GUIDANCE

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Guidance on the assessment of pesticide residues in rotational crops

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Abstract

EFSA has prepared a guidance document on the assessment of studies on the nature and magnitude of pesticide residues in rotational crop studies as defined in Section 6.6 of the Annex to Regulation (EU) No 283/2013. This guidance document supports the practical implementation of the relevant OECD Test Guidelines (TGs) and OECD Guidance Documents in a harmonised way, respecting the EU regulatory framework for the pesticide assessments. The individual steps of the assessment are illustrated by examples, figures and flow charts. Sources of uncertainty in these assessments are identified and recommendations for further work are provided.

Keywords: guidance, rotational crops, MRL setting, consumers risk assessment, residues in feed and food

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1. Background

Studies investigating residues in rotational crops aim at identifying and quantifying the major components of the terminal residue in the relevant crop parts, i.e. parts of crops that are used for food or feed purposes. Information obtained from these studies is used to assess whether residues in food or feed pose a risk to consumers (either via direct intake of the food or via residues in food of animal origin resulting from residues in feed). Depending on the results, risk managers may decide that it is necessary to establish maximum residue levels (MRLs) to cover residues expected in rotational/succeeding crops or to establish restrictions to avoid or reduce the occurrence of residues in crops grown as rotational crops.

To address the different aspects on the nature and magnitude of residues in rotational crops, the EU data requirements set out in Regulation (EU) No 283/2013[1] define the types of studies and the conditions under which such studies have to be provided by applicants. The study protocols for this type of studies are described in OECD Test Guideline 502 and Test Guideline 504.

In 2011, OECD acknowledged that the two Test Guidelines were not sufficiently detailed on certain aspects. To close this gap an OECD Guidance Document was developed (OECD, 2018), which provides additional detailed guidance on design, interpretation, and further refinement of rotational crop field studies with a tiered approach in order to clarify the options for dealing with the active substances and metabolites and standardise the MRL setting process for rotational crops.

Before the OECD Documents were adopted, the EU assessments were performed according to an EU Guidance Document (European Commission, 1997). This Guidance Document is still in place, although more detailed provisions in OECD Test Guideline, Guidance Documents have replaced most of its provisions and therefore most parts of the EU Guidance Document became obsolete.

Practical experience has shown that the implementation of the OECD Guidance Document in the EU regulatory context left room for different interpretation, hampering a harmonised risk assessment approach. Furthermore, the co-existence of the 1997 EU Guidance Document and the OECD Guidance Document/OECD Test Guideline created some ambiguities.

Considering the highly complex provisions for the assessment of rotational crops, further guidance and practical examples illustrating the risk assessment process are needed to provide the necessary background information to applicants and risk assessors.

Hence, it seems appropriate to develop a practical guidance document on the assessment of rotational crops, in line with the EU legal requirements and the OECD Test Guidelines and Guidance Documents.

2. Terms of Reference

The European Commission requested EFSA, in accordance with Article 31 of Regulation (EC) No 178/2002[2], to provide scientific and technical assistance to the European Commission by preparing an EU guidance document on the assessment of rotational crop studies, as defined in Section 6.6 of the Annex to Regulation (EU) No 283/2013. In particular, the guidance document should address the following aspects:

- describe under which circumstances studies investigating the nature and magnitude of residues in rotational/succeeding crops are required,
- provide details on the design of rotational crop studies (metabolism studies in rotational crops, rotational crops field studies),
- develop guidance on the interpretation of the studies in view of performing the consumer risk assessments and develop options on risk mitigation measures, including options for setting MRLs,
- to derive recommendations for the development of tools necessary to perform the assessment consistent with OECD and the recommendations derived in the current guidance document.

[1] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, pp. 1–84.

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 01.2.2002, pp. 1–24.

The guidance document should support the practical implementation of the relevant OECD Test Guidelines (TGs) and Guidance Documents in a harmonised way respecting the EU regulatory framework on data requirements. In order to facilitate the assessment of rotational crops, EFSA is requested to describe in detail how to perform the relevant assessments, illustrated by calculation examples, and calculation templates.

3. Introduction

3.1. What is the purpose of this guidance?

As requested in the Terms of Reference, this guidance provides advice on the interpretation and application of data requirements on rotational/succeeding crops defined in Section 6.6 of the Annex to Regulation (EU) No 283/2013 for maximum residue limit (MRL) applications under Regulation (EC) No 396/2005[3] and for applications on the approval/renewal of the approval of active substances (a.s.) under Regulation (EC) 1107/2009[4]. Where relevant, provisions of the so-called old data requirements specified in Regulation (EU) No 544/2011[5] are reported and put in the context of the current regulatory requirements.

Most of the provisions of the previous EU Guidance Document on the testing of plant protection products in rotational crops (European Commission, 1997) have been replaced by more detailed provisions in OECD Test Guidelines and Guidance Documents and therefore the EU Guidance Document became mostly obsolete. Those aspects that are not covered by the OECD Documents, and that are still relevant for EU assessments, are also reported in the current Document to provide a comprehensive overview on the provisions applicable in the EU.[6]

In this guidance, EFSA presents flow charts, practical examples and technical advice on how the provisions of the OECD Documents on rotational crops (i.e. Guideline on metabolism in rotational crops – OECD TG 502 (OECD, 2007a)) and Guideline on residues in rotational crops (limited field studies – OECD TG 504 (OECD, 2007b)) as well as the OECD Guidance Document on Residues in rotational crops (OECD, 2018)) should be applied to satisfy the EU regulatory requirements.

The guidance document is structured to reflect the tiered approach implemented in the OECD Guidelines/Guidance Documents. Text that was taken over from the referenced sources is reported in text boxes. In Appendices A and B supporting information and practical examples can be found.

It is noted that the current guidance document is intended to give pragmatic advice for future assessments, noting that the methodology for the assessment of residues rotational crops shall be further refined,[7] including models developed for the assessment of the fate and behaviour in the environment and for assessment of ecotoxicological effects on soil organisms (PERSAM Software Tool[8]; VITO NV, 2022). Hence, the current guidance will be further updated, integrating the experience gained and the options that will be offered by the PERSAM tool which shall be adapted to address the specific needs for the assessment of residues in rotational crops. Considering the challenges and the practical experiences of previous assessments, the proposed methodology presented in the current document differs in some respects from the methodology applied in the past; it is expected that the new proposed methodology offers practical improvements for the risk assessment, which can be easily implemented in the regulatory framework, maintaining a high level of consumer protection.

In addition, the guidance provides explanations on how to use the Excel based calculator (PRonTo – **P**esticide **Ro**tational Crop Assessme**n**t **To**ol) developed to facilitate the assessment of rotational crops.

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[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, pp. 1–16.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

[5] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, pp. 1–66.

[6] EFSA recommends further discussions, whether the EU Guidance Document (1997) can be revoked (see Section 9, recommendation 1).

[7] EFSA suggests establishing a platform to exchange experiences gained by experts assessing residues in rotational crops. In addition, this platform could be used to compile examples and collect proposals for future improvements of the current guidance document (Section 9, Recommendation 2).

[8] PERSAM Software Tool was developed by EFSA and Join Research centre in 2015. The tool is available at the following link: https://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool

The current document however does not provide guidance on the following related aspects, as they are already sufficiently addressed in other guidance documents or go beyond the scope of the mandate:

- Uptake of residues from soil resulting from multiannual use of pesticides in permanent or semi-permanent crops;
- Residues in honey resulting from bees foraging on crops grown as rotational crop or non-target crop pollen and/or nectar;
- Details on the assessment of isomers (EFSA, 2019) or on common metabolites.

The provisions on the assessment of other aspects that might be also relevant for rotational crops which are covered by other specific guidelines or guidance documents in place (e.g. guidance on deriving the residue definition, analytical methods, assessment of fate and behaviour of pesticides in soil) should prevail and are out of the scope of this document.

Due to the complexity of the assessment of rotational crops, the current guidance document is not able to address all cases that are expected in reality. In certain assessments, it might be necessary to deviate from the proposed approaches presented in this guidance document (e.g. to request additional data from an applicant). It is also noted that more refined assessments deviating from the approaches presented in the current guidance document, based on real data and scientific expertise are acceptable.

During the development of the EFSA guidance document Member State experts were consulted and an Expert Meeting was held on 4 May 2021. The conclusions of the expert meeting were reported in the report on the pesticide peer review TC 52 (EFSA, 2021). The draft EFSA guidance document was subject to public consultation from 2 February 2023 to 17 March 2023. The comments received by stakeholders during the public consultation, which have all been addressed, are published in Annex A as supporting documentation.

3.2. Are the OECD Test Guidelines and OECD 2018 Guidance Document directly applicable for EU risk assessments regarding residues in rotational crops?

OECD TG 502 (OECD, 2007a) and TG 504 (OECD, 2007b) are reported in Commission Communication[9] which provides the list of methods and Guidance Documents relevant for the implementation of Regulation (EU) No 283/2013. Hence, they are applicable for EU assessments. However, any provisions of the EU data requirements set up under Regulation (EU) 283/2013 prevail the provisions established in OECD Test Guidelines and OECD Guidance Documents.

In 2011, OECD noted that the two guidelines were not sufficiently explicit for some aspects of the assessment of residues in rotational crops.[10] To address these points, the OECD Guidance Document (OECD, 2018) was published, providing advice on MRL setting for rotational crops on a general level and to illustrate how the assessment is performed in different OECD countries. The OECD Guidance Document is not legally binding in the framework of the EU regulatory processes.

3.3. How are residues in rotational crops assessed?

Model studies are used to investigate the possible uptake of soil residues in rotational crops. Considering the complexity of the soil compartment and the interaction of soil with crops that can be grown as rotational crops, these model studies are performed to investigate the effect of the most important parameters influencing the residue situation. However, these model studies are not able to capture/standardise all conditions that may occur in agricultural practice and therefore some simplifications are introduced in the assessment by using model assumptions. The simplifications lead

[9] Commission communications 2013/C95/01 in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ C 95/21, pp. 21–37.

[10] In the foreword of the OECD guidance (OECD, 2018), OECD highlighted that the following issues are not adequately addressed with the OECD TG 502 (OECD, 2007a) and OECD TG 504 (OECD, 2007b): (i) determination of the annual high application rate; (ii) use of proportionality with application rate; (iii) accumulation testing over multiple years of use; (iv) misinterpretation of environmental fate data vs. residue chemistry data requirements; (v) crops grown under protection; (vi) rotational crop testing on permanent and semi-permanent crops; (vii) choice of crops for field rotation studies and possibilities of extrapolation; (viii) MRL setting.

to uncertainties in the overall assessment. In Section 8, an uncertainty analysis is presented which should help to understand the contribution of assumptions implemented in the model studies on the overall conservatism of the assessment approach.

The assessment of the fate and behaviour of a.s. in soil is part of the assessment for the approval of a.s. under Regulation (EC) No 1107/2009. In general, the assessment of residues in rotational crops shall build on this assessment and the endpoints related to soil (predicted concentrations of the a.s. in soil) which are derived in the framework of the approval process (peer review). However, it needs to be highlighted that the predicted soil concentrations derived in the peer review are primarily intended to assess the ecotoxicological effects (VITO NV, 2022), while the current guidance document has the focus on the prediction of residue concentrations in crops grown in soil that were previously treated with the a.s. in view of the dietary exposure of consumers. Hence, the consumer risk assessment and the ecotoxicological assessment have different assessment goals.[11]

The assessment of residues in rotational crops is not only restricted to the a.s. applied to primary crops, but covers also soil metabolites, which are relevant due to their stability and the relative amount in soil. Soil endpoints derived in the framework of the pesticide peer review relevant for the a.s. and for soil metabolites are reported in the List of End Points (LoEP) of EU peer review; these end points are used as trigger value or as input values to calculate parameters for rotational crop studies.[12]

The relevant soil metabolites are identified in the LoEP in the section 'Environmental fate and behaviour; Residues requiring further assessment; Soil'. These metabolites need to be assessed in the context of residues in rotational crops and are referred in this Guidance as **significant soil metabolites**. An example of the presentation of the information related to significant soil metabolites in the LoEP can be found in Appendix B.1.

For the assessment of residues in rotational crops, additional soil related end points would need to be calculated, which are currently not reported in the LoEP for a.s. Hence, there is a need to perform some re-calculations to retrieve the relevant trigger values or input parameters for the assessment of rotational crops. The current document provides guidance on the workarounds to bridge the lack of the specific endpoints required for rotational crop assessments.[13]

To address the different aspects on the nature and magnitude of residues in rotational crops, a tiered approach was proposed in the OECD Guidance Document on the residues for rotational crops (OECD, 2018). If the assessment can be satisfactorily finalised with the information obtained in a lower tier, there is no need to proceed with the next tier. The tiers are as follows:

- Tier 1: Rotational crop metabolism studies (confined studies with radiolabelled active substances) according to OECD TG 502 (OECD, 2007a);
- Tier 2: Limited field studies according to OECD TG 504 (OECD, 2007b);
- Tier 3: Extended rotational crop field studies for MRL setting (OECD, 2007b, 2018);
- Post-registration/authorisation activities: Higher tier studies which may include post-registration testing or monitoring (case-by-case design).

It is noted that Regulation (EU) No 283/2013 also describes a tiered approach, referring to tier 1 studies being the limited field studies and tier 2 studies being the extended rotational crop field studies. To avoid confusion, in the context of the current documents, EFSA prefers to report the respective study type (i.e. rotational crop metabolism studies (or briefly metabolism studies), limited field studies, extended field studies). Where for reasons of better readability of the document, the terminology 'tier 1 study', 'tier 2 study' or 'tier 3 study' is used (e.g. in figures, flow charts), the OECD definitions of the tiers as reported in the bullet points above are applied.

In the following sections, the purpose of metabolism, limited and extended field studies in rotational crops, the conditions when these studies are required and key elements on the design of the studies are provided, as well as useful information on the interpretation of the results of these studies.

[11] EFSA proposes that, based on experience gained with the approach described in the current document, residues experts should discuss whether additional endpoints should be derived from soil studies assessed by experts in fate and behaviour, to increase the robustness of the residue assessment (Section 9, Recommendation 4).

[12] The approach for MRL applications for a.s. for which no or only an outdated EFSA conclusion and LoEP is available (e.g. import tolerances for a.s. not approved/no longer approved in the EU) is described in 4.5.

[13] EFSA suggests that in future, end points derived from studies assessed in the framework of fate and behaviour in the environment that are relevant for the assessment of residues in rotational crops should be reported in the LoEP in a specific section to avoid the work-around described in the current document (Section 9, Recommendation 3).

4. Rotational crops metabolism studies (OECD TG 502)

4.1. What is the purpose of rotational crop metabolism studies?

According to Regulation (EU) No 283/2013, metabolism studies in rotational crops shall:

- *provide an estimate of the total terminal residues in the relevant portion of crops at harvest of rotational crops following treatment of the preceding crop as proposed*;
- *identify the major components of the total terminal residue*;
- *indicate the distribution of residues between relevant crop parts*;
- *quantify the major components of the residue*;
- *indicate additional components to be analysed for in residue quantification studies (field crop rotation studies)*;
- *decide on restrictions in crop rotation*;
- *decide on the necessity of field residue trials in rotational crops (limited field studies)*.

Hence, these studies are an essential element to decide which metabolites need to be characterised/identified, to establish residue definitions for rotational crops and to decide whether limited rotational crop field trials should be performed. Rotational crop metabolism studies can also serve as a source of information to propose risk management options, such as the setting of restrictions for crops planted in rotation.

4.2. When are rotational crop metabolism studies necessary?

The provisions in Regulation (EC) No 283/2013 on rotational crop studies read:

Studies concerning residues in rotational crops shall be performed to allow the determination of the nature and extent of potential residue accumulation in rotational crops from soil uptake and of the magnitude of residues in rotational crops under realistic field conditions. *Rotational crop studies shall not be required for uses of plant protection products in permanent crops (such as citrus and pome fruits crop group), semi-permanent crops (such as asparagus*, *pineapples) or fungi*, *where rotations on the same substrate are not part of the normal agricultural practices*.

In addition, the general provisions on data requirements apply (paragraph 1.1 of the Annex to Regulation (EC) No 283/2013; information to be submitted, its generation and its presentation):

The information shall be sufficient to evaluate foreseeable risks, *whether immediate or delayed*, *which the active substance may entail for humans*, *including vulnerable groups*, *animals and the environment and contain at least the information and results of the studies referred to in this Annex*.

Rotational crop metabolism studies are therefore needed if the use of a plant protection product (PPP) on a primary crop has the potential to lead to residues in rotational crops via uptake from soil due to the characteristics of the a.s. and/or its soil metabolites (persistency in soil, transport mechanisms for a.s. and/or metabolites in roots).

The rotational crop metabolism studies are required if the following conditions are met:

- The plant protection product containing the a.s. under assessment is used in crops which are grown in rotation with other crops (annual crops, see Section 4.2.1 and Appendix A.1, Table A.1) and
- the use of the active substance leads to residues in soil (see Section 4.2.2) and
- the active substance and/or its soil metabolites are stable/persistent in soil to be present in relevant amounts at the time of planting or sowing the rotational crops (see Section 4.2.3) and
- the active substance and/or its soil metabolites are taken up via roots by the rotational crops (see Section 4.2.4).

The flow chart (Figure 1) gives a high-level overview under which conditions further investigation of residues in rotational crops are required.

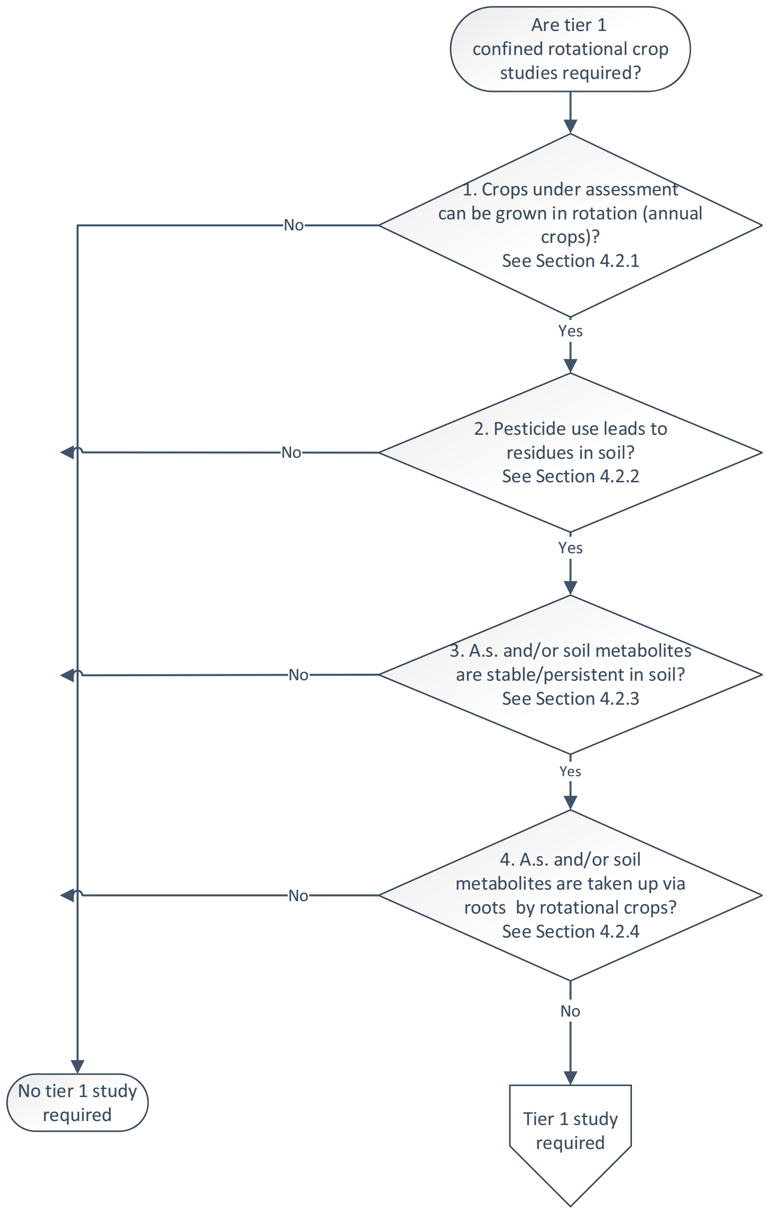

Figure 1: Cases where rotational crop metabolism studies are required

Specific cases regarding the assessment of residue data on rotational crop, which will be discussed separately, are

- Import tolerances (see Section 4.5);
- Use of the a.s. in rice (see Section 4.6).

4.2.1. What are permanent, semi-permanent and annual crops?

If uses are intended in annual crops, the occurrence of residues in rotational crops needs to be assessed.

In Appendix A.1, Table A.1, a classification of food and feed crops[14] as permanent, semi-permanent and annual crops is provided.

Annual ornamental plants (e.g. herbaceous ornamentals and bulbs) should be considered as annual crops that may be rotated with food and feed edible crops unless specific restrictions are defined in

[14] The crop list is based on the food classification of Annex I of Regulation (EC) No 396/2005; it was extended for feed crops and ornamentals.

the Good Agricultural Practices (GAPs) which do not allow rotation with edible crops; woody ornamental plants would fall in the category of permanent/semi-permanent crops.

It is acknowledged that residues taken up by permanent and semi-permanent crops from soil containing residues due to repeated, multiannual use of the a.s. should be considered in the risk assessment. However, the assessment of residues in permanent and semi-permanent crops resulting from previous uses of active substances on the same crop goes beyond the scope of the current document; further guidance should be developed on how to assess accumulation of soil residues in permanent and semi-permanent crops.[15]

4.2.2. Which type of uses are not expected to lead to residues in soil?

The occurrence of residues in rotational crops does not have to be assessed if it can be excluded that the pesticide treatment leads to residues in soil. The following list is not exhaustive but should give an indication on the type of uses for which no further considerations are required concerning residues in rotational crops.

- Use of pesticides in hydroponic systems;
- Cultivation of annual crops on artificial substrate;
- Cultivation of mushrooms in cultivation substrate;
- Chicory roots forcing (direct treatment during forcing);
- Post-harvest uses (i.e. treatment of harvested crop parts, except treatment of seeds intended to be sown);
- Use of pesticides in dispensers or traps with no contact to soil;
- Indoor uses, such as structural treatment of storage rooms;
- Use of pesticides on fresh herbs sold in flowerpots;
- Other treatments that do not involve cultivation in soil.

In the GAP table/GAP form implemented in IUCLID, all relevant details on the use conditions or use restrictions should be reported that may have an impact on rotational crop residues and therefore are required to decide whether the use of the pesticide triggers an assessment of residues in rotational crops.

4.2.3. What are the a.s./metabolite specific criteria to decide whether rotational crop metabolism studies are required for an a.s. or its soil metabolites?

The respective provision in the data requirements (Regulation (EC) No 283/2013) is very generic:

> *Metabolism studies in rotational crops shall be provided if the parent compound or soil metabolites are persistent in soil or significant concentrations of metabolites in soil occur.*

This regulation does not define a specific value to characterise the persistence of the a.s. and/or its soil metabolites or the residue concentration in soil that triggers the investigation of residues in rotational crops.

In contrast, the data requirements applicable until the entry into force of Regulation (EC) No 283/2013 (i.e. Regulation (EC) No 544/2011, often referred to as 'old data requirements') established a trigger value on the occurrence in soil:

> *Where data generated in accordance with point 7.1 of this Annex or point 9.1 of the Annex to Regulation (EU) No 545/2011 shows that significant residues (> **10% of the applied active substance as a total of unchanged active substance and its relevant metabolites or degradation products**) remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, and which could lead to residues above the limit of determination in succeeding crops, consideration shall be given to the residue situation.*

In the EU Guidance Document on rotational crops, trigger values were specified (European Commission, 1997). In regulatory practice, the provisions of this Guidance Document were interpreted that investigation of residues in rotational crops were triggered if the DT_{90} of the active substance in soil was greater than 100 days.

