States may authorize emergency use and deviate from the EC MRLs if there is no "unacceptable risk to consumers." In some circumstances, temporary MRLs may be set, but it is not clear that this is always required. The UK response indicated that such action by a Member State would permit marketing of the treated food or feed only within its own territory.

- Mexico permits emergency use if approved by the Ministry of Health; it is not clear if an MRL is required.

- Switzerland has no explicit requirement for establishing MRLs in such circumstances, but they may be established "if necessary on a case by case basis."

Question 18: Crop Grouping

- All responders either have or are considering crop grouping systems that allow for the establishment of a single MRL to cover residues in related crops based on data developed for specified representative crops, without requiring data on every crop in the group. Australia, Mexico and New Zealand noted that they follow Codex classifications. Canada, the EC, Japan, and the U.S. reported that they also have their own established policies for crop grouping/extrapolating from one crop to another. Korea is considering establishing a crop grouping system, especially for minor crops.

The RCEG has performed a detailed comparison of existing guidance/policies for crop grouping and representative crops used by responding countries. Current crop grouping schemes in use in OECD countries are based on existing Codex crop groups, with some variations in approach. OECD countries generally use representative crops for these crop groups, but the selection of representative crops for which data are required to establish the group MRL is not fully harmonized.

The RCEG has also approved principles for selecting representative crops. The RCEG report on crop grouping and representative crops was approved by the Working Group on Pesticides and made available to the Codex Committee on Pesticide Residues. Harmonized crop groups and representative crops could be an important element of harmonized Crop Field Trial guidance.

At its June 2008 meeting, the RSG recommended that the RCEG continue to harmonize crop grouping and representative crops for this purpose, taking into account the ongoing work to develop a new crop grouping scheme at Codex and incorporating results of the revised Codex system as each new crop group is completed. Harmonization of OECD countries' current practices on an interim basis could provide a foundation for more efficient and uniform data development and interpretation of crop field trial results for work sharing.

***Question 19*: Extrapolation of Data from Similar Crops**

- All but one response indicated that it was possible to permit extrapolation from one crop to another closely-related crop. Mexico responded that current regulations do not address this issue.

***Question 20*: MRLs for Raw Agricultural Commodity as a Whole v. Edible Portion Only**

- Responders indicated that MRLs are set for the commodity as a whole, with the following exceptions:

- In the EC, there are some exceptions, e.g., MRLs for tree nuts apply to the whole product after removal of the shell.

- In principle, Japan sets MRLs for edible portion of the commodity. However, for some commodities, MRLs are set for the whole commodity in accordance with the rules for portions to which MRLs apply.

- New Zealand establishes MRLs based on the edible portion for all commodities except bananas, citrus fruit and kiwi fruit.

- Although existing policies and regulations differ among OECD countries, the RCEG has agreed that data generated for MRL-setting purposes would normally be on the raw agricultural commodity as a whole, consistent with UN Food and Agriculture Organization (FAO) and Codex Alimentarius guidance. This result was reported to the RSG in June 2008. The OECD Crop Field Trial Test Guideline No. 509 identifies uniform sampling procedures for all OECD countries.

***Question 21*: Metabolites and Degradates**

- All responders indicated that they consider metabolites and degradates in making MRL decisions, especially if they are toxicologically significant.

- Some responders noted that the residue definition for risk assessment purposes may differ from the residue definition for the MRL.

- Australia indicated that it considers metabolites and degradates in accordance with FAO and JMPR guidance.

- Switzerland cited a trigger of 5-10% for consideration of metabolites and degradates in the residue definition, and stated that this trigger was also used in the EU.

A harmonized Definition of the Residue guidance document has been developed by the RCEG to provide a common approach for determining when metabolites and degradates should be included in the residue definition for MRL and risk assessment purposes. In a recent work share review, however, some differences in the interpretation of this guidance emerged. Accordingly, the RCEG has amended its guidance for greater clarity (revised guidance is available as document ENV/JM/MONO(2009)30 published in July 2009).

In addition, representatives of the RCEG noted that the International Scientific Advisory Council (InterSAC), comprised of residue experts from OECD countries, has reviewed the proposed residue definition for a multi-nation MRL proposal for a new chemical, using the harmonized Definition of Residue guidance, and provides a venue for consultations on implementation of the guidance in the future.

Part III: Calculation of MRLs

***Question 22:** Calculation of numerical values for MRLs*

- Most responders indicated that values were based on field trials carried out in accordance with Good Agricultural Practice (GAP), but actual calculation methods vary.
- Australia relies on JMPR principles and does not employ statistical calculation methods.
- The EC and several European responders (Austria, Czech Republic, Portugal, Switzerland, and the UK) referred to a 1997 EC policy document. (Portugal's response indicated that this policy was revised in 2002)
- The EC stated that the method is based on a normal distribution.
- Austria cited "method 1" and "method 2" as used in the EU.
- Ireland did not cite a specify policy document but noted that field trials conducted in accordance with GAP were "treated statistically to determine the Rber and Rmax values….used to establish the MRL."
- Canada and the U.S. have adopted a common statistical methodology/ calculator for deriving MRLs from field trial data. Mexico is in the process of adopting this calculator.
- New Zealand applies "technical judgement" to establish MRLs considered sufficient to accommodate expected variability in residue levels consistent with GAP.

From the point of view of promoting harmonization without lowering food safety standards, use of more standardized approaches to calculate MRLs based on field trial data would be desirable (so that, if the underlying data are the same, authorities in different countries would arrive at common values for maximum expected residues and avoid differences that are not based on safety concerns). In light of this the RSG and WGP have recommended that a single harmonized computerized system be developed by the RCEG for calculating the highest expected residues. The RCEG has established a working group for this purpose and work is underway. When completed, it will be published as part of a guidance document for Crop Field Trials.

***Question 23:** Use of Additional Data in Risk Assessment When There Are Dietary Risk Concerns*

- A number of responders indicated that if risk assessment using the MRL indicated possible or theoretical dietary intake concerns, they may conduct more a refined risk assessment using monitoring data, processing studies, etc. (Austria, Canada, Czech Republic, Ireland, Korea, Portugal, U.S.) Other reported approaches included the following:
- Australia follows JMPR practice and may use monitoring data for dietary exposure estimates in some situations.
- The EC uses the Highest Residue (HR) from field trials in assessing acute effects and the Supervised Trial Median Residue (STMR) in assessing chronic risks. The EC response noted that

this methodology is under discussion. Monitoring data may be used in certain limited circumstances.

- Japan reported that if the theoretical maximum daily intake estimate indicates dietary risk, dietary intake is calculated using the mean of residue concentrations in trials.

- New Zealand uses median residues from field trials to estimate dietary risk and does not regularly use residue monitoring data for this purpose.

- Switzerland reported that when risk concerns arise, based on comparing the MRL with acceptable daily intake and acute reference dose values, then risk mitigation measures are taken – either lowering the MRL or withdrawing approval. Monitoring data are not used.

As noted above, the RCEG has harmonized guidance for Processing studies and Magnitude of the Residue studies in livestock (document ENV/JM/MONO(2008)23). A harmonized Crop Field Trial Test Guideline has also been completed (OECD Test Guideline No. 509). These documents, taken together, provide for more uniform data bases for use in MRL calculations. However, as also noted above, countries may consider additional factors when MRL setting once the Magnitude of the Residue data are available. The WGP/RSG may wish to consider whether these approaches are, or should be, harmonized. Once this analysis is done, the RCEG can determine if additional technical areas can be harmonized.

Question 24: Sources of Data

- In general, most data generated in support of MRLs are developed by the pesticide manufacturer. The majority of countries responding to the survey indicated that data from other sources may also be used; a number of responses noted that any person may submit data. In particular, for minor or specialty crops, residue data may be generated by other organizations.

- Austria stated that "as a matter of principle," evaluations are based on data supplied by manufacturers, but that other interested parties may develop residue data for minor uses/minor crops.

- Mexico uses only the data submitted by the manufacturer to establish the MRL.

Part IV: Harmonization Considerations

***Question 25*: Consideration of Codex MRLs**

- All responders stated that they routinely consider Codex MRLs in practice. Australia, Mexico and the U.S. cited specific legal provisions that require consideration of Codex MRLs.

- New Zealand accepts Codex MRLs for imported foods. Consideration of Codex MRLs is not required to set MRLs for domestically produced foods, which are based on New Zealand GAP.

- U.S. law requires that an explanation for any deviation from Codex MRLs be published in the Federal Register. Canada also publishes an explanation for deviations from Codex "where possible."

- In its response to the following question, Australia noted that FSANZ documents include details on the relevant Codex MRLs and that all proposed variations are notified through WTO procedures.

***Question 26*: Use/Acceptance of Codex MRLs**

- Several countries referred to their responses to Question 25. Additional specific points on acceptance:

- Canada and the U.S. do not accept Codex MRLs in the absence of a national MRL.

- Korea and Mexico accept Codex MRLs in the absence of a national MRL.

- The EC will accept a Codex MRL when the EC has agreed to the Codex level in the Codex Alimentarius Commission and there are no dietary risk concerns. [This appears to require an independent evaluation before "acceptance," and therefore to be essentially the same as Canadian and U.S. policy.]

- Japan accepts Codex MRLs as far as possible as Japanese MRLs, where they exist. However, Codex MRLs have to go through a risk assessment review process in Japan.

- In their response to the survey as considered in June, the UK indicated that (1) they advised traders to comply with Codex MRLs in the absence of a corresponding EC or UK MRL and (2) whether this would satisfy the general safety standards in UK law in specific instances would have to be decided by a Court. [Has this approach been modified as of September 1, 2008, to require that an EC-approved MRL be in place to cover the residue?]

***Question 27*: Harmonization in the Absence of Intake/Dietary Risk Concerns**

- The following responses indicated a willingness to harmonize to a higher Codex MRL or trading partner's national MRL, provided there were no intake/dietary risk concerns:

  – Austria

- EC (not clear if response applies only to Codex?)
- Japan
- Korea (response only mentions Codex)
- New Zealand (accepts Codex for imports, would consider another country's national MRL if necessary for trade)
- Portugal
- Switzerland (on a case by case basis)
- U.S.

- Mexico responded that this was a possibility, but had never been done.
- The remaining responses were not as clear-cut/specific.

Note: Austria's comment referred to the importance of discussing differences in "classes" of MRLs, based on experience with a joint review, observing that "Using the same classes and the same calculation may be the crucial point and has to be discussed within the European Union as well."

If time permits, it may be worthwhile to ask for more explanation of what is meant by "classes of MRLs" and the types of issues Austria would like to pursue.

Question 28: Other Questions?

- Australia and Canada proposed additional questions that participants may wish to discuss.

SECTION II

KEY RESPONSES IN MATRIX FORMAT

MATRIX 1A

National Authorities Responsible for Establishing MRLs and Approving Pesticide Products in OECD Countries*

(Questions 2, 3, 6)

OECD country/ Region	Activity		Responsible Authority(ies)
AUSTRALIA	Establishing MRLs (Q.2)	Lead/ Decision-making authority(ies)	Australian Pesticides and Veterinary Medicines Authority (APVMA)
		Input	
	Enforcing MRLs (Q.6)		Australian Quarantine and Inspection Service (AQUIS) for responsibilities under the *Imported Food Control Act 1992* State departments of Primary Industry (agriculture), state health authorities, food regulatory agencies
	Approving pesticide products (Q.3)	Lead/ Decision-making authority(ies)	APVMA
		Input	
CANADA	Establishing MRLs	Lead/ Decision-making authority(ies)	Pest Management Regulatory Agency (PMRA)
		Input	
	Enforcing MRLs		Canadian Food Inspection Agency (CFIA)
	Approving pesticide products	Lead/ Decision-making authority(ies)	PMRA
		Input	

OECD country/ Region	Activity		Responsible Authority(ies)
JAPAN	Establishing MRLs	Lead/ Decision-making authority(ies)	Ministry of Health, Labour and Welfare (MHLW) for foods Ministry of Agriculture, Forestry and Fisheries (MAFF) for animal feeds
		Input	
	Enforcing MRLs		MHLW for foods MAFF for animal feeds
	Approving pesticide products	Lead/ Decision-making authority(ies)	MAFF
		Input	
KOREA	Establishing MRLs	Lead/ Decision-making authority(ies)	Korea Food and Drug Administration (KFDA)
		Input	Korea Rural Development Administration (RDA) develops/supports residue data
	Enforcing MRLs		KFDA
		Input	
MEXICO	Establishing MRLs	Lead/ Decision-making authority(ies)	Ministry of Health, through the Federal Commission for the Protection from Sanitary Risks (FCPSR)
		Input	Ministry of Agriculture (SAGARPA), through the National Service of Health, Food Safety and Agri-food Quality (SENASICA), elaborates guidelines and criteria for field trials.
	Enforcing MRLs		SAGARPA, through SENASICA
	Approving pesticide products	Lead/ Decision-making authority(ies)	Ministry of Health through FCPSR
		Input	Ministry of Environment and Natural Resources (MENR)

OECD country/ Region	Activity		Responsible Authority(ies)
NEW ZEALAND	Establishing MRLs	Lead/ decision making authority(ies)	New Zealand Food Safety Authority (NZFSA)
		Input	Environmental Risk Management Authority (ERMA) sets reference health standards
	Enforcing MRLs		NZFSA
	Approving pesticide products	Lead/ Decision-making authority(ies)	NZFSA
		Input	ERMA
NORWAY	Establishing MRLs	Lead/ Decision-making authority(ies)	Norwegian Food Safety Authority (NFSA)
		Input	
	Enforcing MRLs		NFSA
	Approving pesticide products	Lead/ Decision-making authority(ies)	NFSA
		Input	
SWITZERLAND	Establishing MRLs	Lead/ Decision-making authority(ies)	Federal Office of Public Health (FOPH)
		Input	Federal Research Stations (ACW Agroscope Changins-Wädenswil) evaluates data on efficacy, residues, plant metabolism, etc.
	Enforcing MRLs		State laboratories/authorities of the cantons
	Approving pesticide products	Lead/ Decision-making authority(ies)	Federal Office of Agriculture (FOA)
		Input	

OECD country/ Region	Activity		Responsible Authority(ies)
UNITED STATES	Establishing MRLs	Lead/ Decision-making authority(ies)	U.S. Environmental Protection Agency (EPA)
		Input	U.S. Department of Agriculture (USDA) through Inter-regional Research Project No. 4 for specialty (minor) crop residue trials USDA Agricultural Marketing Service's Pesticide Data Program for actual residue data Scientific Advisory Panel (SAP) for peer review of complex science and science-policy issues.
	Enforcing MRLs		U.S. Food and Drug Administration (FDA) for most fresh and processed foods USDA Food Safety and Inspection Service for meat, poultry and some egg products.
	Approving pesticide products	Lead/ Decision-making authority(ies)	EPA
		Input	

OECD country/ Region	Activity		Responsible Authority(ies)
EUROPEAN UNION (COMMISSION RESPONSE)**	Establishing MRLs	Lead/ Decision-making authority(ies)	European Commission (EC)
		Input	Select member states evaluate application and draft an evaluation report European Food Safety Authority (EFSA) prepares a reasoned opinion on consumer risk Standing Committee on the Food Chain and Animal Health (SCoFCAH) hears EC proposal and forwards favourable opinions to the European Parliament and the Council of the European Union If there is no reaction from Parliament or Council, the Commission adopts the MRLS
	Enforcing MRLs		National authorities of the EU member states. (See list in Annex I)
	Approving pesticide products	Lead/ Decision-making authority(ies)	EC approves active ingredients; national authorities authorize marketing of products containing EC-approved active substances. (See list in Annex 1)
		Input	

*No responses were received from Iceland and Turkey.

