Chemical Risk Assessment at the International Level (JMPR as example)

Yukiko Yamada, Ph.D.

6 December 2018, Tokyo

Contents

Objectives

- To understand the framework and process of establishing Codex standards (MRLs and MLs) for chemicals in foods and feeds
  – using pesticide residues as examples
  - To show the logic in and critical aspects of the whole evaluation process of JMPR
  - To point out the importance of applying basic science and past experiences in interpreting experimental data

Introduction

WTO's SPS Agreement

- The Agreement on the Application of Sanitary and Phytosanitary Measures is one of the WTO Agreements covering food safety
- Article 3 of the SPS Agreement describes "Harmonization"
- The SPS Agreement describes the need for:
  - Scientific principles and sufficient scientific evidence (Art. 2.3);
  - Using Codex standards, guidelines or recommendations as a basis (Art. 3.1); and
  - Conducting risk assessment (Art. 5.1)

SPS Agreement

- However, the SPS Agreement allows:
  - Introduction or maintaining measures which result in higher level of protection, if:
    - There is scientific justification or as a consequence of the level of protection a Member determines to be appropriate
  - Where relevant scientific evidence is insufficient, provisional measures may be adopted on the basis of available pertinent information:
    - Additional information shall be sought
    - Within a reasonable period of time, the measure needs to be reviewed

Codex Statements of Principle Concerning the Role of Science …

- First Statement
  - The food standards, guidelines and other recommendations … shall be based on the principle of sound scientific analysis and evidence ….
- Art. 2.2 of the SPS Agreement
  - Members shall ensure that any sanitary … measure is … based on scientific principles and is not maintained without sufficient scientific evidence ….

Basis

- Science!
- Risk analysis
  - Risk assessors
    - JMPR
    - JECFA
    - Expert consultations as necessary
  - Risk manager
    - Codex Alimentarius Commission
    - Its subsidiary bodies, working in specific areas of food safety
- Without scientific data, no risk assessment or risk management possible.

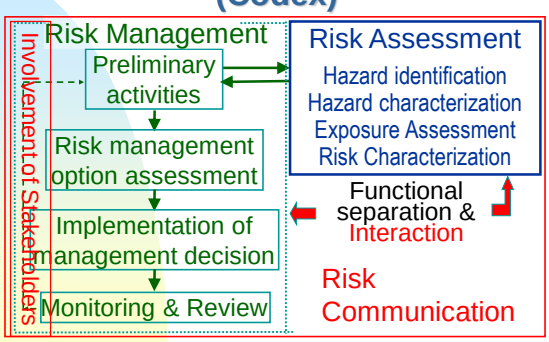
Codex Recommendations on Chemicals

- Chemicals covered
  - Residues of pesticides and veterinary drugs
  - Contaminants and natural toxins
  - Food additives
  - Nutrients
- Recommendations
  - Standards (Maximum Residue Limits, Maximum Levels, Maximum Use Levels)
  - Codes of Practice (to make foods safer)
  - Guidelines (for testing, etc.)

Risk Analysis in Codex

- Implementation decided in 1991 by FAO/WHO and GATT
- Implemented in 1993
- Risk analysis consists of:
  - Risk assessment (by JMPR, JECFA, JMPR and expert consultations)
  - Risk management (by CAC)
  - Risk communication (mostly by gov'ts)
- MRL or ML is one type of risk management measures considered by Codex
  - MRLs are estimated and recommended by JMPR/JECFA
  - MLs are estimated by EWG of CCCF

Risk Analysis Framework (Codex)



Codex MRLs and MLs

- Codex Maximum Residue Limits for pesticides/veterinary drugs
- Codex Maximum Levels for contaminants
- They are within the framework of the SPS Agreement and may be used as reference:
- Considered by the Codex Committees on:
  - Pesticide Residues (CCPR)
  - Veterinary Drugs in Foods (CCRVDF), or
  - Contaminants in Foods (CCCF),
- Adopted by the Codex Alimentarius Commission

Codex Committee on Pesticide Residues

- CCPR:
  - Meets annually
  - hosted by the Netherlands (1966-2007) and then China (2007-)
- Terms of reference:
  - Establish MRLs in foods and feeds
  - Priority lists of pesticides for evaluation
  - Methods of sampling and analysis
  - Extraneous MRLs and other issues