[15] See Section 9, recommendation 11.

In the past, under the old data requirements and the EU Guidance Document of 1997, rotational crop metabolism studies were usually requested, if residues of parent or significant soil metabolites expected to occur individually in soil 100 days after treatment (DAT) of the primary crop are higher than 10% of the applied radioactivity (AR).

For future assessments under the new data requirements, EFSA proposes that rotational crop metabolism studies need to be provided if the DT_{90} in soil of the active substance or any of the significant soil metabolites individually is greater than 100 days. Examples how to identify the relevant DT_{90} for the parent and for the significant soil metabolites to decide whether metabolism studies are triggered can be found in Appendices B.2 and B.3, respectively.

The flow chart (Figure 2) illustrates the criteria of a.s. and metabolites triggering rotational crop metabolism studies.

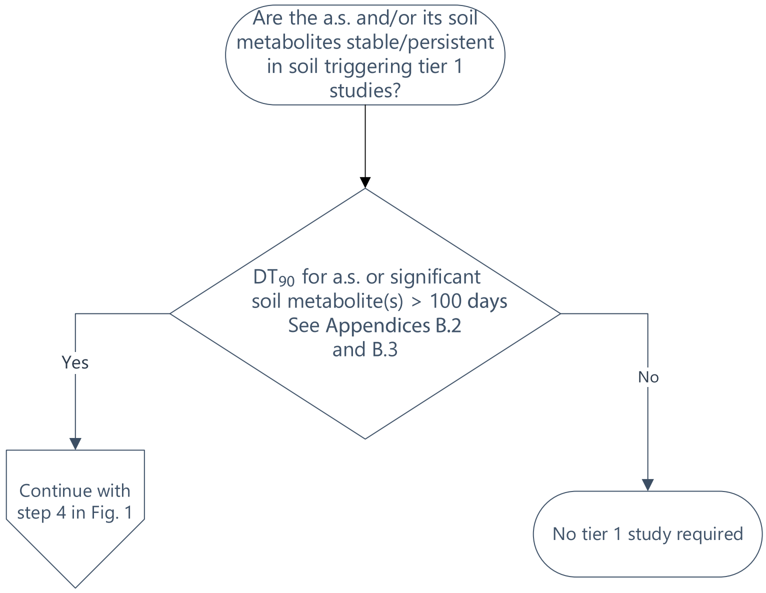

Figure 2: Criteria on stability/persistence of a.s./soil metabolites triggering rotational crop metabolism studies

4.2.4. Uptake of soil residues in rotational crops: Additional waivers for metabolism studies

The uptake of soil residues via roots depends on different factors: the physico-chemical properties of the chemical (e.g. water solubility, log P_{ow}, molecular weight, systemic properties), the nature of the soil (e.g. organic matter content, soil pH, soil texture), plant characteristics (e.g. permeability of plasma membranes of the roots) and climatic conditions. Since reliable models are not available that would allow the prediction of root uptake for different chemicals in different crops, studies are performed in model crops investigating whether and to which extent soil residues (active substance or metabolites) are taken up by plants via roots. However, in certain situations metabolism studies in rotational crops can be waived or replaced with other studies with direct soil application, such as primary crop metabolism studies.

Sometimes, the use of simplified screening tests such as hydroponic assays has been proposed. This kind of experiment is not standardised, but it may be acceptable, on a case-by-case basis, if the studies were adequately designed. Applicants should provide a rationale/justification for the study design implemented in the hydroponic assays, such as the concentration of the a.s./metabolites tested in the hydroponic solution,[16] choice of crops, growth stage, environmental conditions, etc.[17] The

[16] In general, the concentration of the test substance in the hydroponic solution should be representative for the concentration of the a.s. in the soil (pore water).

[17] Experience from assessments of such studies shows that often the rationale with regard to the choice of hydroponic media, plant(s) used in the study, growth stage and conditions of growing is missing. The lack of evidence to support the correlation of the hydroponic media *vs* bare soil applications, where different mechanisms of substance uptake apply, or the lack of reasoning behind the choice of the rate of application in solution versus the plateau concentration in soil are only some of the shortcomings identified.

studies must be representative of the relevant rotational crop groups and must allow extrapolation of the results from the assay to the soil situation.[18]

If it can be clearly demonstrated that soil residues are not taken up by rotational crops, no further investigations are required for the relevant crop groups.

4.3. Design of rotational crops metabolism studies (OECD TG 502)

The OECD TG 502 defines general principles on the design of rotational crop studies; Figure 3 gives the high-level overview on the criteria to decide whether the studies are appropriate.

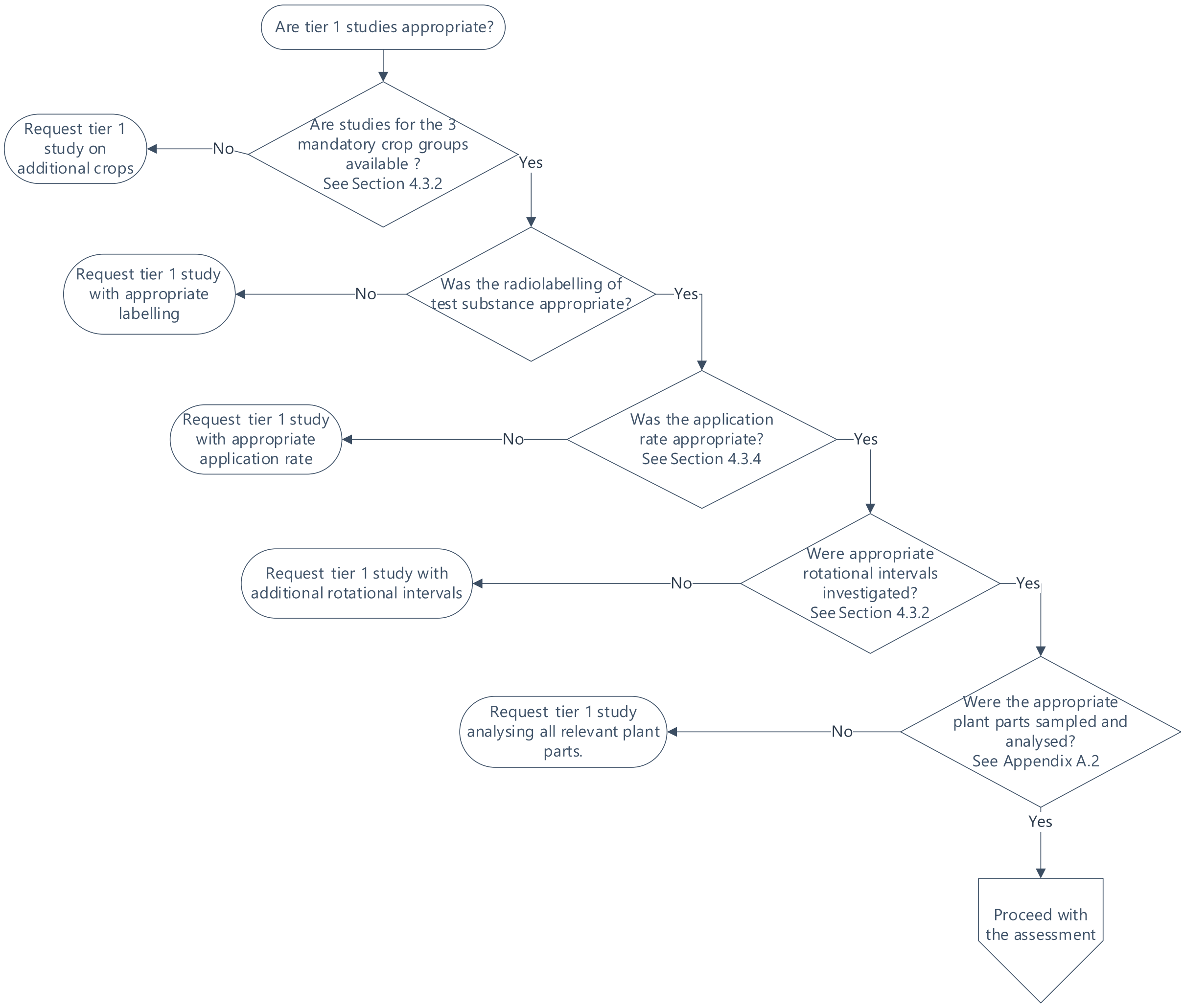

Figure 3: Appropriateness of rotational crop metabolism studies

In the next sections, the following aspects of the design of rotational crop metabolism studies are discussed in detail:

- information on the crops to be used in rotational crop metabolism studies (Section 4.3.2 and Appendix A.2);
- information on the plant parts to be analysed (see Appendix A.2, Table A.1);
- application rates of a.s. to be tested in rotational crop metabolism studies (Section 4.3.4).

Relevant information on the radiolabelling of test substances and on the rotational intervals to be tested are explained in detail in the OECD TG 502 and are not repeated in this document.

[18] OECD discussed the development of a Test Guideline to determine the uptake of chemicals by plant roots (OECD Project 3.15 - OECD, 2021). EFSA recommends exploring the use standardised hydroponic assays replacing tier 1 studies for screening under controlled conditions to decide whether higher tier studies are required (Section 9, Recommendation 5).

4.3.1. Which soil types should be selected for rotational crop metabolism studies and how a.s. should be applied?

According to OECD TG 502, the default soil type to be used in rotational crops metabolism studies is a sandy loam soil. However, there might be reasons to select a different soil type. If for example the degradation path in soil depends on soil properties (e.g. pH, organic matter or if significant soil metabolites are not formed sufficiently in sandy loam), the need to investigate the rotational crop metabolism in a different soil should be considered; the selection of the different soil type should be explained and justified by the applicant (e.g. a particular soil may be selected to maximise the formation of soil metabolites that need to be investigated). Information derived from fate and behaviour in soil should be considered in the selection of the most adequate soil.

Direct soil application provides a better control over the amount of the a.s. reaching the soil. Therefore, EFSA recommends performing these studies by application of the substance under investigation directly on bare soil or mixing the radiolabelled a.s. with the soil used for growing the rotational crops. After the soil treatment, soil incorporation is recommended to ensure a homogeneous distribution over the rooting depth of the rotational crops.

4.3.2. Which crops or crop groups need to be investigated in confined rotational crop studies?

According to the data requirements defined in Regulation (EU) No 283/2013, the nature and magnitude of residues in rotational crops needs to be investigated in crops representative for three different crop groups, i.e.

- root and tuber vegetables,
- small grain (cereals) and
- leafy vegetables.

In Table A.2, Appendix A.2, the allocation of the individual annual crops to the different crop groups is presented. Leafy brassica crops are considered to be equivalent to leafy vegetable crops. Preferably, studies should be performed in crops listed as metabolism example crops.

According to OECD TG 502, rotational crop metabolism studies with oilseeds (oilseed rape or soybeans) may replace studies in leafy vegetables, considering the importance of soybeans. In the EU, a replacement of leafy crops by soybeans is not foreseen. However, the submission of an additional rotational crop metabolism study in oilseed crops might provide a broader picture. Therefore, the applicants are welcome to provide it.

4.3.3. Which rotational intervals (plant back intervals, PBIs) should be tested in metabolism studies?

OECD TG 502 (paragraph 17) states:

Representative rotational crops should be planted at three appropriate rotational intervals, e.g.,

- *7–30 days for assessing circumstances of crop failure or closely rotated crops,*
- *60–270 days to reflect a typical rotation after harvest of the primary crop and*
- *270–365 days for crops rotated the following year.*

The rotational intervals selected should be based on the expected agricultural use for the pesticide and typical rotational practices. The applicant should provide justifications if fewer than three rotational intervals are studied.

The rotational crops should be planted in the soil dosed with the a.s. as calculated in Section 4.3.4 following the plant-back intervals (PBIs) as defined in the OECD TG 502. The time between treatment of the soil and the planting of rotational crops allows for ageing of the residues, including the formation of soil metabolites.

To decide on the PBIs within the ranges defined in the OECD TG 502, it is recommended to reflect on the following issues:

- If the a.s. under assessment degrades to metabolites that need to be taken into account (significant soil metabolites), the PBIs should cover the period where the soil metabolite is expected to be present in the soil (see also Section 4.3.5).
- The choice of PBIs in rotational crop metabolism studies could help to derive reasonable restrictions on rotational crops: e.g. if no residues were found in rotational crops at a certain PBI, the setting of PBI restrictions could be an option instead of performing higher tier studies.

4.3.4. How to derive the application rate for rotational crop metabolism studies?

According to Regulation (EU) 283/2013, rotational crop metabolism studies shall be performed at the recommended maximum total application rate for preceding (primary) crops. Similarly, TG 502 requests that the maximum annual application rate for the primary crop should be used, which is expected to reflect a realistic worst-case situation.

Hence, the application rate for rotational crop metabolism studies is equal to the annual application rate defined in the GAP authorised or intended to be used in annual crops. If more than one GAP is authorised in annual crops, the critical GAP for rotational crops ($cGAP_{RC}$) is the one which has the highest annual application rate (expressed as g or kg per ha). This application rate is also referred to as 1 N-rate.

Frequently, rotational crop metabolism studies are performed in containers where the radio labelled substance under investigation is applied to the soil and mixed thoroughly to obtain a soil concentration reflecting the concentration (in the top 20 cm of the soil) linked to the critical GAP. Assuming a default soil density (ρ) of 1.5 kg/dm^3, the dose rate (expressed as mg a.s./kg soil) is calculated according to Equation 1.

Equation 1: Conversion of the application rate per hectare to the soil concentration (expressed as mg a.s./kg soil)

$$\text{Soil concentration (in mg a.s./kg soil)} = \frac{\text{application rate (g a.s./ha)}}{10,000 * 0.2 * 1.5}$$

Equation 1 is a generic equation to recalculate an application rate to a soil concentration (see also Example 6).

In general, it is recommended that studies are performed with exaggerated dose rates compared to the 1 N-rate, since this may facilitate identification/characterisation of metabolites. The desired goal is the identification and characterisation of at least 90% of the total radioactive residue (TRR) in each raw agricultural commodity (RAC) of the rotated crop (OECD, 2007a). The following aspects should be borne in mind when designing the rotational crop metabolism studies:

- Results of rotational crops metabolism studies can be proportionally scaled down, if the studies were overdosed. Details on scaling can be found in Section 4.4.1.
- In case of underdosed studies, up-scaling might be acceptable in exceptional cases, but this requires careful considerations to ensure that the a.s. and/or metabolites occurring in low concentrations in an underdosed study are not overlooked (see also Section 4.4.1).
- Information on possible phytotoxic effects of the substance or soil metabolites should be taken into account in the planning of the study design.
- Crop interception shall not to be taken into account for rotational crop metabolism studies.

The soil application for the metabolism studies can follow the treatment regime of the critical GAP in primary crops ($cGAP_{PC}$) (e.g. $cGAP_{PC}$: 3 × 1 kg/ha, interval between treatments 21 days; the rotational crop metabolism studies can be performed with the application of three times 1 kg/ha, and the re-treatment interval of 21 days). In this is case, the soil ageing (PBI) starts with the last application. Alternatively, the total amount of the a.s. can be applied in a single application (e.g. 3 kg/ha, the calculation of the PBI starts with the date of the soil treatment). To decide on the option for the soil application, the formation of soil metabolites should be borne in mind (see also next section).

4.3.5. How to design rotational crops metabolism studies to be representative for significant soil metabolites?

In most cases, metabolism studies conducted at three different plant-back intervals are expected to cover in at least one of the trials the periods in which the significant soil metabolites are formed. Hence, the rotational crop metabolism studies, which are simplified model studies would allow to identify the soil metabolites taken up by the rotational crops (see Figures B.4–B.11 in Appendix B.10).

The magnitude of residues in the harvested plant parts of the succeeding crop do not necessarily correlate to the concentration of significant soil metabolites measured at a certain time point as the uptake of the soil metabolites in crops and depends on several factors (e.g. degradation kinetics of a.s. and formation dynamics of metabolites in the soil, bioavailability of the metabolite in the soil, uptake mechanisms of the metabolite by the plant, plant metabolism, etc.). Usually, the significant soil metabolites are expected to be formed at levels that allow at least a qualitative assessment of their uptake. Applicants should provide a rationale and/or supporting information to confirm that the study design was appropriate to address the significant soil metabolites.[19] However, there may be situations where additional studies investigating the potential uptake of significant soil metabolites are requested by risk assessors, e.g. if in the rotational crop metabolism study the formation of significant soil metabolites was not warranted or if the information is not sufficient to exclude the uptake of soil metabolites with high toxicological concern (e.g. genotoxic soil metabolites).[20] It is noted that for soil metabolism studies performed with the application of a soil metabolite, it is not necessary to plant the rotational crops respecting the three plant back intervals, unless the study is intended to investigate further downstream soil metabolites formed in the soil degradation pathway.

To ensure highly persistent significant soil metabolites (i.e. DT90 > 1yr) are properly addressed, it might be reasonable to perform the studies with exaggerated dose rates compared to the 1 N-rate (see Section 4.3.4), e.g. with application rates calculated for the field studies (see Section 5.3). This may avoid the need to perform additional studies, e.g. studies with the direct application of the metabolites.

4.4. Interpretation and evaluation of rotational crop metabolism studies

OECD TG 502 provides detailed explanations on the strategy for identification and characterisation of residues of metabolites found in rotational crop metabolism studies, depending on the concentration of the extractable residue fraction and the relative amount (Table 1 of OECD TG 502).

Hence, the rotational crop metabolism studies provide information on the metabolic pattern of parent and metabolites in rotational crops/parts of the crops that need to be analysed, expressed as percentage of TRR and expressed as mg equivalents per kg.

Usually, the results of the studies are reported in tabular form, following the recommended format of the OECD (Table 1).

Table 1: OECD Template (OHT 85–3) for reporting results of rotational crop metabolism studies – Summary of characterisation and identification of radioactive residues in plant matrices following application of radiolabelled [chemical] at [rate]

Compound	Matrix 1		Matrix 2		Matrix 3	
	%TRR	mg/kg	%TRR	mg/kg	%TRR	mg/kg
[Parent]						
[Metabolite 1]						
[Metabolite 2]						
[Metabolite 3]						
[Metabolite 4]						
Total identified						
Total characterised						
Total extractable						
Unextractable (PES)[(a)]						
Accountability[(b)]						

TRR: total radioactive residue.
(a): Residues remaining after exhaustive extractions.
(b): Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.

If metabolism studies were over-or underdosed, the determined residue concentrations of metabolites (expressed as mg parent eq/kg) need to be scaled as described in Section 4.4.1 to decide whether the trigger value for identification/characterisation is exceeded.

[19] E.g. data on the measured soil concentration of metabolites.
[20] Building on the experience gained, further guidance will be elaborated under which conditions rotational crop metabolism studies need to be performed with soil metabolites, including recommendations on the dose rate that should be tested.

To decide whether the trigger values that require follow-up studies (limited rotational crop field studies) are exceeded, the following steps need to be followed:

- Re-calculation of the residue concentration for the a.s. and the metabolites of over- or underdosed metabolism studies (if relevant), using scaling factors (see Section 4.4.1).
- Re-calculation of the (scaled) residue concentration of metabolites (expressed as mg a.s. eq/kg) to the residue concentration expressed as mg metabolite/kg (see Section 4.4.2).

4.4.1. Scaling of the results over- or underdosed rotational crop metabolism studies

If the application rate of the a.s. in the metabolism studies differs significantly from the annual application rate defined in the critical GAP (see Section 4.3.4), the N-rate and the scaling factor needs to be calculated.

The N-rate is the ratio of the application rate investigated in the study, compared to the application rate for the critical GAP (i.e. maximum annual application rate in primary annual crop) and is calculated with the following formula:

Equation 2: Calculation of the N-rate for over-or underdosed studies (based on soil application rates expressed as g/ha)

$$N = \frac{\text{application rate tested in study } \left(\text{in } \frac{g}{ha}\right)}{\text{maximum annual application rate for critical GAP } \left(\text{in } \frac{g}{ha}\right)}$$

Scaling factors are derived as the inverse value of the N-rate (see below).

Equation 3: Calculation of scaling factor

$$\text{Scaling factor} = \frac{1}{N}$$

In order to re-calculate the residue concentrations for the a.s. and the metabolites (expressed as mg/kg and mg a.s. eq/kg, respectively) of over- or underdosed studies, the results need to be multiplied with the scaling factors. (N.B. Scaling is not appropriate for the results expressed as % of TRR, as the percentage of the TRR is independent of the application rate.)

Scaling is not appropriate, if the scaling factor is lower than 0.3 or higher than 4 (EFSA, 2018). Small deviations from the theoretical application rate (i.e. N-rate between 0.75 and 1.25) do not need to be corrected by scaling.

Scaling-up of residue concentrations measured in underdosed studies need to be considered carefully, to ensure that metabolites occurring in low concentrations in an underdosed study are not overlooked. Hence, upscaling might be appropriate only, if the overall rate of identification is close to 100% (at least 90% of the TRR in each raw agricultural commodity (RAC)) and identification/characterisation of individual factions was done with sufficiently sensitive analytical methods with limit of quantifications (LOQs) proportionate to the scaling factor (e.g. scaling factor of 4, LOQ should be less or equal to 0.0025 mg/kg). Additional data may be requested in situations these requirements are not met.[21]

The results of metabolism studies where a significant soil metabolite has been applied to soil (see Section 4.3.5), can be scaled, following the same principles. The reference dose rate for metabolites (1N rate) shall be derived from the soil concentration of the metabolite derived in the fate assessment, considering the critical GAP.

4.4.2. Molecular weight correction for metabolites

A re-calculation of the scaled residue concentration of identified metabolites (expressed as mg a.s. eq/kg) to the residue concentration expressed as mg metabolite/kg is required to allow a conclusion whether rotational crop field studies are triggered.[22] This re-calculation is performed by multiplying the

[21] E.g. request to provide additional metabolism studies, request for identification of metabolites below the trigger values or request for limited rotational crop field studies in which identified components below the trigger are included in the analytical scope.

[22] According to the data requirement (Regulation (EU) No 283/2013), studies on residues in rotational crops are required, if rotational crop metabolism studies indicate that residues of the a.s. or of relevant metabolites or breakdown products either from plant or soil metabolism occur in concentrations greater than 0.01 mg/kg. This trigger is understood to refer to the concentration of the individual metabolites (expressed as mg metabolite/kg), and not expressed as equivalents of a.s.

result of the scaled residue concentration of the metabolites with a molecular weight correction factor. This correction factor is calculated according to Equation 4.

Equation 4: Molecular weight correction factor

$$\text{Mol. weight CF}(x) = \frac{\text{Mol.weight (met.x)}}{\text{Mol. weight (a.s.)}}$$

Mol. Weight CF(x): Molecular weight correction factor for metabolite x
Mol. Weight (met. X): Molecular weight of metabolite x
Mol. Weight (a.s.): Molecular weight of a.s.

After having corrected the results of rotational crop metabolism studies as described in Section 4.4.1 (scaling), the complete set of results for three representative crops, for the relevant matrices at the three tested plant back intervals should be presented in a table. If more than one radiolabel position was tested, the results for the different label positions shall be presented accordingly.

Hence, the results shall be reported as:

- % of TRR of the individual fractions,
- Measured and scaled residue concentrations a.s. (mg a.s./kg),
- Measured and scaled residue concentrations metabolites (mg eq/kg).

In addition, the residue concentration for identified metabolites (expressed as mg metabolite/kg) following the molecular weight correction as described in Section 4.4.2 should be reported.

The results of scaled metabolism studies, together with information obtained from higher tier studies, serve as the basis to derive proposals for residue definitions for rotational crops. The general approach to decide which metabolites need to be included in the residue definitions (enforcement and risk assessment) is covered by other guidance documents and is therefore not subject to this document. Some specific considerations for the residue definitions for rotational crops are presented in Section 6.4.1.

