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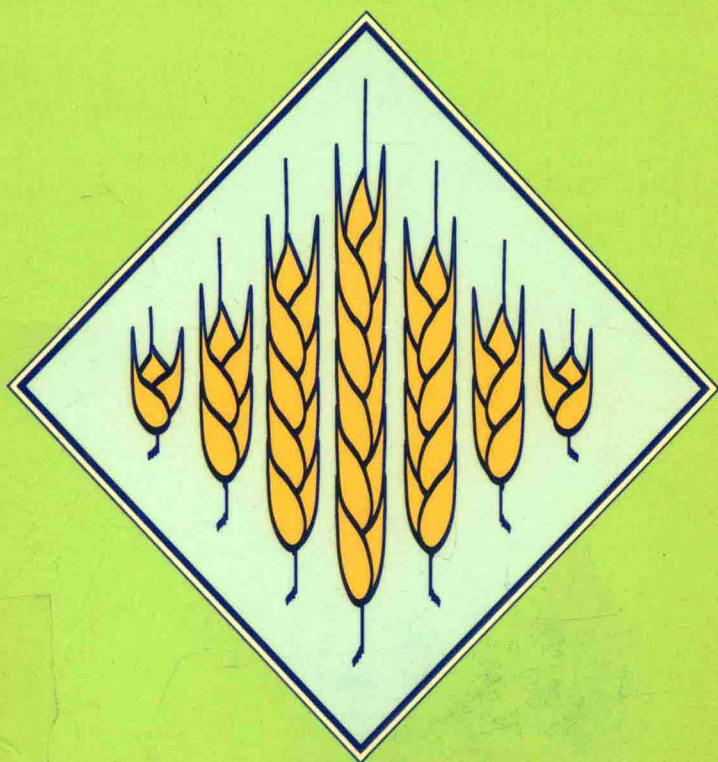
GUIDELINES FOR PREDICTING DIETARY INTAKE OF PESTICIDE RESIDUES

Prepared by the
Joint UNEP/FAO/WHO
Food Contamination Monitoring Programme
in collaboration with the
Codex Committee on Pesticide Residues

World Health Organization
Geneva
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PREFACE

The Codex Committee on Pesticide Residues (CCPR) is an inter-governmental body that advises the Codex Alimentarius Commission on all matters relating to pesticide residues. Its primary objective is to develop Codex maximum residue limits (MRLs), in order to facilitate international trade, while protecting the health of the consumer. Public health considerations are taken into account by establishing the MRLs at levels not higher than those resulting from use of the pesticide in accordance with good agricultural practice.

From time to time the question has been raised at the CCPR of whether acceptance of Codex MRLs could result in a situation in which the acceptable daily intake (ADI) of a pesticide would be exceeded. A definitive answer to this question can only be obtained by means of dietary intake studies (*1*). In cases where such studies are not feasible or where the pesticide has not long been in use, it is necessary to predict the pesticide residue intake on the basis of the available data.

The present guidelines describe procedures for predicting the dietary intake of pesticide residues, and are intended to assist national authorities in their considerations regarding the acceptability of Codex MRLs.

The initial draft of the guidelines was prepared by Dr R.D. Schmitt, Office of Pesticide Programs, Environmental Protection Agency, Washington, DC, USA. They were further developed by an FAO/WHO Consultation which met in Geneva on 5-8 October 1987 under the auspices of the Joint UNEP/FAO/ WHO Food Contamination Monitoring Programme (or GEMS/Food) in collaboration with the CCPR. GEMS/Food forms part of the Global Environment Monitoring System established by the United Nations Environment Programme. Dr Schmitt's continued help throughout all phases of the preparation of this publication is greatly appreciated.

Relevant authorities are invited to consider the basic approaches described here, which are designed to provide reasonable assurance that use of Codex MRLs will not result in a dietary intake of a pesticide that exceeds its ADI.