Codex Definition of Pesticide

- Any substance
  - intended for preventing, destroying, attracting, repelling, or controlling any pests including unwanted species of plants or animals
  - during production, storage, transport, distribution and processing of
  - food, agricultural commodities or animal feeds, or
  - which may be administered to animals for the control of ectoparacites
  - also intended for use as a plant-growth regulator, defoliant, desiccant, fruit-thinning agent, or sprouting inhibitor and
  - before or after harvest to protect the commodity

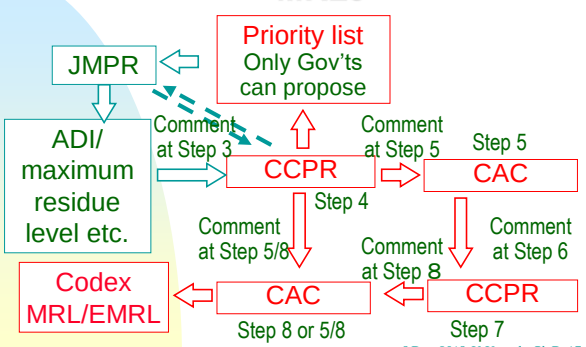
Codex Definition of Pesticide Residue

- Any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide.
- Includes any derivatives or a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

Codex Definition of Maximum Residue Limit for pesticide

- Maximum concentration (in mg/kg) to be legally permitted in or on food commodities and animal feeds
- Based on GAP data
- Foods derived from commodities that comply with the MRLs are intended to be toxicologically acceptable
- Derived from estimation by JMPR following:
  - Toxicological assessment; and
  - Review of residue data from supervised trials reflecting national GAP

Codex Elaboration Procedures of MRLs



Joint FAO/WHO Meeting of Pesticide Residues (JMPR)

Official name

MRL recommendation

Joint Meeting of
the FAO Panel of Experts on Pesticide Residues in Food and the Environment
and
the WHO Core Assessment Group

JMPR is independent from the Codex system
Provides scientific advice to Codex and any other interested parties

History of JMPR

- Apr. 1959: Panel of Experts on the Use of Pesticides in Agriculture organized by FAO
- Oct. 1961: First JMPR (Meeting of WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture)
- After 1963: JMPR held in September every year

Responsibilities of JMPR

- Evaluation of toxicological data, residue data and monitoring data of the following:
  - Residues of pesticides in foods and animal feeds arising from their use in accordance with GAP
  - Compounds previously used as pesticides but no longer registered as pesticides but due to their chemical characteristics (persistence) present in foods and animal feeds
- Unlike Codex meetings, participants must not represent their countries or organizations
- They act as individual scientists

Evaluation by JMPR

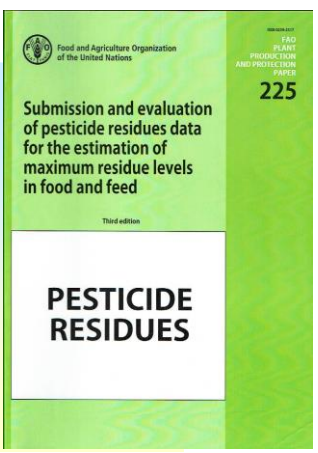
- Toxicological evaluation (WHO Core Group)
  - *Principles and Methods for the Risk Assessment of Chemicals in Food* (EHC 240, WHO 2009) under revision
- Residue data evaluation (FAO Panel)
  - *FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed* (FAO 2016, 1st version in 1997)
  - Exposure assessment also in EHC 240

Basic principles of JMPR operation

- JMPR procedures continue to evolve. Every year changes are recorded in JMPR Reports as general considerations. It is a strength of JMPR that it develops the science as issues are foreseen.
- The guidelines and methods developed are applicable in the context of their origins and they should not be extrapolated too far.
- The JMPR operates as a team making best use of the different experiences and scientific knowledge of its members.

Recommendation of Pesticide MRLs by JMPR

Yukiko Yamada, Ph.D.