4.5. Does the nature and magnitude of residues in rotational crops need to be assessed in the case of the evaluation of import tolerances MRL applications?

Following the current policy, investigation of residues in rotational crops is normally not required for import tolerance applications. However, under the following circumstances, information on residues in rotational crops needs to be provided:

- If metabolites, which were identified in rotational crops are included in the EU residue definition for enforcement or if specific MRLs are established for metabolites occurring in rotational crops (e.g. for difluoroacetic acid, DFA): since imported products need to comply with the EU MRLs, applicants shall submit all data required for the crops intended to be imported to the EU to allow the setting of import tolerances and performing the risk assessment according to the EU residue definitions. The data on the occurrence of soil metabolites in annual crops resulting from applications on preceding (primary) crops shall reflect the authorised uses in the country of origin (critical uses of the a.s. in primary crops in the country of origin).

In future, following further risk management discussion, an assessment of residues in rotational crops might be also required in the following situations:[23]

- Import tolerance applications for a.s for which metabolite(s) specific to rotational crops have been included in the EU residue definition for risk assessment.
- Import tolerance application submitted for active substances that have not (yet) been fully assessed in the EU in view of residues in soil and the potential uptake of residues in rotational crops: To avoid that consumers are exposed to soil residues with unknown toxicological profile that are taken up by succeeding crops, an assessment of the degradation kinetics of the a.s. in soil based on metabolism studies (under the same conditions as described in the sections

[23] See Section 9, recommendation 10.

above) and, if triggered, toxicological studies to characterise the toxicological profile of soil metabolites taken up by rotational crops and eventually higher tier studies might be required.
- Import tolerance applications for a.s. for which the assessment of environmental fate and behaviour of an active substance is outdated (e.g. for a.s. previously approved in the EU): Also in this case, it might be necessary that an applicant is requested to submit studies compliant with the current scientific standards.

For the determination of the dose rate for metabolism studies related to import tolerance applications, information on the critical uses in the country of origin need to be provided (critical GAP); if the a.s. was not assessed previously in the EU, a comprehensive assessment of the fate in soil needs to be performed to get the soil endpoints (i.e. DT_{50}/DT_{90} of parent and significant soil metabolites, formation fraction and maximum occurrence of metabolites).

4.6. Specific considerations on rice

Although rice is a semi-permanent crop, in certain EU rice cropping areas, rice can be rotated with soybeans, sorghum or maize (the typical rotational period is 3–5 years). Soil residues of products applied to rice are investigated with specially designed tests and modelled with the specific tool MEDRICE (European Commission, 2003). Some of the general principles already outlined to decide on the potential occurrence for residues in rotational crops might be also applied for rice. However, if the critical GAP in view of rotational crops is the GAP on rice (see Section 4.3.4), it is recommended to consider whether another GAP would be more appropriate to be used for the assessment of rotational crops (e.g. identify the second most critical GAP).

Applicants and assessors are advised to consider the particularities of uses in rice and the fate of soil residues in this crop when residues in crops rotated with rice are assessed.

5. Studies investigating the magnitude of residues in rotational crops: limited field studies (OECD TGL 504)

5.1. What is the purpose of limited field studies?

Limited field studies are performed to get the following information:

- Information on the amount of pesticide residues taken up from soil in succeeding crops expected under realistic conditions, reflecting the variability in different soil types and variation of other parameters that may have an influence on the residue uptake;
- Information to support risk management decisions on appropriate restrictions to limit the residue uptake in succeeding crops and/or setting MRLs;
- Information to decide on the necessity of field trials in other crop groups not tested (i.e. extended field trials);
- Information on the metabolites that need to be considered for inclusion in the residue definitions for rotational crops (see also Section 6.4.1).

5.2. When are limited field studies required?

According to the data requirements defined in Regulation (EC) No 283/2013, limited field residue trials in rotational crops (according to OECD terminology they are called tier 2 studies) shall be carried out, if in the confined rotational crop metabolism studies residues of the active substance or of relevant metabolites individually occur in rotational crops at levels greater than the trigger value of 0.01 mg/kg. For metabolites, this trigger is understood to refer to the concentration of the individual metabolite(s) (expressed as mg metabolite/kg), and not expressed as equivalents of the parent.

In Section 4.4, more guidance can be found on the practical implementation of the trigger value (i.e. on scaling for over-or underdosed studies and for re-calculation of results for metabolites, taking into account the molecular weight correction).

Metabolites which are qualified to be included in the residue definition for risk assessment and/or enforcement, are considered as relevant metabolites and therefore need to be analysed in the field studies. However, as the final decision on the residue definitions may not have been taken yet when the rotational crop field studies are performed, applicants should consider including additional potentially relevant metabolites in the analytical scope of the studies.

For specific active substances and metabolites which are of toxicological concern (e.g. genotoxic/mutagenic potential or other concerns), risk assessors may decide that lower trigger values are appropriate.

It is highlighted that the trigger value defined by OECD (2018) is different to the EU trigger. According to the OECD (2018), limited field studies are required if residues of the parent compound or relevant metabolites are ≥ 0.01 mg/kg in food commodities and ≥ 0.05 mg/kg in feed commodities. The EU legal requirement (trigger value > 0.01 mg/kg) prevails over the OECD Guidance Documents. However, if residues between 0.01 mg/kg and 0.05 mg/kg were found only in feed commodities (e.g. cereal straw, forage, hay), the field studies may be waived if it can be demonstrated that these feed items do not have a significant impact on the dietary burden calculated for livestock. EFSA proposes to consider the impact as not significant, if the dietary burden for livestock including the rotational crop residues does not exceed the general trigger for livestock studies or if the dietary burden does not increase by more than 25% compared to the dietary burden calculation which is the basis for the current MRLs for livestock.[24] More details on the calculation of the dietary burden can be found in Section 6.4.3.

If in at least one of the samples of rotational crop metabolism studies taken at any PBI the residues of toxicological relevant compounds exceed the level of 0.01 mg/kg, a full set of limited field studies is triggered.

Limited field studies may be waived, if – based on the results of rotational crop metabolism studies – an applicant suggests restrictions that ensure that residues in rotational crops do not occur in harvested food or feed (e.g. restrictions on PBIs, restrictions on application rates for primary crop uses or restrictions for crops/crop groups that may be planted as succeeding crops following treatment of a primary crop).

5.3. Design of limited field studies

The OECD TGL 504 and the OECD Guidance Document (2018) define the general principles of the design of field studies. Many elements of the design of field studies are similar to rotational crop metabolism studies. In the subsequent paragraphs, the explanations focus therefore on aspects where field studies differ from metabolism studies, in particular on

- the selection of the test sites (Section 5.3.1),
- the crops to be tested (Section 5.3.2),
- the PBIs (Section 5.3.10)
- the number of trials,
- the identification of the critical GAP authorised in primary crops (Section 5.3.3) which is the basis for the calculation of the application rate to be tested in rotational crop field studies (Section 5.3.4),
- calculation of the N rates and scaling factors (Section 5.3.9) and
- the analysis of samples.

5.3.1. Where should the rotational crop field trials be performed?

The trials should be performed in at least four different test sites in different geographical regions (two in Northern EU region (NEU) and two in Southern EU region (SEU), as defined in the EU Guidance Document (European Commission, 2020), which are representative for the production areas of the crops in the EU.[25] The test sites should represent different soils type; one of the test sites should be a sandy loam soil (OECD TGL 504).

For selecting soil type and the geographical location for field trials, information gained in studies performed in accordance with section 7.1 of Regulation 283/2023 (data requirements) should be taken into account (e.g. selection of soil types and/or climatic conditions that were found to favour the formation of relevant soil metabolites, or soil types where the degradation rate of the parent substance

[24] The assessment whether the proposed 25% trigger is exceeded, can be performed by adding the input values for feed items, such as cereal straw, forages and hay at the level of 0.05 mg/kg or the actual residue concentration found in metabolism studies in the dietary burden calculation (Animal model, 2017) which was the basis for setting the MRLs for animal products.

[25] Usually, trials in NEU and SEU are expected to be provided if relevant for the crops under consideration. Trials performed outside of EU could be considered acceptable if it is adequately demonstrated that agronomic and climatic conditions of the trial site are comparable to EU (either Neu or SEU). See Section 9, recommendation 13: To discuss with risk managers if rotational crop field studies performed in third countries are acceptable to replace to a certain extent studies performed in the EU.

is substantially different compared to other soils). In any case, soil type tested in rotational crops should be selected to reflect realistic conditions.

5.3.2. Which representative rotational crops should be selected for limited field studies?

At each test site, three crops representative for the following crop groups should be tested:

- root crops,
- leafy vegetables and
- cereals.

If limited field studies are triggered by residues found in rotational crop metabolism studies, the crops should be selected as presented in Figure 4.

If in one or several of the crops tested in rotational crop metabolism studies, residues of the a.s. and of metabolites were below 0.01 mg/kg in all relevant matrices at the three tested plant back intervals, the limited field studies should be performed in crops belonging to one of the following alternative crop groups instead:

- oilseeds,[26]
- brassica vegetables,
- fruits, fruiting vegetables.

Overall, at least 12 limited field trials need to be provided (trials in two test sites in NEU and SEU, respectively; at each test site, at least three crops, representative for three different crop groups). Each trial may require performing experiments in three different plots to investigate the necessary PBIs.

[26] For selecting the crop to be planted as succeeding crop, the importance of the crop in European agriculture should be considered. Hence, first choice of substitute crops might be oilseed rape or soybeans.

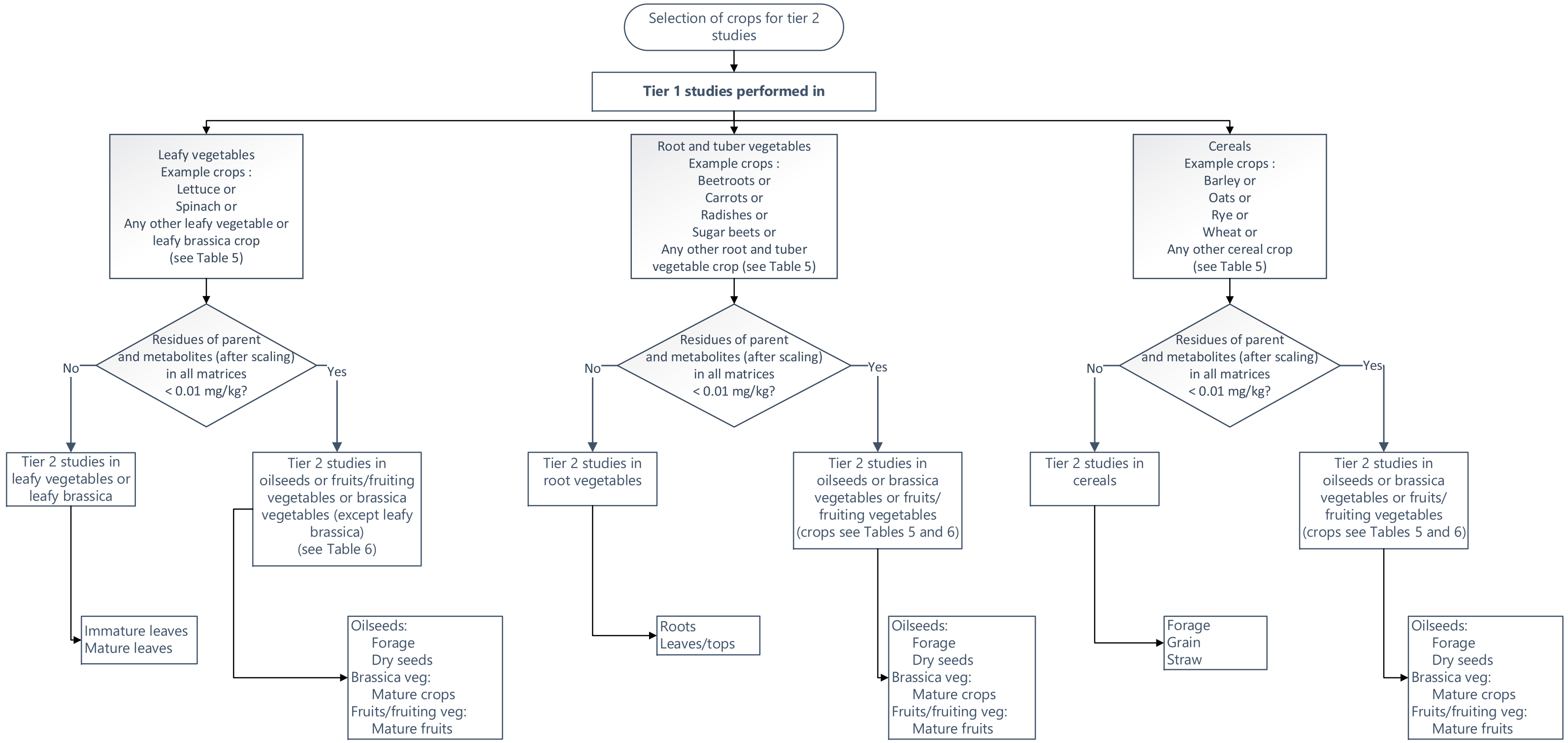

Figure 4: Selection of crops for limited field studies, relevant if in rotational crop metabolism studies in at least one of the samples of rotational crops taken at any PBI the residues of toxicological relevant compounds exceeded the level of 0.01 mg/kg

5.3.3. How is the critical GAP in primary crops identified that is relevant for rotational crop field studies?

In general, the critical GAP in annual primary crops in relation to rotational crop field studies is the one that results in the highest residues (HRs) in soil that, based on rotational crop metabolism studies, are expected to be taken up by rotational crops. This GAP does not necessarily coincide with the most critical GAP under assessment with respect to residues in primary crops which is selected to derive MRLs and the critical GAP identified for rotational crop metabolism studies.

The main parameters of the primary crop GAPs determining the residues in soil are:

- the application rate and the number of applications: usually, the highest seasonal application rate in the primary crop is expected to lead to the highest soil residue concentration; for crops with more than one crop cycle per year, the maximum annual application rate should be the basis to identify the most critical GAP,
- the timing of the application, the crop development and the crop interception at the time of application (crop interception rate, CIR): since the soil is partially covered by the crop, depending on the crop development stage at the application, it is current practice that only the fraction of the applied a.s. that reaches the soil is considered; for crops where usually a substantial part of the crop is incorporated in the soil, the effect of interception may be low and should not be considered (i.e. cover crops or mulching of straw after harvest).[27] However, in this case, the residue declines in the remaining crop parts incorporated in the soil could also be taken into account.

According to the current EU practice, the critical GAP is identified by calculating the seasonal effective application rate (seasonal A_{eff}) for the GAPs authorised or intended in annual primary crops. The seasonal A_{eff} is the portion of the application rate reaching the soil, taking into consideration crop interception.

The A_{eff} of each individual application foreseen during a season according to the GAP under consideration is calculated with Equation 5.

Equation 5: Calculation of effective application rate for the individual application

$$A_{eff} = A \times f_{soil} = A \times \left(1 - \frac{CIR}{100}\right)$$

A_{eff}: effective application rate for the individual application defined in the GAP (in g/ha)
A: individual application rate as defined in the GAP (in g/ha)
f_{soil}: Fraction of the application rate reaching the soil after crop interception
f_{soil} can be calculated as $\left(1 - \left(\frac{CIR}{100}\right)\right)$.
CIR: crop interception rate at a given crop growth stage (BBCH) defined for the individual application of the GAP (ranging from 0% to 90%, see Appendix, Tables A.4 and A.5).

For GAPs with more than one application per season, the A_{eff} calculated for the individual applications are summed up to derive the seasonal A_{eff} (Equation 6).[28] In this case, the timing of the individual applications and the corresponding crop interception need to be taken into account.

Equation 6: Calculation of seasonal effective application rate for a GAP with n applications

$$\text{Seasonal } A_{eff}(g/ha) = \sum_{i=1}^{n} A \times f_{soil} = \sum_{i=1}^{n} A \times \left(1 - \frac{CIR}{100}\right)$$

i: 1 to n applications.

Data on the crop interception rates (CIRs) for different crop growth stages of a number of crops were developed for the environmental assessments (EFSA, 2014; FOCUS, 2021) and are presented in the Appendix A.3. It is recommended to use them also for the assessment of residues in rotational crops. For crops not mentioned in the crop interception table, data from crops with similar crop

[27] As currently, no comprehensive information is available for which crops soil incorporation of plant parts after harvest is the usual practice, it is recommended to collect information from MS/relevant stakeholders. (Section 9, Recommendation 16).
[28] According to the current practice, the degradation of the a.s. between the individual applications is not taken into account. This approach may lead to an overestimation (see Appendix B.5, Figure B.2). An applicant may provide more refined calculations to derive the seasonal effective application rate.

development characteristics should be selected (in Appendix A.4, options for extrapolating CIR to other crops are suggested[29]).

The default assumption for calculating the seasonal A_{eff} is one crop cycle per year; if the default assumption is considered not appropriate for the GAP under assessment (e.g. glasshouse uses in crops grown on soil with short crop cycles), further reasoning should be provided and/or the higher number of crop cycles should be taken into account to calculate the seasonal effective application rate.

An example how to calculate the seasonal A_{eff} for the critical GAP can be found in Appendix B.5 (Example 6). Module 1 of the PRonTo calculator was developed to facilitate the calculation of the effective application rate per treatment based on the application rate per treatment and the BBCH growth stage of the crop at the time of treatment.

The GAP which leads to the highest seasonal A_{eff} is considered the critical GAP with respect to rotational crop field studies. If the critical GAP identified according to the described approach is related to a very minor crop with a low cultivation area in the EU, an alternative critical GAP for a more important crop should be identified.[30]

For non-accumulating active substances, a refined calculation of the highest seasonal A_{eff}, taking into account the degradation of the a.s. between the individual applications within a season could be proposed by an applicant, providing the relevant assumptions and detailed data (see also Appendix B.5, Figure B.2).

5.3.4. How to calculate the application rate of the a.s. for rotational crop field studies?

In this section, the reader will find the description of the calculation of the application rate for

- active substances not accumulating in soil ($DT_{90} \leq 365$ days), (Section 5.3.4.1) and
- active substances accumulating in soil ($DT_{90} > 365$ days (or under certain conditions $DT_{90} > 500$ days[31])), (Section 5.3.4.2).

Instructions on how to identify the relevant DT_{90} for the active substance to decide which case is relevant for the a.s. under assessment can be found in Appendix B.2.

The flow chart (Figure 5) gives a general overview on the approach proposed to derive the application rate for field studies.

In Section 5.3.8, specific considerations on the testing of significant metabolites can be found.

[29] Further guidance shall be developed on the crop interception factors for these crops not explicitly addressed in the Focus model (Section 9, recommendation 6).

[30] In collaboration with risk managers, more specific criteria on the relevance of crops for rotational crop studies should be developed, e.g. by defining the acreage of minor crops in view of rotational crop studies (Section 9, recommendation 6bis).

[31] At EU level, active substances are considered as accumulating in soil, if the DT_{90} is greater 365 days. It is noted that the OECD Guidance Document (OECD, 2018) suggests a different trigger value, i.e. $DT_{90} > 500$ days. The rationale for the different values can be found in paragraph 24 of the OECD Guidance Document. It is acknowledged that for a.s. with degradation following SFO kinetics, the difference in soil concentration is less than 25% of the applied seasonal dose if the DT_{90} is 500 days compared to the DT_{90} of 365 days. Hence, for a.s. following a SFO degradation kinetics, the trigger value of 500 days can be considered acceptable, if no other factors impact significantly on the soil concentration calculated according to the methodology described in the subsequent sections.

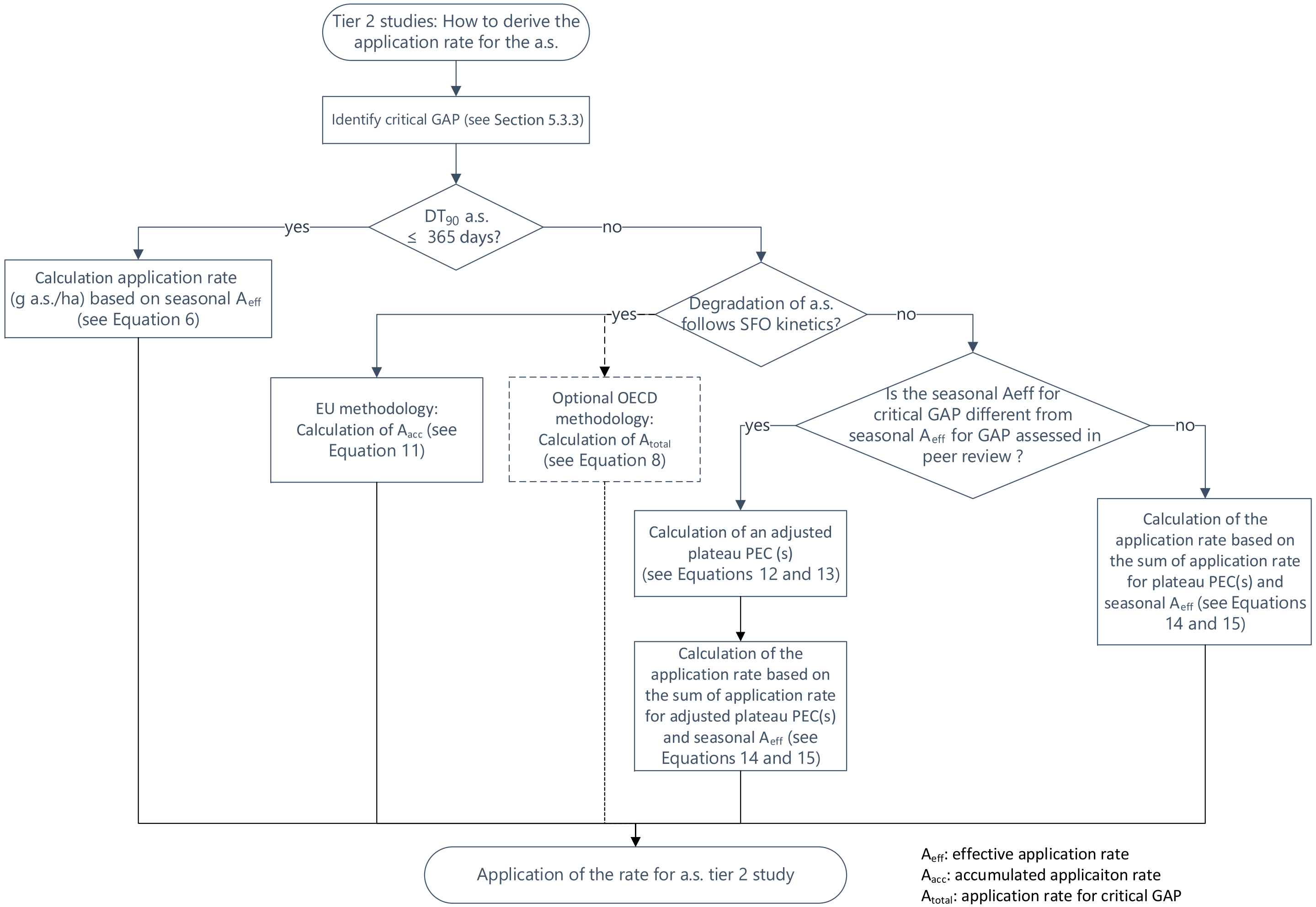

Figure 5: Determination of application rate of the a.s. for rotational crop field studies

5.3.4.1. Active substances not accumulating in soil ($DT_{90} \leq 365$ days)

In the case of non-accumulating a.s., the application rate of the a.s. is equivalent to the calculated seasonal A_{eff} derived according to provisions described in Section 5.3.3 (**Equation 7**).

