

ACN WI 2.2:

GUIDELINES FOR THE CALCULATION OF CONSUMER INTAKE AND EVALUATION OF THE RISK FOR PESTICIDE RESIDUES

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1. DOES THE PESTICIDE RESIDUE FOUND EXCEED THE MAXIMUM RESIDUE LEVEL (MRL)?

- The substance must be a residue of an active substance currently or formerly used in a plant protection product; to be verified in the EU Pesticides database under "active substances": https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en
- It should be verified whether the current Maximum Residue Level (MRL) is exceeded, taking into account the measurement uncertainty. How to apply the measurement uncertainty is explained in the chapter "Interpretation of results for enforcement purposes" (sections E.9 – E.12) of this document:

https://food.ec.europa.eu/document/download/d4786faf-c574-4222-a5c6-45086b3920b8_en

The default measurement uncertainty is 50%. However, when the level found in a sample leads to an international estimated short-term intake (IESTI) that exceeds the acute reference dose (ARfD) - see section 2 of this working instruction) - a measurement uncertainty with a lower confidence level can be applied as a precautionary measure.

- MRLs are published in the Official Journal of the European Union¹, but they can also be found in the EU Pesticides database under "pesticide residues":

https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en

The database also provides information on the future date of entry into force of draft MRLs, the expiry date of existing MRLs and the list of substances for which no MRL is necessary.

2. IS THE ARfD EXCEEDED?

- A serious risk cannot be excluded if the pesticide residue found in a sample is higher than the EU MRL and the ARfD is exceeded for at least one EU consumer group.
The ARfD and the acceptable daily intake (ADI) can be found in the EU Pesticides database under "active substances":
https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en
- To estimate whether the ARfD is exceeded, the most recent EFSA Pesticide Residue Intake Model (PRIMO) should be used:
[Pesticide evaluation: Tools | European Food Safety Authority \(europa.eu\)](https://www.efsa.europa.eu/en/pesticide-evaluation-tools)
- A serious risk may also be present when no ARfD was established (unless it was decided that no ARfD is needed or applicable). In such cases the ADI may serve as a surrogate for precautionary reasons. In many cases the ADI is considerably lower than the ARfD. Since the

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC; please consult Eur-Lex on <http://eur-lex.europa.eu/homepage.html> for the consolidated text including the amending Regulations

ADI covers chronic effects instead of acute effects, it is recommended to look into details of the effects upon which the ADI was based, including safety factors, in order to evaluate the risk with all available information. Toxicological expert judgement is required for such appreciation. A RASFF notification can be made pending such judgement, updating the notification with the outcome of the risk evaluation as a follow-up to the notification as soon as it becomes available.

- If there is no information available at all on the toxicology of an active substance, it is prudent to consider the presence of residues above the established MRL of a pesticide as a potential serious risk and notification is mandatory upon exceedance of the MRL.

3. RISK EVALUATION

If the MRL and the ARfD are exceeded, the risk is considered "serious" and a RASFF notification is mandatory.

If the MRL is exceeded but not the ARfD, a RASFF notification can be submitted provided that there are specific reasons to launch such notification on account of a health risk. Such reasons may include a previously unreported substance or a concern for a chronically high consumer exposure or any other particular reason why the infringement could present a higher concern than usual. These reasons should be well documented in the RASFF notification.

It should be noted that the criterion of MRL exceedance should always be applied because decisions about the MRLs may have been taken using additional information on edible portion, metabolites, precise distribution and variability of residues and processing. This information may be present on the EFSA website.

Note:

- The notification classification will be made on the basis of the definitions in Article 2 of the IMSOC Regulation and will depend not only on the risk evaluation but also on the distribution of the product; e.g. an ARfD exceedance will only lead to an alert notification if the product is also (potentially) available on the market in other member countries than the notifying country. More guidance is provided in SOP 5.
- This Working Instruction applies to any consignments, independently of their origin.
- No exceptions should be made for consignments that already may have been consumed by the time the analytical results become available. Even easily perishable raw products might have been canned, frozen, dried or processed otherwise, and further consignments from the involved food business operator, originating from the same production stage, might have been placed on the market.
- All pesticide residues found in the sample above MRL are hazards for which a risk evaluation is necessary. Therefore, they should be recorded in the notification. Although each substance is evaluated separately, these substances could have a combined effect on health. There is not yet an adopted methodology to assess such effect. However, due the fact that AAC and RASFF are integrated, it is important to also highlight such non-compliances.

4. HOW TO USE THE PRIMO MODEL FOR THE INTAKE ASSESSMENT

The Primo model (spreadsheet) is made available on EFSA's website (<https://www.efsa.europa.eu/en/applications/pesticides/tools>) and it contains instructions for use. The ARfD (or instead the ADI if no ARfD is available, unless it is not needed

or not applicable) must be entered and the residue found (taking into account the residue definition for risk assessment), without subtracting any measurement uncertainty, to achieve a sufficiently conservative calculation. The residue value must be entered in the worksheets for the calculation of the acute intake for adults and for children.

It is important to note that the model has been designed for dietary exposure assessment to ensure that MRLs to be established are safe for consumers. The prediction of the expected residues is normally based on measured concentrations in composite samples obtained from a series of supervised residue field trials. On average, variability factors estimated from samples collected in the marketplace are higher than those from samples obtained in the supervised trials². In order to account for the variability amongst single units, (normally samples analysed are composite samples of 5-20 units), a default variability factor is applied in the model. In case single units were analysed by official control authorities, the default factor may be replaced in the model by the measured factor.

² The EFSA Journal (2005) 177, 1-61