New proposed Residues on Fruits (RUD's) for frugivore scenarios in EFSA Bird and Mammal Risk Assessment

European Crop Protection

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Introduction

The Guidance Document on Risk Assessment for Birds and Mammals (EFSA 2009) provides default 'Residue per unit dose' or RUD values for food items to be used in wildlife risk assessments. Most of these RUD values are based on large numbers of registration relevant residue studies conducted by industry members and provided to EFSA. However, RUD values for fruits were taken from Baril et al. (2005) and comprise only relatively few trials of unclear relevance for European regulatory purpose.

Therefore, field study data of fruit residue levels from applications of pesticides in different crops from five companies (ADAMA, BASF, Bayer, Corteva, FMC, Syngenta), all conducted during the last 20 years, were evaluated.

This comprehensive data set provides a solid basis for reviewing the registration relevant RUD values for fruits as diet items in wildlife risk assessments as given in the current EFSA (2009) Guidance Document.

Material and methods

From a large data set of residue field trials which were conducted in different climate zones throughout Europe, studies were selected based upon the following criteria:

- Studies providing residue values at appropriate fruit ripening stages on the day of application and shortly thereafter
- GLP-studies evaluated at EU member state level
- For 'grapes' and 'large fruits from orchards' trials with only 1 application were considered due to large dataset (N ≥ 100)
- For 'other berries', 'gourds', 'small fruits from orchards' and 'strawberries', studies with 1 to 4 application were used.

Analysis of data extrapolation

- Calculation of RUDs selecting the highest value after the last application (irrespective of the sampling time), including multiple applications
- Fruit groups showing different residue loads related to the same application rate (due to e.g. fruit type, texture of peel, leaf cover, climatic zones) were checked

Results and Recommendations

Food item	Proposed RUD values for frugivore scenarios			Current default RUD values of EFSA (2009) GD		
	Mean ± s.d. [mg/kg]	90th percentile [mg/kg]	Number of trials	Mean ± s.d. [mg/kg]	90th percentile [mg/kg]	N
Grapes	1.6 ± 1.2	3.3	100	8.3 ± 7.2*	16.7*	9*
Berries[1]	5.0 ± 3.6	9.2	180			
Large fruits from orchards[2]	0.9 ± 0.6	1.5	126	19.5 ± 16.8	41.1	33
Gourds[3]	0.7 ± 0.6	1.3	267	34.3 ± 54.7	61.5	19
Small fruits from orchards [4]	2.6 ± 1.4	4.3	126	3.3 ± 2.6	6.5	33
Strawberries	1.3 ± 1.4	2.3	143	*Not given, substituted by values of berries*		

1. currants, raspberries and gooseberries; 2. apple, peach, pear, lemon, mandarin and orange; 3. pumpkins, cucumbers, squash and melons; 4. apricot, cherry, plum; * Grapes and berries taken together in the current GD

- The database for **'grapes'**, is the most homogeneous in terms of fruit type, development stage (all within BBCH 79 - 95) and number of applications (one). There is no significant difference between the data from Southern and Central Europe. Therefore it is proposed to derive one RUD for risk assessments.
- In the category **'large fruits from orchards'**, different fruits have been combined (apple, peach, pear, lemon, mandarin, orange (BBCH 75-88) as in EFSA (2009)). There are no differences between the different fruits or between Southern and Central Europe. One RUD for frugivorous scenarios seems appropriate.
- In the category **'gourds'**, pumpkins, cucumbers, squash and melons have been combined as in EFSA (2009). Here no difference in RUD values between round and elongated fruits was found, and the number of applications had no significant effect on the residue level measured. Comparing the results of the geographical sub-sets resulted in small but statistically significant differences in residue data from Central (0.5 mg/kg) and Southern Europe (0.7 mg/kg) (Mann-Whitney U Test P = <0.05). However, in order to define a single conservative value the mean and 90th percentile of the Southern data is proposed as a new default RUD value.
- No difference was found between different **berries** (currants, raspberries, gooseberries). The number of applications and the geographical location had no significant influence on the residue level. The RUD values of pooled data showed the highest level and largest standard deviation (though less than the current value in EFSA (2009). Therefore, also here a new default RUD value is proposed.
- In the category of **'small fruits from orchards'**, different fruits have been combined (apricot, cherry, plum as per EFSA 2009). Residues of one or two application studies do not differ as well as the location of the study showed no influence. Plums exhibited significantly lower residues (0.6 mg/kg) than cherries and apricot (2.6 mg/kg). Therefore it may seem justified to give a separate value for plums. However, a single default value is proposed that covers all small fruits for the lower Tier assessments.
- A separate RUD for **strawberries** is proposed here as a separate Tier 1 scenario for wildlife risk assessment. There were no significant differences in RUDs following one or multiple applications or between Southern and Central Europe. So a single RUD value is given for this category.

Regulatory Conclusion

The objective of this project was to investigate and derive robust residue levels in fruits determined under field conditions in different climatic zones in Europe and in the course of a fruiting season. Based on a large and reliable dataset of ≥100 residue trials per 'fruit group' from studies evaluated and considered valid at EU level significantly lower RUD's compared to the default RUD's (EFSA 2009) were found. These new RUD values are proposed as more relevant and robust values than current defaults for use in bird and mammal risk assessments.

REFERENCES:

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