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| **Metabolism in primary crops**  Reference material: Test No. 501: Metabolism in Crops (OECD, 2007a) |
| **Question 1:** Are the provided metabolism studies in primary crops submitted in the residue section sufficient to depict a metabolic pathway of residues? If yes, which are the crop groups covered by the available metabolism studies?  Is a metabolism study available in a crop that belongs to the same metabolism crop group than the GAP(s) under assessment? Please provide an overview of the available information.[[1]](#footnote-1) |
| **RMS comment** |
| **Question 2:** Which are the plant metabolites recovered in the study(s) in relative amount and absolute amount (greater than 10 (TRR %) and/or 0.05 mg/kg)[[2]](#footnote-2) addressing the metabolic pathway of the representative use(s) [[3]](#footnote-3)? |
| **RMS comment** |
| **Question 3:** Is any translocation of pesticide residues observed in the different parts of the plants? Could it be drawn a general conclusion on translocation of residues based on the available data?  I.e. is there any particular distribution of the residues observed in specific plant tissues (leaves, grains, roots, etc)? Is this occurring over time?[[4]](#footnote-4) |
| **RMS comment** |
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| **Metabolism in rotational crops**  Reference material: Test No. 502: Metabolism in Rotational Crops (OECD 2007b), Test No. 504: Residues in Rotational Crops (OECD, 2007d) |
| **Question 4:** Do results of the rotational crops show any translocation of residues (uptake from soil) from roots to the aerial parts of the plant[[5]](#footnote-5)? If so, which metabolites might be of relevance?  Is there any indication of accumulation of residues over time occurring in the rotational crop scenario? If so, in which crop categories (leafy, roots, cereals)/crop parts is the accumulation observed? |
| **RMS comment** |
| **Question 5:** If the GAP is for a seed treatment or other pre-emergency[[6]](#footnote-6) treatment, is any information related to the magnitude of residues at early post-emergence (BBCHs<10) for the crop(s) under assessment? |
| **RMS comment** |
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| **Magnitude of the residues in supervised residue trial**  Reference material: Test No. 509: Crop Field Trial (OECD, 2009); Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017) |
| **Question 6:** From the supervised residue trials, is there any indication of a residue decline over time?[[7]](#footnote-7),[[8]](#footnote-8)If so, please indicate the reference to the residue trial and the part of the plants where the decline was observed.  Were the residue determinations performed at 0 days after the last application or at a given time close to the last application(s)?[[9]](#footnote-9) |
| **RMS comment** |
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| **Question 7:** On which crops were field residue trials performed? [[10]](#footnote-10) Has an extrapolation been suggested and is it considered appropriate?[[11]](#footnote-11) |
| **RMS comment** |
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| **Metabolism studies in animals (livestock, fish)**  Reference material: Test No. 503: Metabolism in Livestock (OECD, 2007c); Test No. 505: Residues in Livestock (OECD, 2007e); Test No. 305: Bioaccumulation in Fish (OECD, 2012) |
| **Question 8:** Is a metabolism study in fish/bioaccumulation study part of the residue section? If the fish metabolism study is available, does it indicate an accumulation of residues in fish tissues? [[12]](#footnote-12) |
| **RMS comment** |
| **Question 9:** Can the metabolism in animals (mammals/fish/hens) bring any information on accumulation/exposure[[13]](#footnote-13) to different metabolites in addition to those present in the plants?  Is it possible to observe an accumulation of residues in fatty tissues/other animal tissues considering all available metabolism studies? |
| **RMS comment** |
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| **Magnitude of residues in pollen and bee products**  Reference material: Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (EC, 2018); Guidance on the risk assessment to plant protection products on bees (*Apis mellifera*, *bombus* spp. and solitary bees (EFSA, 2013). |
| **Question 10:** Are data on the magnitude of residues on pollen and bee products part of the residue section? If so, please indicate which data are available and sampling times.[[14]](#footnote-14) |
| **RMS comment** |

References

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OECD (Organisation for Economic Co-operation and Development, 2012. Test No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, https://doi.org/10.1787/9789264185296-en.

