codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 10 (ii)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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MILK AND MILK FAT MAXIMUM RESIDUE LIMITS

(Prepared by Australia)

Introduction

Codex recommends that the MRL for fat-soluble pesticides in milk are expressed on a whole milk basis, assuming that all milks contain 4% fat. For a "milk product" with a fat content less than 2%, the MRL applied should be half that specified for milk. The MRL for "milk products" with a fat content of 2% or more should be 25 times the MRL specified for milk, expressed on a fat basis. Milk MRLs for fat soluble pesticide to which the above applies are indicated with the letter "F".

Member countries do not universally appreciate this approach. Furthermore, the approach leads to an overestimate of residues in milk fat for pesticides of intermediate fat-solubility where the greater proportion of residues could be present in the non-fat portion of milk. For example, if the ratio of residue concentrations between the fat and aqueous phases of milk containing 4% fat is 24:1, the mass of residue will be equally divided between the fat and aqueous portions of the milk.

In response, the 2004 JMPR decided a simpler approach for fat-soluble pesticides would be to establish separate MRLs for whole milk and milk fat when sufficient data are available. The JMPR suggested that 'for enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk (fat) or the residue in whole milk with the MRL for milk' (Report of 2004 JMPR, General Consideration 2.7).

Discussion

The JMPR recognized that there could be problems associated with the approach of establishing separate MRLs for whole milk and milk fat, if for enforcement purposes, a measurement of the residue concentration in milk fat is compared to the MRL for milk fat. The problem arises for pesticides with intermediate fat-solubility if the milk fat tested is not physically separated from milk. For instance, if solvent extraction of whole milk were used to obtain the milk fat for testing, pesticide residues would also be extracted from the aqueous fraction of the milk leading to inflated measurements in the milk fat.

Spinosad is a pesticide of intermediate fat solubility with MRLs of 5 mg/kg milk fat and 1 mg/kg whole milk. Data shows that, on average, the concentration of Spinosad in cream (50% fat) is about 4.2 times the concentration in whole milk. Consider a sample containing residues of the pesticide at 0.3 mg/kg whole milk containing 4% milk fat. Different analytical results will occur depending on how the milk is analysed:

• If solvent extraction was used to obtain milk fat for testing it is likely that all residues present in the milk would be extracted with the fat and the measured residue level would be about 7.5 mg/kg, well

above the MRL for milk fat.

- If whole milk were analyzed and compared to the MRL for whole milk, we would expect the analytical result to 0.3 mg/kg, less than the MRL for whole milk.
- If physically separated fat were analysed and compared to the MRL for milk fat we would expect the analytical result to be 1.26 mg/kg for separated cream having 50% water and 2.52 mg/kg for 100% milk fat, less than the MRL for milk fat.

With this potential confusion in mind, it was argued that it would be useful if Codex provided authoritative advice regards an efficient method for the physical separation of milk fat from whole milk on a laboratory scale. Over the last two years the CCPR ad hoc Working Group on Methods of Sampling and Analysis has tried to tackle this issue and has twice asked national governments for information on current practices for the analytical determination of fat-soluble pesticides in milk and milk fat. Nearly all methods so far described in responses to Circular Letters¹ are not appropriate for separating fat from milk without also extracting residues from the non-fat portion of the sample. This demonstrates that many authorities have not yet come to appreciate the technical issues involved.

It might be better to tackle this issue differently. The potential regulatory issue mentioned above will not arise if for regulatory (and monitoring) purposes, irrespective of the fat-solubility of a pesticide, whole milk is tested and the result compared with the MRL for whole milk. This proposal could be effectively implemented by adding a suitable note against the MRL for whole milk in all cases where MRLs are established for both whole milk and milk fat. The suggested wording for a suitable note is; *"for monitoring and regulatory purposes, whole milk is to be analysed and the result compared to the MRL for whole milk"*.

This proposal is consistent with, and will serve to emphasize, the Codex Classification of Foods and Animal Feeds that states for milk the portion of the commodity to which the MRL applies <u>and which is analyzed</u> is the whole commodity. The proposal also achieves harmonization with CCRVDF regarding residues in whole milk².

There is reason for Codex to continue to establish MRLs for fat-soluble pesticides in milk fat, since these MRLs are intended to cover processed dairy products where residues might be higher than for whole milk. The MRLs for milk products may be calculated based on the MRLs for whole milk and milk fat, taking into account the fat content of the product and the residue contribution from the non-fat fraction of the product.

With time it should be possible to replace MRLs that have the F annotation with separate values for whole milk and milk fat. The data required to establish separate MRLs for milk fat and whole milk is detailed in OECD guidelines for the generation of test data as part of the registration process and the establishment of MRLs for new chemicals. Registrants are aware of these data requirements and the processes by which it must be obtained.

Recommendations

- 1. That to regulate and monitor residues of fat-soluble pesticides in milk, where MRLs have been established for both whole milk and milk fat, whole milk is analyzed and the result compared with the Codex MRL for whole milk.
- 2. That CCPR agree to ask the JMPR to add a suitable note to this effect alongside the MRL for whole milk in all cases where MRLs are established for both milk fat and whole milk, *"for monitoring and regulatory purposes, whole milk is to be analyzed and the result compared to the MRL for whole milk"*.

¹ CL 2006/9-PR and CL 2007/15-PR

² Currently CCRVDF does not consider residues in processed commodities.