1. ACCEPTABLE DAILY INTAKE AND MAXIMUM RESIDUE LIMITS

The acceptable daily intake (ADI) of a pesticide is established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), on the basis of a complete review of the available data (biochemical, metabolic, pharmacological, toxicological, etc.) from a wide range of experimental animal studies and observations in humans. The no-observed-adverse-effect level (NOAEL) for the most sensitive toxicological parameter, normally in the most sensitive species of experimental animal, is used as the starting-point. A safety factor that takes into consideration the type of effect, the severity or reversibility of the effect, and the problems of inter- and intra-species variability is applied to the NOAEL to determine the ADI for humans. Pertinent human data may outweigh experimental animal data in the estimation of the ADI for man.

Pesticide residue levels that would be expected from the use of good agricultural practice are estimated from globally generated data, and are likely to change as this practice is modified. The maximum residue limits (MRLs) recommended by the JMPR, on which the Codex MRLs are usually based, reflect the considered decision of the experts present at the meeting after examination of all pertinent data.

Neither the ADI nor the MRL is immutable. Both are determined according to the best judgement of a group of internationally recognized experts on the data available to them at the time of the evaluation. Summaries of these data are published in the JMPR Evaluations (6). However, as new data become available, the ADI or MRL may be revised.

From time to time, concern has been expressed over the possibility of adverse health effects arising from exposure to residues of more than one pesticide in food. This matter was considered by the 1981 JMPR (2), which concluded that, with the levels of pesticide residue intake found at that time, there was no need to alter the general approach for estimating ADIs. By extension of this conclusion, the approaches recommended here for the assessment of pesticide residue intake are also appropriate for the assessment of the concurrent intake of residues of more than one pesticide.

2. PREDICTING THE DIETARY INTAKE OF PESTICIDE RESIDUES

General considerations

In order to reach a conclusion as to the acceptability of an MRL from a public health point of view, it is necessary to predict the dietary intake of pesticide residues resulting from application of the MRL, and to compare this prediction with the ADI. The dietary intake of any particular pesticide residue in a given food is obtained by multiplying the residue level in the food by the amount of that food consumed. Total intake of the pesticide residue is then obtained by summing the intakes from all commodities containing the residue concerned.

Indices of residue level

Several indices of residue level can be used to predict pesticide residue intake. The MRL is one such index and represents the maximum residue level that is expected to occur in a commodity following the application of a pesticide according to good agricultural practice. Factors that may be taken into consideration when choosing an index to be used in predicting pesticide residue intake include the residue levels found in practice, their distribution in the commodity, and the effect on residues of the various processes used in the preparation of food.

It should be appreciated that the use of the MRL in the prediction of pesticide residue intake will lead to an overestimation of actual pesticide residue intake (3).

The prediction of intake of a particular pesticide residue should include all commodities for which MRLs have been established, unless the value has been estimated to be at, or about, the limit of determination.

Indices of food consumption

There are several possible indices of food consumption, a commonly used index being the average daily consumption. Others

include average portion sizes, percentile consumption values, and the average consumption by people who actually eat the commodity. In predicting pesticide residue intake an effort should be made to reflect long-term food consumption habits and not day-to-day variations, in order to permit a valid comparison with the ADI, which is based on acceptable intake over a lifetime. Thus, it is recommended that average daily food consumption values be used in predicting pesticide residue intake for comparison with the ADI.

Food consumption patterns vary considerably from country to country and even within a country; thus, to a large extent, individual countries will have to estimate their own consumption pattern. However, for the purpose of predicting pesticide residue intake at the international level, the use of average food consumption data given in FAO Food Balance Sheets is recommended (4). Although the food consumption data derived from such sheets are subject to many uncertainties and limitations, they represent the best available source for international comparison and provide an approximate picture of the overall food situation in countries. Such an approximation of the overall patterns of food consumption is adequate for predicting pesticide residue intake, given the associated uncertainties in all of the components involved.