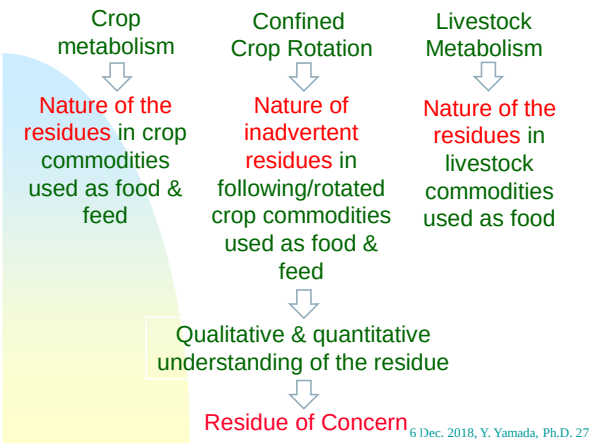


- Basis for evaluation by the FAO Panel
- Also contains what kinds of data shall be submitted
- The latest version (3rd) published in 2016

Overview of pesticide evaluation process for estimating maximum residue levels

1. Identification of the pesticide and its physical and chemical properties
   a. For unambiguous identification
   b. Name, structure (isomer information)
   c. Physical properties
   d. Chemical properties
   e. Such as hydrolysis, photolysis and volatility

2. Metabolism and environmental fate studies provide the essential data to decide on the likely nature of the residue occurring in food and feed commodities, and on residue definition for enforcement and risk assessment purposes.
   a. Crop (plant)
   b. Livestock (animal)
   c. Rotational crop
   d. They are not a part of toxicological studies
   e. Residues in edible portions and in feedingstuffs are of concern
   f. Residues in excreta are not of significant relevance



Conducting metabolism studies

- In metabolism studies, pesticide is applied to crops or administered to livestock in amounts and for durations of time that could occur in practice when the compound is used for pest control.
- In the case of crops, food and feed commodities are harvested after an interval expected under good agricultural practice.
- In the case of livestock, milk and eggs are collected and in due course the animal is slaughtered for collection of muscle (meat) and offal.
- The harvested animal and plant commodities are then examined for content of total residues and major residue components arising from the compound. Animal excreta and, in some cases, exhaled air are examined for elimination of the residue.

Five categories of crops

- Should be submitted for each type of crop group for which use is proposed
- Crops can be considered to belong to one of the five categories for metabolism studies:
  - Root crops (root and tuber vegetables, bulb vegetables);
  - Leafy crops (Brassica vegetables, leafy vegetables, stem vegetables, hops);
  - Fruits (citrus fruits, pome fruits, stone fruits, berries, grapes, banana, tree nuts, fruiting vegetables, persimmon);
  - Pulses and oilseeds (legume vegetables, pulses, oilseeds, peanuts, legume fodder crops, cacao beans, coffee beans); and
  - Cereals (cereals, grasses and forage crops).

3. Sampling and analysis generate the data needed for residue studies. Checking the applicability of the procedures is crucial for obtaining valid results.
   a. Can we use the data submitted?
      a. Specific?
      b. Interference?
      c. Sufficiently low LOQ? etc.
   b. Are the samples representative of the population?
   c. Can we enforce MRLs?

4. Selection of residue definitions suitable for enforcement and for risk assessment requires the examination of many studies: chemical properties such as isomer composition, hydrolysis and photolysis; metabolism in laboratory animals, livestock and crops; methods of analysis; and toxicity of metabolites. The situation may be further complicated if one pesticide is the metabolite of another or if two pesticides produce a common metabolite.

- The most important task of evaluators
- Determines the residue level.

5. Selection of appropriate trials for the evaluation is a key task of the evaluator, as it will influence the outcome of the evaluation.
   - Need full study reports describing the location, size of the lot, rows, trees, variety, weather, timing, application conditions, equipment, analytical methods, frozen storage period, etc. which affect the residue concentrations
   - Summary reports are not sufficient to estimate MRLs

6. The central part of the whole process: evaluating supervised trials data to produce MRLs suitable for Codex, and STMR and HR values suitable for use in risk assessments. Many factors affecting residue levels must be considered - application rate, number of applications, formulation and timing and pre-harvest interval.

- Comparison with GAP information on the approved labels
- Labels need to be approved by the respective governments. If not approved, JMPR is not in a position to use them.

Use pattern

The nationally authorized safe uses of pesticides are defined by the 'use patterns'.