**Since September 2008, the EC is responsible for MRL setting for all EU countries; therefore, individual member state responses are not listed separately.

MATRIX 1B

National Authorities of the European Union Member States

(As Provided in Original MRL Survey Responses)

Country	National Authority	Website
Austria	Austrian Agency for Health and Safety (AGES)	www.ages.at
Czech Republic	State Phytosanitary Administration (SPA)	www.srs.cz
Ireland	The Department of Agriculture Fisheries and Food (DAFF)	www.agriculture.gov.ie/
Portugal	The General Direction of Agriculture and Rural Development (DGADR)	www.dgadr.pt
United Kingdom	Pesticides Safety Directorate (PSD)	www.pesticides.gov.uk/

MATRIX 2

Matrix of Types of MRLs Established by OECD Countries*

(Questions 11, 12)

COUNTRY/ REGION	ESTABLISH "IMPORT ONLY" MRLS (Q. 11)	ESTABLISH MRLS FOR PROCESSED FOODS (Q. 12)				
		Always	Only if residues concentrate	Use standard processing factors	Use compound-specific processing factors	Other comment
AUSTRALIA	NO		X follows current JMPR practice	Not stated (NS)	NS	
CANADA	YES		X	NS	NS	
JAPAN	YES					Sets MRLs for "some processed foods;" circumstances not defined
KOREA	NO		X	NS	NS	
MEXICO	NO					Does not set MRLs for processed foods
NEW ZEALAND	YES					Does not set MRLs for processed foods

COUNTRY/ REGION	ESTABLISH "IMPORT ONLY" MRLS (Q. 11)	ESTABLISH MRLS FOR PROCESSED FOODS (Q. 12)				
NORWAY	No response					No response
SWITZERLAND	YES				X	Sets processed food MRLs only for wine
UNITED STATES	YES		X	NS	NS	
EUROPEAN UNION (COMMISSION RESPONSE)**	YES	RAC MRLs are to be "corrected" by processing factors (for both concentration and dilution?)		To be established	To be established	

*No responses were received from Iceland and Turkey.

**Since September 2008, the EC is responsible for MRL setting for all EU countries; therefore the individual member countries are not listed separately.

MATRIX 3

Process Issues Related to Establishment of MRLs in OECD Countries*

Country/Region	Timing of approvals of 'pesticide products and MRLs (Q.4)		Opportunity for public comment before MRL takes effect (Q.5)	Who can apply for MRL (Q. 7)	Periodic Review Requirement (specify frequency, if given (Q.8)
	Sequential	Simultaneous			
Australia	X (MRLs first)		X	anyone	
Canada	X (products first, but no enforcement if residues comply with proposed MRLs)		X	anyone	X (15 year cycle)
Japan		X	X	anyone	
Korea	X (products first)		X	anyone	
Mexico	X (MRLs first)			industry/ registrants	X (five years)
New Zealand		X (usually)	X	anyone	
Norway	X		X	no response	no response
Switzerland	X (MRLs first)			"applicants" (registrants / manufacturers?)	X
United States		X	X	anyone	X (15 year cycle; for MRLs based on actual/ anticipated residues, five years and thereafter as determined by EPA; for MRLs based on percent of crop treated, "periodically")

Country/Region	Timing of approvals of 'pesticide products and MRLs (Q.4)		Opportunity for public comment before MRL takes effect (Q.5)	Who can apply for MRL (Q. 7)	Periodic Review Requirement (specify frequency, if given (Q.8)
European Union (Commission Response)**	X (MRLs first)		X (through World Trade Organization system)	applicants according to Directive 91/414/EEC, civil society organizations, commercially interested parties, member states	X (one year after first approval; for temporary MRLs, after four years)

* No responses were received from Iceland and Turkey.

** Since September 2008, the EC is responsible for MRL setting for all EU countries; therefore the individual member countries are not listed separately.

NS = Not stated: the survey response did not include this information.

X = yes, or affirmative response

MATRIX 4 – Types of MRLs Established by OECD Countries

Country/ Region	Ïmport Only" MRLs (Q.11)	MRLs for Processed Foods (Q.12)					MRLs for Animal Feed Commodities	MRLs for livestock commodities (Q.14)		Exemptions from LRL requirement (Q.14)
		Always	Only if residue concentrate	Use standard processing factors	Use compound specific processing factors	Other comments		Always	Only if exceed LOG	
Australia			X follows current JMPR practice	NS	NS		X	X		x
Canada	x		x	NS	NS			X when measurable residues are expected, or at LOQ when method is submitted		X (7 chemicals)
Japan	x			NS	NS	Sets MRLs for ‘”some processed foods.” circumstances not defined	x	x		x
Korea			x	NS	NS				x	x
Mexico						Does not set MRLs for processed foods				X for seed treatments
New Zealand	x					Does not set MRLs for processed foods		X at LOQ if residues are below LOQ		z
Norway	No respon se					No response				
Switzerland	x				x	Sets processed for MRLs only for wine	x			X for compounds “not detectable as foreign compounds”
United States	x		x		NS		x		x	
European Union (Commission response) **	x	RAC MRLs are to be corrected by processing factors (for both concentration and dilution?)		To be established	To be established		X (currently, only if also used in human foods, in future will be set to other feed items)	X at LOQ if residues are below LOQ		X guidance being developed

Country/Region	MRLs for rotational Crops (Q.16)			MRLs for Emergency Pesticide Uses (Q. 17) Crop MRLs (Q.18)					
	Require Rotational crop studies	**Establish MRLs for residues**	**Specify use conditions to prevent residue**	**MRLs required**	**Default MRL applies (specify level)**	**No provision**	**Based on representative commodities**	**No representative commodities**	**No group MRLs**
Australia	NS	NS	NS	x				X (based on Codex	
Canada	x	x	x		X (must not exceed 0.1 ppm)		x		
Japan							NS (guidance available in Japanese)		
Korea	NS	"MRL setting of general crops also apply to Rotational crops"		x					X (under construction)
Mexico				NS					
New Zealand				X (0.1 mg/kg)			x		No response
Norway				No response					
Switzerland			x				X (groups EU groups)		
United States		x	x	x			x		
European Union (Commission response) **	NS	x	X member state responsibility	May allow deviations or set temporary MRLs			x		

SECTION III:

INDIVIDUAL COUNTRY RESPONSES

Australia
Austria
Canada
Czech Republic
Ireland
Japan
Korea
Mexico
New Zealand
Norway
Portugal
Switzerland
United Kingdom
United States
European Commission

Establishment of MRLs

Question 1. Are National MRLs required to be set by law? If yes, what is the law?	
Australia	MRLs are required to be set as part of the registration of an Agricultural or Veterinary product in accordance with the Agricultural and Veterinary Chemicals Code Act 1994 and amendments thereof. Food legislation requires residues of agricultural and veterinary chemicals to comply with specific MRLs. This legislation references those MRLs in the *Australia New Zealand Food Standards Code* (www.foodstandards.gov.au/_srcfiles/Standard_1_1_1%20Interpretation_v952.doc and http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm)
Austria	Yes; according to SchädlingsbekämpfungsmittelHöchstmengenVO based on the Austrian Food Law (LMSVG 2006). Since 1st September 2008 Regulation 396/2005 is in force within the whole European Community directly. By 1.9.2008, there is no possibility to set national MRLs; all MRLs have to be set on Community level.
Canada	Yes, MRLs are required to be set by law. Currently, MRLs are established under the Food and Drug Regulations (FDR) of the *Food and Drugs Act* (FDA), where Health Canada Pest Management Regulatory Agency (PMRA) has determined that the consumption of the pesticide residues that could remain on the food will not pose any health concerns. In 2008, Health Canada PMRA intends to amend the FDA and FDR to allow MRLs to be legally established under the *Pest Control Products Act* (PCPA) without having to adopt MRLs by regulation under the FDA.
Czech Republic	Yes, Decree no.381/2007 Collection of laws of the Czech Republic (just in CZ language) http://www.mvcr.cz/sbirka/2007/sb117-07.pdf In case of settings MRL for active substances or uses of PPPs on new commodities, which are not stated in mentioned decree, CZ proposed new MLR. The implementation of such proposed MRLs are lately amended in according with our and EU legislation.

Ireland	Regulation (EC) No 396 of 2005 establishes harmonized MRLs for pesticide residues in all food commodities. These MRLs apply automatically within EU member states.
Japan	The answer is yes. Japanese MRLs are established in accordance with the Food Sanitation Law. The law stipulates in Article 11 that the Minister of Health, Labour and Welfare, from the view point of public health, may establish compositional specifications for food and food additives. Individual MRLs are established in the Specifications and Standards for Food, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, 1959). On May 29, 2006, Japan introduced a so-called "positive list" system for residues of agricultural chemicals, feed additives and veterinary drugs in foods. The objective of establishing the positive list is to prohibit the distribution of foods that contain agricultural chemicals above a certain level unless individual MRLs are established. The current MRLs are available at http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p
Korea	Yes, Food Sanitation Act
Mexico	- Article 17 bis, fraction II, III and IV and Article 207 of the General Health Act - Article 7, fraction VIII, Article 7-A, fraction XI, Article 38, fraction III and Article 42 of the Federal Act of Plant Health - Articles 3 and 12 of the Regulation of the Federal Commission for the Protection from Sanitary Risks - Article 12 of the Regulation for Registries, Authorizations of Imports and Exports and Export Certifications for Pesticides, Fertilizers and Toxic or Dangerous Substances and Materials.
New Zealand	Yes, MRLs are required to be set under section 11B of the Food Act 1981. The requirement is that MRLs are set to maintain and monitor the good agricultural practice of any agricultural compound used in New Zealand. In setting these MRLs the following conditions are also to be taken into account: the need to protect public health, the desirability of avoiding unnecessary restrictions on trade, the desirability of maintaining consistency between New Zealand's food standards and those applying internationally and New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol. For a complete listing of all current MRLs, see New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008, available at the following link: http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm#mrl
Norway	*Yes, Food Law*
Portugal	Yes, D.L. 94/98 from 15 April complemented by D.L.144/2003 from 2 of July. Electronically at: http://www.dgadr.pt/default.aspx
Switzerland	Yes, based on the "Verordnung über das Inverkehrbringen von Pflanzenschutzmitteln" Pflanzenschutz-mittelverordnung, PSMV vom 18. Mai 2005 Stand am 1. Januar 2008 (Swiss Ordinance for the Approval of Plant Protection Products).

UK	The EC regime set up under Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/462/EEC establish MRLs for a number of pesticides. UK legislation transposes these MRLs by means of the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs) (England and Wales) Regulations 2005 (as amended) with similar Regulations in place for Scotland and Northern Ireland. For details see http://www.pesticides.gov.uk/food_industry.asp?id=548 In addition, further UK national MRLs have been set administratively and via specific UK pesticide authorisations.
US	Yes, section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 7 U.S.C. 346a, requires MRLs (also known as tolerances in the U.S.) to be set for pesticide residues at levels that meet the strict safety standard of "a reasonable certainty of no harm" to consumers of the food, taking into account all non-occupational exposure to the pesticide and related pesticides with the same mechanism/mode of toxicity. For details, see http://www.fda.gov/opacom/laws/fdcact/fdcact4.htm#sec408 For a complete list of MRLs (tolerances), see Title 40 of the *Code of Federal Regulations* Part 180, available electronically at http://ecfr.gpoaccess.gov.
EC	Yes. In the European Union, since 1 September 2008, all MRLs are fully harmonized and directly applicable in the Member States. Framework legislation: **Regulation (EC) No 396/2005** http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:058:0001:0398:EN:PDF Annexes to Regulation (EC) No 396/2005 that have been established so far are: **Annex I**, covering crop and group of crops to which the MRLs apply. This Annex has been established by Regulation (EC) No 178/2006 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:029:0003:0025:EN:PDF **Annex II** (fixed MRLs), **Annex III** (temporary MRLs) and **Annex IV** (substances for which no MRLs are needed). These three annexes have been established for the first time by Regulation (EC) No 149/2008 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:076:0031:0032:EN:PDF **Annex VII** (covering derogations as regards post harvest treatments with a fumigant), established by Regulation (EC) No 260/2008 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:076:0031:0032:EN:PDF The EC response stated that, since 1 September 2008, all MRLs are fully harmonized and applicable in the Member States. Does this mean that all previously established MRLs (as described by some member states in their responses to Question 2) are no longer in effect?