In order to predict pesticide residue intake at the international level, hypothetical diets will need to be developed for a number of dietary patterns that are representative of various regions of the world ("cultural" diets). As a first approximation, a hypothetical global diet consisting of the highest average value of food consumption for each "cultural" diet may suffice. Selection of this value for individual commodities from each "cultural" diet will, however, result in an unrealistic total food consumption. For the prediction of pesticide residue intake, these values should be normalized to a total daily consumption of 1.5 kg of solid food, i.e., excluding the liquid content of juices or milk.

For more realistic predictions, the "cultural" diets should be used individually. This would make it possible to predict a range of potential intakes.

For predictions of pesticide residue intake carried out at the national level, the best available food consumption data should be used. Countries should be cautious in the use of food consumption values other than average values, if such use results in a hypothetical level of consumption that would not be attained in practice. In carrying out predictions of pesticide residue intake for identifiable subgroups, e.g., vegetarians, it would be appropriate to use relevant average food consumption data for such subgroups.

Assessment of intake

Pesticide residue intake through the diet can be predicted with different degrees of accuracy. However, the more realistic predictions involve the consideration of many factors and therefore may be rather time-consuming. The options in the process are shown in Fig. 1.

Fig. 1. Options for the prediction of dietary intake of pesticide residues

	1	Measured pesticide residue intake
Increasingly realistic predictions	2	"Best estimate" — estimated daily intake (EDI)
	3	"Intermediate estimate" — estimated maximum daily intake (EMDI)
	4	"Crude estimate" — theoretical maximum daily intake (TMDI)
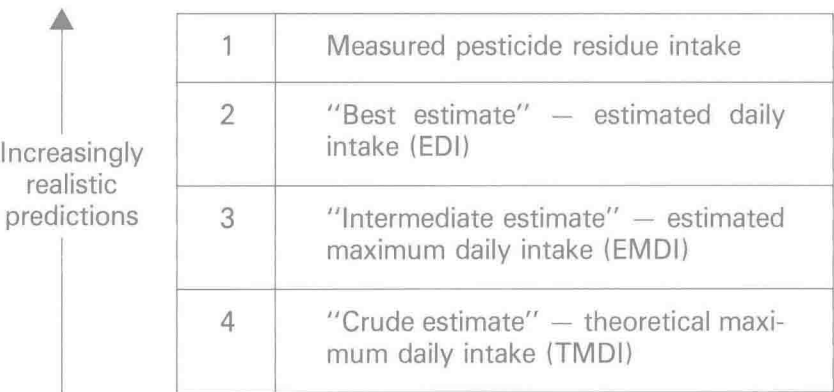
The procedures described here start with the most exaggerated and proceed towards more and more realistic intake predictions. It should be noted that the less realistic predictions, which are relatively straightforward to carry out, give an overestimate of the true pesticide intake. By starting with the most exaggerated predictions, it is therefore possible to eliminate at an early stage pesticides whose intake is clearly unlikely to exceed the ADI. More realistic predictions using refined data then make it possible to eliminate other pesticides from further consideration. Such an approach would facilitate acceptance of Codex MRLs for the majority of pesticides and allow the national authority concerned to direct its attention to those most likely to be of public health concern. The three-tier approach to predicting pesticide residue intake outlined in Fig. 2 is therefore proposed.

Fig. 2. Outline of proposed procedures for predicting pesticide residue intake

	TMDI[a]	EMDI[a]	EDI[b]
Residue level	Codex or national MRL.	Codex or national MRL. Corrections for: (i) edible portion; and (ii) losses on storage, processing, and cooking.	Known residue level. Corrections for: (i) edible portion; and (ii) losses on storage, processing, and cooking.
Food consumption	Hypothetical global or national diet. All commodities with a Codex or national MRL.	"Cultural" or national diet. All commodities with a Codex or national MRL.	National diet. Known uses of pesticide, taking account of: (i) range of commodities; (ii) proportion of crop treated; and (iii) home-grown and imported crops.