- The pesticides may be applied at different dose rate and time before the harvest within the authorized maximum dose and over the minimum pre-harvest intervals (PHI).
- The 'critical GAP' (cGAP) comprises conditions when commodities are harvested after the authorised minimum pre-harvest intervals following the repeated applications at the permitted minimum intervals and maximum dose rates.
- The maximum residue levels should cover the residues in/on commodities treated according to the cGAP.
- The STMR and HR values used for estimation of long- and short-term intakes should correspond to residues deriving from the cGAP.

Supervised trials

- Supervised field trials (crop field trials) are conducted to determine pesticide residue levels in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues within GAP.
- For reliable estimation of maximum residue levels an adequate number of *independent trials* are required reflecting the cGAPs and conducted according to well-designed protocols that consider geographical distribution and the inclusion of a number of different growing and management practices, and growing seasons.

Selection of supervised trials

- The selection of supervised trials, which correspond to the critical GAP and suitable for estimation of MRL, STMR and HR values, is one of the most important phases of the evaluation of pesticide residues .
- It must not be performed automatically as it requires expert judgement in many cases taking into account several factors and the information obtained from the previous trials and relevant scientific studies.
- *The estimated MRLs can only reflect the maximum residues likely to occur if the residue data used for the estimation are properly selected regardless of whether computerised methods are used or not for assisting the procedure.*

GAP information required

- Valid copies of current labels must be provided, together with English translations of the relevant sections.
- Information should be provided on the list of individual crops that are included in a crop group indicated on a label.
- Labels reflecting current GAP should be clearly distinguished from 'proposed' labels.
- Summary information on GAP relevant to the submitted supervised trials and (current GAP with higher rates or smaller PHIs, etc. for the same pesticide on the same crop) should be submitted.

6 Dec. 2018, Y. Yamada, Ph.D. 37

Information on USE Pattern

- State the number of treatments per season only if specified on the label.
- Application rate should always be presented in metric units.
- In cases where g/hl or kg/hl (spray concentration) is given on the label, state this spray concentration but do not calculate the kg ai/ha equivalent with the average amount of spray liquid used per hectare.
- The pre-harvest interval (PHI) in days prescribed or recommended and stated on the label - should be presented for the commodities concerned.
- If different PHIs are recommended for the same or similar commodity, e.g. for glasshouse or outdoor grown crops, or in the case of higher dose rates, the particular circumstances should be clearly indicated.

6 Dec. 2018, Y. Yamada, Ph.D. 38

Criteria for selecting supervised trials

- Trials are usually conducted before registration is obtained; in many cases, the trials are based on the intended use, which is sometimes different from the registered one.
- Typically trials reflecting cGAP should be provided.
- Results from other supervised trials can provide supporting information, such as residue decline study or treatments with higher rates leading to residues below LOQ.
- Residue data are required primarily for mature crops at normal harvest. But residue dissipation studies on consumable crops complement the residue data obtained at normal harvest.

6 Dec. 2018, Y. Yamada, Ph.D. 39

Representative trials

- Residue data should be available from *independent* trials, preferably carried out in at least two separate years or at least representative areas of different weather conditions.
- If uses are authorised in regions with substantially different climatic conditions, trials should also be carried out in each region.
- Residue data from only one season may be considered sufficient provided that crop field trials are located in a wide range of crop production areas such that a variety of climatic conditions and crop production systems are taken into account.

6 Dec. 2018, Y. Yamada, Ph.D. 40

Timing of application in supervised trials

- *Application timing* is governed by plant growth stage (e.g., pre-bloom, 50% head emergence, etc.) or as number of days prior to harvest.
- Where a specific PHI is indicated on the label (e.g., "Do not apply this product less than 14 days prior to harvest."), that specific PHI must be used in the crop field trials as a component of the *c*GAP, while the growth stage at application is of minor importance.