Establishment of MRLs (continued)

Question 2. What organization(s) is responsible for establishing MRLs in your country? If more than one organization (including outside academic/advisory groups) is involved, please list the name of each organization and its corresponding role	
Australia	The Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for determining MRLs as part of the registration or reconsideration of chemical products used in Australia. Food Standards Australia New Zealand is the statutory authority responsible for developing food regulatory measures for inclusion in the *Australia New Zealand Food Standards Code*, including MRLs for Australia only. Australia and New Zealand independently and separately develop MRLs. MRLs for domestic produce in Australia are established by the Australian Pesticides and Veterinary Medicines Authority, as a result of a risk assessment associated with registration or approval of pesticides or veterinary medicine products. The resulting MRLs determined by the APVMA are notified to Food Standards Australia New Zealand (FSANZ). FSANZ then assesses for inclusion in the Australia New Zealand Food Standards Code in accordance with criteria in the Food Standard Australia New Zealand Act 1991. New Zealand develops its own MRLs, in accordance with registrations or approvals of pesticides and veterinary medicines in New Zealand which can differ from Australia. Both countries operate in accordance with the Trans Tasman Mutual Recognition Agreement (TTMRA), as described below in relation to MRLs. The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the joint food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food. The Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA: □ Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand; and □ Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 2007 (and amendments) can be legally sold in Australia. Therefore, different standards (MRLs) are set and published separately but are recognised for trade through the TTMRA. There is no single set of MRLs that apply both to Australia and New Zealand.
Austria	Responsible bodies are: - Austrian Agency for Health and Food Safety (AGES): scientific evaluation of the residue data including MRL proposals - Federal Ministry for Health and Family (BMGFJ): formal implementation of the MRLs proposed by AGES into national law

Canada	Health Canada, Pest Management Regulatory Agency (PMRA) is the federal agency responsible for establishing pesticide MRLs in Canada.
Czech Republic	For all issues concerning residue section – establishing values of MLRs (as risk assessment, not monitoring purpose) is responsible: National Reference Centre for Pesticides, Centre of Health and Environment, National Institute of Public Health (NIPH) in Prague (www.szú.cz)
Ireland	Regulation (EC) No 396 of 2005 establishes MRLs for pesticide residues in Food. Regulations apply automatically within all EU member states so there is no requirement for a specific organization to establish MRLs in Ireland. In the past The Department of Agriculture Fisheries and Food (DAFF) was responsible for transposing the EC pesticide residue Directives into Irish law.
Japan	Two Ministries are responsible for establishing MRLs: the Ministry of Health, Labour and Welfare (MHLW) is responsible for setting MRLs for agricultural chemicals in foods; and the Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for setting MRLs in animal feeds. See also Q13.
Korea	The Korea Food & Drug Administration (KFDA) is responsible for establishing MRLs. The KFDA uses the residue data developed or supported by the Korea Rural Development Administration (RDA).
Mexico	If more than one organization (including outside academic/advisory groups) is involved, please list the name of each organization and its corresponding role. - Ministry of Health through the Federal Commission for the Protection from Sanitary Risks, which undertakes the dietary risk assessment and the authorization of the MRL. - Ministry of Agriculture (SAGARPA), through the National Service of Health, Food Safety and Agri-food Quality (SENASICA), which elaborates the guidelines and criteria for the field trials.
New Zealand	The New Zealand Food Safety Authority is responsible for establishing and maintaining MRLs for pesticides and veterinary medicines, specifically the Agricultural Compounds and Veterinary Medicines Group. 1. I believe that the situation with regard to the relationship between the APVMA and FSANZ is as described but you would need to check with Australia on that point. 2. There are essentially two sets of food standards applying to residues in New Zealand Foods for sale in New Zealand. The Joint Australian/New Zealand Food Standards Code, which in New Zealand only applies to those residues that do **not** arise from the use of agricultural chemicals or veterinary medicines, and the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008, which applies to residues arising from the use of pesticides and veterinary medicines. This latter piece of legislation is updated three times per year and applies only to foods produced in, or imported into, New Zealand for the domestic New Zealand market.
Norway	*The Norwegian Food Safety Authority*
Portugal	The General Direction of Agriculture and Rural Development (DGADR) is responsible for establishing MRLs. It belongs to the Ministry of Agriculture, Rural Development And Fishery.

Switzerland	MRL setting is in the responsibility of the Federal Office of Public Health; the process of establishing MRLs is however a leveled process, where the input of the Federal Research Stations (ACW Agroscope Changins-Wädenswil) is an important part. The evaluation of efficacy data, residue data, plant metabolism etc. is conducted at ACW.
UK	In the UK, the Pesticides Safety Directorate (PSD), an Agency of the Health and Safety Executive, is responsible for setting/proposing MRLs where appropriate to feed in to the EC system.
US	The U.S. Environmental Protection Agency (EPA) is responsible for establishing MRLs. EPA may use residue data developed or supported by the U.S. Department of Agriculture through Inter-regional Research Project No. 4 (IR-4) for specialty (minor) crop residue trials, and/or the Agricultural Marketing Service's Pesticide Data Program for monitoring of actual residues. For peer review of complex science/science policy issues, EPA may also consult the Scientific Advisory Panel (SAP). The SAP is composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice to the EPA on a wide-range of health and safety issues related to pesticides. It acts as a peer review body for current scientific issues that may influence the direction of OPP's regulatory decisions.
EC	The European Commission is responsible for setting MRLs. Several organizations are involved in the MRLs setting process: - An applicant (private or public body) submits an application for an MRL - A selected Member State has to evaluate the application and draft an evaluation report - The European Food safety authority (EFSA) has to prepare a reasoned opinion on the risk to consumers deriving from the proposed MRL - On the basis of the EFSA's opinion, the European Commission (EC) may propose to set or not to set the requested MRL. The proposal is notified to trade partners (SPS). - The EC proposal is submitted to all the 27 Member States in the Standing Committee on the Food Chain and Animal Health (SCoFCAH) - In case of favourable opinion of the SCoFCAH, the proposal is forwarded to the European Parliament and to the Council of the European Union for scrutiny (2 months) - If there is no reaction from these two institutions, the Commission adopts the MRL.

Establishment of MRLs (continued)

Question 3. What organisation(s) is responsible for approving pesticide products?	
Australia	The APVMA is the authority that is responsible for the registration and approval of pesticide products in Australia.
Austria	Austrian Agency for Health and Food Safety (AGES) under the Pflanzenschutzmittel-Gesetz 1997
Canada	Health Canada, Pest Management Regulatory Agency (PMRA) is the federal agency responsible for approving pest control products established under the PCP Act and Regulations in Canada.
Czech Republic	State Phytosanitary Administration (SPA – www.srs.cz), Section of Plant Protection Products in Brno, however NRC for Pesticides in Prague is fully responsible of evaluation for authorization of PPPs in following sections: toxicology, operator exposure and residues and in most of cases (it depends on kind of applications) the authorizations of PPPs can not be done without assessment of mentioned sections above done by NIPH – NRC for pesticides.
Ireland	DAFF through its Pesticide Control Service is responsible for approving pesticide products in Ireland.
Japan	The registration of pesticide products is under the jurisdiction of MAFF under the Agricultural Chemicals Regulation Law.
Korea	The Korea Rural Development Administration (RDA) is responsible for approving and registering pesticide products for use in Korea under Pesticide Management Act
Mexico	The Ministry of Health, through the Federal Commission for the Protection from Sanitary Risks, supported by the Ministry of Environment and Natural Resources, whose its authority is established on the Article 9 of the Regulation for Registries, Authorizations of Imports and Exports and Export Certifications for Pesticides, Fertilizers and Toxic or Dangerous Substances and Materials.
New Zealand	The New Zealand Food Safety Authority is also responsible for approving pesticide products; this is undertaken under the provisions of the Agricultural Compounds and Veterinary Medicines Act 1997 and its associated regulations. Pesticides, also require approval under the Hazardous Substances and New Organisms Act 1996 administered by the Environmental Risk Management Authority which is responsible for the overarching human and environmental health aspects of all chemical use in New Zealand. This authority sets the reference health standards which NZFSA will use in the assessment of the acceptability of any proposed MRL.
Norway	The Norwegian Food Safety Authority

Portugal	Also DGADR is responsible for approving (registering) plant protection products (PPP).
Switzerland	The Federal Office of Agriculture.
UK	PSD is responsible for the approval of agricultural pesticides on behalf of other Departments and administrations (namely, the Department for Environment, Food and Rural Affairs, the Department for Transport and Local Regions (for the Health and Safety Executive), the Department of Health, the Scottish Executive Environment and Rural Affairs Department, the National Assembly of Wales and the Department of Agriculture and Rural Development in Northern Ireland). The Food Standards Agency has oversight on all matters relating to the safety of food. The relevant legislation is the Plant Protection Products Regulations 2005 (as amended) which transposes the EC regime set up under Directive 91/414/EEC for England and Wales, with similar regulations for Scotland and Northern Ireland.
US	EPA is responsible for approving (registering) pesticide products for use in the U.S. under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The FIFRA standard for approval requires EPA to determine that the pesticide use will pose "no unreasonable adverse effects" on the environment. "Unreasonable adverse effects" are further defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues …inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act." Thus, no pesticide use that results in residues on food may be registered in the U.S. unless EPA also makes the safety findings required by FFDCA. (See response to Question 1).
EC	The European Commission is responsible for approval of active substances used in plant protection products. National authorities in the Member States of the European Union are responsible for authorization of plant protection products containing approved active substances. By applicant: the MRL is linked to the authorisation in the relevant EU member state. For import tolerances it is the rapporteur country under the EU evaluation who evaluates the MRL.

Establishment of MRLs (continued)

Question 4. Are approvals for the use of pesticide products and the establishment of MRLS done simultaneously or sequentially?	
Australia	The process is sequential due to the different responsibilities of the two authorities that are involved in the MRL process in Australia. MRLs are set and may be consulted upon by the APVMA as part of the registration process. In accordance with the *Food Standards Australia New Zealand Act 1991*, FSANZ is required to consider MRLs for inclusion in the *Australia New Zealand Food Standards Code*.
Austria	RLs are established simultaneously with the pesticide product approval. By 1.9.2008 (coming into force of Regulation 296/2005) MRLs have to be established first (before approval of a plant protection product.
Canada	The MRL are presently established sequentially with the pesticide product approval. Canada issues registration certificates before the proposed MRLs are posted on the Pest Management Regulatory Agency's website for consultation. However, shortly after the registration has been granted, the proposed MRLs are published for comments and the Canadian Food Inspection Agency (CFIA), which is responsible for the monitoring and enforcement of pesticide MRLs, is notified. Through this notification, CFIA is informed that PMRA has recommended these MRLs, for which there is no anticipated human health concern. As such, CFIA will not take action should pesticide residues be found in foods (domestically produced or imported) at levels at or below the proposed MRLs.
Czech Republic	The MRL must be established either before or simultaneously with the pesticide product approval.
Ireland	Sequentially
Japan	The registration of agricultural chemicals and the establishment of MRLs occur simultaneously since 2003 when the Food Safety Basic Law was enacted and the Agricultural Chemicals Regulation Law was amended.
Korea	After the approvals of pesticide products, their MRLs are established sequentially
Mexico	Sequentially, before the approbation of the use of the pesticide, the MRL has to be established.
New Zealand	Usually simultaneously, however, a pesticide product cannot receive final approval under the Agricultural Compounds and Veterinary Medicines Act 1997 until an appropriate MRL is in force. It is possible to establish MRLs independently from an approval if good agricultural practice has been established, and this occurs when MRLs are set for imported produce that may contain residues of a pesticide that has not been approved in New Zealand.
Norway	Sequentially: Norway has implemented EU's legislation for pesticide residues and implements EU MRLs. Norway has its own legislation for approval of pesticide products.

Portugal	The MRL are established simultaneously with the pesticide product approval. For new uses requested for the PPP, after the authorization, new MRLs have to be set.
Switzerland	Sequentially, in that MRLs have to be established before the approval is granted.
UK	Under the existing EC regime MRLs are agreed following registration in one or more Member States. However, this approach is due to change in September 2008 when EC Regulation 396/2005 comes into effect. his Regulation picks up the existing EU MRLs and also provides agreed temporary EU MRLs to cover Member States' existing national levels wherever possible. Under 396/2005 it is no longer possible to register a new use or pesticide until an agreed EU MRL is in place.
US	The MRL must be established either before or simultaneously with the pesticide product approval.
EC	No authorisation on plant protection products can be granted by a Member State before an EU-MRL has been set. As of 1 September 2008 there should be an MRL before approval.