Equation 7: Calculation of the application rate for rotational crop field studies (non-accumulating a.s.)

$$\text{Application rate (g/ha)} = \text{seasonal } A_{eff}\text{(g/ha)}$$

Equation 7 is applicable for all non-accumulating a.s., independently from the degradation kinetics of the a.s. in soil.

After the active substance was applied to the soil following the dose rate derived according to the calculations described in this section, the period of soil ageing starts. The crops tested in the field studies are planted/sown after the relevant ageing period (plant-back intervals, see also Section 5.3.10).

5.3.4.2. Active substances accumulating in soil ($DT_{90} > 365$ days)

In general, the decline of the a.s. in soil can be described with mathematical models, depending on the degradation kinetics (European Commission, 2006; FOCUS, 2014). Examples for different soil degradation kinetics for active substances with a similar DT_{90} are presented in Figure 6. The methodology for calculating the application rate for rotational crop field studies depends on the degradation/dissipation kinetics in soil.

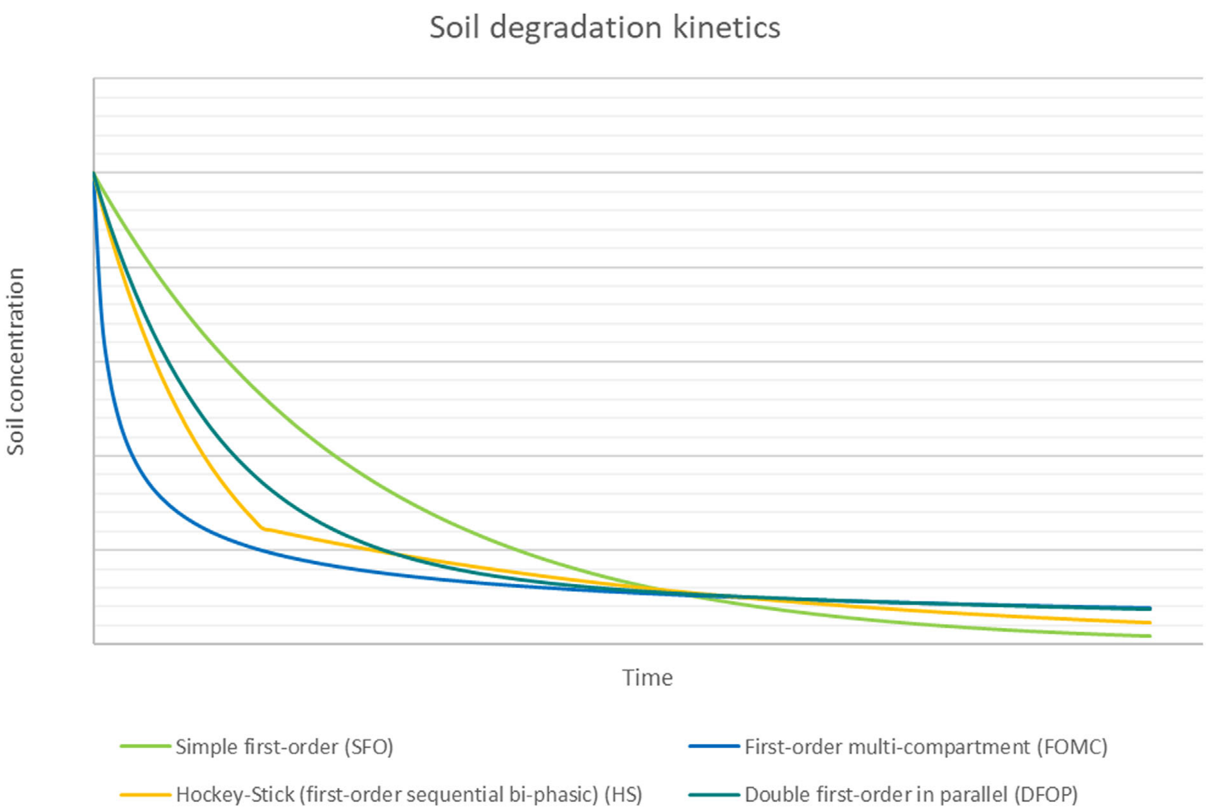

Figure 6: Examples for soil degradation kinetics

The use of a pesticide in the same field over multiple years, may lead to an accumulation of soil residues over time (see Figure 7), leading to a plateau residue concentration in soil.[32] In the design of rotational crop field studies the accumulation of residues in soil needs to be taken into account. Hence, the studies should be performed with soil containing residues at the peak accumulated $PEC_{(s)}$ (see Figure 7).

[32] It is noted that the calculating of the soil plateau concentration is based on the effective application rate for primary crops, considering crop interception (see also Section 5.3.4.1).

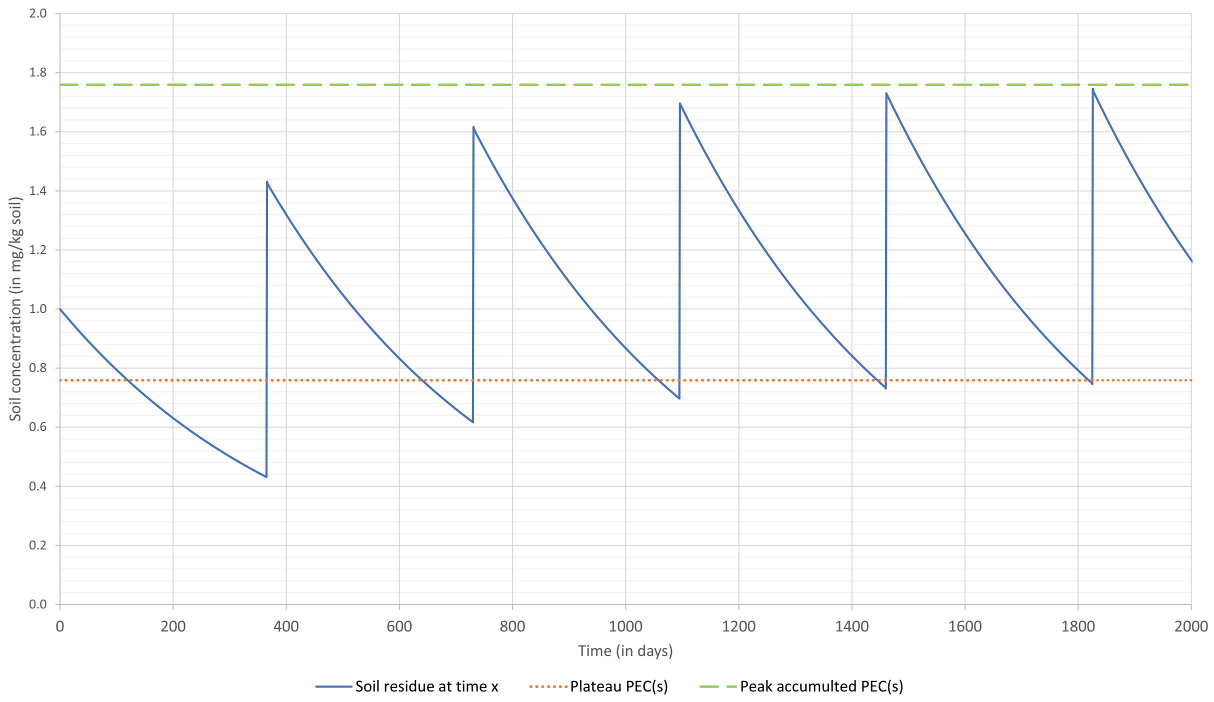

Figure 7: Example for soil accumulation of a persistent a.s. (application rate 1 kg/ha, SFO kinetics, DT_{90} 1000 days, multiannual use)

Section 5.3.4.3 describes the methodology for calculation of the application rate for rotational crop field studies for active substances which follow first-order kinetics, while for active substances with other degradation kinetics, the relevant information can be found in Section 5.3.4.4.

5.3.4.3. Active substances with degradation/dissipation following simple first-order kinetics

OECD Guidance Document (OECD, 2018) presents a method to calculate the application rates for active substances that accumulate in soil, which is applicable if the degradation follows simple first-order (SFO) kinetics. According to this OECD approach, rotational crop studies should be performed in soil that contains the residue concentration accumulated over time following treatment according to the critical GAP (soil plateau concentration) (in Figure 7 represented as orange dashed line) plus the soil residues resulting from an additional treatment according to the maximum seasonal rate defined in the critical GAP (peak accumulated $PEC_{(s)}$, represented in Figure 7 as green dashed line). OECD guidance proposes to calculate the application rate according to **Equation 8**.

In contrast to the OECD approach, the EU assessments usually consider crop interception not only for the calculation of the soil plateau concentration, but also for the treatment in the year of planting of rotational crops. Hence, at EU level, a different calculation methodology (**Equation 11**) is used. The EU option is less conservative and is considered to provide a more realistic basis for the soil concentration as crop failure is a rather exceptional event.

Equation 8: OECD method for calculation of the application rate for field studies (a.s. accumulating in soil, dissipation following first-order kinetics)

$$A_{total} = A_0 + A_{plateau}$$

A_{total}: Application rate for critical GAP for field studies (in g a.s./ha)
A_0: Total seasonal application rate to target crop (in g a.s./ha), without considering crop interception
$A_{plateau}$: Application rate corresponding to residues in the soil from long-term use of the product (in g a.s./ha); it can be calculated by multiplying the application rate for the critical GAP with f_{soil} and f_{acc}.

The application rate corresponding to $A_{plateau}$ is calculated according to **Equation 9**.

Equation 9: Calculation of $A_{plateau}$

$$A_{plateau} = (A_0 \times f_{soil} \times f_{acc})$$

f_{soil}: Fraction of the seasonal application rate reaching the soil after crop interception f_{soil} can be calculated as $\left(1-\left(\frac{CIR}{100}\right)\right)$.
f_{acc}: Accumulation factor; the accumulation factor f_{acc} is derived according to **Equation 10.**

Equation 10: Calculation of the accumulation factor f_{acc}: for the a.s. accumulating in soil, dissipation following first-order kinetics

$$f_{acc} = \frac{e^{-k\Delta t}}{1-e^{-k\Delta t}} = \frac{e^{-\frac{\ln 2}{DT50}\Delta t}}{1-e^{-\frac{\ln 2}{DT50}\Delta t}}$$

Δt: application interval, usually 365 days (for annual application)
k: degradation rate in soil derived from the half-life ($k = \ln 2/DT_{50}$)

Module 3.1 of the PRonTo calculator can be used to derive the accumulation factor.

The DT_{50} of the a.s. can be retrieved from the LoEP. Example 5 in Appendix B.4 illustrates how to identify the relevant DT_{50} in the LoEP derived by fate and behaviour experts.[33]

Equation 11: Alternative EU method for calculation of the accumulated application rate, taking into account crop interception (a.s. accumulating in soil, dissipation following first-order kinetics)

$$A_{acc} = \text{seasonal } A_{eff} + A_{plateau}$$

A_{acc}: accumulated application rate (expressed as g a.s./ha)
seasonal A_{eff}: seasonal effective application rate (in g a.s./ha) for the GAP under consideration is identified as outlined in Section 5.3.3, **Equation 6**
$A_{plateau}$: see **Equation 9**

The two options for calculating the application rate for accumulating a.s. following first-order kinetics (A_{total} and A_{acc}) for field studies can be calculated in Module 3.2 of the PRonTo calculator.

In general, it is recommended that an applicant provides a justification for the approach used to derive the application rate for the rotational crop field studies (EU methodology or OECD methodology). For the majority of cases, the EU method seems to be already a sufficiently conservative approach (see also Section 8 on uncertainty analysis); however, the consideration of interception may not be appropriate when the crop failure or where a substantial part of the crop is incorporated in the soil (i.e. cover crops or mulching of straw after harvest).

5.3.4.4. Active substances with degradation/dissipation that does not follow first-order kinetics(SFO)

The soil concentration to be tested in limited field studies should reflect the soil residues accumulated over time (plateau or accumulated background before annual application) plus the residues resulting from the use in the last year of treatment; hence, the studies should be performed with the peak accumulated $PEC_{(s)}$ (see Figure 7).

If the cGAP under assessment is different to the GAP assessed in the peer review, the application rate to achieve this soil concentration can derived in four steps as described below:[34]

If the cGAP is identical with the GPA assessed in the peer review, step 1 and 2 can be skipped; the adjustment of the plateau PEC(s) reported in the LoEP is not required.

Step 1: As the relevant endpoint reported in the LoEP which is used for this calculation (i.e. background/plateau $PEC_{(s)}$) refers to the representative GAP assessed in the peer review, an adjustment factor is calculated (**Equation 12**) to take into account the critical GAP under assessment for rotational crops.

[33] See also recommendations number 3, 4 and 7 in Section 9.
[34] It would be desirable that the relevant end point of the assessment of soil studies (i.e. $Acc(PEC_{(s)(20cm)})$ is reported in the LoEP, avoiding the work around as described in this section (see also Section 9, Recommendation 2).

Equation 12: Calculation of adjustment factor for recalculation of $PEC_{(s)(plateau)}$ for critical GAP

$$AF = \frac{\text{seasonal } A_{eff\ (critGAP)}}{\text{seasonal } A_{eff\ (repGAP)}}$$

AF: Adjustment factor
seasonal $A_{eff\ (critGAP)}$: Seasonal effective application rate (in g a.s./ha) for critical GAP relevant for rotational crop assessment (calculated according to **Equation 6**).
seasonal $A_{eff(repGAP)}$: Seasonal effective application rate (in g a.s./ha) for the representative GAP assessed in peer review (calculated according to **Equation 6**). This value is normally also reported in the LoEP as input parameter for the $PEC_{(s)}$.

An example how to identify the seasonal A_{eff} for the representative GAP is presented in Appendix B.6, Example 7.

Step 2: The plateau $PEC_{(s)}$ reported in the LoEP for the representative GAP is recalculated with Equation **13** to the critical GAP under assessment, applying an adjustment factor (**Equation 12**).

Equation 13: Calculation of the plateau $PEC_{(s)(20\ cm)}$ for the critical GAP

$$\text{plateau } PEC_{(s)(20cm)(critGAP)} = \text{plateau } PEC_{(s)(20cm)(repGAP)} \times AF$$

plateau $PEC_{(s)(20cm)(crit\ GAP)}$: plateau soil concentration calculated for the critical GAP under assessment (in mg/kg soil).
plateau $PEC_{(s)(20cm)(repGAP)}$: plateau soil concentration for the representative GAP assessed in the peer review (in mg/kg soil).

In Appendix B.7, an example is presented how to identify in the LoEP the plateau $PEC_{(s)(20cm)}$ of the representative GAP (Example 8).

Step 3: The plateau $PEC_{(s)(20cm)(critGAP)}$ is recalculated to an application rate per hectare, using **Equation 14.**

Equation 14: Conversion of the soil concentration expressed for 20 cm soil horizon (e.g. Acc $PEC_{(s)(20\ cm)}$) to the application rate (expressed as g a.s./ha)

$$\text{Application rate for plateau } PEC_{(s)(20cm)(critGAP)} = \text{plateau } PEC_{(s)(20cm)(critGAP)} \times 0.2 \times 1.5 \times 10000$$

The factors included in **Equation 14** accommodate for the soil horizon (0.2 m), the soil density (1.5 kg/dm^3) and the surface (expressed in hectare, recalculated to m^2 (10000)).

Step 4: The application rate for field studies is derived by adding the application rate reflecting the treatment in the last year (seasonal A_{eff} for critical GAP) to the application rate required to get the plateau PEC(s) for the critical GAP (see **Equation 15**).

Equation 15: Calculation of the application rate for field studies (accumulating a.s., not following first-order kinetic)

$$\text{Appl. rate forfield studies} = \text{appl. rate for plateau } PEC_{(s)(20cm)(critGAP)} + \text{seasonal } A_{eff\,(crit\ GAP)}$$

Appl. rate for field studies: peak accumulated $PEC_{(s)}$ (expressed as g a.s/ha).

Table 2 summarises the recommendations on the calculation of the application rates for a.s. to be used also for rotational crop field studies, reflecting the different degradation kinetics and soil persistence of the a.s.

Table 2: Determination of application rates for field studies (tier 2 and tier 3 studies)

Stability/ persistence of the a.s.: DT_{90}	Application rate for a.s. to be tested in tier 2 and tier 3 studies (g/ha)	
	SFO degradation kinetics	**Non-SFO degradation kinetics**
≤ 100 days	Not relevant	
Between 100 days and 365 days	Seasonal A_{eff}[(a)] (see Equation 6)	

Stability/ persistence of the a.s.: DT_{90}	Application rate for a.s. to be tested in tier 2 and tier 3 studies (g/ha)	
	SFO degradation kinetics	**Non-SFO degradation kinetics**
> **365 days**	OECD methodology: A_{total} (see Equation 8)	cGAP = cGAP assessed in peer review: plateau $PEC_{(s)}$ (recalculated to g/ha) + seasonal A_{eff} (see Equations 14 and 15)
	EU methodology: A_{acc} (see Equation 11)	cGAP ≠ cGAP assessed in peer review: Adjusted plateau $PEC_{(s)}$ (recalculated to g/ha) + seasonal A_{eff} (in g/ha) (see Equations 12–15)

(a): For practical reasons, it may be preferable to apply the maximum seasonal rate in one application rather than applying several applications in accordance with the Good Agricultural Practices (GAP). However, it should be carefully considered how this approach affect the levels of the soil metabolites at time of sowing in order to optimise the use of the studies.

Usually, a representative formulation containing the a.s. under assessment is used for these studies.

5.3.5. Should the plant protection product be applied to the primary crop or to bare soil?

In general, EFSA recommends performing field studies by application of the spray solution directly on bare soil which is in line with the recommendation of the OECD Guidance Document (OECD, 2018).[35] Direct soil application provides a better control over the amount of the a.s. reaching the soil.

After the soil treatment, soil incorporation is recommended to ensure a homogeneous distribution over the soil horizon for which the application rate was calculated, i.e. 20 cm. Rotational crops are planted/sown in ploughed soils.

Rotational crop residue trials where the active substance was applied on the primary crop might be acceptable, on a case-by-case basis, if all relevant information is provided to verify the amount of a.s. reaching the soil. In these cases, analysis of soil is useful to verify the residues concentrations in the tested soil. Also, in this type of studies, soil incorporation of the a.s. is required to ensure a distribution of the a.s. over the soil horizon of 20 cm.

5.3.6. Is it necessary to take soil samples and analyse them?

According to OECD TGL 504, the analysis of soil to determine the actual residue concentration for a.s. and soil metabolites is not mandatory. However, soil analysis may provide useful information to confirm that the study is sufficiently addressing soil metabolites (see Section 5.3.8). The soil samples should be taken in accordance with the respective soil sampling provisions; the soil samples should also reflect 20 cm soil horizon.

When assessing rotational crop field studies, it needs to be kept in mind that due to the complexity of the soil compartment, the measured soil concentrations for parent and metabolites may deviate from the soil concentrations predicted by modelling and from $PEC_{(s)}$ values reported in the LoEP. Deviations are expected and are acceptable, as long as a plausible reasoning for the sufficient formation of soil metabolites can be provided.

5.3.7. Which residue components need to be investigated in field studies?

The analysis of samples derived from rotational crop field studies should focus on parent compound as well as soil- and plant metabolites found at levels above 0.01 mg/kg in rotational crop metabolism studies (see Section 4.4). Hence, the samples should be analysed for the components included in the proposed residue definitions for risk assessment and enforcement derived from the rotational and primary crop metabolism studies. In addition, it is recommended to consider the inclusion of persistent significant soil metabolites ($DT_{90} > 365$ d) in the analytical scope, even if these soil metabolites were not detected in rotational crop metabolism studies at levels exceeding the trigger of 0.01 mg/kg. This should ensure that soil metabolites are not overlooked if they were not formed or were present only in low concentrations in the soil used for rotational crop metabolism studies.

[35] OECD TG 504 considers both options as possible.

If information on the residues in soil is available and the measured soil concentration of metabolites was in the expected range according to the assessment in the fate and behaviour, the absence of these metabolites in rotational crops provides sufficient evidence that the soil metabolites are unlikely to be taken up in rotation/succeeding crops. In extended field studies, these soil metabolites do not need to be further investigated.

5.3.8. How to make sure that soil metabolites are sufficiently addressed in rotational crop field studies?

Field studies should be performed in soils that reflect the presence of significant soil metabolites. In Appendix B.10, some examples are presented to illustrate under which circumstances field studies are considered representative/non-representative for metabolites. Normally, field trials are expected to address soil metabolites adequately, if during the period of the field study the concentration of the soil metabolite reaches its maximum.

In principle, rotational crop studies for metabolites can be performed according to three different options (see Figure 8) which are described below.

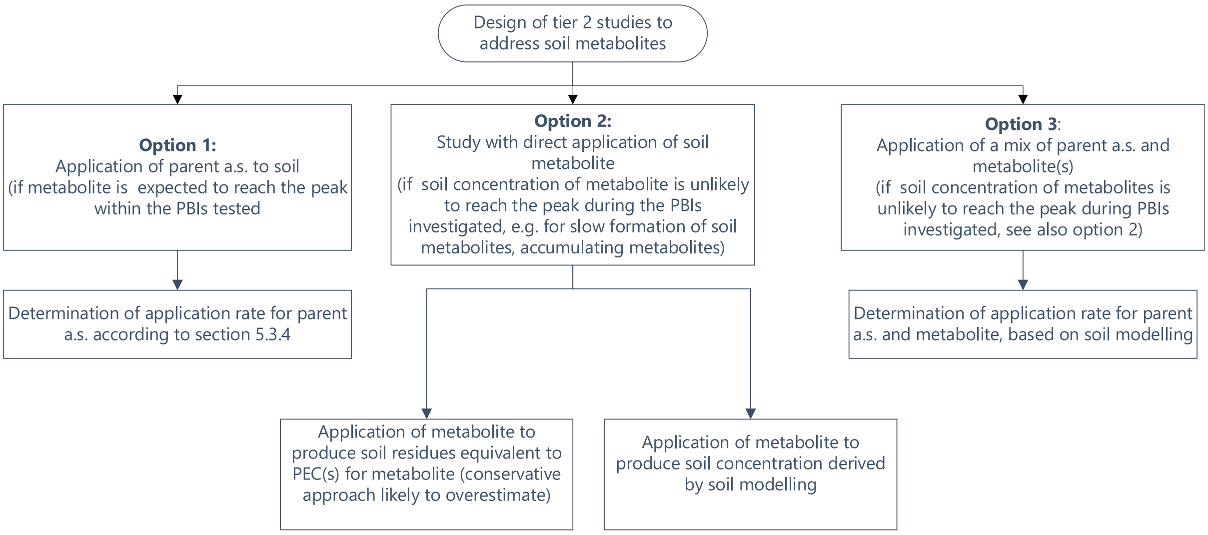

Figure 8: Design of field studies to be representative for soil metabolites

5.3.8.1. Option 1 studies: studies performed with the a.s.

For active substances that degrade rapidly to significant metabolites and that do not form persistent soil metabolites, in general, field studies are expected to address soil metabolites adequately, if the parent a.s. was applied on the soil at a dose rate that corresponds to the application rate calculated as suggested in Section 5.3.4 and the rotational crops are planted/sown after an appropriate ageing period which allows the formation of soil metabolites before the rotational crops are planted/sown or during the field study.

Applicants could consider modifications of the study design when setting up the study protocol for field studies, in particular for soil metabolites that accumulate and/or have a slow formation rate, ensuring that the actual residues for the metabolites in soil reflect a realistic worst-case situation, e.g.