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013/9789264076457-en

1. The metabolism study should be conducted on a crop which belongs to the crop category representative of the GAP/intended use/representative use (e.g., a metabolism on fruit crops should be provided to support the GAP on pome fruit). It is also relevant to highlight that the metabolism study should be compliant with the GAP in terms of type of application (foliar, soil treatment, etc.), location, covering the dose rate of application, BBCH growth stage at application, PHI. [↑](#footnote-ref-1)
2. These trigger values of 0.05 mg/kg or 10%TRR of total radioactive residues are only meant as guidance. In some circumstances, generally governed by toxicological concerns, it may be necessary to identify terminal metabolites, which are present at concentrations lower than 0.05 mg/kg or <10%TRR of total radioactive residues (European Commission, 1997). [↑](#footnote-ref-2)
3. For the ecotox section, a selection of the relevant metabolites should reflect only the representative uses. It is not necessary to cover the residue situation for consumer risk assessment but the expected residue situation in the field for the use(s) under assessment. It is recommend consulting whether metabolism studies were summarized following harmonized templates for further assessment (I.e. EFSA/OECD templates). [↑](#footnote-ref-3)
4. Special attention must be given to compare results at same BBCH/sampling time; particularly, for avoiding erroneous assessments due to crop growth and dissipation. [↑](#footnote-ref-4)
5. It must be noted that this information may not only refer specifically to the succeeding crops/crops growing in rotation; but also, it may be useful to give indications on a possible residue situation for the new emerging plants in the crop area after certain uses. For instance, the data can be used to disregard a possible residue situation to non-target organisms originated due to the consumption of contaminated seedlings /residues in weeds. [↑](#footnote-ref-5)
6. Consideration for the seedling scenario, relevant for bird&mammals and the guttation water scenario for bees might be necessary. [↑](#footnote-ref-6)
7. Please report if the residue trials were fully validated in terms of storage stability, GAP compliance, etc. [↑](#footnote-ref-7)
8. It is mentioned in the EU data requirement that when planning residue trials, it shall be borne in mind that information on the residues in ripe or unripe crops may be of interest with respect of the risk assessment in other areas like ecotoxicology and worker safety. Please include this information if available. [↑](#footnote-ref-8)
9. Residue determinations close to the application(s) and/or the last application may provide relevant information for certain non-target taxa that can forage in the crop area at a time close to the application(s). [↑](#footnote-ref-9)
10. The minimum number of supervised residue trials considers for MRL setting might not be applicable for the ecotox. We might build a residue decline curve with less than 4 residue data points. For this consideration, please do not disregard the residue data only based on the minimum number of residue trials. If the residue trials are compliant with the GAP table, ecotox experts might use them for further refinements. [↑](#footnote-ref-10)
11. Ecotox colleagues might need advice on questions such as e.g. can residue decline studies in tomato be used to refine the residues entering throughout diet of frugivorous birds when the representative use is on pome trees? And can we use residue data generated in the SEU for refinements in the NEU zone when the representative use is in whole EU? [↑](#footnote-ref-11)
12. If we observe any accumulation in tissues, it might help in case that further assessment of bioaccumulation and/or biomagnification (accumulation throughout trophic chain) are necessary. [↑](#footnote-ref-12)
13. If there is information of new metabolites in the excreta, it might be relevant for the environment. Non-target organisms might be exposed to these new metabolites if there is a release in the environment after animal metabolization. [↑](#footnote-ref-13)
14. Residue section may contain information of residues in pollen, leaves and flowers. For residues assessment, data on nectar and pollen would be also useful for deriving a more realistic MRL/PF for nectar/honey and pollen/honey. Specific residue data can be used for refinement of higher tier studies in the risk assessment for bees if considered representative of the situation under assessment. [↑](#footnote-ref-14)