Establishment of MRLs (continued)

Question 5. Are there opportunities for public comment on MRLs before they are put into force?	
Australia	Both APVMA and FSANZ have public consultation or public comment processes. At APVMA these relate to specific types of applications and do not include approvals for minor uses etc. In accordance with the *Food Standards Australia New Zealand Act 1991*, FSANZ is required to publicly consult on all proposed MRL variations to the *Australia New Zealand Food Standards Code*.
Austria	Yes; before MRLs are established on national level, several bodies (like consumer organizations, trade organizations, ministries) can comment on the draft MRLs within a certain time frame.
Canada	Presently, there is a 75 day public consultation period when establishing pesticide MRLs by regulations under the FDA. In 2008, Health Canada PMRA intends to amend the FDA and FDR which will allow MRLs to be legally established under the PCPA. Once in force, the 75 day public consultation period will continue.
Czech Republic	No, only Ministry of Health interdepartmental commenting round and inter-ministerial commenting round are used for draft MRLs comments.
Ireland	Pesticide MRLs are set in accordance Regulation (EC) No 396 of 2005. Article 6(2) of that Regulation allows interested parties to apply to have an MRL changed. MRLs proposed under this Regulation are subject to the SPS notification under WTO rules.
Japan	Yes. Before MRLs take effect, the MHLW and MAFF seek public comments thereon from inside and outside Japan. Both Ministries also notify the WTO about these MRLs.
Korea	Yes. According to Food Sanitation Act, upon receiving a petition for the establishment of an MRL, KFDA must publish a notice of the petition in the *Korea Food Code.* The petitioner must include with its petition an informative summary of the data supporting the petition, and under KFDA regulations, KFDA must make this summary available on its website. After completing its review, KFDA publishes a final rule in the *Korea Food Code* that establishes the MRL, explains the basis for KFDA's decision, and sets an effective date.
New Zealand	Yes, MRLs are listed for public comment for 60 days before final promulgation, this consultation is accompanied by a background document explaining the purposes of MRLs and how they are set in New Zealand for an example of the public consultation document see the following link: http://www.nzfsa.govt.nz/consultation/mrl/ http://www.nzfsa.govt.nz/consultation/mrl/mrl-background/index.htm Submissions received and NZFSA responses are publicly advised following the consultation period.
Mexico	No, it is not considered in the legal framework.
Norway	Yes

Portugal	No, it is not used to give opportunity for comments on the MRL proposals. In the past, effectively in the cases of inexistence of harmonized MRLs, we legally established national MRLs using the EU guidance documents. The European Commission was informed and the values published in the Portuguese law. Since a long period before the 1st of September 2008, date of the entry into force of EC Regulation nº 396/2005, no more national MRls were or can be set, only EC (harmonized) MRLs. In the EC procedure there is an opportunity for public comment through the WTO-SPS system.
Switzerland	No
UK	There are limited opportunities at present (for example, PSD publishes the draft EC proposals on its website, and interested stakeholders are emailed to bring their attention to draft MRL proposals). Under EC Regulation 396/2005, the European Food Safety Authority's opinions on applications for MRLs will be made publicly available.
US	Yes. According to FFDCA, upon receiving a petition for the establishment of an MRL, EPA must publish a notice of the petition in the *Federal Register*. The petitioner must include with its petition an informative summary of the data supporting the petition, and under EPA regulations, EPA must make this summary available on its website. After completing its review, EPA publishes a final rule in the *Federal Register* that establishes the MRL, explains the basis for EPA's decision, and sets an effective date. There is also generally an opportunity after the final rule for objections and requests for a hearing to be submitted for EPA consideration.
EC	Yes through the WTO-SPS system

Establishment of MRLs (continued)

Question 6. What organisation is responsible for enforcing MRLs?	
Australia	MRL enforcement in Australia is the responsibility of numerous jurisdictions (authorities at the federal and state level). These include the federal Australian Quarantine and Inspection Service which has enforcement responsibilities under the *Imported Food Control Act 1992*, state departments of Primary Industry (Departments of Agriculture) that are involved in control of use of pesticide products, state health authorities that may also have some control of use function as well as human health enforcement role and also food regulatory agencies. There are different levels of enforcement in Australia in accordance with various jurisdictional responsibilities. For Control of Use of Pesticides, enforcement is the responsibility of State and Territory departments of Primary Industry (or Agriculture) as well as the health departments in some States. This only involves compliance and enforcement to determine whether a farmer has used a registered product in accordance with label instructions. There are different residues surveys in the States conducted with samples taken at the markets, where produce is sampled for compliance against MRLs. If there are problems, the State authority can give the farmer a warning or take appropriate legal action if an MRL is exceeded. The diversity of residues testing in various States does not normally lead to disputes. Laboratories generally use methods which are well validated and audited through NATA (the National Association of Testing Authorities).
Austria	Austrian Agency for Health and Food Safety Federal Ministry for Health and Family (BMGFJ)
Canada	The Canadian Food Inspection Agency (CFIA) is responsible for monitoring and enforcing MRLs published in Table 2, Division 15 of Part B of the *Food and Drug Regulations* (FDR) regarding pesticide residues.
Czech Republic	The Ministry of Health is responsible for enforcing MRLs, after consultations, revisions and finally drafts made by NIPH - NRC for pesticides (both organizations situated in Prague).
Ireland	The Pesticide Control Service (PCS) is responsible for enforcing pesticide MRLs. The Food Safety Authority of Ireland (FSAI) is responsible for food safety and the Irish pesticide residue monitoring plan to control residues in food is carried out by the PCS of DAFF as part of a service contract between DAFF and the FSAI.
Japan	The MHLW is responsible for enforcing MRLs for foods; and the Ministry of Agriculture, Forestry and Fisheries is responsible for enforcing MRLs in animal feeds.
Korea	The Korea Food and Drug Administration is responsible for enforcing MRLs for foods at market while the Korea Agricultural products quality management service is before market
Mexico	The Ministry of Agriculture (SAGARPA), through the National Service of Health, Food Safety and Agri-food Quality (SENASICA).

New Zealand	The New Zealand Food Safety Authority through its Compliance and Investigation Group.
Norway	The Norwegian Food Safety Authority
Portugal	The official services responsible for the enforcing are ASAE (Authority for food and economic security) belonging to the Ministry of Economy in collaboration with DGADR (General Direction of Agriculture and Rural Development) from the Ministry of Agriculture, Rural Development And Fishery.
Switzerland	The State laboratories/authorities of the cantons.
UK	In the UK, PSD is responsible for enforcing MRLs.
US	The U.S. Food and Drug Administration is responsible for enforcing MRLs for most fresh and processed foods. The U.S. Department of Agriculture Food Safety and Inspection Service is responsible for enforcing MRLs for meat, poultry and some egg products.
EC	National authorities of the EU (Member States). In EU enforcement is decentralised, but quality is co-ordinated (obligatory proficiency tests organised by community reference labs). Also there is division of labour and the sampling is partly harmonised.

Establishment of MRLs (continued)

Question 7. Who can apply or petition for the establishment of MRLs?	
Australia	Mainly chemical manufacturers apply to have MRLs considered as part of the registration of a pesticide product. User groups through the approval of minor use permits can also apply to have MRLs set. Other applicants are food manufacturers and state authorities as part of any APVMA approval. Anyone may apply to FSANZ to change the *Australia New Zealand Food Standards Code* including for MRLs and information for applicants explains how to do this. Also, proposed MRLs may be varied if the need is identified during public consultation.
Austria	In the most cases, pesticide manufacturers/registrants petition for the establishment of an MRL when they apply for a national approval/registration of their pesticide products for use in Austria. AGES can act on its own initiative as well (e.g. when consumer risk is concerned)
Canada	Anyone can petition for the establishment, modification or revocation of a pesticide MRL, or PMRA can act on its own initiative. Most often, pesticide manufacturers/registrants petition for the establishment of an MRL when they apply for approval/registration of their pesticide products for use in the Canada.
Czech Republic	Most often, pesticide manufacturers/registrants apply for the establishment of an MRL when they apply for approval/registration of their pesticide products for use in the Czech Republic, or for extension of use.
Ireland	Any party with a legitimate interest, see Article 6 of Regulation (EC) No 396 of 2005
Japan	Anybody can apply for the establishment of MRLs or the revision of the existing MRLs as long as that person submits necessary documents to the MHLW. For agricultural chemicals to be used in Japan, an application for registration shall be filed with MAFF under the Agricultural Chemicals Regulation Law. Upon reviewing the submitted data, the MAFF requests the MHLW to establish MRLs. In case of agricultural chemicals not registered in Japan but registered in other country(ies), an application for MRLs can be done based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (published on February 2004). The guideline is available at http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html
Korea	KFDA commissioner can petition for the establishment, modification or revocation of an MRL. Anyone can apply or petition for the establishment of MRLs who can submit a wide variety of scientific studies for the establishment, modification or revocation of an MRL.
Mexico	The industries can apply the establishment of MRLs, when submitting for a new registry or a use addition.

New Zealand	Any party may petition for the establishment, modification or deletion of an MRL, MRLs are primarily modified as a result of changes to pesticide product approvals, in terms of use or changes to good agricultural practice. In New Zealand third parties e.g. grower groups, may request changes to suit growing practices but NZFSA requires the same data in any case and strongly prefers the inclusion of the registrant company in the process.
Portugal	Anyone can petition for the establishment, modification or revocation of an MRL, or DGADR can act on its own initiative. Most often, pesticide manufacturers/registrants ask for the establishment of an MRL when they apply for DGADR approval/registration of their pesticide products for use in Portugal.
Switzerland	MRL proposals have to made by the applicant; in the case, where an MRL has already been established (e.g. in context with an earlier approval of a different product) and the applicants proposal is consistent with the established MRL, the applicant has to present the arguments of comparison and conclusion.
UK	Anyone can petition for the establishment or modification of an MRL, including Member State or EC authorities. Most often, pesticide registrants petition for the establishment of an MRL when they apply for registration of their pesticide products for use in a Member State.
US	Anyone can petition for the establishment, modification or revocation of an MRL, or EPA can act on its own initiative. Most often, pesticide manufacturers/registrants petition for the establishment of an MRL when they apply for EPA approval/registration of their pesticide products for use in the U.S.
EC	According to Article 6 of Regulation (EC) No 396/2005, the following persons and organisations can apply for an MRL: - applicants according to Directive 91/414/EEC (Article 6.1); - parties demonstrating, through adequate evidence, a legitimate interest in health, including civil society organisations (Article 6.2); - commercially interested parties such as manufacturers, growers, importers and producers of products covered by Annex I of Regulation (EC) No. 396/2005 (Article 6.2); - Member Sate of the European Union (Article 6.3).

Establishment of MRLs (continued)

Question 8. Do you have a requirement for periodic review and/or reporting of new data after a MRL is established?	
Australia	This can occur as part of the chemical review process for the reconsideration of approvals of existing chemicals or as part of the renewal of approval for minor uses. The *Food Standards Australia New Zealand Act 1991* includes provisions on the conduct of reviews of food regulatory measures in the *Australia New Zealand Food Standards Code.* There is no automatic review of the MRLs in the Code and no reporting of new data. However, FSANZ does co-ordinate monitoring of the Australian food supply by the Australian Total Diet Survey.
Austria	Yes, under the framework of re-registrations of plant protection products according to Pflanzenschutzmittel-Gesetz 1997.
Canada	The new *Pest Control Products Act* provides that all pest control products be re-evaluated on a 15-year cycle. Current focus of PMRA's pesticide re-evaluation program considers potential risks to human health and environment, including dietary risks. Where dietary risks are of concern, MRLs will be revised as required. PMRA will also propose revocation of obsolete MRLs.
Czech Republic	All procedures regarding of peer review programs (Review of Active Substances (Art. 8(1) and 8(2) of Directive 91/414/EEC, Art. 11(2) of Regulation (EC) No 1490/2002), re-registrations process (http://www.ec.europa.eu/food/plant/protection/resources/re-reg-guidancev10-3.pdf), new data after established national or EU MLR is perfectly described on this link: http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm As an EU MS we regularly take part in all standing committees and working parties to deal with these issues, namely SCFCHAH – Standing Committee of Food Chain and Animal Health and CODEX ALIMENTARIUS working party (Brussels, China) and PRAPeR Experts′ Meeting in Parma.
Ireland	There is a requirement for agrochemical companies to submit relevant new data on pesticides which have been approved for use within the EU. All pesticide active substances are subject to periodic review under Council Directive 91/414/EEC.
Japan	Periodic review has not been conducted. The MHLW is reviewing the MRLs for chemicals that had been provisionally established at the time of the introduction of the positive list system, based on risk assessment by the Food Safety Commission in the Cabinet Office.
Korea	There is no requirement for periodic review and/or reporting of new data after a MRL is established. But KFDA may re-establish MRL whenever necessary (e.g. Re-entry, etc).
Mexico	The registries in Mexico are valid for five years, after that they have to submit the more recent information to renew the registry.

New Zealand	While there is no requirement for periodic review under the Food Act 1981, any party may submit data to support a proposal to change a current MRL. In addition NZFSA undertakes periodic reassessments of existing MRLs. There is a requirement under the ACVM Act that any new data affecting the registration of a product is provided to the regulator, and this also may prompt reconsideration of an MRL. Finally, our residue monitoring programmes may signal a need to review an MRL if consistent breaches are found.
Portugal	As member of the European Union, most of the MRLs we have at the moment were set at E.U. level. The national MRLs were all considered in the E.U. harmonization process of all the national MRLs, according to the new Regulation (CE) 396/2005, from 23 of February, which is fully applicable at 1 of September of 2008. According to that legislation no more national MRLs can be set. We have to review the MRLs for the active substances for which we are rapporteur member state when we are asked by the E.U. Commission to do so.
Switzerland	Yes
UK	The review of EC MRLs is largely tied in with the review programme for active substances under Directive 91/414/EEC. This Directive also requires pesticide registrants to report new information on adverse effects of pesticides.
US	EPA recently completed a reassessment of all MRLs in effect when the 1996 Food Quality Protection Act amendments to FFDCA and FIFRA were enacted. In the future, FIFRA requires that pesticide registrations (including the corresponding MRLs) be reviewed on a 15- year cycle. If at any time after a pesticide is registered the registrant becomes aware of new factual information on adverse effects of the pesticide, it must be reported to EPA. In addition, when appropriate, EPA may require new data to support continuing registrations and MRLs in effect at any time. (See FIFRA for details at: http://www.epa.gov/opp00001/regulating/fifra.pdfm). EPA may establish or modify MRLs based on refined risk assessments that use anticipated or actual residue levels, rather than assuming that residues will always be present at the maximum level permitted by the MRL. For example, EPA may use actual residue monitoring data developed under the USDA Pesticide Data Program (for details on this database, see http://www.ams.usda.gov/science/pdp/). If EPA relies on anticipated or actual residue data in establishing an MRL, updated data that are reasonably required to verify residue levels must be provided 5 years after the MRL is established, and thereafter as required by EPA. Similarly, if EPA relies upon data on the percent of a crop that is treated with a pesticide in estimating chronic risk, EPA must periodically re-evaluate that assessment.
EC	MRLs shall be reviewed within one year after their inclusion or non inclusion in the positive list of Directive 91/414/EEC. Moreover, temporary MRLs (annex III) are subject to review within 4 years from their inclusion in Annex III to Reg. (EC) No 396/2005. In addition a review is necessary whenever MRLs covered by Regulation (EC) N0 396/2005 may endanger human or animal health and immediate action is required (Article 35).