- Performing the study with a higher application rate than the application rate as described in Section 5.3.4; in this case the results should be scaled (see Section 5.3.9 on how to scale results);
- Performing field studies with different PBIs within the ranges defined in OECD TG 504 or additional PBIs to ensure that the peak of the significant soil metabolites is covered by the study;
- Performing field studies on soil types in which the formation of the specific metabolite is expected/favoured;
- Performing field studies in soils that have received treatment over several years (this might be an option for accumulating metabolites);

An applicant should provide data or explanations to demonstrate that studies performed with the parent compound are sufficiently addressing the soil metabolites, e.g. by providing data to demonstrate that the soil metabolite is not taken up via roots (e.g. studies in hydroponic systems with a solution containing the soil metabolite: if the soil metabolite is not taken up from the roots, the lower soil concentration of the metabolite compared to soil modelling would not be of relevance). Although not mandatory, the analysis of soil could provide useful information facilitating the interpretation of the study.

5.3.8.2. Option 2 studies: separate studies for metabolites

For soil metabolites that are characterised by a slow formation rate and a high persistence/ accumulation potential in soil, the soil concentration formed after treatment of the soil with the parent compound may not be sufficiently high. In these cases, it might be necessary to perform additional field studies with soil treated directly with the relevant soil metabolites. It is recommended to discuss with experts whether separate field studies with metabolites are required in case the concentration of soil metabolites designed as described in option 1 is lower than the levels predicted by fate models and no plausible explanation for the low concentration can be provided by the applicant.

For studies performed with the direct application of soil metabolites to the soil, the application of a dose rate equivalent to the peak $PEC_{(s)}$ of metabolites may be used as conservative worst-case test conditions (Example 9 in Appendix B.8 illustrates how to derive the $PEC_{(s)}$ for accumulating metabolites). However, in real field conditions, in most cases the actual soil concentrations might be significantly lower than the peak $PEC_{(s)}$, depending on the degradation kinetics in different soil types. Thus, rotational crop studies performed in soil with lower soil concentrations of soil metabolites might be also considered acceptable. An applicant shall provide the rationale for the soil concentrations tested in the field study (e.g. soil concentrations calculated based on soil modelling). It is expected that the development of new tools will in future facilitate the determination of relevant concentrations for soil metabolites to be considered in residues in rotational crop field studies.[36]

The application rate for metabolites reflecting the peak $PEC_{(s)}$ can be calculated according to the following generic equation, which allows to convert a soil concentration (expressed as mg/kg soil) to an application rate (expressed as g/ha).

Equation 16: Conversion of the soil concentration expressed for 20 cm soil horizon to an application rate (expressed as g ha)

$$\text{Application rate}\left(\frac{\text{g}}{\text{ha}}\right) = \text{soil concentration}\left(\text{in}\,\frac{\text{mg}}{\text{kg}}\,\text{soil}\right) \times 0.2 \times \text{soil density}\left(\text{in}\,\frac{\text{kg}}{\text{dm}^3}\right) \times 10{,}000$$

Soil density: default soil density 1.5 kg/dm^3; if the study is performed in soil with significantly different soil density, the default soil density should be replaced.

For field studies performed with soil directly treated with the metabolite(s), it is noted that the usual PBI testing regime may not be fully applicable as rotational crops are planted/sown in a soil that contain the expected soil concentration of the metabolite. Therefore, field studies with a short PBI may be sufficient. However, a short ageing period after the treatment of the soil with the metabolite should be allowed to allow proper adsorption of the substance in soil (mimicking bioavailability under more realistic conditions, as default 3–7 days[37] are proposed).

5.3.8.3. Option 3 studies: studies with a mix of parent a.s. and metabolite(s)

The field study can also be designed to assess the a.s. and the significant metabolites in one assay, by spiking the soil simultaneously with the a.s. and metabolites (e.g. for situations where the a.s. and the significant metabolites are rather persistent). However, the interpretation of option 3 studies may be more complex and will require further considerations/assumptions, due to the inter-relation of soil concentrations of parent and metabolites which will increase the overall level of uncertainty. Also in this case, if soil is treated with parent a.s. and metabolites in one assay, a justification should be

[36] The development of new tools (based on the soil modelling implemented in PERSAM) will allow a more realistic estimation of the soil concentration for metabolites shall be promoted to allow more refined assessments for rotational crops (Section 9, recommendation 8).

[37] In this option, the studies are not performed with the commercially available formulation. In some instances, this may lead to some additional uncertainties. The purpose of a short aging period after application is to simulate a realistic incorporation of the metabolite to soil. The adequacy and extension of such period may depend on the properties of the metabolite and conditions of the test site. A period of 3–7 days is proposed as indicative.

provided for the selection of the dose rates of the different soil residue components (parent and metabolites).

5.3.9. Scaling of results of over- or underdosed rotational crop field studies

The scaling factor is the inverse value of the N-rate (see Equation 3). In the following paragraphs, it is described how to calculate the N-rate for rotational crop field studies.

Similar to rotational crop metabolism studies, the field studies may be performed with higher application rates than the one derived for the critical GAP. If this is the case, the results for the a.s. should be scaled as described in Section 4.4.1, Equation 2.

If soil analysis data for the parent a.s. following the soil treatment are available, the measured concentration of the a.s. can be used in calculating the N-rate, instead of using the application rate tested in the study (i.e. replacing the application rate tested (nominator in Equation 2) by using the measured soil concentration).

For soil metabolites, different N-rates/scaling factors might need to be derived compared to the parent compound. This is to accommodate for the fact that the soil concentration of the parent and the metabolite follow different formation/degradation kinetics (e.g. for the parent compound that degrades quickly, the study might be overdosed, while for a persistent metabolite ($DT_{90} > 365$ days) which is accumulating over time the study might be considered as underdosed). The N-rates/scaling factors should be calculated, depending on the study design that was chosen.

For field studies performed with the a.s. (option 1 studies, see Section 5.3.8.1), scaling may not be required, if the soil metabolites are expected to reach the maximum concentration during the duration of the study.

If this is not the case, and soil concentrations of metabolites were measured, a theoretical N-rate can be calculated, comparing the measured soil concentration with the expected soil concentration. The N-rate can be calculated following **Equation 17**.

Equation 17: Calculation of the N-rate for metabolites for field studies according to option 1, with measured soil concentration (see Section 5.3.8).

$$N = \frac{\text{measured soil concentration (option 1)}}{PEC_{(s)} \text{ or modelled soil conc.}}$$

Measured soil concentration (option 1): expressed in mg metabolite/kg soil. Soil concentration measured at a certain time point (usually at the time of planting the rotational crops).

$PEC_{(s)}$: in mg metabolite/kg soil; $PEC_{(s)(20cm)}$ (for non-accumulating metabolites) or Acc $PEC_{(s)(20cm)}$ (for accumulating metabolites).

Modelled soil concentration (in mg metabolite/kg soil), derived by using refined soil modelling approaches (e.g. modelling of soil concentrations for the soil type used in the study).

If no soil analysis data are available, the N-rate/scaling factor could be calculated considering the formation kinetics of the metabolites and the actual application rate tested in the study (**Equation 18**).

Equation 18: Calculation of the N-rate for metabolites for field studies according to option 1 without measured soil concentration (see Section 5.3.8).

$$N = \frac{\text{estimated max. soil concentration}}{PEC_{(s)} \text{ or modelled soil conc.}}$$

Estimated max. soil concentration: Maximum expected soil concentration during the duration of the rotational crop study (derived by modelling) reflecting the dose rate of the a.s. applied in the study.

The N-rates derived for metabolites according to **Equations 17** and **18** and the related scaling factors are expected to be affected by a high level of uncertainties as the soil concentration is not constant and may increase or decrease during the field trial (see Section 8 on uncertainties analysis).

An applicant shall explain how the modelled reference soil concentration (used as denominator in **Equations 17** and **18** was derived, by providing data on the soil modelling. Overall, the calculated N-rate for metabolites is expected to be affected by an elevated level of uncertainties.[38]

[38] More guidance and tools need to be developed for realistic, fit-for purpose modelling of soil concentrations for metabolites (see Section 9, recommendation 8).

Results of field studies which were performed with metabolites (option 2 studies, see Section 5.3.8.2) can be scaled in the same way as studies performed with the parent a.s. (see Section 4.4.1). The N-rate/scaling factors can be calculated by comparing application rate of the metabolite with the application rate derived from the theoretical soil concentration (i.e. the $PEC_{(s)}$ derived as described in Example 9, Appendix B.8 or the modelled soil concentration of the metabolite).

Currently, only limited experience is available regarding the scaling of results for metabolites where a mixture of the a.s. and metabolites was applied (option 3 studies, see Section 5.3.8.3).

It seems appropriate that – based on experience gained by following the approach described in this document – further guidance should be developed to clarify and agree in which situations scaling of results for field studies, in particular for soil metabolites, is appropriate.[39]

5.3.10. How many rotational intervals need to be investigated for limited field study?

In general, three plant back intervals need to be addressed, reflecting circumstances of crop failure or closely rotated crops (PBI 7–30 days), PBI representative for the usual agricultural practice of planting succeeding crops for the following year (PBI 270–365 days) for crops and an additional PBI to reflect the typical harvest interval (PBI 60–270 days, preferably between 90 and 180 days).

For a.s. that degrade to metabolites, additional considerations on the choice of PBIs should be taken into account, to ensure that the soil metabolites are sufficiently addressed.

If limited field studies are performed with the soil metabolite (see Section 5.3.8.2), a deviation of the default PBI schema might be justified, as the soil ageing (i.e. time required for the formation of the metabolites) can be shortened.

5.4. Interpretation and evaluation of rotational crop field studies

Rotational crop field studies provide a comprehensive data set which covers at least three crops representative for three crop groups; for each crop samples from three PBI are taken. Depending on the crop, one or several relevant matrices are analysed. If separate studies were performed with soil metabolites or with formulations fortified with soil metabolites, additional data sets from these studies are reported.

Over- or underdosed field studies (performed with an exaggerated or a lower dose rate compared to the nominal dose rate calculated as outlined in Section 5.3.4) should be scaled using a scaling factor described above. Scaling-up of underdosed studies requires careful considerations, in particular if the a.s. and/or significant metabolites were occurring at low concentrations (i.e. below a concentration that allows a reliable quantification; below the LOQ).

Scaling of individual components of the residue definition (e.g. in case soil metabolites did not reach the maximum concentration during the duration of the study) is affected by a high level of uncertainty. In Appendix B.9 an example is presented explaining in more details the related uncertainties that may lead to a bias in the assessment.

6. Extended field studies for MRL setting and/or determination of appropriate risk mitigation measures (tier 3)

6.1. What is the purpose of extended field studies?

The purpose of the extended rotational crop field studies (tier 3 studies) is to complement the metabolism and limited field data sets, in order to obtain a more comprehensive and more representative picture of expected residues in a wider range of succeeding crops under realistic field conditions, reflecting a wider range of variability with respect to soil types and other relevant parameters. The combined data sets (metabolism and field studies) can be used

- to derive the final conclusion on the residue definition (see Section 6.4.1);
- to derive risk assessment values and MRL proposals for rotational crops and/or
- to define restrictions for cultivation of succeeding crops on fields previously treated with the a.s. under assessment to avoid/limit the uptake of residues in the individual rotational crops.

[39] See Section 9, recommendation 9.

6.2. When are the extended field studies necessary?

If – based on metabolism and limited field studies – residues in rotational crops are expected to occur at significant levels (i.e. one or several of the individual components of the residue definition are equal or above 0.01 mg/kg in any of the matrices of limited field studies at any PBI tested), extended field studies in rotational crops (tier 3 studies) are required. The trigger value of 0.01 mg/kg refers to the scaled result of the limited field studies.[40]

If there is sufficient evidence that in one or several of the tested crop groups residues of all individual relevant compounds are below the trigger value of 0.01 mg/kg (e.g. data from metabolism studies and limited field studies or studies in primary crops with soil treatment), extended field studies can be waived for the relevant crop group(s). More details on the triggering of extended field studies for crop groups can be found in Section 6.3.1.

An additional option to waive these studies is the definition of restrictions which should ensure that no residues are taken up from soil that has been previously treated with the a.s. Possible restrictions are the definition of plant back intervals or the limitation of the application rate in primary crops. More detailed options on setting restrictions can be found in 6.4.6. An applicant is free to propose additional waivers which will be checked in detail on a case-by-case basis.

6.3. Design of extended field studies

The OECD TG 504 guideline applies both to limited and extended field studies (tier 2 and tier 3). Most of the general design principles presented for limited field studies apply equally to extended field studies. Hence, the recommendations for limited field studies on the geographical distribution of field trials (see Section 5.3.1), the application rates to be tested to ensure that the rotational crop studies are representative for the parent a.s. and the significant soil metabolites (see Sections 5.3.4 and 5.3.8), and recommendations on the analysis of the crop samples and of soil samples (see Section 5.3.7) are also valid for the extended field studies. The results of the limited field trials can be used to decide on the PBIs to be tested.

In the following section, some specific aspects on the selection of the crops to be tested are presented.

6.3.1. Selection of crops for extended field studies; number of studies

According to OECD (2018) the annual crops are classified in six so-called 'super crop groups', being

1) root and tuber crops,
2) bulb and stem vegetables,
3) cereals,
4) leafy vegetables and brassica,
5) oilseeds and pulses and
6) fruits and fruiting vegetables.

The allocation of annual crops to the six super crop groups can be found in Appendix A.2. Within each super crop group, one to three subgroups are established, resulting in a total of 12 subgroups (see Figure 9).

Extended field studies in crops belonging to the super crop groups should be performed if triggered by limited field studies. If in the tier 2 study, residues were below 0.01 mg/kg in all matrices of a crop tested, the relevant crop group does not need to be tested in tier 3. The triggering schema is presented in Figure 9.

For each crop subgroup, four or eight trials (depending on the importance of the crop for human consumption and/or agricultural production) are required; data need to be provided for the relevant parts of the crops as described in Appendix A.2, Tables A.2 and A.3. Overall, up to 60 residue trials might be required, unless studies in certain crop groups/subgroups are waived or are not triggered.

[40] Feed items are a special case: if residues above 0.01 mg/kg but below 0.05 mg/kg are expected in feed items (products that are exclusively used for feed purpose), and if it can be demonstrated that these residues do not contribute significantly to the dietary burden calculation, extended field studies can also be waived.

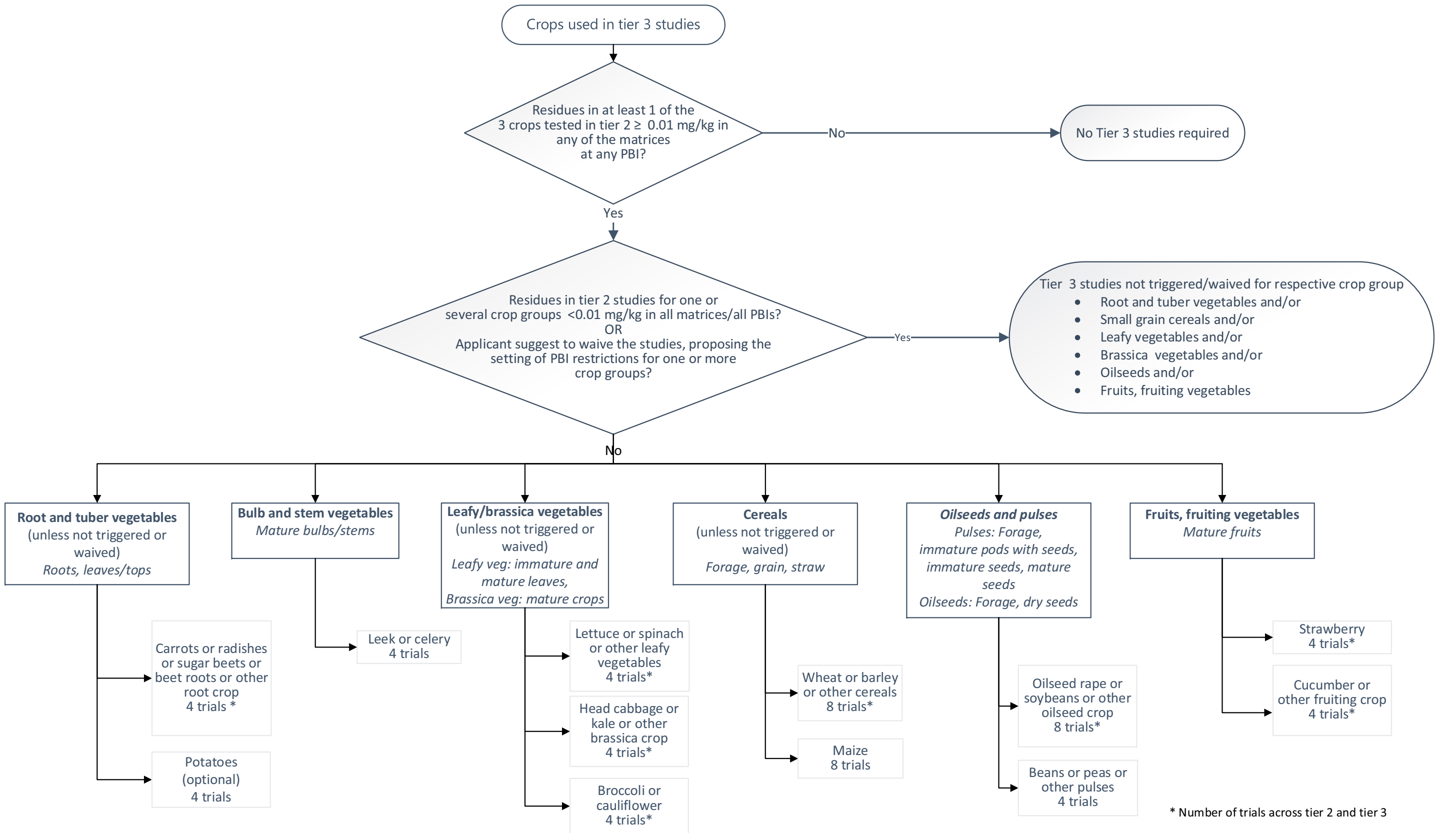

Figure 9: Selection of crops for extended field studies

6.4. Interpretation and evaluation of rotational crop field trials

Overall, the data set on rotational crop studies consists of up to 60 rotational crop trials (pooled limited and extended field studies), with typically three PBIs, respectively (under certain conditions trials on certain PBIs may be waived).[41] For each crop, data for several matrices may be available.

The individual results of the field studies need to be scaled, if the studies were over- or underdosed (for details on scaling, see Section 5.3.9); however, scaling up of underdosed studies and/or scaling of individual components of the residues (e.g. if the concentration of a soil metabolite was lower than expected) is an option that needs to be carefully checked, as it may lead to a high level of uncertainties (see also Appendix B.9).

The data set is used to derive:

- the final conclusion on residue definitions for rotational crops (see Section 6.4.1),
- input values for dietary risk assessment (HR and supervised trials median residue (STMR), see Section 6.4.2),
- input values for livestock dietary burden calculation (see Section 6.4.3) and
- MRL proposals (see Section 6.4.5) and/or
- possible risk management restrictions (see Section 6.4.6).

6.4.1. Considerations on residue definitions for rotational crops

The setting of residue definitions is not subject of the current guidance document. The provisions of the specific guidance at EU or OECD level should be applied. In general, information from rotational crop metabolism and field studies should be taken into account to take a decision which components are candidates to be included in the residue definitions. As regards the residue definition for enforcement, the existing enforcement residue definition derived for primary crops would be the preferred option, as in MRL enforcement, the origin of the residue (e.g. resulting from direct treatment or uptake of residues in succeeding crops from soil cannot be distinguished). However, it might be necessary that an additional enforcement residue definition is established for rotational crops to address metabolites that occur only in rotational crops.

For each individual rotational crop study, the results should be expressed according to the residue definitions for enforcement and for risk assessment. If necessary, the results for individual components (metabolites) need to be re-calculated to the parent compound or the common moiety for which the residue definition refers to, considering the molecular weight correction factor.

These results are used for the subsequent statistical analysis as described in the following sections.

6.4.2. Deriving input values for dietary risk assessment for consumers and for dietary burden calculation for livestock

In general, the input values for performing the dietary risk assessment and dietary burden calculations reflecting the residue definition for risk assessment are derived according to the following procedure:

1) The eight or four results of trials in crops belonging to a subgroup of the super crop groups reflecting the same PBI are combined to be assessed as a group (e.g. combining of data for mature lettuce and mature spinaches reflecting a PBI of 30 days[42]).
2) For each matrices/PBI combination within a subgroup, the HR according to the residue definition for risk assessment (HR) is derived.
3) Identify the PBI with the highest HR in the relevant matrix and calculate the median residue level (STMR) for this PBI.
4) For crops/plant commodities, for which no specific rotational crop trials are available, the estimates for dietary risk assessment are derived by extrapolation from the data set representative for the crop/commodity. Table 3 of the OECD guidance (OECD, 2018) provides some recommendations for extrapolations; based on this, more detailed

[41] OECD Guidance Document proposes that the design of tier 3 studies should address the conclusions from tier 1 and tier 2 studies concerning the most critical PBI to be investigated. Considering that in tier 2 only a limited number of studies is available, reflecting also a limited variability of soil types, it would be desirable to have data from all PBIs analysed in tier 3 as this would allow to get a more comprehensive picture on the actual residue situation.

[42] If the PBIs tested in the different rotational crops differ significantly (e.g. PBI 7 days for crop 1 and 30 days for crop 2) it may not always be appropriate to pool them. A case-by-case assessment is recommended.

recommendations for extrapolations to each rotational crop/commodity are suggested in Appendix A.4, Table A.6.[43]

5) Table A.7 provides recommendations for extrapolations for feed items, relevant for the dietary burden calculation.
6) For animal products, risk assessment values shall be derived that reflect the difference between livestock exposure with and without considering the residues in rotational crops (see Section 6.4.2).

A practical example illustrating the approach for plant products relevant for human consumption can be found in Appendix B.11 (Example 12). Example 13 describes the approach for deriving the input values for feed items to be used in the dietary burden calculation.

At the end of this procedure, STMR and HR values are allocated to each individual annual crop used for human consumption and for feed items.

These input values for plant and the derived input values for animal products are the values to be used in the dietary risk assessment (see Section 6.4.4).

6.4.3. Calculation of the dietary burden for livestock considering residues in rotational crops; calculations and risk assessment values for food of animal origin

The dietary burden calculation for livestock which is the basis for the calculation of the risk assessment values for consumers risk assessment and the setting of MRLs for animal products needs to take into account that livestock is not only exposed to residues resulting from primary crop treatment, but also to residues in feed items taken up from soil (resulting from previous application of the a.s. on the field). EFSA proposes to follow the approach as outlined in the six steps below.

Step 1: Deriving the input values for dietary burden calculation reflecting only primary crop uses (standard approach for assessing residues in animal products).

Step 2: Calculation of the dietary burden for livestock and the expected residues in animal products without consideration of rotational crop residues (HR and STMR for individual animal commodities without rotational crops reflecting the residue definition for risk assessment for animal products). For this calculation, the Animal Model 2017[44] shall be used.

Step 1 and 2 calculations follow the usual approach for primary crop assessment, independent of the rotational crop assessment.

Step 3: Deriving the input values for feed items included in the dietary burden calculation that reflect residues in rotational crops.

The feed items can be classified in four categories:

a) Feed items from annual crops that can also serve for human consumption (e.g. head cabbage, root and tuber crops, cereal grains, pulses (seeds);
b) By-products derived from food production based on annual crops (e.g. soybean meal, sugar beet by products, potato dried pulp);
c) By-products derived from food production based on permanent crops (e.g. citrus dried pulp, coconut meal, apple pomace);
d) Forages.

For feed items belonging to category (a), the STMR/HR values are derived according to the procedure described in Section 6.4.2.

For feed items of category (b), the input values for the dietary burden calculation can be derived from the STMR of the respective unprocessed agricultural commodity, multiplied with an appropriate processing factor. In absence of specific processing factors, the default processing factors can be used.

Category (c) is not relevant in view of the discussion of rotational crops.

For category (d) feed items, the results of rotational crop studies are available for the following matrix subgroups:

- Leaves of root and tuber vegetables;
- Cereals forage;
- Oilseed forages;
- Forages of legume vegetables.