6 Dec. 2018, Y. Yamada, Ph.D. 41

- Inversely, there are cases where the growth stage is a critical component of the GAP, (e.g., pre-emergence, at planting, pre-bloom, flag leaf or head emergence, etc.) while the PHI is of secondary importance. In these cases it is important to include as many varieties of the crop as possible in order to evaluate an appropriate range of PHIs (e.g., shorter and longer intervals from planting to maturity in the case of pre-emergence application to an annual crop). Basically in all trials both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

6 Dec. 2018, Y. Yamada, Ph.D. 42

Crop characteristics

- *Row crops* (potatoes, wheat, soya beans, etc.) are typically treated with broadcast sprays for which the treated plot area (length × width) is a key consideration.
- In contrast, for some crops such as tree nuts, tree fruits, trellised vegetables and vines, the crop height, crown height or tree height, i.e., treated foliage height, should be considered in order to allow crop row volume or tree row volume estimations or rate per unit area calculation as needed.

- Special consideration may be needed for foliar applications to '*tall' crops,* e.g., orchard and vine crops, hops, greenhouse tomatoes, where flat boom spraying is not common practice and (air assisted) mist blowing equipment is often used. It is important to consider and report both the spray concentration, e.g., kg ai/100 litres, and spray volumes, e.g., litres spray mixture/ha, at the various crop growth stages.

Number of supervised trials

- For reliable estimation of maximum residue levels an adequate number of independent trials is required reflecting the highest of national maximum GAPs , geographical distribution, different growing and management practices, and growing seasons.
- The JMPR has not specified the minimum number of trials required for estimation of maximum residue levels, high (HR) and supervised trial median residues (STMR).
- Currently there is no international agreement on the minimum number of trials to be provided for the estimation of STMR, HR and MRL.

Number of supervised trials

- For a comprehensive submission with similar critical GAPs, a minimum of 8 greenhouse trials is needed.
- For such greenhouse trials, the geographic distribution typically is not an issue. However for active ingredients which are susceptible to photodegradation, consideration should be given to locations at different latitudes.
- The number of post-harvest trials on a commodity should be at least four, taking into consideration the application techniques, storage facilities, and packaging materials used. At least three samples should be collected and analyzed in studies on bulk and bagged commodities.

General principles of selecting the residue data population(s)

- Only the results of supervised trials reflecting cGAP are considered.
- If sufficient number of trials reflecting cGAP are available from one country or geographical region, the MRL estimates should be based on those residue data alone.
- Where prior experience indicates that the agricultural practice and climatic conditions lead to similar residues, the critical GAP of one country can be applied for the evaluation of supervised trials matching this critical GAP but carried out in another country.

Selection of trials for evaluation

- Consider uniformity or continuity of residue population reflecting GAPs. When there is a large gap in residue values, the residue data and trial conditions need more stringent analysis.
- A larger data set *representing statistically not different residue populations* provides a more accurate estimation of the selected percentile than a small data set derived from trials representing only one critical GAP.
- Therefore, those GAPs which may possibly lead to a similar magnitude of residues may also be considered, and residue data may be combined for estimation of residue levels.

Combining residue data

- When considering combining different residue data, the distribution of residue data is carefully examined and only those datasets are used which may be expected to arise from the same parent populations, based on comparable GAP.
- This assumption can be confirmed based on prior experience and with suitable statistical methods. Mann-Whitney U-test or Kruskal-Wallis H-test. The calculations are easy using the available Excel template.

6 Dec. 2018, Y. Yamada, Ph.D. 49

General principles of selecting the residue data population(s)

- Dose rate may be within ± 25% of dose of cGAP. Note that the 2010 JMPR decided to take into account the proportionality of residues where applicable.
- Tolerances on the parameters should be those that would result in ± 25% change in the residue concentration, not ± 25% changes in the parameters themselves. It is ± 25% for application rate because application rate is directly proportional to residue concentration.
- The latitude of acceptable intervals around the PHI depends on the rate of decline of residues of the compound under evaluation.

6 Dec. 2018, Y. Yamada, Ph.D. 50

Proportionality concept

- Contained in REP 13/PR, Appendix VIII
- Active substances for which the concept can be used include insecticides, fungicides, herbicides, and plant growth regulators, except desiccants.
- The concept can be applied to data from field trials conducted within a rate range of between 0.3x and 4x the GAP rate. This is only valid when quantifiable residues occur in the dataset. Where there are no quantifiable residues, values may only be scaled down.

