codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ESTABLISHMENT OF MRLS FOR PROCESSED AND READY-TO-EAT FOODS

Establishment of MRLs and/or processing factors for processed and ready-to-eat foods

Document prepared by a drafting group consisting of the EC, The Netherlands, USA, Canada, Australia, Belgium, Norway, Peru, Brazil, Germany, CEFS, WPTC, IFU

Summary

CR/PR 06/38/10 prepared by The Netherlands, EC and USA presented at CCPR 38, described the problem, 5 possible policy options and made 14 recommendations. Based on these options and recommendations CL 2006/20-PR was circulated requesting information on national/regional policies, the factors in use nationally, the most important commodities for which information on processing is needed and recommendations for the best way forward.

A. Summary of National Policies

Table 1 gives a summary of the national policies in the countries that responded to CL 2006/20-PR (the policy of the 27 EU member states are given under EU27). It can be concluded from the contributions that national policies are quite diverse and thus difficult to combine into one Codex policy.

Practice inmost of the responding countries is that studies are required and evaluated on the magnitude of residues in processed commodities in order to quantify levels of residues in these commodities. These studies include:

- information on the distribution of residues (active ingredient, metabolites, degradation products) in various processed products resulting from the processing of a commodity
- information about reduction and concentration of residues
    - refined dietary intake assessments with primary processed products for consumer safety has to be conducted

- results on residues in commodities that may be used as animal feeding stuffs[1] and thus to allow a more realistic calculation of the dietary burden of the animals has to be provided
- in certain circumstances, the basis for establishing maximum residue limits (MRLs) in processed commodities or processing factors, in order to facilitate monitoring of residues.

At the international level there is no agreement at the moment, whether CXLs for raw agricultural commodities (RACs) may apply also to some processed commodities (PCs). JMPR recommends MRLs for a limited number of PCs depending on the available information submitted to JMPR. In order to obtain more clarity at the international level, a recommended approach is suggested based on the response to CL 2006/20-PR

B. Recommended Approach by CCPR

Table 2 shows the recommendations by the members of the drafting group.

Based on these recommendations and in order to allow for the differences in national policies the following way forward is recommended and given to CCPR for consideration:

(1) Processing studies should be mandatory for a relatively short list of commodities (e.g. the 16 commodities proposed by the US). Draft CXLs for the RACs do not advance to Step 8 without the submission to and acceptance by JMPR of the requisite processing studies.

(2) CXLs **or** processing factors should be established or recommended for those processed commodities where a significant increase (more than1.3 times) of residue of concern occurs from RAC to processed commodity. It should be decided in advance for which commodities CXLs and for which processing factors will be established.

(3) CXLs **or** processing factors should be established or recommended for those processed commodities where a significant decrease in residue occurs from RAC to processed commodity ***and*** the processing factor must be considered in order to achieve a satisfactory dietary exposure assessment. It should be decided in advance for which commodities CXLs and for which processing factors will be established.

(4) A limited number of default (generic) processing factors should be established or recommended for some predefined common processes, starting with dehydration (e.g. dried vegetables, spices, fruits herbal infusions, milk powder). These can be used nationally and internationally for risk assessment purposes.

The approach, when considered and agreed by CCPR, should be laid down in a guideline, specifying the relevant details, and adopted in the stepwise procedure.

[1] For products in question cf. Table 4 of OECD "Guidance Document on Overview of Residue Chemistry Studies" Environment, Health and Safety Publications

Table 1: National Policies for processed commodities

Country/ Organisation	No policy on processed commodities	Specific MRLs fixed in legislation only for RAC	Processing studies must be submitted for MRLs for RAC	MRLs RAC directly applicable on all PC and ready to eat food	MRLs enforced on PC and ready to eat food corrected using transfer factor or relative proportions	Specific MRLs fixed for processed/composite commodities	Default processing factors (irrespective of pesticide)
EU 27		Yes, with the exception of some dried commodities, (tea, hops), baby food and occasionally for post harvest uses on some processed commodities (dried fruit and vegetables, starch)	Yes, guidance document on processing studies. Studies to be submitted for registration of uses. Main aim at the moment: risk assessment	No, MRLs on RAC applies only after a correction for processing or a separate MRL applies for the PC.	Yes (only primary processed commodities)	Is possible but hardly ever done for PC For composite commodities never done so far, because too complicated	Not used in field of pesticides. Is possible, but so far no common factors established yet
USA			Yes for 38 RAC (not required if 5X GAP leaves no residues, except for extreme concentration) Test guideline available. Extrapolation is possible. If no studies submitted generic factors may be applied if exaggerated (this is done not to dissuade generating studies)	Only if no concentration		Only if processing factor >1.3 and only for specific industrial-type processes. MRLs never set where residue declines (factor <1).	For 56 processes. Mainly done for risk assessment, rarely used for MRL setting. Dehydration and separation (concentration)
Brazil	No specific rules for PFs, no systematic setting of MRLs for processed products	Yes					
Norway	No specific policy, follows the rules of the EC (EEA)	Yes, with the exception of some dried commodities, (tea, hops) and baby food	Studies to be submitted for registration of uses	Not when diluted	Yes		
Canada			Only when concentrated, for risk assessment	Only if no concentration		Only if concentration takes place	
Peru		Yes					

Table 2: Processed commodities and ready to eat foods. Recommended policy for Codex

Country/Organisation	Interested in an international solution for PC	Commodities needed in codex	Processing factors as codex standards would be useful	Generic/default processing factors would be useful	Processing studies should be required for MRLs setting for RAC (for risk assessment and/or to allow the setting of MRLs for PC or processing factors)	MRLs for RAC should also be directly applicable on all PC and ready to eat food	Specific MRLs should be fixed for processed/composite commodities
EU 27	Yes, participates in OECD group	Both concentrated and diluted To add grape juice, citrus juice, apple juice, tomato juice	Yes, if based on sufficient data, and representive for all methods of processing used in industry	Yes, if indicated when they may be applied and when not. Guidance needs to be developed for some common processes (probably only dehydration is relevant). Dried fruit consumption should be taken into account in risk assessment	Yes, for risk assessment. EC has guidance document on processing studies. Other uses of results may be MRL setting or derivation of processing factors as foreseen in EU legislation.	No	Possible, if based on sufficient data. The EC preference would be to fix processing factors rather than MRLs, because this would give more flexibility
USA	Yes, the US is leading OECD group on guidelines	Major in trade (traded and consumed); primary processed commodity; commercial processing	Yes	Yes, the US can already offer information on 56 processes.	Yes, US Test guideline is available. Extrapolation to similar crops possible. US propose list of 16 RAC for which processing studies on 36 PC needed for codex.	Only if no concentration	Only if processing factor >1.3 US in favour of such approach in codex, also when dilution and the risk assessment is based on the assumption of dilution.
Norway	no	none				Not when diluted	
Canada	Yes				Only when concentrated, or for risk assessment	Only if no concentration	Only if concentration takes place MRLs for PC may be higher, not lower than RAC
Brazil	Yes, because several processed products exported	Soybean oil, cane sugar, fruit juice	Yes				
Peru	yes				no		No, certainly not when lower than MRLs for RAC
CEFS (European sugar	yes	Not needed: sugar beet/cane molasses because not					

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industry)		significant in trade and diet (animal feed)					
World processing tomato council		Processed tomato concentrates, tomato powder					
IFU International fruit juice producers		Juice concentrates	For concentrates processing factor			The same MRL for juices as for RAC.	