[43] More guidance on the extrapolation of rotational crop studies should be developed (Section 9, Recommendation 15).
[44] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

The results of the rotational crop studies for the relevant feed items need to be extrapolated to all the feed items included in the dietary burden calculator. Where necessary, processing/dehydration factors need be taken into account.

Appendix A.4, Table A.7 provides further recommendations on how to derive the input values for the dietary burden calculation from rotational crop studies by extrapolation. Table A.7 also proposes default processing factors to be used to recalculate the residues measured in the matrices of rotational crop field studies to match with the commodities in the dietary burden calculator (e.g. default dehydration factors, etc).[45]

In Appendix B.11, Example 13, the derivation of the input values for rotational crops is illustrated. The HR and STMR values for feed items (feed items grown as rotational crops) are used in the calculation described in step 4.

Step 4: A calculation of the dietary burden for livestock using the animal model is performed; the dietary burden should reflect residues in primary crops plus residues resulting from rotational crop residues. For this calculation, the input values derived in step 3 are added to the input values derived in step 1. Hence, two separate files of the Animal Model 2017 need to be prepared (one as described in step 2 and the second as described in this step).

Step 5: If the dietary burden calculated in step 4 is below the trigger for feeding studies, no further assessment of residues in animal commodities is required.

If the dietary burden calculated in step 2 was below the trigger and the dietary burden calculated in step 4 was above the trigger, the risk assessment values for animal products need to be derived (see step 6).

If the dietary burden calculated in step 4 does not differ by more than 25% from the dietary burden calculated in step 2,[46] no further assessment is required, as the contribution of rotational crop residues is sufficiently covered by the dietary burden calculated on the basis of primary crops.

If the dietary burden increases by more than 25% compared to the one of step 2, the expected residues in animal products (HR and STMR for the individual animal commodities) should be derived that reflect the contribution of residues intake via rotational crops (continue with step 6).

Step 6: The results of the feeding study need to be included in the two dietary burden calculations performed with the Animal Model 2017 (see step 2, reflecting the uses of the pesticide in primary crop and step 4 reflecting the combined dietary exposure of primary crop uses and residues in rotational crops). From both calculations, the differences of the HR/STMR values are calculated for the different animal matrices/species. These HR and STMR differences can be used as input values in the dietary exposure assessment for the rotational crop scenario (see Section 6.4.2). These values represent the increased dietary exposure of consumers related to residues in rotational crops.

6.4.4. Dietary risk assessment for consumers

EFSA proposes that the risk assessment shall be performed in two separate PRIMo (Pesticide Residues Intake Model) calculations, i.e.

- the exposure assessment/risk assessment reflecting the uses in primary crops/animal commodities resulting from the uses in primary crops and
- the exposure assessment/risk assessment reflecting residues in plant and animal products occurring as a consequence of the residue uptake in rotational crops from the soil (see Section 6.4.2).

For the decision-making process, the results of both calculations need to be combined and presented in a format that allows to derive conclusions on consumer health risks.

In the **combined chronic exposure/risk assessment**, the results of the exposure calculation for the individual diets (expressed as % of the ADI) are summed up.

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[45] It is recommended to further develop the approach for dietary burden calculation for rotational crops. In addition, it would be desirable to update the dietary burden calculator to facilitate the calculations (Section 9, Recommendation 17bis).

[46] The 25% rule is usually applied to decide whether results are comparable (e.g. for residue trials, deviations of 25% of the application parameters are accepted). The 25% difference is proposed by EFSA to be used in this context by analogy, considering the overall conservatism of the dietary burden calculation and the estimation of residues in food of animal origin.

> *Example*: *The chronic consumer exposure from the intake of primary crops for NL toddler accounts for up to 35% of the ADI; the chronic consumer exposure calculated from the intake of rotational crops for NL toddler diet accounts for 17% of the ADI. The combined chronic exposure is 52% of the ADI for the NL toddler diet. Attention should be paid to sum up the results for the same diets (NL toddler plus NL toddler) and not mixing diets (e.g. NL toddler for primary crop uses plus DE child reflecting rotational crop residues)*.

The **combined acute consumer** exposure is calculated by summing up the exposure calculated for the respective commodity (expressed as % of the ARfD).

> *Example*: *The acute consumer exposure to residues in escarole resulting from the use of the pesticide in escaroles (primary crop treatment) is 96% of the ARfD; the acute consumer exposure calculated from the HR derived from rotational crop studies in leafy vegetables is 32% of the ARfD. The combined acute exposure from the intake of residues in escarole is 128% of the ARfD. In this case the setting of a combined MRL for escaroles that reflects the use in primary crops and the uptake from soil would not be acceptable*.

This approach of calculating separate PRIMo scenarios for primary crop uses and rotational crop residues is considered to be the most transparent approach to allow an informed risk management decisions and/or to easily refine the calculations to implement risk management considerations. In addition, the separate calculations of dietary exposure for uses in primary crops and for rotational crops would allow an update of risk assessment calculations for new applications (e.g. for new uses in primary crops not having an impact on the rotational crop assessment (update of the primary use calculations only) or new uses which will trigger an overall re-evaluation of rotational crops). In addition, the proposed approach will simplify the risk assessment in case different residue definitions for risk assessment are applicable for primary and rotational crops.

6.4.5. Deriving MRL proposals

The setting of MRLs is a risk management decision that should ensure that pesticides are used in accordance with the authorised use conditions and that residues in food does not pose an unacceptable risk to consumers. While the setting of MRLs for uses in primary crops follows a well-established procedure, limited experience is available at EU level on the setting of MRLs that reflect the residues taken up from the soil by succeeding crops. It is noted that the OECD Guidance Document on rotational crops proposes several options for MRL setting in rotational crops. JMPR also developed practices that follow the spirit of the OECD Guidance Document on rotational crops, but that deviate to a certain extent from the OECD methodologies.[47]

In the following paragraphs, EFSA proposes a pragmatic, transparent approach for setting MRLs for rotational crops that should ensure that MRLs are set sufficiently high to cover realistic worst-case situation, but that are not grossly overestimating the expected residues, respecting the ALARA principle, as setting MRLs at a level higher than necessary might bear the risk to cover illegal uses.

For pesticides that have the potential to lead to residues in succeeding/rotational crops, two situations should be distinguished:

- The use of the pesticide is not approved for being used in a crop, but residues may occur if this crop is grown as rotational crop (MRL setting option 1, setting specific MRLs for rotational crops).
- The use of the pesticide is approved in the primary crop. Hence, the final residues in the crop reflect the primary crop use and the residues taken up from the soil containing residues from previous uses of the pesticide (MRL setting option 2, setting combined MRLs).

The approach for setting MRLs for these two options are outlined in Sections 6.4.5.1 and 6.4.5.2.

[47] JMPR noted that the 'use of statistical methods for the estimation of MRL is not possible when considering potential carry-over of residues in succeeding crops since the basis arising from the additional root uptake cannot be adequately calculated, using OECD MRL calculator' (FAO, 2020). Therefore, the MRLs are derived by increasing the MRL derived for primary crops, adding a contribution of rotational crops.

In order to identify the crops for which MRL setting option 1 or option 2 is relevant, the annual crops covered by the pesticide MRL regulation (Regulation (EC) No 396/2005) should be screened, verifying whether

- uses for primary crop treatment are authorised in the EU for the respective crop;
- residues above the LOQ are expected following the primary crop treatment;
- the applicant requested to set restrictions that should ensure that residues do not occur in the crop crops grown as rotational crop;
- extended rotational crop field studies were not triggered for the respective crop group (i.e. residues in tier 1 and tier 2 were all below the LOQ).

Alternatively, if the restrictions suggested by the applicant ensure that residues are not taken up in crops grown as succeeding/rotational crops (see Section 6.4.6), a specific MRL covering rotational crops is not required.

6.4.5.1. Specific MRLs for rotational crop

The OECD Guidance Document (OECD, 2018) does not explicitly provide guidance on the calculation method to derive rotational crop specific MRLs, i.e. MRLs derived only from the dataset of residues remaining from the treatment of preceding crops. In previous assessments, MRLs were set either

1) by using the OECD MRL calculator and inserting the residues derived from the rotational crop field trials (pooled results for a crop group/subgroup taken at a certain PBI reflecting the residue definition for enforcement) or
2) by rounding the HR of the respective data set to the next MRL class.

For future assessments, EFSA recommends to use the OECD MRL calculator, as this would guarantee that the MRL proposal derived from a relatively small data set reflects the variability within the available results in rotational crops.

The proposed approach should be also applied, if the MRL for the primary crop use is set at the LOQ (e.g. for no-use or no-residue situations in primary crops) and residues above the LOQ were identified in rotational crop studies.

6.4.5.2. Combined MRLs

If the screening described in Section 6.4.5 identified the potential need to re-consider the existing MRL for a given crop (group) the following points should be checked:

1) According to the OECD Guidance Document, the additional residues taken up by succeeding crops from the soil has to be considered, if the contribution of residues in rotational crops is $>$ 25% of the residues arising after primary treatment. EFSA suggests that the condition is considered to be fulfilled, if the HR (according to the residue definition for enforcement) of the respective data set relevant for a crop is greater than 25% of the MRL reflecting the primary crop use or in case the MRL for primary crops is set at the LOQ, if the HR in rotational crops is greater than the LOQ.
2) If the soil uptake is low compared to the residues resulting from the primary crop use (HR of rotational crop $\leq$ 25% of the MRL derived for primary crop uses), the MRL for the primary crop is considered to cover these additional residues and no modification of the MRL is required.
3) If the existing EU MRL is an import tolerance or it is a Codex MRL, it is not appropriate to amend the MRL, including additional residues from soil uptake reflecting the worst-case EU uses. In this case, the most critical EU use needs to be identified and checked whether the primary crop use plus the residues taken up via soil in the crop grown as rotational crop is sufficiently covered by the existing EU MRL.
4) In Section 4.5, more details are reported on the requirements if an applicant requests the setting of an import that should also reflect rotational crop residues. In principle, the MRL for rotational crops required for EU uses (calculated in accordance to the procedure outlined in Section 6.4.5.1) might be higher than the existing import tolerance or Codex MRL. In this case, the MRL should be amended accordingly. However, if the existing import tolerance or Codex MRL is higher, or there are no EU uses no change in the respective MRL is required.

For the situation where a combined MRL needs to be established, OECD presented different approaches.

For pragmatic reasons, EFSA proposes the following approach which can be easily implemented in the EU regulatory workflows (i.e. MRL applications, MRL reviews and approval of a.s.):[48]

- The HR of the respective data set relevant for a crop (i.e. the value that was used to check if the setting of a combined MRL is required) is added to the MRL reflecting the primary crop use.
- The calculated value (existing MRL plus HR of rotational crop) is then rounded up to the next MRL class.

6.4.5.3. MRLs for animal commodities

If the dietary burden for livestock increases significantly due to a livestock exposure via rotational crops (see Section 6.4.3), a modification of the existing MRL might be required. In this case, the MRL calculation performed with the Animal model[44] as described in step 4 of Section 6.4.3 is the basis for the MRL calculation.

6.4.6. Restrictions for rotational crops to avoid/limit residues in succeeding crops

An alternative or a complementing risk management option to the setting of MRLs is the setting of restrictions for the use conditions that should limit or avoid residues in succeeding/rotational crops. The OECD Guidance Document (OECD, 2018) provides a list of typical label restrictions, such as.

- Type of crops excluded from being planted directly in rotation;
- Plant-back intervals;
- Limitations/restrictions on the number of applications of the a.s. per year;
- Limitations/restrictions on the maximum amount of the a.s applied per season or year;
- Limitations/restrictions on use of a.s. in consecutive years.

If an applicant proposes use restrictions to waive field studies in rotational crops (tier 2 and/or tier 3), the impact of the proposed restrictions need to be assessed carefully to ensure that they have the desired effect.

If residues were observed only at shorter PBIs (e.g. at PBI 30 days), the setting of a restriction for plant back intervals at the next highest PBI tested in which the residues were below the LOQ in the tested crop (e.g. PBI 270 days) is an option to avoid that soil residues lead to significant residues in rotational crops. It is recommended that risk assessors should inform risk managers routinely on this option to define PBI restrictions as alternative to MRL setting.

Additional risk mitigation measures could be suggested by risk managers for which specific assessments would be required.[49]

As setting of restrictions opens a wide range of risk management options, it is recommended to discuss with risk managers which options should be assessed to provide practical alternatives to the MRL setting.

7. Higher tier studies (monitoring data)

The OECD Guidance Document mentions that in certain cases higher tier studies such as post-registration testing and post-authorisation monitoring may be requested by regulatory authorities. Such requirements are not standard in the EU, but could be considered by risk managers on a case-by-case basis, e.g. studies investigating the development of soil residues over multiannual use of a persistent a.s. or an a.s. producing persistent soil metabolites and the corresponding residues in crops

[48] The approach described in the body text of the OECD Guidance Document which requests to calculate the adjusted residue levels for each primary crop residue trial is for reasons of data availability and work load not feasible in the EU. This approach can be implemented in an assessment for approval of the a.s., but for Art. 10 applications, MRL reviews under Art. 12 and assessment of confirmatory data requested in Art. 12 reviews, the approach would require a complete re-evaluation of all uses, in case a new uses are assessed or new data are provided which are more critical in view of rotational crops compared to previously assessed uses. In this case, all existing EU MRLs need to be re-assessed, adjusting all individual residue trials.

[49] E.g. for a.s. and metabolites that accumulate in soil, risk managers could define a soil plateau concentration (e.g. 0.1 mg/kg soil) that should not be exceeded. The corresponding annual application rate of the a.s. could be derived in the assessment of EFSA to ensure that this plateau level is not exceeded and to define restrictions on the maximum seasonal/annual application rate accordingly. Hence, the annual application rate should be equal to the annual degradation of the a.s. in the soil for a certain soil concentration.

grown in these intensively treated soils. Such data might be useful to refine the conservative assumptions on the plateau residue levels which are the basis for setting MRLs in rotational crops.

It is noted that in the EU a comprehensive monitoring system is in place to analyse food products placed on the market for pesticide residues. In the EU coordinated monitoring programmes, active substances are defined, for which Member States shall perform residue analysis in certain commodities. When the EU coordinated programmes is established, EFSA recommends considering the inclusion of pesticides/commodity combinations that are of high relevance for rotational crops (i.e. pesticide/commodities with MRLs set based on rotational crop studies or with combined MRL for uses in primary crops and the uptake of residues in succeeding crops).[50] Risk managers could also take into consideration the available monitoring data when deciding whether the amendment of MRLs in rotational crops is necessary.

8. Uncertainty analysis

EFSA analysed the assumptions implemented in the assessment for rotational crops that are considered as sources of uncertainties, in accordance with the EFSA guidance on uncertainty analysis (EFSA Scientific Committee, 2018). These underlaying assumptions were assessed in view of the impact on the conservatism of the assessment. A qualitative overview of the main sources of uncertainties is presented in Table 3, together with the direction of the expected impact. Due to the complexity of the assessment approach described in the current guidance document and the individual properties of the compounds (a.s./metabolites), a quantitative analysis could not be performed in the current framework.

Table 3: Qualitative evaluation of the influence of uncertainties on the rotational crop residue assessment

Sources of uncertainties	Direction of impact[(a)]	Comments
Trigger values for rotational crop assessment based on DT_{90} for the a.s./soil metabolites Selection of the highest/worst-case DT_{90} for the a.s. and soil metabolites among the soil types tested to decide on the necessity to perform a rotational crop assessment.	+	The selection of the most critical DT_{90} value for a.s. and metabolites with potential for soil accumulation is driving the rotational crop assessment. The variability of soil degradation kinetics in different soil types which may be of relevance for the critical GAP driving the assessment is not considered in the assessment.
For a.s. with a **DT_{90} less than 100 days**, uptake in rotational crops is not considered	(–)	Residue uptake in rotational crop could occur if the period between last application and harvest of succeeding crop (e.g. baby leaf salads planted shortly after a treated crop with a short PHI) is short.
Trigger on soil **DT_{90}** applied to individual residue components	(–)	In rare cases, the total soil residues (parent plus significant soil metabolites) after 100 days may be higher than 10%, although the DT90 of the individual components (parent and significant soil metabolites) is below the trigger value of 100 days.
Selection of the soil type to be tested for confined rotational crop metabolism studies	+/–	Only 1 soil type tested per crop group; some soil metabolites may not be formed in the soil type used in the studies (see Section 4.3.1)
Selection of most critical GAP with respect to residues in soil: The critical GAP identified for rotational crops ($cGAP_{RC}$) (see Sections 4.3.4 and 5.3.3) is the basis for the calculation of the soil concentration tested in rotational crop studies (metabolism and field studies)	+	The cGAP in view of residues in rotational crops may be authorised only in limited areas/for minor crop use or for uses against pests/diseases which are occurring only in a limited area/time (‘minor use”). Therefore, this critical GAP driving the rotational crop assessment may lead to an overestimation of residues in soil and the residues in rotational crops.

[50] See Section 9, recommendation 14.

Sources of uncertainties	Direction of impact[(a)]	Comments
For non-accumulating a.s. (DT_{90} < 365 days): **Maximum seasonal application rate for primary crops** is used to estimate the expected soil residues.	+	Decline between individual applications is not taken into account, which may lead to an overestimation of residues. See Figure B.2
For accumulating a.s. (DT_{90} > 365 days): For calculating the **$PEC_{(s)}$ for a.s.** which is the basis for the soil concentration used in rotational crop studies, a **multiannual use of the a.s.** according to the critical GAP in primary crops is assumed.	+	Several years/decades of consecutive use of the a.s. on the same field is assumed; crop rotation with other crops with less critical primary crop uses or years without application of the a.s. under assessment are not considered. The calculated worst-case $PEC_{(s)}$ is a concentration that is not expected to be reached in most soil types.
Maximum $PEC_{(s)}$ for metabolites is the soil concentration to be tested in rotational crop studies.	+	The maximum $PEC_{(s)}$ for metabolites is derived from the most critical study in different soil types tested; soil type with the maximum formation rate. The calculated worst-case $PEC_{(s)}$ is a concentration that is not expected to be reached in most soil types.
For a.s. that form significant metabolites in soil: **Assumption of simultaneous occurrence of soil residues at the level of the highest concentration of a.s. and the highest concentration of metabolite(s)**	+	A high concentration of soil metabolite(s) in soil is likely to correlate with a low concentration of the parent a.s. and *vice versa*.
Assumptions on **crop interception**	+/–	Limited data on crop interception for a wide range of crops. Available crop interception data are rough estimates which under real field conditions may differ, e.g. depending on crop varieties.
Assumption that **crop parts remaining on the field** are not ploughed into soil after harvest	(–)	The incorporation of plant parts into soil is not reflected in the calculation of the application rate to be tested in rotational crop studies which may lead to an underestimation. Residues in plant parts that remain on the field are subject to metabolism and degradation processes; the residues in the plant parts remaining on the field, may not be fully addressed.
Not consideration of wash-off from plants after interception.	(–)	Residues intercepted by plants can be washed-off as result of subsequent rain, leading to higher residues in soil.
Consideration of **indoor *vs* outdoor GAP**	+/–	Residues in rotational crops may differ significantly between field and protected environments.
Influence of soil ageing on bioavailability of soil residues	(+)	Rotational crop studies are usually performed in soils spiked with the a.s. and/or soil metabolites. The ageing of soil and the possible reduced bioavailability of residues in aged soil is not captured by the standard study design (see also OECD, 2018).
Scaling of residues in rotational crop studies if measured soil concentration of a.s./metabolite was lower than the estimated/predicted worst-case $PEC_{(s)}$	+	The measured soil concentration at the time of planting the rotational crop is a point estimate that does not provide information on the residue soil concentrations throughout the full duration of the cultivation of the rotational crop. See Section 5.3.8 and Figure B.3 Using the $PEC_{(s)}$ calculated with several conservative assumptions as reference concentration is a worst-case assumption (see also above).

Sources of uncertainties	Direction of impact[(a)]	Comments
The **limited number of trials** (tier 2 and tier 3 studies) might not cover all possible situations.	(+/−)	The different field trials cover various conditions and overall may not be representative for all annual crops. The data may over- or underestimate the residues in crops grown as rotational crop.
MRL setting: 25% rule (HR_{RC} vs MRL_{PC})	(−)	The contribution of residues taken up from the soil is considered only, if residues in rotational crops were found at levels > 25% of the existing MRL derived for primary crop uses (see Section 6.4.5)
Specific MRL for rotational crops Most critical result of rotational crop studies (PBI leading to HR, HR among the available rotational crop studies (HR_{RC}))	(+/−)	See Section 6.4.5.1
Combined MRL Relevance of critical GAP in view of residues in soil for the most critical GAP in primary crops	+	The critical GAPs selected for estimating the maximum soil residue and the GAPs which are the basis for MRL setting in primary crop may not be authorised in the same Member State; the crops are not commonly rotated/grown on the same field. See Section 6.4.5.2
Setting of a **combined MRL reflecting critical GAP for primary crop and residues taken up from the soil**	+	The co-occurrence of the worst-case for residues in primary crops and for the soil uptake is a concatenation of worst-case assumptions likely to overestimate the residues in the agricultural commodity leading to a conservative MRL proposal.
Extrapolation from rotational crop studies (tier 2 and tier 3) to other crops	+/−	The residue uptake may be different in crops for which no specific rotational crop studies are available.

+: the assumptions used in the specific case are expected to lead to an overestimation of residues in rotational crops.
−: possible underestimation of residues in rotational crops.
(−) or (+): it the uncertainty source identified is applicable only in specific cases.
+/−: the assumptions used can lead to an over-or underestimation.
HR: highest residue; RC: rotational crop; PC: primary crop.
(a): Direction of impact.

The overall assessment approach presented in the current guidance document is complex and is built on a concatenation of conservative assumptions (e.g. worst-case GAP in primary crops, worst-case soil degradation, worst-case metabolite formation, worst-case combination of residues in primary crops and rotational crops etc.).

EFSA concludes that overall, following the general approach described in the current guidance document, the risk assessment and the MRL setting is conservative. Hence, the probability is very low that the actual dietary exposure of consumers to residues in food resulting from rotational crops is equal or higher than the exposure estimated in accordance with the current guidance document. Similarly, the probability is low that residues in crops exceed the MRLs derived in line with the recommended approach.

The uncertainty analysis should help to identify options for performing more refined assessments of rotational crop studies for individual substances assessed: assessors are invited to explore possible options to reduce the overall uncertainties, that would reflect more realistic field conditions as required according to Regulation (EC) No 283/2013. In addition, further discussions with risk managers is encouraged to agree on these refined risk assessment scenarios.

9. Recommendations

In the course of drafting the current guidance document, EFSA identified issues for which further discussions at risk assessor and/or risk management level are required.

Hence, Member State experts and risk managers are invited to discuss the following recommendations in view of prioritising them for follow-up actions to further refine the risk assessment approach for rotational crops.

Recommendation 1: EFSA recommends further discussions whether the EU Guidance Document (1997) can be revoked.

Recommendation 2: EFSA suggests establishing a platform to exchange experiences gained by experts assessing residues in rotational crops. In addition, this platform could be used to compile examples and collect proposals for future improvements of the current guidance document.

Recommendation 3: EFSA suggests that in future the end points derived from studies assessed in the framework of fate and behaviour in the environment that are relevant for the assessment of residues in rotational crops should be reported in the LoEP in a specific section to avoid the work-around described in the current document.

Recommendation 4: EFSA proposes that, based on experience gained with the approach described in the current document, residues experts should discuss whether additional endpoints should be derived from soil studies assessed by experts in fate and behaviour, to increase the robustness of the residue assessment (e.g. calculation of alternative $PEC_{(s)}$ or DT_{90} and DT_{50} than the one reported in the LoEP, estimation of time-weighted average $PEC_{(s)}$ reflecting the residue levels expected during the cultivation of the rotational crop, instead of using peak $PEC_{(s)}$).