Establishment of MRLs (continued)

Question 9. What is the process for revoking MRLs?	
Australia	The process for revoking MRLs in Australia is largely the same as the establishment of an MRL. Any revocation or deletion must also be consulted upon. The process for varying MRLs, including revoking them, is detailed in the *Food Standards Australia New Zealand Act 1991*.
Austria	The same procedure as for establishing MRLs. By 1.9.2008 (coming into force of Regulation 296/2005) MRLs can be revoked in a faster way than to be established.
Canada	In general, the process for revoking or modifying MRLs is the same procedure used to establish MRLs. PMRA publishes a proposal to revoke the MRL in the *Canada Gazette*, Part I for public comment, reviews the comments, and then publishes a final decision in the *Canada Gazette,* Part II. If amendments to the *Food and Drugs Act* (FDA) are approved in 2008, any proposed revocation of MRLs will be posted on PMRA's website for public comment, along with the final decision once comments are taken into consideration.
Czech Republic	In general, the process for revoking or modifying MRLs tracks is based on a lack of sufficient data to support the required safety margins and in response to the proposals; there is a used to establish MRLs. Or in light of new facts come out can NRC for pesticides, SPA, EFSA, European Commission or companies proposed revoking or modifying MLR.
Ireland	An MRL may be revoked by the EU Commission, in consultation with the member states, following discussions in the Standing Committee for Food Chain and Animal Health (SCFCAH). The rationale for revoking the MRL is discussed at the committee meeting.
Japan	Revocation of MRLs may occur depending on a risk assessment by the Food Safety Commission.
Korea	In general, the process for revoking or modifying MRLs tracks the same basic procedure used to establish MRLs.
Mexico	The revocation of a MRL goes with the revocation of the registry. According to the General Health Act, are two basic procedures, the first is when the registrant requests the revocation of the registry through an official communication to the Ministry of Health, and the second procedure is when the Ministry of Health revokes the MRL based on scientific evidence and a legal procedure.
New Zealand	MRLs are usually revoked 5 years following the cancellation or withdrawal of the relevant use pattern, MRLs may be revoked at any time if NZFSA becomes aware of a public health risk or inappropriate agricultural practices. Revocation follows the same process as for setting new or changing MRLs.

Portugal	When an MRL has to be revoked, the information that the authorized use must be cancelled is given by a circular letter fully divulgated, before the new MRL entries into force by setting it in our legislation, usually resulting from transposition of the E.U. Directives.
Switzerland	The triggers are 1) new and more stringent toxicological evaluation or 2) loss of efficacy and hence withdrawal of the authorization for use. In the process different institutions/organizations as described under 2. are involved.
UK	In general, the EC process for revoking or modifying MRLs follows the same basic procedure used to establish MRLs. A draft proposal to revoke an MRL is considered by a standing committee of Member State and EC authorities. Unless the proposal to revoke is due to an unacceptable risk requiring immediate action, pesticide registrants can be given the opportunity to provide additional supporting data if appropriate.
US	In general, the process for revoking or modifying MRLs tracks the same basic procedure used to establish MRLs. EPA publishes a proposal to revoke the MRL in the *Federal Register* for public comment, reviews the comments, and then publishes a final decision in the *Federal Register*. If the proposal to revoke was based on a lack of sufficient data to support the required safety findings and, in response to the proposal, there is a commitment to provide the necessary data, EPA may, depending on the extent of the missing data, continue the MRL in effect for the time required for data development and review.
EC	In case of simple revocation because the MRL is no longer needed (e.g. the relevant authorisation has been revoked): amendment to Annexes II or III anticipated by an SPS notification. No EFSA's opinion is needed in this case. In case of intake concern: EFSA opinion and following amendment to Annexes II or III anticipated by an SPS notification.

Establishment of MRLs (end)

Question 10. Do the same MRLs apply to domestically produced and imported foods?	
Australia	The MRLs in the *Australia New Zealand Food Standards Code* apply equally to domestic and imported food. In relation to food from New Zealand, there are specific Trans Tasman Mutual Recognition Arrangements.
Austria	Yes, once established, the MRLs apply equally to domestically produced and imported foods
Canada	Both the current process and proposed new process for establishing pesticide MRLs will apply to domestically produced and imported foods.
Czech Republic	Please see document below: http://www.ec.europa.eu/food/plant/protection/resources/working_en.pdf
Ireland	Yes
Japan	Yes. The same MRLs apply, regardless of whether foods are domestically produced or imported.
Korea	Yes. Once established, an MRL (or specific exemption from the requirement for an MRL) applies equally to domestically produced and imported foods.
Mexico	Yes, the MRL apply to domestically produced and imported food.
New Zealand	Yes, however since MRLs are based on New Zealand GAP, imported foods may instead comply with any current Codex Alimentarius MRLs, or in the case of food imported from Australia, under the provisions of the Trans Tasman Mutual Recognition Arrangement, compliance with any Australian domestic MRL.
Portugal	The MRLs set at E.U. level have in consideration the Codex MRLs and the requested Import Tolerances for the E.U.
Switzerland	Yes
UK	Yes. Once agreed, an MRL applies equally to domestically produced and imported foods.
US	Yes. Once established, an MRL (or specific exemption from the requirement for an MRL) applies equally to domestically produced and imported foods.
EC	Yes

Categories of MRLs Established

Question 11. Are "import only" MRLs established? (MRLs for pesticides that are not used in your country, to cover potential residues in imported foods, provided your safety standards are met)?	
Australia	The MRLs in the *Australia New Zealand Food Standards Code* apply equally to domestic and imported food. In relation to food from New Zealand, there are specific Trans Tasman Mutual Recognition Arrangements.
Austria	Yes. "Import tolerances" are established based on the same safety standards as for domestically produced products.
Canada	PMRA will establish "import MRLs" (for pesticides that are not registered in Canada) provided adequate data are submitted. These data would include crop field trial data from trials conducted in the exporting country according to the registered label in that country. The same scientific assessment is conducted for import MRLs as is conducted for domestic MRLs and the same safety standards must be met before an "import" MRL will be established.
Czech Rep	Please see point No 10.
Ireland	Regulation (EC) No 396 of 2005 establishes MRLs to deal with import requirements of trading partners. Prior to the MRL being established it must be shown to be safe for EU consumers.
Japan	MRLs for agricultural chemicals that are not registered in Japan can be established if an application is filed with the MHLW based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan. Japan has a system in which any person can request the Japanese government to establish MRLs or to revise current ones for agricultural chemicals that are registered elsewhere.
Korea	No.
Mexico	No.
New Zealand	Yes a party can request an MRL for a pesticide/commodity where either or both are not used or grown and sold in New Zealand.
Portugal	Yes, if adequate data are submitted to support the safety findings required. These import tolerances must meet the same standards as all other MRLs.
Switzerland	Yes.
UK	Yes, currently import tolerances can be set under UK national and EC arrangements and there is a mechanism for setting them under the forthcoming EC regime.
US	Yes, if adequate data are submitted to support the safety findings required under FFDCA, EPA will establish "import MRLs" (MRLs with no corresponding registration for use in the U.S.). These "import MRLs" must meet the same standards as all other MRLs and are also codified in Title 40 of the *Code of Federal Regulations* Part 180, available electronically at http://ecfr.gpoaccess.gov
EC	Yes, see also response to question 10.

Categories of MRLs Established (continued)

Question 12. Are MRLs established for processed foods? If yes, under what conditions?	
Australia	MRLs for processed food are established if there is a demonstrated concentration of a chemical in various processed fractions which cannot be accommodated by the limit for the Raw Agricultural Commodity (RAC). In such cases, a separate MRL may be established for the processed commodity. This is in accordance with current JMPR practice.
Austria	No. MRLs are based on raw agricultural commodities only (the same is true for Regulation 396/2005 to be in force by 1.9.2008). The use of processing factors is used only for risk assessment purposes. The processing factor has to be considered for processed food when enforcing MRLs.
Canada	In most cases, MRLs established for the raw agricultural commodity (RAC) will apply to both the raw commodity and any processed food derived from it. However, when processing studies demonstrate that residues concentrate during processing at levels higher than the MRL for the RAC, separate MRLs for processed foods may be established.
Czech Republic	MRLs for processed products and composite foodstuffs are normally calculated on the basis of the MRLs set for the agricultural commodity by application of an appropriate dilution or concentration factor. For composite foodstuffs MRLs are calculated taking into account the relative concentrations of the ingredients in the composite foodstuff. Only exceptionally may specific MRLs be determined for certain processed products or certain composite foodstuffs.
Ireland	Indirectly. The MRL is established for the raw commodity and is then applied to the processed product in accordance with Article 20 of Regulation (EC) No 396 of 2005.
Japan	Japan establishes MRLs for some processed foods in addition to raw agricultural commodities. In principle, Codex MRLs are adopted as Japanese MRLs.
Korea	In general, KFDA establishes MRLs for raw agricultural commodities which apply to the raw commodity and any processed food derived from it. If necessary (e.g., to cover residues that concentrate at higher levels during processing), KFDA may establish separate MRLs for processed foods.
Mexico	No
New Zealand	No – New Zealand applies a “carry-over” principle in establishing the acceptability or otherwise of residues in processed foods.
Portugal	No, the MRLs are set for the raw commodity, having in consideration the residues in the processed product. Processing factors are established.

Switzerland	The MRLs are established for the raw agricultural commodity. A special case is to be mentioned, that is the setting of an MRL for wine; the establishing of an MRL in this case is based on the MRL of grapes (raw commodity) applying a compound-specific processing factor.
UK	At present, the EC regime is directed to establishing MRLs for raw agricultural commodities which apply to the raw commodity and (by application of processing factors) any processed food derived from it. EC Regulation 396/2005/EEC will establish details of processing factors that can be applied.
US	In general, EPA establishes MRLs for raw agricultural commodities which apply to the raw commodity and any processed food derived from it. If necessary (e.g., to cover residues that concentrate at higher levels during processing), EPA may establish separate MRLs for processed foods.
EC	MRLs are currently established for raw commodities. MRLs for raw commodities also apply to processed products, corrected, if applicable, by a processing factor accounting for the possible increase or decrease of pesticide residues in the product transformation. Such processing factors are to be established in Annex VI of Reg. (EC) No 396/2005. If they are established normally they will be chemical/commodity specific except for some common processes as dessication. Presently nothing is specified and left at the discretion of the enforcement.

Categories of MRLs Established (continued)

Question 13. Are MRLs established for commodities used in animal feeds? How do you deal with residues in foods derived from animals that may have residues as a result of feed consumption? (as opposed to direct treatment of the animal)	
Australia	Separate MRLs are established by the APVMA for commodities that are used as livestock feeds. These are found in Table 4 of the APVMA MRL Standard and in Table 1 of the Standard for whole commodities such as grains etc. http://www.apvma.gov.au/residues/downloads/table04.pdf http://www.apvma.gov.au/residues/downloads/table01.pdf Residues in livestock commodities are determined using well-developed principles determined by the JMPR and FAO and are described in APVMA guidance. http://www.apvma.gov.au/residues/stockfeed.shtml Receival and testing of imported food and feed is the responsibility of the Australian Quarantine and Inspection Service (AQIS). AQIS say that imports of livestock feed are sometimes distinguishable from human food depending on what type of custom tariff code accompanies the consignment. An example of the types of codes that are used for livestock feeds is attached. So essentially those feeds identified according to the codes in the attached listing are able to be distinguished from human foods, while others may not be. In reality, Australia does not import much grain or other raw commodities that are used as both human and livestock feeds as we grow much of these ourselves. Any imported grain or raw commodity which is a human food and animal feed would have to comply with Standard 1.4.2 of the Food Standards Code and any livestock feed would have to comply with the APVMA MRL Standard Table 4, as this specifies limits in livestock feeds only. The Australian government is currently developing a national standard for all types of livestock feeds that will be implemented into all State and Territory legislations.
Austria	MRLs are not considered for animal feed in Austria. By 1.9.2008 (coming into force of Regulation 296/2005), MRLs will apply for animal feed as well (once the respective commodity list is established). Animal feed with residues of plant protection products is considered by establishing MRLs of animal origin (using metabolism data on livestock, animal feeding studies, residues on animal feed, dietary burden calculations).
Canada	PMRA does not establish MRLs for commodities used as animal feeds. Based on the residues found in the animal feed, a maximum theoretical dietary burden is calculated. The livestock feeding studies are then used to determine the potential transfer of residues from animal feeds to foods derived from animals. These residue levels form the basis of the MRLs for livestock commodities. Canada only sets MRLs on food destined for human consumption. Canada does not set MRLs on feed items (e.g., forage, hay and straw). However, an MRL may be established on a food intended for human consumption that may also be used as an animal feed (e.g., grain). This MRL will apply to both domestically produced and imported food/feed.