[a] May be estimated at either the national or international level.
[b] Can be estimated only at the national level.

Theoretical maximum daily intake (TMDI)

The TMDI is an estimate of dietary intake calculated using the MRL and the average daily per capita consumption of each food commodity for which an MRL has been established. The TMDI is calculated by multiplying the MRL by the average food consumption for each commodity and then summing the products:

$$TMDI = \sum F_i \times M_i$$

where

F_i = the average food consumption for the relevant commodity, as derived from the hypothetical global or national diet in kg of food per person per day; and

M_i = the MRL for the relevant commodity in mg of pesticide per kg of food.

Thus, the TMDI is given in units of mg per person. The ADI is, however, expressed in units of mg of pesticide per kg of body weight. In order to compare the TMDI with the ADI, the TMDI is divided by an assumed average body weight (this is usually taken to be 60 kg).

The TMDI will be a gross overestimate of the true pesticide residue intake because:

- the proportion of a crop treated with a pesticide is usually far less than 100%;
- very few of the crops treated with a pesticide contain the maximum residue level;
- residues are normally dissipated during storage, transport, preparation, commercial processing, and cooking of the treated commodity; and
- the MRL applies to the whole raw agricultural commodity, which frequently includes inedible portions. A large proportion of the residue may thus be discarded upon removal of the inedible portion.

It should therefore not be concluded that proposed Codex MRLs are unacceptable when the TMDI exceeds the ADI. Instead, a TMDI calculation should be used only as a screening process that may eliminate the need for further consideration of the intake of a pesticide residue.

On the other hand, if the TMDI does not exceed the ADI, it is highly unlikely that the ADI would be exceeded in practice, provided that the main uses of the pesticide are covered by the Codex MRL. Thus, more refined predictions of pesticide residue intake are not necessary.

Estimated maximum daily intake (EMDI)

The EMDI is a more realistic prediction of the pesticide residue intake. It is calculated using data on the edible portion of the commodity and takes into account the effects of the preparation, processing, and cooking of food, as follows:

$$EMDI = \Sigma \; F_i \times R_i \times P_i \times C_i$$

where

F_i = food consumption for the relevant commodity as derived from a specific hypothetical "cultural" or national diet in kg of food per person per day;

R_i = the residue level in the edible portion of the commodity given in mg of pesticide per kg of food (see Annex 2, Note A);

P_i = a correction factor that takes into account the reduction or increase in the residue on commercial processing, such as canning or milling (see Annex 2, Note B);[a] and

C_i = a correction factor that takes into account the reduction or increase in the level of residue on preparation or cooking of the food (see Annex 2, Note C).[a]

The units of the EMDI are the same as for the TMDI (mg of pesticide per person). In order to compare the EMDI with the ADI, the EMDI is therefore divided by an assumed average body weight (usually 60 kg), as in the comparison of the TMDI with the ADI.

Although the EMDI is a more realistic estimate of true pesticide residue intake than the TMDI, it is still an overestimate because it does not take into account that:
– the proportion of a crop treated with a pesticide is usually far less than 100%; and
– very few of the crops treated contain residue levels as high as the MRL, from which R is usually derived.

If the EMDI exceeds the ADI, it will be necessary to try to estimate more closely the true intake, as described below.

Estimated daily intake (EDI)

Calculation of the EDI takes into account the following factors:
– data on food consumption, including that of subgroups of the population;
– known uses of the pesticide concerned (see Annex 2, Note D);
– known residue levels (see Annex 2, Note E);
– the proportion of the crop treated;
– the ratio of the amount of home-grown to imported food; and
– the reduction in the level of pesticide during storage, processing, and cooking.

Since this type of information is usually only available at the national level, EDI predictions can only be performed on a national basis by those who have adequate information on food consumption, the use of a given pesticide locally, and the nature and the amount of imported food.

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[a] The correction factors for residue losses during processing or cooking may be derived from information given in various JMPR evaluations (see, for example, 6).