Recommendation 5: OECD discussed the development of a Test Guideline to determine the uptake of chemicals by plant roots (OECD Project 3.15 – OECD, 2021). EFSA recommends exploring the use of standardised hydroponic assays under controlled conditions to replace or complement rotational crop metabolism studies.

Recommendation 6: Further guidance shall be developed on the concept of crop interception factors for the assessment of residues in rotational crops, in view of getting a robust basis for the risk assessment.

Recommendation 6bis: In collaboration with risk managers, more specific criteria on the relevance of crops for rotational crop studies should be developed, e.g. by defining the acreage of minor crops in view of rotational crop studies.

Recommendation 7: For certain parameters used in the assessment of rotational crops (e.g. accumulated soil background concentration), the terminology used in the LoEP, section environmental fate and behaviour, was found to be inconsistent, which may cause confusion. Hence, it is recommended that more attention is paid to use consistent terminology to describe the relevant parameters.

Recommendation 8: Modelling of soil concentrations for a.s. and metabolites would allow deriving more realistic estimation for the assessment of residues in rotational crops, including options for refinements. Hence, the development of tools for soil modelling for parameters relevant for the assessments of rotational crops (based on tools that are also used in fate modelling, e.g. PERSAM) should be promoted.

Recommendation 9: Further guidance should be developed to clarify and agree in which situations scaling of results for rotational crop field studies, in particular for soil metabolites, is appropriate.

Recommendation 10: Further advice from risk managers should be provided under which circumstances rotational crop studies need to be provided for import tolerance applications.

Recommendation 11: Further guidance should be developed on the assessment of residues accumulating in permanent and semi-permanent crops by uptake of residues via soil resulting from repeated, multiannual use of the a.s.

Recommendation 12: The list of example crops that are recommended for rotational crop metabolism and limited field studies should be further elaborated.

Recommendation 13: To discuss with risk managers if rotational crop field studies (tier 2 and tier 3 studies) performed in third countries are acceptable to replace to a certain extent studies performed in the EU.

Recommendation 14: When the EU coordinated program under Article 31 of Regulation (EC) No 396/2005 is established, EFSA recommends considering the inclusion of pesticides/commodity combinations that are of high relevance for rotational crops (i.e. pesticide/commodities with MRLs set on the basis of rotational crop studies or with combined MRL for uses in primary crops and significant residues in rotational crops).

Recommendation 15: The list on extrapolations to derive MRLs for annual crops from rotational crop studies needs to be further elaborated (Appendix A.4).

Recommendation 16: EFSA recommends collecting information from Member States on the agricultural practices on incorporation of crop parts after harvest. This information would be helpful to decide whether the assumptions on crop interception are valid.

Recommendation 17: Furthermore, information on frequency of crop failure should be compiled that would allow to estimate the relevance of scenarios reflecting crop failure.

Recommendation 17bis: It is recommended to further develop the approach for dietary burden calculation for rotational crops. In addition, it would be desirable to update the dietary burden calculator (Animal model, 2017[44]) to streamline the calculations.

Recommendation 18: Collect information on typical crop rotation schemes in EU Member States. In addition, a catalogue on possible restrictions (risk mitigation measures) should be elaborated.

Recommendation 19: Discuss with risk managers how to deal with data gaps identified in the framework of MRL reviews related to rotational crop studies. There is a need to clarify whether these data gaps related to a critical use in a primary crop should be also linked to all individual annual crops for which the setting of specific or combined MRLs as outlined in Sections 6.4.5.1 and 6.4.5.2 may be necessary.

Recommendation 20: Discuss and agree on an implementation plan for the current the guidance document for the different workflows affected, i.e. Art.10 applications, Art. 12 MRL reviews, assessment of confirmatory data identified in Art. 12 reviews, approval/renewal of the approval of a.s., assessment of Codex MRLs.

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Abbreviations

A	individual application rate as defined in the GAP (in g/ha)
AF	adjustment factor
A_{eff}	effective application rate (for the individual application defined in the GAP (in g/ha)
a.s.	active substance
CIR	crop interception rate
DAT	days after treatment
$DT50_{lab}/DT90_{lab}$	disappearance time of 50/90% of the substance in laboratory studies
$DT50_{field}/DT90_{field}$	disappearance time of 50/90% of the substance in field studies
eq	Equivalent
f_{soil}	Fraction of the application rate reaching the soil after crop interception
GAP	Good Agricultural Practice
HR	highest residue
LOQ	limit of quantification
MRL	maximum residue limit
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop
$PEC_{(s)}$	Predicted Environmental Concentration in soil
PELMO	Pesticide Leaching Model. A pesticide fate model intended for higher-tier exposure and leaching assessments
PERSAM	Persistence in Soil Analytical Model. Software tool for performing lower tier soil exposure assessments
PRIMo	(EFSA) Pesticide Residues Intake Model
PRonTo	Pesticide Rotational Crop Assessment Tool
seasonal $A_{eff\ (critGAP)}$	seasonal effective application rate (in g a.s./ha) for critical GAP relevant for rotational crop assessment
seasonal $A_{eff(repGAP)}$	seasonal effective application rate (in g a.s./ha) for the representative GAP assessed in peer review
SFO	simple first-order kinetics significant soil metabolites relevant soil metabolites identified in the LoEP in the section Environmental fate and behaviour; Residues requiring further assessment; Soil
STMR	supervised trials median residue
TRR	total radioactive residue

Appendix A – Supporting information

A.1. Annual/semi-permanent/permanent crops

Table A.1: Crop classification with regard to rotational crop assessment: permanent/semi-permanent/annual crops

Crop code[(a)]	Commodity – name	Permanent/semi-permanent/ annual crop
110000	Citrus fruits	Permanent
120000	Tree nuts	Permanent
130000	Pome fruits	Permanent
140000	Stone fruits	Permanent
151000	Grapes	Permanent
152000	Strawberries	Annual[(b)]
153000	Cane fruits	Permanent
154000	Other small fruits and berries	Permanent
161000, except 163020, 163080	Miscellaneous fruits except bananas and pineapples	Permanent
163020	Bananas	Semi-permanent
163080	Pineapples	Semi-permanent
211000	Potatoes	Annual
212010	Cassava roots/manioc	Annual, but not relevant for EU
212020	Sweet potatoes	Annual
212030	Yams	Annual, but not relevant for EU
212040	Arrowroots	Annual, but not relevant for EU
213010	Beetroots	Annual
213020	Carrots	Annual
213030	Celeriacs/turnip rooted celeries	Annual
213040	Horseradishes	Annual[(c)]
213050	Jerusalem artichokes	Annual
213060	Parsnips	Annual
213070	Parsley roots/Hamburg roots parsley	Annual
213080	Radishes	Annual
213090	Salsifies	Annual
213100	Swedes/rutabagas	Annual
213110	Turnips	Annual
220000	Bulb vegetables	Annual
231000	Solanaceae and Malvaceae	Annual
232000	Cucurbits with edible peel	Annual
233000	Cucurbits with inedible peel	Annual
234000	Sweet corn	Annual
241000	Flowering brassica	Annual
242000	Head brassica	Annual
243000	Leafy brassica	Annual
244000	Kohlrabies	Annual
251000	Lettuces and salad plants	Annual
252000	Spinaches and similar leaves	Annual
253000	Grape leaves and similar species	Permanent
254000	Watercresses	Annual

Crop code[(a)]	Commodity – name	Permanent/semi-permanent/ annual crop
255000	Witloofs/Belgian endives	Chicory roots used for forcing are an annual crop; specific considerations required.
256010	Chervil	Annual
256020	Chives	Semi-permanent
256030	Celery leaves	Annual
256040	Parsley	Annual
256050	Sage	Semi-permanent
256060	Rosemary	Permanent
256070	Thyme	Semi-permanent
256080	Basil and edible flowers	Annual
256090	Laurel/bay leave	Permanent
256100	Tarragon	Semi-permanent
260000	Legume vegetables	Annual
270010	Asparagus	Semi-permanent
270020	Cardoons	Annual
270030	Celeries	Annual
270040	Florence fennels	Annual
270050	Globe artichokes	Semi-permanent
270060	Leeks	Annual
270070	Rhubarbs	Semi-permanent
270080	Bamboo shoots	Permanent
270090	Palm hearts	Permanent
280010	Cultivated fungi	Not relevant
280020	Wild fungi	Not relevant
290000	Algae and prokaryotes organisms	Not relevant
300000	Pulses (dry)	Annual
401010	Linseeds	Annual
401020	Peanuts/groundnuts	Annual, but not relevant for EU
401030	Poppy seeds	Annual
401040	Sesame seeds	Annual
401050	Sunflower seeds	Annual
401060	Rapeseeds/canola seeds	Annual
401070	Soyabean	Annual
401080	Mustard seeds	Annual
401090	Cotton seeds	Annual
401100	Pumpkin seeds	Annual
401110	Safflower seeds	Annual
401120	Borage seeds	Annual
401130	Gold of pleasure seeds	Annual
401140	Hemp seeds	Annual
401150	Castor beans	Permanent
402010	Olives for oil production	Permanent
402020	Oil palms kernels	Permanent
402030	Oil palms fruits	Permanent
402040	Kapok	Permanent
500010	Barley grains	Annual
500020	Buckwheat and other pseudo-cereal grains	Annual

Crop code[(a)]	Commodity – name	Permanent/semi-permanent/ annual crop
500030	Maize/corn grains	Annual
500040	Common millet/proso millet grains	Annual
500050	Oat grains	Annual
500060	Rice grains	Semi-permanent, specific considerations required
500070	Rye grains	Annual
500080	Sorghum grains	Annual
500090	Wheat grains	Annual
610000	Teas	Permanent
620000	Coffee beans	Permanent
631010	Chamomile flowers	Annual
631020	Hibiscus flowers	Permanent
631030	Rose petals	Permanent
631040	Jasmine flowers	Permanent
631050	Lime (linden)	Permanent
632010	Strawberry leaves	Semi-permanent
632020	Rooibos leaves	Permanent
632030	Maté	Permanent
633010	Valerian root	Semi-permanent
633020	Ginseng root	Semi-permanent
640000	Cocoa beans	Permanent
650000	Carobs/Saint John's breads	Permanent
700000	Hops	Semi-permanent
810010	Anise	Annual
810020	Black caraway	Annual
810030	Celery seed	Annual
810040	Coriander seed	Annual
810040	Cumin seed	Annual
810060	Dill seed	Annual
810070	Fennel seed	Annual
810080	Fenugreek	Annual
810090	Nutmeg	Permanent
820010	Allspice	Permanent
820020	Anise pepper (Japan pepper)	Permanent
820030	Caraway	Annual
820040	Cardamom	Semi-permanent
820050	Juniper berries	Permanent
820060	Pepper, black and white	Permanent
820070	Vanilla pods	Not relevant
820080	Tamarind	Permanent
830010	Cinnamon	Permanent
840010	Liquorice	Permanent
840020	Ginger	Semi-permanent
840030	Turmeric (Curcuma)	Semi-permanent
840040	Horseradish, root spices	Annual[(c)]
850010	Cloves	Permanent
850020	Capers	Permanent
860010	Saffron	Semi-permanent
870010	Mace	Permanent

Crop code[(a)]	Commodity – name	Permanent/semi-permanent/ annual crop
900010	Sugar beet roots	Annual
900020	Sugar canes	Semi-permanent[(d)]
900030	Chicory roots	Annual
1200000	Products or part of products exclusively used for animal feed production, except pasture	Case-by-case
–	Grasses for animal feed (forage, hay, silage)	Permanent
–	Legume animal feeds (forage, hay, silage) with or without seeds	Annual
–	Cereal forage, hay, silage and straw	Annual
–	Sugar beet tops and similar products	Annual
–	Rape seed forage, hay and similar	Annual
–	Ornamental crops	Case-by-case
–	Herbaceous ornamental crops	Annual
–	Woody ornamental crops	Permanent/semi-permanent

(a): Code number in accordance with Annex I of Regulation EC No 395/2005.
(b): Strawberries are classified as a semi-permanent crop in OECD guidelines (OECD, 2007a, but strawberries are considered as annual crop at EU level, since annual cropping is possible.
(c): Horseradish is produced as an annual or biennial, rarely as a perennial crop, by planting an annual underground stem (cuttings). For the purpose of this guidance document, horseradish is considered as annual crop.
(d): Sugarcane fields are replanted every 2–4 years. Since sugar cane is not grown in the EU, it is not further considered in this guidance document.

A.2. Representative crops (metabolism, field studies)

Table A.2: Recommended representative crops for metabolism (tier 1) and field (tier 2) studies and specification of the parts of the crops to be analysed

Crop group	Crop code	Crop	Comments/ Example crop for tier 1 and 2[(a)]	Part of the crop to be analysed
Leafy vegetables, Leafy brassica	251010	Lamb's lettuces/corn salads	Not recommended for tier 1 studies	Immature leaves Mature leaves
	251020	Lettuces	Tier 1 and 2 example crop leafy vegetables	
	251030	Escaroles/broad-leaved endives		
	251040	Cresses and other sprouts and shoots	Not recommended for tier 1 studies	
	251050	Land cresses		
	251060	Roman rocket/rucola		
	251070	Red mustards		
	251080	Baby leaf crops (including brassica species)	Not recommended for tier 1 studies	
	252010	Spinaches	Tier 1 and 2 example crop leafy vegetables	
	252020	Purslanes		
	252030	Chards/beet leaves		
	254000	Watercresses	Not recommended for tier 1 studies	
	256010	Chervil		

Crop group	Crop code	Crop	Comments/ Example crop for tier 1 and 2[(a)]	Part of the crop to be analysed
	256030	Celery leaves		
	256040	Parsley		
	256050	Sage		
	256080	Basil and edible flowers		
	243010	Chinese cabbages(pe-tsai), incl. mustards green		
	0243020	Kale	Tier 2 example crop (see Table A.3)	
Root and tuber vegetables	211000	Potatoes	Not recommended for tier 1 studies	Root, Leaves/tops
	212020	Sweet potatoes		
	213010	Beetroots	Tier 1 and 2 example crop root and tuber vegetables	
	213020	Carrots	Tier 1 and 2 example crop root and tuber vegetables	
	213030	Celeriacs/turnip rooted celeries		
	213040	Horseradishes	Not recommended for tier 1 studies	
	213050	Jerusalem artichokes		
	213060	Parsnips		
	213070	Parsley roots/Hamburg roots parsley		
	213080	Radishes	Tier 1 and 2 example crop root and tuber vegetables	
	213090	Salsifies		
	213100	Swedes/rutabagas	Alternative option for Tier 1 and 2 example crop root and tuber vegetables	
	213110	Turnips	Tier 1 and 2 example crop for root and tuber vegetables	
	900010	Sugar beet roots	Tier 1 and 2 example crop root and tuber vegetables	
	900030	Chicory roots		
Small grain cereals	500010	Barley grains	Tier 1 and 2 example crop small grain	Grain, Forage, Straw
	500020	Buckwheat and other pseudo-cereal grains	Not recommended for tier 1 studies	
	500030	Maize/corn grains	Not recommended for tier 1 studies	
	500040	Common millet/proso millet grains	Not recommended for tier 1 studies	
	500050	Oat grains	Tier 1 and 2 example crop small grain	

Crop group	Crop code	Crop	Comments/ Example crop for tier 1 and 2[(a)]	Part of the crop to be analysed
	500060	Rice grains	Not recommended for tier 1 and tier 2 studies	
	500070	Rye grains	Tier 1 and 2 example crop small grain	
	500080	Sorghum grains	Not recommended for tier 1 studies	
	500090	Wheat grains	Tier 1 and 2 example crop small grain	

(a): Not mandatory according to OECD TG 502. However, if the results in the three mandatory crop groups differ substantially and if lipophilic substances are among the expected residues or if the intended uses of the a.s. are primarily expected in oilseed crops and rotational crop metabolism studies in the three mandatory crop groups are expected to be not sufficiently representative, tier 1 studies in oilseeds might be requested.

Table A.3: Recommended representative crops for field studies (tier 2 and 3) and specification of the parts of the crops to be analysed

Crop group	Crop code	Crop	Example crop	Part of the crop to be analysed
Leafy vegetables, Leafy brassica	See Tables A.1 and A.2 (Example crops for tier 1 and 2 are also valid for tier 3)			Immature leaves Mature leaves
Root and tuber vegetables				Roots Leaves/tops
Small grain cereals				Grain, Forage, Straw
Oilseeds and Pulses	401010	Linseeds		Forage, Dry seeds
	401030	Poppy seeds		
	401040	Sesame seeds		
	401050	Sunflower seeds		
	401060	Rapeseeds/canola seeds	Tier 3 example crop	
	401070	Soybean	Tier 3 example crop	
	401080	Mustard seeds		
	401090	Cotton seeds		
	401100	Pumpkin seeds		
	401110	Safflower seeds		
	401120	Borage seeds		
	401130	Gold of pleasure seeds		
	401140	Hemp seeds		
	300010	Beans (dry)	Tier 3 example crop	Forage, Immature pods, with seeds, Immature seeds, Mature seeds
	300030	Peas (dry)	Tier 3 example crop	
Brassica vegetables	241010	Broccoli	Tier 3 example crop	Not specified in TG 504, proposal to analyse Mature crops
	241020	Cauliflowers		
	242010	Brussels sprouts		
	242020	Head cabbages	Tier 2 and tier 3 example crop	
	243010	Chinese cabbages/pe-tsai, incl. mustards green		
	243020	Kales	Tier 2 and tier 3 example crop	

Crop group	Crop code	Crop	Example crop	Part of the crop to be analysed
	244000	Kohlrabies		
Fruits, fruiting vegetables	152000	Strawberries	Tier 3 example crop	Not specified in TG 504, proposal to analyse Mature fruits
	231010	Tomatoes		
	231020	Sweet peppers/bell peppers		
	231030	Aubergines/eggplants		
	231040	Okra/lady's fingers		
	232010	Cucumbers	Tier 3 example crop	
	232020	Gherkins		
	232030	Courgettes		
	233010	Melons		
	233020	Pumpkins		
	233030	Watermelons		
	234000	Sweet corn		
Bulb and stem vegetables	220010	Garlic		Not specified in TG 504, proposal to analyse Mature bulbs/stems
	220020	Onions		
	220030	Shallots		
	220040	Spring onions/green onions and Welsh onions		
	270020	Cardoons		
	270030	Celeries	Tier 3 example crop	
	270040	Florence fennels		
	270060	Leeks	Tier 3 example crop	

A.3. Standard crop interception rates (CIR) for annual crops

Table A.4: Crop interception table (implemented in FOCUS model (FOCUS, 2021) used in the context of the assessment of environmental fate and behaviour of pesticides)

Case (FOCUS)	Crop	Crop interception: Soil covered by developing crop (expressed as % of soil surface)						
		Growth stage of the crop (BBCH)						
		0–09	**10–20**	**20–29**	**30–39**	**40–69**	**70–89**	**90–99**
		Bare emergence (sprouting)	**Leaf development**	**Stem elongation**	**Stem elongation**	**Flowering**	**Development of fruit/ ripening**	**Senescence**
1	Bean (field, vegetable)	0	25	40	40	70	70	80
2	Cabbage	0	25	40	40	70	70	90
3	Carrots	0	25	60	60	80	80	80
4	Cotton	0	30	60	60	75	75	90
5	Grass	0	40	60	60	90	90	90
6	Linseed	0	30	60	60	70	70	90
7	Maize	0	25	50	50	75	75	90
8	Oil seed rape (summer)	0	40	80	80	80	80	90
9	Oil seed rape (winter)	0	40	80	80	80	80	90
10	Onions	0	10	25	25	40	40	60
11	Peas	0	35	55	55	85	85	85

Case (FOCUS)	Crop	Crop interception: Soil covered by developing crop (expressed as % of soil surface)						
		Growth stage of the crop (BBCH)						
		0–09	10–20	20–29	30–39	40–69	70–89	90–99
		Bare emergence (sprouting)	Leaf development	Stem elongation	Stem elongation	Flowering	Development of fruit/ ripening	Senescence
12	Potatoes	0	15	60	60	85	85	50
13	Soybean	0	35	55	55	85	85	65
14	Spring cereals	0	0	20	80	90	80	80
15	Strawberry	0	30	50	50	60	60	60
16	Sugar beets	0	20	70	70	90	90	90
17	Sunflower	0	20	50	50	75	75	90
18	Tobacco	0	50	70	70	90	90	90
19	Tomatoes	0	50	70	70	80	80	50
20	Winter cereals	0	0	20	80	90	80	80

Table A.5: Crop interception rates for annual crops extended by extrapolation to include also crops not covered by the FOCUS model[51]

Crop code	Crop	Case (FOCUS)[(a)]
152000	Strawberries	15
211000	Potatoes	12
212020	Sweet potatoes	12
213010	Beetroots	16
213020	Carrots	3
213030	Celeriacs/turnip rooted celeries	16
213050	Jerusalem artichokes	
213060	Parsnips	16
213070	Parsley roots/Hamburg roots parsley	3
213080	Radishes	3
213090	Salsifies	
213100	Swedes/rutabagas	
213110	Turnips	
220010	Garlic	10
220020	Onions	10
220030	Shallots	10
220040	Spring onions/green onions and Welsh onions	10
231010	Tomatoes	19
231020	Sweet peppers/bell peppers	19
231030	Aubergines/eggplants	19
231040	Okra/lady's fingers	

[51] Data on the crop interception rates (CIR) for different crop development stages of different crops developed for the environmental assessments (FOCUS, 2003, 2021; EFSA, 2014) are presented in the Table A.3. For annual crops not mentioned in the crop interception table, CIR from crops with similar crop development characteristics should be used. Considering the different crop development characteristics of crops and the current practice of defining BBCH classes in the GAPs, the use of CIR is expected to introduce an element of uncertainties in the risk assessment. Further discussion of residue experts and risk managers to elaborate more details on an approach that gives a robust basis for the risk assessment (see recommendation 6 in Section 9).

Crop code	Crop	Case (FOCUS)[(a)]
232010	Cucumbers	19
232020	Gherkins	19
232030	Courgettes	19
233010	Melons	19
233020	Pumpkins	19
233030	Watermelons	19
234000	Sweet corn	7
241010	Broccoli	2
241020	Cauliflowers	2
242010	Brussels sprouts	
242020	Head cabbages	2
243010	Chinese cabbages/pe-tsai	
243020	Kales	2
244000	Kohlrabies	
251010	Lamb’s lettuces/corn salads	
251020	Lettuces	
251030	Escaroles/broad-leaved endives	
251040	Cresses and other sprouts and shoots	
251050	Land cresses	
251060	Roman rocket/rucola	
251070	Red mustards	
251080	Baby leaf crops (including brassica species)	
252010	Spinaches	
252020	Purslanes	
252030	Chards/beet leaves	
254000	Watercresses	
255000	Witloofs/Belgian endives	
256010	Chervil	
256030	Celery leaves	3
256040	Parsley	3
256080	Basil and edible flowers	
260010	Beans (with pods)	1
260020	Beans (without pods)	1
260030	Peas (with pods)	11
260040	Peas (without pods)	11
260050	Lentils (fresh)	
270020	Cardoons	
270030	Celeries	
270040	Florence fennels	
270060	Leeks	
300010	Beans (dry)	1
300020	Lentils (dry)	
300030	Peas (dry)	11
300040	Lupins/lupini beans (dry)	
401010	Linseeds	6
401030	Poppy seeds	
401040	Sesame seeds	
401050	Sunflower seeds	17
401060	Rapeseeds/canola seeds	8 or 9
401070	Soyabean	13

Crop code	Crop	Case (FOCUS)[(a)]
401080	Mustard seeds	8 or 9
401090	Cotton seeds	4
401100	Pumpkin seeds	
401110	Safflower seeds	
401120	Borage seeds	
401130	Gold of pleasure seeds	
401140	Hemp seeds	
500010	Barley grains	
500020	Buckwheat and other pseudo-cereal grains	
500030	Maize/corn grains	7
500040	Common millet/proso millet grains	
500050	Oat grains	
500060	Rice grains	
500070	Rye grains	
500080	Sorghum grains	
500090	Wheat grains	14 or 19
631010	Chamomile flowers	
810010	Anise	
810020	Black caraway	3
810030	Celery seed	3
810040	Coriander seed	3
810040	Cumin seed	
810060	Dill seed	
810070	Fennel seed	3
810080	Fenugreek	
820030	Caraway	3
900010	Sugar beet roots	16
900030	Chicory roots	
–	Legume animal feeds (forage, hay, silage) with or without seeds	1 or 11
–	Cereal forage, hay, silage and straw	14 or 19
–	Sugar beet tops and similar products	16
–	Rape seed forage, hay and similar	8 or 9
–	Herbaceous ornamental crops	(b)

(a): The case number reported in this column refer to the case in Table A.4 (first column), describing the crop interception cases implemented in the FOCUS model. The crop interception rates that are recommended for the calculation of the application rates for rotational crop field studies should be further elaborated for the cases for which no proposals are currently reported in the table (Section 9, recommendation 6).
(b): Case-by-case decision, depending on the crop.

