

CODEX ALIMENTARIUS COMMISSION



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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

43rd Session

Beijing, P.R. China, 4 - 9 April 2011

DISCUSSION PAPER ON THE APPLICATION OF PROPORTIONALITY IN SELECTING DATA FOR MRL ESTIMATION

(Prepared by Australia)

Background

1. At the last session of the CCPR, concerns were expressed by some delegations that the JMPR had not recommended MRLs for some commodities as application rates in supporting residue trials were more than 25% greater than the critical GAP (cGAP) application rates (ALINORM 10/33/24, paras. 72 and 73). Similar concerns had been raised at previous sessions for other compounds, however a way forward had not been proposed.
2. Australia offered to present a paper on proportionality and its application to better inform the Committee about how such an approach could be used by the JMPR. The Australian regulator uses proportionality (or scaling) of residues for the purposes of MRL estimation.
3. Following the last session of the CCPR, the 2010 JMPR considered the concept of proportionality and has published a general consideration item in the meeting report (JMPR Report 2010, Item 2.8, p. 14 – 17).

Discussion

4. The 2010 JMPR reviewed relevant residue trial data published in JMPR monographs between 2000 and 2009 to determine if residues are indeed proportional to application rate.
5. A total of 1146 comparisons of application rate were reviewed for crops treated side-by-side where the application rate or spray concentration was the only parameter that varied between the plots. Data were analysed for 52 different active ingredients (herbicides, insecticides and fungicides) where rates ranged from 1.3× to 10× the lowest application rate used at the trial location. Modes of applications included foliar and soil sprays and seed treatments.
6. The conclusion of the 2010 JMPR was that residues are generally proportional to application rate and that in estimating MRLs, use can be made of the proportionality of residues. The general consideration item also provided examples of how to apply the principle of proportionality, potential situations where it may not apply and situations where more data are required.
7. Acceptance that a proportional relationship exists between pesticide application rate and residues on the harvested commodity allows data to be used from field trials where application rates are higher than (or lower than) the application rate according to cGAP. Residues from trials where the application rates are outside the previously employed range of ±25% of the cGAP rate can be adjusted (scaled) to provide a larger data set from which to estimate an MRL.

Residue values can be calculated according to the following equation:

$$\text{Scaled Residues} = \text{Measured Residue} \times \frac{\text{cGAP Rate}}{\text{Trial Application Rate}}$$

8. The JMPR general consideration paper also provides detailed examples of where using the proportionality approach would lead to an MRL estimate, whereas restricting acceptable trials to those with application rates within ± 25% of cGAP would not.
9. Adoption of this approach addresses the concerns raised by some member governments on lack of MRL estimates in some cases, where the data have supported national registrations. This approach provides greater flexibility to the JMPR for use of residue field trial data.

10. Chlorantraniliprole residues in alfalfa forage was provided as an example (JMPR Report 2010, p. 16 and 71). The data submitted to the Meeting were for application rates at 1.5× the cGAP and therefore would not normally be used to estimate an MRL or residue levels for use in livestock dietary burden calculations¹. Use of proportionality allowed 30 data points to be used to estimate an STMR and HR for alfalfa forage, which in this case is the largest contributor to livestock dietary burden. The range of residues, following scaling was from 6.3 to 28.7 mg/kg. This allowed an STMR of 17 mg/kg to be estimated leading to revised MRL recommendations for milk, edible offal and meat.

Recommendation

11. It is recommended that the Committee support the JMPR approach to using proportionality as described in the general consideration item of the 2010 Report. The JMPR agreed to use proportionality and "*...decided it would only consider the method of proportionality in cases where the residue data according to GAP are not sufficient for a recommendation or where additional information on residues in treated commodities useful for the evaluation, may be achieved.*"
12. It is recommended that the Committee welcome and endorse this approach, which gives greater flexibility to the JMPR in the use of residue field trial data. And that the Committee notes that such an approach would allow MRL estimates to be made in situations where the current $\pm 25\%$ rule excludes such estimates.

¹ Although forage MRLs are not recommended by the JMPR, the STMR and HR estimates are used for livestock dietary burden and for setting MRLs for livestock commodities as well as for the dietary risk assessment.