6 Dec. 2018, Y. Yamada, Ph.D. 51

- Scaling is only acceptable if the application rate is the only deviation from critical GAP (cGAP). In agreement with JMPR practice, additional use of the ± 25% rule for other parameters is not acceptable. For additional uncertainties introduced, these need to be considered on a case-by-case basis so that the overall uncertainty of the residue estimate is not increased.
- Proportionality cannot be used for post-harvest situations at this time. It is also recommended that the concept is not used for hydroponic situations due to lack of data.

6 Dec. 2018, Y. Yamada, Ph.D. 52

- Proportionality can be applied for both major and minor crops. The main difference between minor and major crops is the number of trials required by national/regional authorities, which has no direct relevance to the proportionality of residues.
- Regarding processed commodities, it is assumed that the processing factor is constant within an application rate range and resulting residues in the commodity being processed. Therefore existing processing factors can also be used for scaled datasets.

6 Dec. 2018, Y. Yamada, Ph.D. 53

- With respect to exposure assessments, no restrictions appear to be necessary. Scaled datasets for feeds may also be used for dietary burden calculations for livestock.
- The approach may be used where the dataset is otherwise insufficient to make an MRL recommendation (even after applying the ± 25% rule). This is where the concept provides the greatest benefit. The concept has been used by JMPR and different national authorities on a case-by-case basis and in some cases MRLs may be estimated from trials where all of the data (100%) has been scaled.

6 Dec. 2018, Y. Yamada, Ph.D. 54

- Although the concept can be used on large datasets containing 100% scaled residue trials, at least 50% of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors. In addition, some trials at GAP might be useful as confirmatory data to evaluate the outcome in cases where the uses result in residue levels leading to a significant dietary exposure.

7. Commodity group MRLs may be proposed where adequate residue data are available and where pesticide residues may be expected on the group, e.g. if there is a registered pesticide use on a crop group (GAP for a group) that corresponds to the commodity group.
- Codex Classification of Foods and Animal Feeds
  - Groups and subgroups
  - Under revision
  - Fruits, vegetables, cereal grains were already revised

8. Some residues in food arise from persistent compounds in the environment that were once used as pesticides (e.g., DDT, aldrin) in agriculture. As there is no registered uses, monitoring data are examined and extraneous maximum residue limits (EMRLs) are established, subject to risk assessment, to cover a high percentage of such residues so that trade is not inadvertently interrupted by the extraneous residues.

9. Spices are very minor crops and mostly do not generate sufficient revenue to pay for residue trials. In such circumstances, MRLs based on monitoring data may be established subject to risk assessment for spices or groups of spices.

- No residue trials were expected.

10. When raw agricultural commodities are processed into processed foods, the residues in the raw agricultural commodity may be concentrated, diluted, degraded or transformed into other compounds. Processing studies determine the nature and concentration of residues during food processing, which permits dietary risk assessments and the setting of MRLs for processed foods when necessary.

Need for data on pesticide residues in processed foods

- Dietary exposure estimates are refined for
  - raw agricultural commodities (RACs) that are always processed before consumption, e.g. wheat.
  - raw agricultural commodities that may be consumed directly, e.g. apples, or after processing, e.g. apple juice.
- MRLs are needed for processed commodities where the residue levels are higher than the MRLs of the raw agricultural commodities.

Examples where higher residue levels are expected in the Processed food than in the RAC?

Why not MRLs for all processed foods?

Food processes

- Food preparation, e.g. cleaning and peeling
- Cooking
- Juicing
- Brewing and vinification (wine making)
- Canning
- Milling and baking
- Oil production
- Drying

Commodities that are subject to food processing

- Rice – mostly consumed as polished rice: never consumed with husks
- Wheat – always consumed after certain processing
- Oranges, tomato – frequently consumed after processing
- Commercial processes (pilot scale)
- Household operations – washing, cleaning and cooking
- Whole fruit → edible portion - bananas

Definition (JMPR Manual)

- The "processing factor" for a specified pesticide residue, commodity and food process is the residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity.

Processing factor

- Processing factor =
  $$\frac{\text{residue level [mg/kg] in processed product}}{\text{residue level [mg/kg] in RAC}}$$
  Examples where residue concentrations are higher in the processed food than in the RAC?
- Alternative terms:
  "concentration factor" when residue levels increase, and
  "reduction factor" (inverse of processing factor) when residue levels decrease.