Czech Republic	Yes, NIPH - NRC for pesticides establishes MRLs for commodities used in animal feeds and requires animal feeding studies in order to establish MRLs for residues that remain in foods derived from animals fed the feed, if necessary.
Ireland	MRLs are established for all commodities listed in Annex 1 of Regulation (EC) No 396 of 2005. Article 20 allows the MRL for raw products to be extrapolated to all processed products.
Japan	Japan establishes MRLs for commodities used as animal feeds. If these commodities are used also as foods, MRLs are set by the MHLW based on the Food Sanitation Law. The established MRLs apply to the corresponding feeds as well. The setting of MRLs for commodities used only as animal feeds is under the authority of MAFF in accordance with the Law Concerning Safety Assurance and Quality Improvement of Feeds. Currently, MRLs are set for 60 agricultural chemicals in animal feed commodities. MRLs for livestock commodities that may contain residues resulting from the feed consumption are established following the JMPR method of estimation. Are imports intended as animal feed clearly distinguishable from those intended for human consumption? Imported feeds are legally distinguishable from imported foods. However, as what is imported as food may in some cases be used also as feed, they are not clearly distinguishable from a practical point of view. Are there instances when the presence of residues without an MRL could create trade problems? There have been cases of rejection of import of feed into Japan where pesticide residues were detected in the feed while no MRL had been established for the combination of pesticide/feed item, and the available animal transfer study indicated that commodities from livestock given the above mentioned feed might contain residues higher than the MRL set for these commodities.
Korea	No, KFDA doesn't establishes MRLs for commodities used in animal feeds
Mexico	No
New Zealand	No, MRLs under the Food Act are only established for crops/commodities for direct human consumption, transfer of residues from feed to animals is managed through the establishment of animal commodity maximum permissible levels in other legislation, and residues in animal tissues used for foods must comply with MRLs set for that food.
Portugal	Yes, for some commodities used in animal feeds the E.U. establishes MRLs and requires animal feeding studies in order to establish MRLs for residues that remain in foods derived from animals fed the feed.

Switzerland	Yes, in certain situations; MRLs would be established for animal feed commodities, when it is to be expected based on the data available, that the threshold level of 0.1 ppm is exceeded.
UK	Currently, MRLs are set for meat and animal products, but not specifically for animal feeds. Under the forthcoming EC Regulation 396/2005 there are future plans to establish specific MRLs for crops used exclusively as animal feed, but these arrangements are not yet in place.
US	Yes, EPA establishes MRLs for commodities used in animal feeds and requires animal feeding studies in order to establish MRLs for residues that remain in foods derived from animals fed the feed.
EC	MRLs for products used as animal feed are covered, if these are also used in human consumption, e. g. cereal grain. In addition, MRLs for animal feed like cereal straw and alfalfa will be set in future. In any case, residues in feeding stuff are taken into account in the calculation of animal dietary burden and in the evaluation of feeding studies, being the basis for MRL setting in products of animal origin.

Categories of MRLs Established (continued)

Question 14. Are MRLs established for livestock commodities (foods derived from animals)? If the data show residues are below the level of quantitation (LOQ), would the MRL be set at the LOQ?	
Australia	MRLs are established for livestock commodities such as meat, milk, eggs etc where the use of a chemical may occur directly or indirectly on a livestock feed or directly to an animal. It is standard practice in Australia to set MRLs at the LOQ of a validated method for livestock commodities, if residues in such commodities are expected to be below LOQ. This is in accordance with current Codex policy.
Austria	If it is shown, that animals are not exposed to pesticide residues at all, no MRL will be established. If there are residues in/on animal feed, and no residues are expected in food of animal origin, the LOQ will be established. The development and validation of respective analytical methods are required.
Canada	PMRA sets MRLs for livestock commodities when measurable residues are expected in these commodities. However, PMRA may set MRLs for livestock commodities at the method LOQ, even when no residues are expected in these commodities, provided an acceptable enforcement method has been submitted.
Czech Republic	Critical appraisal of study and results: – a residue at or about the limit of determination in control samples – adverse effects on egg production, milk yield and health of the livestock – the relationship between the dose rate used in the study and the highest likely residue levels in feed – proposal for MRL and/or limit of determination with reasoning
Ireland	When there is no animal intake MRLs are not usually established. Where there is animal intake and the residue is less than the LOQ then the MRL is normally set at the LOQ.
Japan	MRLs are established for livestock commodities. The establishment of MRLs uses animal transfer studies. Even if residues are below the LOQ, the MRL is not always set at the LOQ.
Korea	KFDA sets MRLs for livestock commodities when finite residues are expected in such commodities. KFDA does not set MRLs when no residues are expected in livestock commodities. Establishment of an MRL at any level, including the LOQ, would require the development and validation of an analytical method.
Mexico	No.
New Zealand	Yes, MRLs are established to allow use of veterinary medicine products and to take into account the transfer of pesticide residues from feed to animal products. These are set at the limit of quantification if the submitted residue data supports this limit.
Portugal	E.U. sets MRLs for livestock commodities when finite residues are expected in such commodities. E.U. decided recently not to set MRLs when no enough information exists as it was not required about the residue definition, in the cases where no residues are expected.
Switzerland	No, see comment 13.

UK	Yes, MRLs are established for livestock commodities. Even if the data show that residues are likely to be below the level of quantification (LOQ), an MRL is still likely to be set at the lowest detectable level in order to establish a legal limit.
US	EPA sets MRLs for livestock commodities when finite residues are expected in such commodities. EPA does not set MRLs when no residues are expected in livestock commodities, even if there are residues in the animal feeds (the feed would require a MRL). Establishment of an MRL at any level, including the LOQ, would require the development and validation of an analytical method.
EC	MRLs are established for livestock commodities (foods derived from animals). If the data show that residues are below the level of quantitation (LOQ), the MRL is set at the LOQ.

Categories of MRLs Established (continued)

Question 15. Do you have the option of establishing specific exemptions from the requirement of setting a MRL? If so, under what circumstances may exemptions be established?	
Australia	Exemptions from requiring an MRL in certain situations are determined by the APVMA and published in Table 5 of the APVMA MRL Standard. http://www.apvma.gov.au/residues/downloads/table05.pdf The criteria for exemptions are shown in the preface of Table 5.
Austria	Yes. For substances that do not require MRLs like quartz sand etc. These substances, for which no MRL is necessary, are listed in Annex IV of Regulation 396/2005 (coming into force by 1.9.2008).
Canada	Provision B.15.002(2) of the Food and Drug Regulations (FDR) provides a list of 7 agricultural chemicals which are exempted from the requirement of setting a MRL. Exemptions may be established only if there is scientific data demonstrating that any exposure to a particular pesticide will not pose a risk to human health. Yes, Canada agrees that the development of common criteria/guidance for establishing exemptions is an area worth pursuing.
Czech Republic	In special cases (e.g. minor crop situation) it might be necessary to calculate a MRL or PHI on the basis of 3 – 4 results. This limited data base is not sufficient for a statistical calculation using the methods recommended here as a tool. Nevertheless there is a need to access and/or propose PHIs or MRLs on that basis.
Ireland	Regulation (EC) No 396 of 2005 establishes an Annex IV which lists those pesticide active substances which do not require an MRL. Decisions in relation to pesticides to be included in Annex IV are made by the Commission consulting with EU member states in the SCFCAH. In all other cases an MRL value will be established.
Japan	There are specific exemptions from the requirement of setting an MRL. In the positive list system, MHLW has designated substances having no potential to cause damage to human health based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law. The exempted substances are contained in Ministry of Health, Labour and Welfare Notification No. 498, 2005
Korea	Yes. Specific exemptions can be established by KFDA. Exemptions may be established where the pesticide does not pose a dietary risk under reasonably foreseeable circumstances.
Mexico	Yes, for pesticides applied in seeds for agricultural use based on scientific evidence.
New Zealand	Yes, MRLs may be exempted where a chemical concentration limit is inappropriate either through the low risk of the product, its non-chemical nature or because of no requirement to regulate good agricultural practice. Examples of this include microbial pesticides and low toxicity active ingredients such as some mineral oils. Exemptions from MRLs are done under the Food Act and are publicly notified.
Portugal	Once more the decision is taken at E.U. level. Annex IV of Regulation 396/2005 includes the active substances that at E.U. level were considered exemptions of setting MRLs.

Switzerland	Yes, in the situation, where the active substance does not comply with the definition of a "foreign substance", e.g. compounds that are incorporated into natural biochemical cycles and are thus not detectable as foreign compounds.
UK	No such option exists at present, but EC Regulation 396/2005/EEC will establish a list of active substances which do not require MRLs.
US	Yes. Specific exemptions may be established by EPA. All MRLs (tolerances) and exemptions are codified in Title 40 of the *Code of Federal Regulations* Part 180. For details, see www.gpoaccess.gov/ecfr/ Exemptions may be established where the pesticide does not pose a dietary risk under reasonably foreseeable circumstances.
EC	As stated under point 1, Annex IV of Regulation (EC) No 396/2005 contains a list of active substances for which the setting of MRLs is not necessary. The inclusion of a substance is annex IV is subject to the EFSA's opinion. A guidance document is under preparation.

Categories of MRLs Established (continued)

Question 16. How do you handle inadvertent residues from rotational crop situations?	
Australia	Recent policy determined with state agricultural jurisdictions has been conveyed to CCPR via CL 2007/15-PR, which is attached for information
Austria	Rotational crops studies are required. Based on the information/results from the studies and/or application regime, evaluation is performed if residues are expected in rotational crops or not. AGES has the possibility to establish minimum time periods before other crops can be planted (to be specified on the label) or to establish MRLs for rotational crops above the LOQ.
Canada	PMRA requires rotational crop studies which are used to a) establish plant-back intervals so that no residues will be found in rotational crops for which no MRLs have been established or to b) set MRLs for rotational crops. The label may specify what plant-back intervals (also recognized as rotational crop restrictions) and what secondary crops are permitted either because (1) the pesticide is already approved for direct application to the primary crops, or (2) data have been submitted to support establishment of rotational crop MRLs
Czech Republic	We require rotational crop studies. To avoid inadvertent residues from rotational crops we can establish minimum time periods before other crops can be planted, or the label may specify which crops are permitted in rotation The only rotations permitted are those specified on the label.
Ireland	If residue occurs after rotational crop trials then the LOQ may be raised to deal with such residues. Product labels will also contain restrictions in relation to time periods allowed between treatments and follow up crops.
Japan	In establishing MRLs, inadvertent residues from rotational crop situations have not been considered.
Korea	MRL setting of general crops also apply to Rotational crops.
Mexico	There is no a procedure set for this situation.
New Zealand	NZFSA is currently developing policies to handle rotational crop residues. Any such residues found are subject to a risk assessment to direct appropriate risk management activity.

Portugal	Rotational crop studies are required for an authorization of a PPP what permits to establish either rotational crop MRLs or conditions for use of the PPP. A minimum time period can be set before other crops can be planted, or the label may specify which crops are permitted in rotation, either because (1)the pesticide is already approved for direct application to the other crops, or (2) data have been submitted to support establishment of rotational crop MRLs for the inadvertent residues.
Switzerland	To avoid inadvertent residues CH applies various measures such as recommendations for rotational crops, which means that critical crops for which inadvertent residues are to be expected have to be avoided.
UK	In calculating MRLs, account is taken of residues that may arise from residual amounts of pesticides in soil resulting from previous spraying on other crops.
US	EPA requires rotational crop studies that permit the agency to establish either rotational crop MRLs or conditions for use of the pesticide that will not result in residues in crops for which no MRL or exemption is in place. EPA may establish minimum time periods before other crops can be planted, or the label may specify which crops are permitted in rotation, either because (1) the pesticide is already approved for direct application to the other crops, or (2) data have been submitted to support establishment of rotational crop MRLs for the inadvertent residues. The only rotations permitted are those specified on the label.
EC	The occasional occurrence of high residues in rotational crops requires intensive regulation. In general several management options occur. 1. Setting of restrictions concerning crop rotation is the most common option. 2. Not granting any authorisation is the less favourable option. 3. The third option is establishing MRLs for rotational crops. Overall a case by case decision has to be taken, after careful examination of the overall database, the envisaged uses of the compound in question, the risk for consumers, the environment and other factors. The first and second options have to be taken into account by Member States as a management decision during the authorisation process of plant protection products. The third option is taken by the European Community when setting MRLs.

