

Opinion of the Scientific Committee on Plants regarding variable pesticide residues in fruit and vegetables (Opinion expressed by SCP on 14 July 1998)

Terms of references

The SCP is asked to consider the following question:

Does the evidence of variable pesticide residues in fruit and vegetables, submitted by the UK Government, indicate that current risk assessment procedures involved in the authorisation of plant protection products and the fixing of maximum residue levels need to be amended? If so, in what way?

Background

Risk assessment of long-term hazards

Methods for assessing the potential long-term (chronic) hazards resulting from ingestion of low levels of pesticide residues in the diet over a life-time were prepared by the **Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)** in collaboration with Codex Committee on Pesticide Residues (1).

For the prediction of the long-term dietary daily intake of a pesticide residue the average daily food consumption per person as given in the food balance sheets compiled by FAO are used at the international level. Out of these food balance sheets GEMS/Food derived five regional diets; one of these diets is the „European diet“, used in the current risk assessment procedure in the EC. In the step procedure first a Theoretical Maximum Daily Intake (TMDI) is calculated assuming that residues are present at the MRLs. A more realistic calculation is the International (or National) Estimated Daily Intake (IEDI or NEDI) using median residues from supervised trials, allowing for residues in the edible portion of a commodity and including processing factors for changes in residue levels resulting from preparation, cooking, or commercial processing. At the national level further factors may be taken into account.

The intake has to be compared with the Acceptable Daily Intake (ADI), the estimate of the amount of a substance in food, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer.

Risk assessment of acute hazards

An acute dietary exposure assessment is the exposure resulting from a single eating occasion or short-term (e. g. single day) exposure including the maximum residue level expected in food as consumed. The intake has to be compared with the toxicological effects that are of concern from short-term exposures, i. e. an Acute Reference Dose (ARfD) has to be used instead of the ADI.

A Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals, held in Geneva, February 1997, considered various issues related to acute dietary

exposure assessments. The Consultation developed a methodology for performing acute dietary exposure assessment (2).

The Consultation agreed that a probabilistic approach would be the best approach because it allowed the consideration of more than one commodity, but recognised also that it may not always be necessary or possible to use probabilistic methods on a routine basis due to the detailed requirements and the resources required.

Recent data indicate that residue levels in individual commodity units could exceed the MRL, even though all the residues reported for the composite samples were well below the MRL.

Therefore, the recommended alternative procedures include two cases:

1. Composite sampling data reflect the residue level in the food commodity
2. Composite residue data does not reflect the residue level in individual food commodities. In this case the potential variability of residues in individual commodity units should be taken into account.

The Consultation recommended the incorporation of a variability factor $\hat{A}' n \hat{A}'$, this factor reflects the ratio of the highest level of residue in the individual commodity unit to the corresponding residue level seen in the composite sample.

At present little data are available to establish specific variability factors and the Consultation recommended default values of 5 and 10 for $\hat{A}' n \hat{A}'$ (5 for large crops - commodity units > 250 g; 10 for medium crops - commodity units 25-250 g) if no specific factor can be determined.

Further prerequisites for the acute dietary exposure assessments are large portion consumption data.

Assessment

Current risk procedures in the EC

The **risk assessment of long-term hazards** posed by pesticide residues is introduced for some years in context with fixing of maximum residue limits (MRLs).

The Committee noted with interest the UK information on variable residues in fruit and vegetables and the Report of the FAO/WHO Consultation about exposure assessment of chemicals. It was agreed that residue variability is not relevant with respect to chronic dietary intake but the Committee agreed it is important with respect to acute dietary intake.

A risk assessment of acute hazards is not yet routinely carried out in the EC for the following reasons:

- an appropriate risk assessment methodology was recommended by the Joint FAO/WHO Consultation first in 1997, the Report was not available before the 30th CCPR meeting, April 1998

- at present, Acute Reference Doses (ARfD) are only available for few active substances (derived by WHO in context with the periodic review)

- representative large portion consumption data at Community level are lacking.

Additionally the question of residue variability needs further investigations to introduce specific variability factors, if necessary.

The Committee wishes to emphasise that the establishment of Acute Reference Doses and the subsequent estimation of acute (short-term) dietary intake is a relatively new development for which the full detailed methodology has still not been fully elaborated neither nationally nor internationally.

Nevertheless, the Committee agreed that the current risk procedure should be amended in order to include short-term intake estimates. The WHO methodology given in the report of the Consultation (2) will be an appropriate scientific basis for estimating short-term (i.e. acute) dietary intake.

The Committee made the following recommendations for amending the current risk assessment procedure in the EC:

Recommendations

(i) Short-term (i.e. acute) dietary exposure to pesticide residues should be considered on a routine basis and that short-term intake estimates for relevant pesticide/commodity combinations be carried out using the methodology recommended by the Joint FAO/WHO Consultation on Food Consumption and Risk Assessment of Chemicals (2).

(ii) Acute Reference Doses (ARfD) should be derived, for all active substances where relevant, in the context of the evaluation of the pesticide active substances under Council Directive 91/414/EEC taking into account recommendations made by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and those of the Joint FAO/WHO Consultation (2).

(iii) Large portion consumption data representative of different regions within the EC should be compiled and if necessary new data generated taking into account the request for such information made by the Joint FAO/WHO Consultation (2).

(iv) Residue variability (i.e. the possible higher residues in an individual commodity unit) should be taken into account in short-term (i.e. acute) intake estimates, where relevant.

(v) Further research and development should be undertaken on the unit to unit variability of residue levels for relevant commodities/pesticide combinations in order that specific variability factors (to replace the default variability factors of 5 and 10) can be derived.

(vi) The result of short-term (i.e. acute) dietary exposure estimates should be taken into account in fixing of maximum residue limits (MRLs).

References

1. WHO 1997a, Guidelines for predicting dietary intake of pesticide residues (revised), prepared by the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) in collaboration with Codex Committee on Pesticide Residues, WHO/FSF/FOS/97.7.

2. WHO, 1997b, Report of a FAO/WHO Consultation entitled, Consultation on food consumption and intake assessment of chemicals. Geneva Switzerland 10 - 14 February 1997. Food Safety Unit. Programme of Food Safety and Food Aid. World Health Organisation 1997; WHO/FSF/FOS. 97.5.

Acknowledgements

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