Processing factor

- The processing factor calculation assumes that all of the compound in the processed commodity originated from that same compound in the RAC.
- It is therefore incorrect to calculate processing factors for compounds that are generated during the process.
  - e.g. ETU residues in apple juice originate from ETU in the apples as well as mancozeb residues in the apples.

11. Livestock feeding studies are used to predict the residue levels in foods of animal origin from the residues in feed or from direct treatment for ectoparasites. The residues from both sources must be reconciled. The results are used in dietary risk assessments and setting MRLs.

- Pesticide residues in feed may be transferred to edible portions of livestock
  - Fat solubility is important to know if there is any accumulation into fat or fatty tissue

Sources of residues in livestock

- Pesticide residues may occur in meat, milk and eggs as a result of residues in feed materials.
- Residues may also arise from direct treatment of livestock for ectoparasites (pesticide use) or with veterinary drug.
- The residues from both sources must be reconciled in the process of residue evaluation.

Primary animal feeds

- Legume animal feeds – Codex Code AL
  - alfalfa fodder
  - pea hay
  - peanut forage
- Straw, fodder and forage of cereal grains – Codex Code AS and AF
  - barley straw and fodder
  - maize forage
- Miscellaneous fodder and forage crops – Codex Code AM and AV
  - fodder beet
  - turnip leaves or tops

Dry-weight basis

- MRLs for animal feeds should be set and expressed on a "dry-weight" basis.
- A “dry-weight” basis implies that the commodity is analyzed for pesticide residues as received, that the moisture content is determined, preferably by a standard method for use on the relevant commodity, and that the residue content is then calculated as if it were wholly contained in the dry matter.

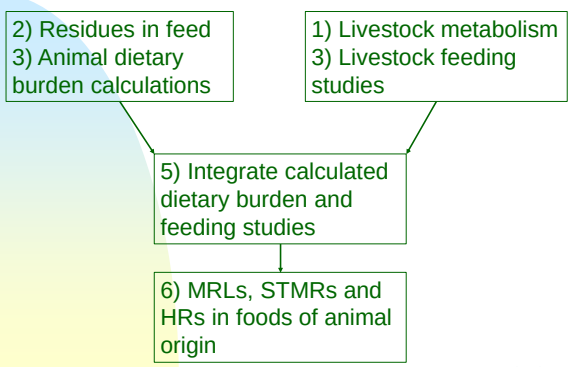
Processed commodities used for animal feed

- Milled cereal products - Codex Code CM
  - wheat bran
  - rice hulls
- By-products of fruit and vegetable processing – Codex Code AB
  - apple pomace
  - sugar beet pulp
- Miscellaneous secondary food commodities of plant origin – Codex Code SM
  - cotton seed meal
  - soybean hulls

Food commodities used as animal feeds

- Root vegetables – Codex Code VR
  - potato culls
- Pulses - Codex Code VD
  - dry beans
- Cereal grains - Codex Code GC
  - maize

The evaluation process



12. In the dietary risk assessment, estimates of residues in food are combined with data on human diets to calculate dietary intakes for comparison with ADIs (acceptable daily intakes) and ARfDs (acute reference doses). Many of the calculations are done using the Excel spreadsheet, but careful selection of the correct residue levels and food consumption data are needed for valid results.
13. A pesticide residue evaluation is completed when the risk assessment is satisfied and the JMPR can recommend that the estimated maximum residue levels are suitable for establishing maximum residue limits.

Dietary Exposure Assessment

- Important process of risk assessment
- Safety and appropriateness of MRLs or MLs can only be demonstrated by the exposure assessment
- At the international level, only point estimates are available (showing one value for each estimate); using GEMS/Food Cluster Diets
- At the national level, if data are available, probabilistic approach is possible
  - Requires many data on the concentrations of chemicals and consumption of foods

- Dietary exposure is different from country to country (concentration of chemicals & consumption: unique in each country)
- For food consumption, many countries use the consumption data obtained from nutrition surveys
- If no data are available, GEMS/Food Cluster Diets may be used (find in which cluster your country is categorized)
- Therefore, exposure assessment is essential.
- ADIs recommended by JMPR can be used
- Codex MRLs may also be used

Thank you for your attention!