Categories of MRLs Established (continued)

Question 17. Do you have any provisions for setting MRLs for residues that result from use of a pesticide to deal with unexpected emergency pest outbreaks, and if so, what standards apply?	
Australia	The APVMA has the ability under its governing legislation to issue emergency permits (approvals) specifically for emergency outbreaks. Specific MRLs may be established in association with any permit approval if required.
Austria	If an emergency exemption is granted to allow use of a pesticide on a crop for which it is not registered, the MRL has to be kept. This has to be proved by data. If the MRL cannot be kept, no exemption can be granted.
Canada	If an emergency registration is granted to allow use of a pesticide on a crop for which it is not registered, residues of the pesticide must not exceed the 0.1 ppms default MRL set under provision B.15.002(1) of the FDR. The same food safety standards apply to this emergency use registration and the same safety determinations must be made.
Czech Republic	In some cases, Temporary MRLs may be set and should then be listed in Annex III part A and B. Temporary MRLs should in particular be set in the following cases: – for national MRLs which have not yet been harmonized – for honey and herbal infusions; – in exceptional circumstances where contamination by plant protection products has taken place; – where new products are listed in Annex I and a Member State requests it, in order to have enough time for a comprehensive scientific assessment and provided that no risk to the consumer has been detected. See http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm for details please.
Ireland	Article 16(1)(a) of Regulation (EC) No 396 of 2005 can be used for such emergencies.
Japan	We do not have such provisions.
Korea	If an emergency exemption under KFDA is granted to allow use of a pesticide on a crop for which it is not registered, KFDA must also establish an MRL in order to allow foods with residues of the pesticide to be legally distributed in Korea.
Mexico	In an emergency, the Ministry of Health may approve the use of a pesticide for a specific pest control, in a specific crop. This is made in coordination with the agency that responds directly the emergency. The product approved is restricted to avoid diversion and once the pest is controlled, it is cancelled.
New Zealand	No. However, New Zealand does have a default MRL limit of 0.1mg/kg for any pesticide on any crop where no specific MRL has been set for that pesticide/crop combination and will register products if the default MRL is considered appropriate.
Portugal	In certain circumstances as when unexpected emergency pest outbreaks, an MRL is set, by DGADR usually based on the information we can get from other E.U. Member States or even from the Codex.

Switzerland	No; the legal basis for the application of plant protection products for emergency cases is the PSMV, where no explicit requirement for the establishment of an MRL is formulated. Based on evaluation of the data available it would be possible however to established an MRL if necessary on a case by case basis.
UK	No such provisions exist at present, but EC Regulation 396/2005/EEC will provide derogation for Member States to authorize use in emergency situations (and allow the consequent marketing of such treated food or feed within its own territory) provided it does not constitute an unacceptable risk. Such authorizations will be immediately notified to other Member States and the EC authorities with a view to setting a temporary MRL or taking any other necessary measures.
US	If an emergency exemption under FIFRA is granted to allow use of a pesticide on a crop for which it is not registered, EPA must also establish an MRL in order to allow foods with residues of the pesticide to be legally distributed in the U.S. The same FFDCA food safety standards apply to these MRLs as apply to all other MRLs, and the same safety determinations must be made.
EC	Article 18.4 of Regulation (EC) No 396/2005 gives to the Member States the opportunity to react on unexpected emergency pest outbreaks and to deviate from EU MRLs provided that such food or feed does not constitute an unacceptable risk to consumers. Such deviations have to be notified immediately to the European Commission, EFSA and the other Member States in order set temporary MRLs or taking other necessary measures.

Categories of MRLs Established (continued)

Question 18. Do you have a crop grouping system that allows for the establishment of a single MRL to cover residues in related crops through the use of representative crops? Please describe	
Australia	The crop grouping system applied by Australia is based on the Codex Classification of Food and Animal Feeds and the guideline which includes the crop grouping scheme is at the link :http://www.apvma.gov.au/guidelines/rgl24.shtml
Austria	Yes. In Austria, crop grouping is possible according to the rules outlined within the European Community (see Guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs).
Canada	Yes, PMRA has established crop groupings in the Residue Chemistry Guidelines (Dir98-02; Section 15) and has established the same MRL for all crops in a crop group or sub-group based on residue data from the specified representative commodities.
Czech Republic	Yes, Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_029/l_02920060202en00030025.pdf
Ireland	Yes. There is an EC guidance document, 7525/95, detailing how MRLs can be applied to crop grouping system.
Japan	We have a crop grouping system which applies to specific commodities, such as citrus fruits. For grouping commodities, they should meet the requirements given on the web site at the address below. When Japan adopts MRLs of other countries as Japanese MRLs, we may take the crop grouping in those countries into consideration. http://www.acis.famic.go.jp/shinsei/3986/3986hyou4.pdf (in Japanese) http://www.acis.famic.go.jp/shinsei/3986/3986hyou5.pdf (in Japanese)
Korea	No. But KFDA is considering setting a crop grouping system especially for the minor corps.
Mexico	Yes, MRLs may be established for a crop group, it depends on the use and consumption of these crops, based on the crop groups established by the Codex Alimentarius.
New Zealand	NZFSA follows the Codex Crop Grouping classification system, and has identified suitable representative crops for most crop groups for which MRLs are usually requested.
Portugal	Yes, we have a guidance document from the European Commission informing about possible extrapolations from a representative crop to a group of crops: SANCO 7525/VI/95-rev.8.

Switzerland	Yes; CH applies the same system as the EU (Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 - rev.8, 1February 2008).
UK	Crop grouping is not employed in setting MRLs. However there are established procedures that allow for the extrapolation of an MRL from one crop to another under specific circumstances. These procedures are used for the setting of both UK and EC MRLs.
US	Yes, EPA has established crop groupings in Title 40 of the *Code of Federal Regulations* Part 180.40-41 and will establish MRLs to cover all crops in the group or sub-group based on residue data from the specified representative commodities. In addition, Section 180.1 establishes commodity definitions to permit MRLs established for one crop to apply to closely related commodities (e.g. bananas and plantains, peaches and nectarines, etc.).
EC	Annex I of Regulation (EC) No 396/2005 provides a crop grouping system. The system in place allows for the establishment of a single MRL to cover residues in related crops through the use of representative crops. Possible extrapolations of results from residue trials data generated in one crop to other crops or crop groups under certain circumstances are described in detail in the document Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs, SANCO 7525/VI/95 - rev.8 of 1 February 2008 (http://ec.europa.eu/food/plant/protection/resources/app-d.pdf).

Categories of MRLs Established (continued)

Question 19. In cases where crop-specific residue data may not exist, do you allow data to be transferred from a similar crop in order to establish a MRL?	
Australia	Crop extrapolations are also described in the document at the link above.
Austria	Yes. In Austria, "extrapolation" is possible according to the rules outlined within the European Community (see Guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs).
Canada	Only in very limited cases, will PMRA extend residue data from one crop to another similar crop for the purpose of setting an MRL.
Czech Republic	Yes, following Guidelines on comparability, extrapolation, group tolerances and data requirements for pesticides residues in food and raw agricultural commodities. It is aimed not only at those intending either to register a plant protection product or to establish a maximum residue limit (MRL) for a plant protection product in a specific commodity in the European Union but also at those responsible for regulating such substances and commodities. Although self-standing, it is complementary to other guideline documents with which it is best read: http://ec.europa.eu/food/plant/protection/resources/app-d.pdf
Ireland	Yes in accordance with extrapolation guidance.
Japan	If data allow, we may use extrapolation.
Korea	Yes. MRLs established for one crop may be applied to closely related crops (e.g. pepper and sweet pepper, etc.).
Mexico	This case is not considered on the current regulation.
New Zealand	Yes, Page 35-38 of the ACVM data requirements for a food or feed use clearance plant compound details the ACVM process for undertaking this, this document can be located at the following web link: http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/pc-food-clearance.pdf
Portugal	Yes, in accordance with the guidance document SANCO 7525/VI/95-rev.8.
Switzerland	Yes, see comment 18.
UK	Yes, as described above. The details are provided in an EC guidance document 'Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs' see http://ec.europa.eu/food/plant/protection/resources/app-d.pdf
US	As mentioned above, Title 40 of the *Code of Federal Regulations* Section 180.1 establishes commodity definitions to permit MRLs established for one crop to apply to closely related crops (e.g. bananas and plantains, peaches and nectarines, etc.)
EC	See answer to question 18.

Categories of MRLs Established (continued)

Question 20. Are MRLs based on residues in the raw agricultural commodity as a whole, or only are they based only on the edible portions?	
Australia	MRLs are based on the whole commodity as described in the Codex Classification of Food and Animal Feeds.
Austria	Generally, MRLs are based on the residues in the raw agricultural commodity as a whole (in order to reflect the commodity in commerce). The same is true for Regulation 396/2005 (coming into force by 1.9.2008).
Canada	Generally, MRLs are established to cover the residues in the raw agricultural commodity as a whole and are intended to reflect the commodity in commerce.
Czech Republic	Generally, MRLs are based on the residues in the raw agricultural commodity as a whole. The MRLs are intended to reflect the commodity in commerce.
Ireland	MRLs are based on the whole commodity.
Japan	It is decided on a case by case basis. In principle, MRLs are set for edible portion of the commodity. However, for some commodities, MRLs are set for the whole commodity in accordance with the rules for portions to which MRLs apply. These rules are shown at: http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/r01_a.pdf"
Korea	Generally, MRLs are based on the residues in the raw agricultural commodity as a whole. The MRLs are intended to reflect the commodity in commerce.
Mexico	The MRLs are based as a whole.
New Zealand	MRLs are based on the edible portion for all commodities except bananas, citrus fruit and Kiwifruit. New Zealand MRLs generally follow those set for Codex Pesticide MRLs.
Portugal	Generally, MRLs are based on the residues in the raw agricultural commodity as a whole. The MRLs are intended to reflect the commodity in commerce.
Switzerland	On the raw agricultural commodity.
UK	Under the EC regime, MRLs are based on residues in the raw agricultural commodity, however dietary risk assessments considered as part of the authorisation of use underpinning MRLs proposal may also make use of residues in the edible portion.
US	Generally, MRLs are based on the residues in the raw agricultural commodity as a whole. The MRLs are intended to reflect the commodity in commerce.
EC	In most cases as a whole, but there are exceptions (e.g. for tree nuts, the MRLs refer to the whole product after removal of the shell).

Categories of MRLs Established (end)

Question 21. How are metabolites and degradates considered in establishing MRLs?	
Australia	Metabolites and degradates are considered in accordance with guidance and principles as described in the FAO Manual and as currently employed by the JMPR.
Austria	Metabolites are considered (based on the quantity as a result of the metabolism studies on plants and based on their toxicological significance). The metabolites of concern are included into the residue definition (the residue definition for risk assessment may be different from the residue definition for monitoring purposes).
Canada	Plant and livestock metabolism studies form the basis for determining the residue definitions for risk assessment and enforcement, which may be different. Where appropriate, metabolites and degradates may be included in the residue definition for enforcement (i.e. MRL expression).
Czech Republic	A proposal for the residue definition should be made. There are three general considerations (their basic toxicology; their presence in significant amounts and the suitability of the analytical procedure for routine monitoring) which are fundamental to the decision as to whether or not specific metabolites/degradation products should be included in the definition and expression of a residue. After establishing residue definition we can establish MLRs.
Ireland	Residue definitions are established for consumer risk assessment and for monitoring purposes. Where metabolites/degradates are of toxicological concern then they are included in the consumer risk assessment residue definition. The residue definition for monitoring is dependent on the ability of the available analytical methods to detect and quantify the molecules which may be used in the residue definition for monitoring.
Japan	We consider whether metabolites and degradates should be included in the residue definition, based on toxicological evaluation and residue trials.
Korea	KFDA considers metabolites and degradates in making the required safety findings for pesticide residues in food and includes them as part of the MRL definition or expression. The residue definition for an MRL may be different from the residue definition for risk assessment.
Mexico	The metabolites and degradates are considered as appropriate.
New Zealand	Where a metabolite or degradate is significant for determination of the residue it is specified in the residue definition of the proposed MRL. Where a metabolite or degradate is considered toxicologically significant its levels will be considered in the dietary exposure assessment for the pesticide.
Portugal	PT considers metabolites and degradates of toxicological relevance for the residue definition or expression. The residue definition for an MRL may be different from the residue definition for risk assessment.

Switzerland	Metabolites and degradates are considered in the residue definition triggered by the 5-10% criteria as used in the EU. Moreover the evaluation of the toxicological profile of metabolites/degradates in the risk assessment is the basis to decide about the inclusion if metabolites/degradates in the monitoring.
UK	Potential metabolites and degradates are considered during the review of an active substance when a residue definition for monitoring (MRL) purposes is proposed. MRL proposals will then be based on this residue definition.
US	EPA considers metabolites and degradates in making the required safety findings for pesticide residues in food under FFDCA and, where appropriate, includes them as part of the MRL definition or expression. The residue definition for an MRL may be different from the residue definition for risk assessment.
EC	Metabolites are taken into account in different ways. Metabolites that occur in plants but not in the test animal are normally described in the residue definition for enforcement. If metabolites may pose a risk for consumers or animals they may be taken into account by using a residue definition for risk assessment.

Calculation of MRLs

Calculation of MRLs (continued)

Question 23. Is the numerical value of the MRL used to determine if there are intake (dietary risk) concerns associated with the use of a chemical? Are data generated that could be used in place of the MRL such as residue monitoring data on commodities?	
Australia	The residue inputs into the dietary exposure models are those as determined by the JMPR and WHO in accordance with the processes of the JMPR. In some situations where monitoring data are available such as data generated by the Australian National Residues Survey, such information may be used for dietary exposure estimates in place of field trial data
Austria	If the consumer risk could not be excluded using the MRLs in the respective calculations, further refinement will be performed (like STMRs, processing studies, HRs). Monitoring data are not used.
Canada	PMRA conducts dietary exposure assessments in a tiered approach. If the first tier (basic) of the exposure assessment, which incorporates the MRLs, indicates a potential health concern, PMRA conducts a more refined assessment based on median or anticipated residues, processing studies, monitoring data, etc.
Czech Republic	If risk assessment using the MRL indicates possible or theoretical risk concerns, EFSA and Rapporteur MS conduct more refined analyses based on anticipated or actual residues derived from statistically representative residue data, processing studies, etc. in conjunction with other MSs and EC.
Ireland	A tiered risk assessment is carried out where one starts with the TMDI assessment which uses the MRL values. If the TMDI estimate is acceptable then no further calculations are required. Where the TMDI calculation exceeds the toxicological end point then refinements are introduced to ensure that the dietary estimates are as realistic as possible.
Japan	The numerical value of the MRL is used in the calculation of long-term dietary intake of residues from individual food commodities. If the theoretical maximum daily intake estimate indicates dietary risk, long-term dietary intake is calculated using the mean of residue concentrations in trials.
Korea	If risk assessment using the MRL indicates possible or theoretical risk concerns, KFDA conducts more refined analyses based on anticipated or actual residues derived from statistically representative residue monitoring data, processing studies, etc.
Mexico	Yes, MRL are used for risk evaluation, regarding other data they are available only for specific products.
New Zealand	No, intake concerns are determined from the calculated supervised trial median residue figure, residue monitoring data on commodities is not regularly used for estimation of dietary risk. However New Zealand does have extensive residue monitoring programmes that are compared against existing MRLs and potential daily intakes estimated in each case where breaches are found.

Portugal	Till now the STMR (Supervised Trials Median Residue) is he value used in the chronic risk assessment and the HR is used for the acute risk assessment. In cases of risk, information of residues in the processed commodity is also used. At E.U. level sometimes residue monitoring data are used for setting MRLs.
Switzerland	Yes; consistent with the international practice in CH the numerical value of the MRL is compared with toxicological relevant values such as ADI, ARfD considering also intake estimations. If the comparison indicates a concern, risk mitigation measures are taken either by lowering the MRL or withdrawal of the corresponding approvals. No.
UK	In the EU MRLs are generally proposed in relation to an authorised use in at least one member state, and a dietary risk assessment is conducted as part of the evaluation of that use. This uses the HR (Highest Residue) for acute (short term) risk and STMR (Supervised Trials Median Residue) value for chronic (long term) risk. It is UK policy that MRLs should not be set at a level that would lead to intakes greater than the relevant toxicological end point (e.g. ARfD). Under EC Regulation 396/2005/EEC an assessment of the dietary risk for each MRL value will be undertaken before the MRL is set.
US	If risk assessment using the MRL indicates possible or theoretical risk concerns, EPA conducts more refined analyses based on anticipated or actual residues derived from statistically representative residue monitoring data, processing studies, etc.
EC	The risk is calculated using the HR for the acute intake and the STMR for the chronic. The methodology is however under discussion. The use of monitoring data for MRL setting is only in certain circumstances foreseen, as described in Article 16 of Regulation (EC) No 396/2005, and in particular: (a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Article 8(4) of Directive 91/414/EEC; or (b) where the products concerned constitute a minor component of the diet of consumers, and do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals; or (c) for honey; or (d) for herbal infusions; or (e) where essential uses of plant protection products have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC; or (f) where new products, product groups and/or parts of products have been included in Annex I, and one or more Member States so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated, provided that no unacceptable safety concerns for the consumer have been identified.

Calculation of MRLs (end)

Question 24. Are data other those generated by the manufacturer used in the establishment of a MRL?	
Australia	As indicated in the response for Question 7, data from sources other than chemical manufacturers may be used to establish an MRL. Scientific studies including toxicology, residue, animal transfer, processing and metabolism studies are reviewed in relation to determining MRLs. Data requirements include stringent criteria concerning rigor and independence of studies evaluated in assessments. Dietary exposure assessments conducted in determining MRLs are based on food consumption data for raw commodities derived from individual dietary records from the latest National Nutrition Survey.
Austria	As a matter of principle, the evaluations are based on data provided by the manufacturer. For minor uses/minor crops, interested parties as well (like crop producers) can develop residue data.
Canada	Any person may submit data in support of the establishment of an MRL. For example, the Pest Management Centre of Agriculture and Agri-Food Canada works with growers and specialty crop producers to develop residue data for "minor" (or specialty) crops.
Czech Republic	It depends; usually we used submitted or available data by manufacturer or residue data for specialty (or "minor") crops.
Ireland	Any relevant available data may be used to set an MRL.
Japan	Yes, in particular in the case of minor crops.
Korea	As indicated above, any person may submit data in support of the establishment of an MRL. For example, pesticide manufacturer and universities can develop residue data for major (or "minor") crops.
Mexico	No, the only data used are the one submitted by the manufacturer.
New Zealand	Yes, feedback on residues from surveillance and monitoring programmes, or through growers may lead to a modification of an MRL. We also take into account trade-related information such as MRLs set in countries importing New Zealand foods, and Codex MRLs.
Portugal	In the past the official services of the Ministry of Agriculture developed a large number of residue trials in away to support some uses. At the moment only sporadically the crop producers of minor crops develop residue data.
Switzerland	Yes; Minor use situations: Data from residue trials conducted in neighbour countries may be taken into consideration.
UK	As indicated above, any person may submit data in support of the establishment of an MRL. In addition generally available data on food consumption and consumption trends may be employed during the assessment of intake (dietary risk) as part of the MRL establishment process.
US	As indicated above, any person may submit data in support of the establishment of an MRL. For example, the U.S. Department of Agriculture Inter-regional Research Project No. 4 (IR-4) works with specialty crop producers and universities to develop residue data for specialty (or "minor") crops.
EC	Yes, also growers or other organizations may submit data (see also answer to question 7).

Harmonisation Considerations

Question 25. Do your national laws or policies include routine consideration of MRLs established by the Codex Alimentarius Commission?	
Australia	Codex MRLs (CXLs) are considered as part of the APVMA requirement to consider trade as a criterion prior to registration of a product. In accordance with the *Food Standards Australia New Zealand Act 1991*, FSANZ is required to have regard to international standards when developing MRLs for inclusion in the *Australia New Zealand Food Standards Code*.
Austria	Yes, but manly via the MRL harmonization process within the European Community. With respect to harmonized MRLs within the EU (coming into force by 1.9.2008), all CXLs have been considered if no risk for the consumer has been identified.
Canada	In practice, PMRA considers Codex Alimentarius MRLs when setting Canadian MRLs, and where possible, provides an explanation when a deviation exists between the Canadian MRL and the Codex MRL.
Ireland	Yes.
Japan	Yes.
Korea	Yes, KFDA does consider Codex Alimentarius MRLs when setting Korea MRLs.
Mexico	Yes, it is considered in Article ninth (transitory) of the Regulation for Registries, Authorizations of Imports and Exports and Export Certifications for Pesticides, Fertilizers and Toxic or Dangerous Substances and Materials.
New Zealand	As imported food may comply with CAC MRLs, and New Zealand MRLs are based on New Zealand GAP, under New Zealand Law this consideration is not required. MRLs are however, compared against Codex MRLs where they exist.
Portugal	Yes, Codex Alimentarius MRLs are considered when we have to propose MRLs for an active substance for which we are rapporteur Member State, at E.U. level. Also, in cases of imports, those MRLs were evaluated for risk assessment and when acceptable they were introduced in the legislation. At the moment as we can not set national MRLs anymore, the procedure of Reg.396/05 must be followed.
Switzerland	Yes; for instance for the establishing of "import MRLs".
UK	Codex MRLs are considered as a part of the EC MRL setting process.
US	Yes, FFDCA requires EPA to consider Codex Alimentarius MRLs when setting U.S. MRLs, and to harmonize with them or publish an explanation for the deviation in the *Federal Register.*
EC	Yes.

Harmonisation Considerations (continued)

Question 26. How are Codex MRLs factored into your MRL setting process? Under what circumstances would you accept a Codex MRL for a given chemical/commodity combination? (for example, in the absence of a national MRL)	
Australia	In accordance with the *Food Standards Australia New Zealand Act 1991*, FSANZ is required to have regard to international standards when developing MRLs for inclusion in the *Australia New Zealand Food Standards Code*. FSANZ relies on public consultation to determine those foods which may be implicated by MRL variations, specifically reductions and deletions. FSANZ notifies all proposed variations to the WTO and publicly consults on proposed changes to MRLs listing all amendments on the FSANZ website to assist member nations, industry sectors and other interested parties in identifying any impacts of proposed deletions or reductions of specific MRLs. FSANZ includes details of Codex MRLs in consultation documents. FSANZ routinely requests comment on any possible ramifications of approving proposed MRLs including issues in relation to differences from international MRLs. Submissions including data demonstrating a requirement for certain MRLs to be retained or varied may be made in relation to proposed MRL variations. FSANZ considers retaining MRLs proposed for deletion or incorporating MRLs at levels other than those consulted on where this is necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not present public health or safety concerns. This may result in incorporating a Codex MRL in the *Australia New Zealand Food Standards Code* in the absence of a national MRL.
Austria	See point 25.
Canada	As indicated in question #25, PMRA takes into consideration Codex MRLs when setting Canadian MRLs; however, Canada does not accept Codex MRLs in the absence of a national MRL.
Ireland	Codex MRLs are normally included into EU legislation where they are required to support international trade and they are shown to be safe for European consumers
Japan	Japan accepts Codex MRLs as far as possible as Japanese MRLs, where they exist, regardless of whether the pesticides concerned are registered in Japan. However, Codex MRLs should still undergo the risk assessment process in Japan.
Korea	Korea does accept Codex MRLs in the absence of a national MRL.
Mexico	According to the Mexican Regulation, it is possible adopt a Codex MRL, as long as a national MRL is not in place.
New Zealand	Any imported foods may comply with CAC MRLs, (the setting of national MRLs is specific to New Zealand good agricultural practice with some consideration given to imported commodities).
Portugal	It will be accepted if the Good Agricultural Practice in which it was based is similar to the proposed for the E.U. and if it provides no intake concern.

Switzerland	Codex MRLs may be directly used in the situation where no national MRL has been established as mentioned above in comment 25.
UK	Under the current MRLs regime, where no statutory EC or UK MRL has been set, traders are advised to comply with appropriate MRLs set by Codex. The UK's Food Safety Act states that foodstuffs must be fit for consumption and not contaminated by material that may injure the health of consumers. In the absence of statutory MRLs, Codex MRLs provide an indicator of fitness for consumption and exceeding these levels would not necessarily be an offence (although this would ultimately be a matter for the Courts).
US	As described in the response to Question 26, EPA considers Codex MRLs in establishing U.S. MRLs. The U.S. does not accept Codex MRLs in the absence of a national MRL.
EC	When the EC has agreed to the safety of this CXL in the Codex Alimentarius Commission and when there is no dietary intake concern associated with such MRL.

Harmonisation Considerations (continued)

Question 27. Would you harmonize with a Codex MRL or another national MRL that is higher than the MRL set by your national authority, provided there were no intake or dietary concerns?	
Australia	The *Food Standards Australia New Zealand Act* 1991 stipulates the objectives of food regulatory measures that FSANZ must consider when considering MRLs for inclusion in the *Australia New Zealand Food Standards Code*.
Austria	Yes. Austria took part in a work sharing project including USA and Canada for the active substance Spirotetramat. During this process, we realized some problems for harmonizing MRLs between Europe and NAFTA mainly because of the different classes of MRLs used. The calculation itself may not be the main contributor of these differences. Using the same classes and the same calculation may be the crucial point and has to be discussed within the European Union as well.
Canada	In any request to establish or revise an MRL, the available scientific data determines the appropriate MRL.
Czech Republic	Answer is related to all given questions concerning Codex MRLs. It is very well known that Codex standards are safety-based standards for public health protection purposes and that the Codex Committee on Pesticide Residues (CCPR) is charged to develop MRLs for pesticides (CZ participates on CCPR). – Some MSs expressed their concern that although Codex MRLs were established in order to ensure harmonisation at the international level, and involved considerable efforts from governments participating in the process, the value of this work was diminished by the application of national regulations or commercial requirements without taking into account Codex MRLs. – Some MSs have taken into account Codex MRLs when establishing national MRLs or have actually integrated Codex MRLs into their national or regional regulations.
Ireland	It is normal to harmonise EU legislation with the relevant CODEX MRL where they are necessary to support international trade and where the MRL is shown to be safe for EU consumers. The residue data base supporting the CODEX MRL would also have to contain a sufficient number of valid residue trial data to support the MRL.
Japan	In principle, yes.
Korea	Yes. If it has scientific data, Korea will accept Codex MRL.
Mexico	The possibility to do so exists, but it has never been done.
New Zealand	Due to the provision in the MRL Standard to allow the use of CAC MRLs in imported foods harmonization to a higher CAC MRL would not be required. New Zealand would not harmonize to another national MRL unless there was considered necessary for trade purposes as the New Zealand MRL is used to monitor compliance with New Zealand domestic GAP. However, if a pesticide used on imported crops does not have either a Codex MRL or a domestic MRL, we will consider setting an import MRL where there are no dietary intake concerns.

Portugal	Yes, in the past. For the moment no more national MRLs can be set, all have to be firstly evaluated and Regulated at E.U. level and only after that an authorization at Member State level can be given.
Switzerland	Yes; on a case by case basis.
UK	Under the present system, Member States may set national import tolerances to cover residues in imported food, provided these do not conflict with EC levels set on a definitive basis.
US	Yes, EPA would set a U.S. MRL at a higher level to cover residues in imported foods, provided FFDCA safety standards were met.
EC	Yes, if there is a request to do so and if the CXL is relevant for trade/export to the EU.

Harmonisation Considerations (end)

Question 28. Are there any other questions that would make this template more useful for future discussions?	
Australia	Does your country require efficacy data to determine the use pattern or GAP that relates to the MRL establishment process? Are your MRLs on the internet? If so, where? If not, attach a hard copy for scanning. Do you recognise another MRL group e.g. ASEAN Harmonization of MRLs for vegetables or Gulf States harmonisation? Do you have a default MRL (e.g. 0.01mg/kg) or another default value? Do you recognise Codex MRLs for all imports? Do you recognise Codex MRLs where there are no MRL set in your country? Does a zero tolerance apply where your country does not have its own MRLs or accept Codex MRLs?
Canada	Does your national MRL setting policy/approach rely on domestic GAP (good agricultural practice)?
Czech Republic	Not at this moment.
Mexico	No.
New Zealand	None that come to mind.