A.4. Extrapolation of results from tier 2 and tier 3 studies to commodities relevant for setting MRLs and for deriving risk assessment values

Table A.6: Proposed extrapolation scheme for setting MRLs and for deriving risk assessment values from source commodity to target commodity[52]

Crop code	**Target commodity**: Commodity for which MRL proposal and/or RA value to be derived	**Source commodity**: Result of Tier 2 and/or 3 study used for extrapolation to derive MRL/RA values in commodity – relevant matrix	Comment
152000	Strawberries	Strawberries	
211000	Potatoes	Potatoes (tuber) or Tier 2 and tier 3 (root and tuber vegetables) – roots	Residues in rotational potatoes are likely to be lower than those in smaller, shorter-season root crops such as radish, carrot or beet. Therefore, OECD proposes not to use potatoes to derive MRLs by extrapolation. However, EFSA suggests allowing extrapolation to sweet potatoes. Data on potatoes to be used primarily for refinement of dietary risk assessment due to the relatively high consumption of potato in relation to other root crops. (OECD, 2018). Results on mature tubers.
212020	Sweet potatoes	See potatoes	Results on mature tubers.
213010	Beetroots	Root of root vegetables	Results on mature roots.
213020	Carrots		Results on mature roots.
213030	Celeriacs/turnip rooted celeries		Results on mature roots.
213050	Jerusalem artichokes		Results on mature roots.
213060	Parsnips		Results on mature roots.
213070	Parsley roots/Hamburg roots parsley		Results on mature roots.
213080	Radishes		Results on mature roots.
213090	Salsifies		Results on mature roots.
213100	Swedes/rutabagas		Results on mature roots.
213110	Turnips		Results on mature roots.
220010	Garlic	Bulb and stem vegetables	Preferred option: tier 3 studies in leeks. Results on mature leeks.
220020	Onions		
220030	Shallots		
220040	Spring onions/green onions and Welsh onions		
231010	Tomatoes	Fruits and fruiting vegetables (cucumber, tomatoes, peppers, aubergines, okra, courgette, gherkins)	Preferred option: tier 3 studies in cucumbers. Results on mature crop.
231020	Sweet peppers/bell peppers		
231030	Aubergines/eggplants		
231040	Okra/lady's fingers		
232010	Cucumbers		
232020	Gherkins		
232030	Courgettes		

[52] The extrapolations for deriving MRLs for rotational crops should be further elaborated (Section 9, recommendation 15).

Crop code	**Target commodity**: Commodity for which MRL proposal and/or RA value to be derived	**Source commodity**: Result of Tier 2 and/or 3 study used for extrapolation to derive MRL/RA values in commodity – relevant matrix	**Comment**
233010	Melons		
233020	Pumpkins		
233030	Watermelons		
234000	Sweet corn	Maize	Results on immature crop only.
241010	Broccoli	Flowerhead brassica (broccoli or cauliflower)	Results on mature crop.
241020	Cauliflowers		
242010	Brussels sprouts	Head cabbage or kale or other leafy brassica vegetable	Results on mature crop.
242020	Head cabbages		
243010	Chinese cabbages/pe-tsai		
243020	Kales		
244000	Kohlrabies		
251010	Lamb's lettuces/corn salads	Lettuce or spinach or other leafy vegetable	Results on immature crop.
251020	Lettuces	See lamb's lettuce	Results on mature crop.
251030	Escaroles/broad-leaved endives	See lamb's lettuce	Results on mature crop.
251040	Cresses and other sprouts and shoots	See lamb's lettuce	Results on immature crop.
251050	Land cresses	See lamb's lettuce	Results on immature crop.
251060	Roman rocket/rucola	See lamb's lettuce	Results on immature crop only.
251070	Red mustards	See lamb's lettuce	Results on immature crop only.
251080	Baby leaf crops (including brassica species)	See lamb's lettuce	Results on immature crop only.
252010	Spinaches	See lamb's lettuce	Results on mature or immature crop.
252020	Purslanes	See lamb's lettuce	Results on immature crop only.
252030	Chards/beet leaves	See lamb's lettuce	Results on mature crop only.
254000	Watercresses	See lamb's lettuce	Results on immature crop only.
255000	Witloofs/Belgian endives	See lamb's lettuce	Results on mature crop only.
256010	Chervil	See lamb's lettuce	Results on immature crop only.
256030	Celery leaves	See lamb's lettuce	Results on immature crop only.
256040	Parsley	See lamb's lettuce	Results on immature crop only.
256080	Basil and edible flowers	See lamb's lettuce	Results on immature crop only.
260010	Beans (with pods)	Dried beans or dried peas, legume vegetables	Results on immature seeds with pods
260020	Beans (without pods)	Dried beans or dried peas, legume vegetables	Results on immature seeds without pods
260030	Peas (with pods)	See beans (with pods)	Results on immature seeds with pods
260040	Peas (without pods)	See beans (without pods	Results on immature seeds without pods
260050	Lentils (fresh)	See beans (without pods)	Results on immature seeds without pods
270020	Cardoons	Leek or celery or other stem vegetable	Results on mature crop
270030	Celeries	See cardoons	
270040	Florence fennels	See cardoons	

Crop code	**Target commodity**: Commodity for which MRL proposal and/or RA value to be derived	**Source commodity**: Result of Tier 2 and/or 3 study used for extrapolation to derive MRL/RA values in commodity – relevant matrix	Comment
270060	Leeks	See cardoons	
300010	Beans (dry)	Dried beans or dried peas (legume vegetables)	Results on mature seeds
300020	Lentils (dry)	See beans (dry)	Results on mature seeds
300030	Peas (dry)	See beans (dry)	Results on mature seeds
300040	Lupins/lupini beans (dry)	See beans (dry)	Results on mature seeds
401010	Linseeds	Oilseed rape or soybeans (dry) or other oilseeds	Results on mature seeds
401030	Poppy seeds	See linseeds	
401040	Sesame seeds	See linseeds	
401050	Sunflower seeds	See linseeds	
401060	Rapeseeds/canola seeds	See linseeds	
401070	Soyabean	See linseeds	
401080	Mustard seeds	See linseeds	
401090	Cotton seeds	See linseeds	
401100	Pumpkin seeds	Cucumber or oilseed rape: To be discussed/ agreed	
401110	Safflower seeds	See linseeds	
401120	Borage seeds	See linseeds	
401130	Gold of pleasure seeds	See linseeds	
401140	Hemp seeds	See linseeds	
500010	Barley grains	Wheat or barley (small grains: wheat, barley, triticale, oats and rye)	Results on mature grain
500020	Buckwheat and other pseudo-cereal grains	See barley	Results on mature grain
500030	Maize/corn grains	Maize	Results on mature grain
500040	Common millet/proso millet grains	See barley	Results on mature grain
500050	Oat grains	See barley	Results on mature grain
500060	Rice grains	To be discussed/agreed	
500070	Rye grains	See barley	Results on mature grain
500080	Sorghum grains	See barley	Results on mature grain
500090	Wheat grains	See barley	Results on mature grain
631010	Chamomile flowers	Leafy vegetables and Brassicas	Results on immature crop only.
810010	Anise	Cucumber or oilseed rape: To be discussed/ agreed	OECD 2018 recommends extrapolation from strawberries or cucumbers. However, EFSA considers more appropriate to extrapolate from oilseeds rape or soybeans (dry), mature product.
810020	Black caraway	See anise	See anise
810030	Celery seed	See anise	See anise
810040	Coriander seed	See anise	See anise
810040	Cumin seed	See anise	See anise

Crop code	**Target commodity**: Commodity for which MRL proposal and/or RA value to be derived	**Source commodity**: Result of Tier 2 and/or 3 study used for extrapolation to derive MRL/RA values in commodity – relevant matrix	**Comment**
810060	Dill seed	See anise	See anise
810070	Fennel seed	See anise	See anise
810080	Fenugreek	See anise	See anise
820030	Caraway	See anise	See anise
900010	Sugar beet roots	Roots of root vegetables	Results on mature roots only.
900030	Chicory roots	Roots of root vegetables	Results on mature roots only.
–	Feed items	See Table A.7	See Table A.7
–	Herbaceous ornamental crops	Not relevant	–

Table A.7: Feed items included in EU dietary burden calculator; proposed extrapolation scheme and proposed default processing factors (PF) for deriving input values for EU livestock dietary burden calculation.[53]

Feed category	Feed crop	Feed item	Rotational crop study used to retrieve input value for dietary burden calculation by extrapolation (source crop)	Default PF[(a),(c)]
1 – Forages	Alfalfa	Forage (green)	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	
1 – Forages	Alfalfa	Hay (fodder)	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	1.5–4[(b)]
1 – Forages	Alfalfa	Meal	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	2.5
1 – Forages	Alfalfa	Silage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	0.5–1.6[(b)]
1 – Forages	Barley	Forage	Results of RC studies in cereal forage	
1 – Forages	Barley	Straw	Results of RC studies in cereal straw	
1 – Forages	Barley	Silage	Results of RC studies in cereal forage	0.6–1.3[(b)]
1 – Forages	Bean	Vines (fodder green)	Results of RC studies in pulses forage	
1 – Forages	Beet, mangel	fodder	Results of RC studies in root crops (tops)	
1 – Forages	Beet, sugar	Tops	Results of RC studies in root crops (tops)	
1 – Forages	Cabbage, heads	Leaves	Results on RC studies in mature had cabbage, kale or other leafy brassica vegetable	
1 – Forages	Clover	Forage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	
1 – Forages	Clover	Hay	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	1.5-4[(b)]
1 – Forages	Clover	Silage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	0.5–1.6[(b)]
1 – Forages	Corn, field	Forage/silage	Results of RC studies in cereal forage	
1 – Forages	Corn, field	Stover (fodder)	Results of RC studies in cereal forage	
1 – Forages	Corn, pop	Stover (fodder)	Results of RC studies in cereal forage	
1 – Forages	Cowpea	Forage	Results of RC studies in pulses forage	
1 – Forages	Cowpea	Hay	Results of RC studies in pulses forage	2.9
1 – Forages	Grass	Forage (fresh)	Not relevant (permanent crop)	
1 – Forages	Grass	Hay	Not relevant (permanent crop)	
1 – Forages	Grass	Silage	Not relevant (permanent crop)	
1 – Forages	Kale	Leaves (forage)	Results on RC studies in mature had cabbage, kale or other leafy brassica vegetable	
1 – Forages	Lespedeza	Forage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	
1 – Forages	Lespedeza	Hay	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	1.5–4[(b)]
1 – Forages	Millet	Forage	Results of RC studies in cereal forage	
1 – Forages	Millet	Straw (fodder, dry)	Results of RC studies in cereal straw	

[53] Further guidance on the extrapolation of rotational crop studies to feed items used in the dietary burden calculation need to be developed (Section 9, recommendation 15).

Feed category	Feed crop	Feed item	Rotational crop study used to retrieve input value for dietary burden calculation by extrapolation (source crop)	Default PF[(a),(c)]
1 – Forages	Oat	Forage	Results of RC studies in cereal forage	
1 – Forages	Oat	Hay	Results of RC studies in cereal forage	2.9–3.5[(b)]
1 – Forages	Oat	Straw	Results of RC studies in cereal straw	
1 – Forages	Pea	Vines (green)	Results of RC studies in pulses forage	
1 – Forages	Pea	Hay (hay or fodder)	Results of RC studies in pulses forage	3.5
1 – Forages	Pea	Silage	Results of RC studies in pulses forage	1.6
1 – Forages	Rape	Forage	Results of RC studies in oilseed forage	
1 – Forages	Rice	Straw	Results of RC studies in cereal straw	
1 – Forages	Rye	Forage (greens)	Results of RC studies in cereal forage	
1 – Forages	Rye	Straw	Results of RC studies in cereal straw	
1 – Forages	Sorghum	Forage	Results of RC studies in cereal forage	
1 – Forages	Sorghum, grain	Stover	Results of RC studies in cereal forage	
1 – Forages	Sorghum	Silage	Results of RC studies in cereal forage	0.6–1.3[(b)]
1 – Forages	Soybean	Forage (green)	Results of RC studies in oilseed and/or pulses forage	
1 – Forages	Soybean	Hay (fodder)	Results of RC studies in oilseed and/or pulses forage	1.5–4[(b)]
1 – Forages	Soybean	Silage	Results of RC studies in oilseed and/or pulses forage	0.5–1.6[(b)]
1 – Forages	Trefoil	Forage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	
1 – Forages	Trefoil	Hay	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	1.5–4[(b)]
1 – Forages	Triticale	Forage	Results of RC studies in cereal forage	
1 – Forages	Triticale	Hay	Results of RC studies in cereal forage	2.9–3.5[(b)]
1 – Forages	Triticale	Straw	Results of RC studies in cereal straw	
1 – Forages	Turnip	Tops (leaves)	Results of RC studies in root crops (tops)	
1 – Forages	Vetch	Forage	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	
1 – Forages	Vetch	Hay	Results of RC studies in cereal forage and/or oilseed forage and/or pulses forage	1.5–4[(b)]
1 – Forages	Wheat	Forage	Results of RC studies in cereal forage	
1 – Forages	Wheat	Hay (fodder dry)	Results of RC studies in cereal forage	2.9–3.5[(b)]
1 – Forages	Wheat	Straw	Results of RC studies in cereal straw	
2 – Roots & Tubers	Carrot	Culls	Results of RC studies in mature and immature root crops	
2 – Roots & Tubers	Cassava/tapioca	Roots	Grown in tropical and subtropical areas. To consider, whether cGAP assessed is relevant. If relevant, results on mature roots only.	

Feed category	Feed crop	Feed item	Rotational crop study used to retrieve input value for dietary burden calculation by extrapolation (source crop)	Default PF[(a),(c)]
2 – Roots & Tubers	Potato	Culls	Preferably, results of RC studies for mature tubers. If not available, results on mature root crops.	
2 – Roots & Tubers	Swede	Roots	Results of RC studies on mature root crops.	
2 – Roots & Tubers	Turnip	Roots	Results of RC studies on mature root crops.	
3 – Cereal/seeds	Barley	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Bean	Seed (dry)	Results of RC studies on mature seeds	
3 – Cereal/seeds	Corn, field (Maize)	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Cotton	Undelinted seed	Results of RC studies on mature seeds	
3 – Cereal/seeds	Cowpea	Seed	Results of RC studies on mature seeds	
3 – Cereal/seeds	Lupin	Seed	Results of RC studies on mature seeds	
3 – Cereal/seeds	Millet	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Oat	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Pea (Field pea)	Seed (dry)	Results of RC studies on mature seeds	
3 – Cereal/seeds	Rye	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Sorghum	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Soybean	Seed	Results of RC studies on mature seeds	
3 – Cereal/seeds	Triticale	Grain	Results of RC studies on mature grain	
3 – Cereal/seeds	Wheat	Grain	Results of RC studies on mature grain	
4 – By-products	Apple	Pomace, wet	Permanent crop, not relevant	
4 – By-products	Beet, sugar	Dried pulp	Results of RC studies in mature root crops	18[(b)]
4 – By-products	Beet, sugar	Ensiled pulp	Results of RC studies in mature root crops	3
4 – By-products	Beet, sugar	Molasses	Results of RC studies in mature root crops	28
4 – By-products	Brewer's grain	Dried	Results of RC studies on mature grain	3.3
4 – By-products	Citrus	Dried pulp	Permanent crop, not relevant	
4 – By-products	Coconut	Meal	Permanent crop, not relevant	
4 – By-products	Corn, field	Milled by-pdts	Results of RC studies on mature grain	1[(b)]
4 – By-products	Corn, field	Hominy meal	Results of RC studies on mature grain	6[(b)]
4 – By-products	Corn, field	Gluten feed	Results of RC studies on mature grain	2.5[(b)]
4 – By-products	Corn, field	Gluten, meal	Results of RC studies on mature grain	1[(b)]
4 – By-products	Cotton	Meal	Results of RC studies on oilseeds	1.3[(b)]
4 – By-products	Distiller's grain	Dried	Results of RC studies on mature grain	3.3[(b)]

Feed category	Feed crop	Feed item	Rotational crop study used to retrieve input value for dietary burden calculation by extrapolation (source crop)	Default PF[(a),(c)]
4 – By-products	Flaxseed/Linseed	Meal	Results of RC studies on oilseeds	2[(b)]
4 – By-products	Lupin seed	Meal	Results of RC studies on pulses (seeds)	1.1[(b)]
4 – By-products	Palm (hearts)	Kernel meal	Permanent crop, not relevant	
4 – By-products	Peanut	Meal	Not relevant in EU	
4 – By-products	Potato	Process waste	Preferably, results of RC studies for mature tubers. If not available, results on mature root crops.	20[(b)]
4 – By-products	Potato	Dried pulp	Preferably, results of RC studies for mature tubers. If not available, results on mature root crops.	38[(b)]
4 – By-products	Rape	Meal	Results of RC studies on pulses (seeds)	2
4 – By-products	Rice	Bran/pollard	Results of RC studies on mature grain	10[(b)]
4 – By-products	Safflower	Meal	Results of RC studies on oilseeds or pulses (seeds)	2[(b)]
4 – By-products	Soybean	Meal	Results of RC studies in oilseeds	1.3[(b)]
4 – By-products	Soybean	Hulls	Results of RC studies in oilseeds	13[(b)]
4 – By-products	Sugarcane	Molasses	Not grown in EU. Not relevant for RC	
4 – By-products	Sunflower	Meal	Results of RC studies in oilseeds	2
4 – By-products	Wheat gluten	Meal	Results of RC studies on mature grain	1.8
4 – By-products	Wheat	Milled by-pdts	Results of RC studies on mature grain	7

(a): The same default PF applies as for primary crops.
(b): Depending on the source crop (crop in which the field study was performed), a different processing factor may need to be chosen.
(c): Grey cells: not relevant for EU.

Appendix B – Examples illustrating the assessment of residues in rotational crops

The assessment of residues in rotational crops is based on certain endpoints of the environmental fate and behaviour assessment in soil, both for the active substance and for soil metabolites which are reported in the respective chapter of the list of end points (LoEP). This Appendix should provide examples how to find the relevant information in the LoEP, since residue experts may not be fully familiar with the structure of the information provided in this section of the LoEP. In general, a re-assessment of fate and behaviour studies by residue experts should be avoided.[54]

Currently, the following endpoints of the fate assessment have to be used to perform the rotational crop assessment:

- Significant soil metabolites (soil metabolites requiring further assessment)/residue definition for risk assessment (soil); in the current guidance these metabolites are referred to as 'significant soil metabolites') (see Section 3.3);
- Molecular weight of soil metabolites (see Section 4.4.2);
- DT_{90} for a.s. (see Section 4.2.3);
- DT_{90} for significant soil metabolites (see Section 4.2.3);
- Degradation kinetics of a.s. (see Section 5.3.4.2);
- Degradation kinetics of metabolites;
- $PEC_{(s)}$ of the a.s. (see Section 5.3.4.4);
- $PEC_{(s)}$ of significant soil metabolites (see Section 5.3.8.2).

In addition, examples illustrating the calculations described in the current guidance document are provided below.

B.1. Significant soil metabolites: Soil metabolites requiring further assessment

In the LoEP, Section 'Environmental fate and behaviour', soil metabolites that need to be considered with respect to potential residues in rotational crops can be found under the point 'Residues requiring further assessment (Regulation (EU) No 283/2013, Annex Part A, point 7.4.1), soil'. An example of how the information is presented can be found below (Example 1).

[54] In Section 9, a number of recommendations was derived on how to improve the presentation of end points relevant for the assessment of residues in rotational crops or to report additional end points. However, as such modifications of the LoEP will require some time, the current guidance proposes to make best use of the available information presented in the LoEP on fate and behaviour in the environment.

Example 1: Identification of significant soil metabolites

Peer review of the pesticide risk assessment of the active substance methoxyfenozide

EFSA Journal

	hours
	from soil surfaces (BBA guideline): *negligible after x24 hours*
Metabolites	No information available

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Methoxyfenozide, RH-131154 (M08) Surface water: Methoxyfenozide, RH-131154 (M08), RH-117236 (M14) Sediment: Methoxyfenozide, RH-131154 (M08), RH-117236 (M14) Ground water: Methoxyfenozide, RH-131154 (M08) Air: Methoxyfenozide by default

Result: Metabolite RH-131154 is a significant soil metabolite of methoxyfenozide that needs to be considered in the assessment of rotational crops.

B.2. DT_{90} in soil for active substances

In the LoEP, different DT_{50} and DT_{90} values are reported for different soil types, investigating aerobic/anaerobic conditions; values are derived from field studies or from laboratory studies. The DT_{90} value are used to decide whether rotational crop metabolism studies are triggered (see Section 4.2.3). Since the relevant DT_{90} used as trigger value is often not explicitly reported in the LoEP, EFSA describes a simple method how to derive it. In Example 2, the approach for a.s. with SFO degradation kinetics is outlined; for a.s. that do not degrade according to SFO kinetics, 2 options for deriving the DT_{90} are described (Examples 3a and 3b).[55]

[55] To facilitate the assessment for rotational crops, it is recommended that in future, the relevant end points should be clearly reported in the LoEP to avoid the work around procedure described in this section (see also recommendation 2).

Example 2: Calculation/identification of DT_{90} for the a.s., SFO kinetics

Step 1: Look up the DT_{50} and Kinetics (Method of calculation) in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013[56], Annex Part A, points 9.1.3/9.3.1)'.

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT_{50} (d): *470* days Kinetics: *SFO* Field: *longest non-normalised field DT_{50}.*
Application data	Crop: Leafy veg Depth of soil layer: *5cm* Soil bulk density: *1.5g/cm³* % plant interception: 70 Interval (d): *70* Application rate(s): Leafy Veg: 1 or 2 x *120* g a.s./ha (1 application per successive crop)

Result of step 1 for example 2: $DT_{(50)}$ for the a.s.: **470 days***, SFO kinetics.

*If the DT_{50} is already greater than 100 days, the second step can be skipped. However, for illustrating the general approach, the step 2 is reported also for this example.

Step 2: Calculation of DT_{90}.

For a.s. with degradation kinetics SFO, the DT_{90} is calculated according to the following equation:

$$DT_{90} = DT_{50} \times 3.32.$$

The factor 3.32 is a generic factor derived by the following equation:

$$(\ln 10/\ln 2) = 3.321928^{*)}$$

*) usually, the rounded value of 3.32 is used for the re-calculations.

Result of step 2 for example 2:

$$DT_{90} = 470\text{ d} \times 3.32 = \mathbf{1,560.4\ days}.$$

Conclusion: Tier 1 studies are triggered as the DT_{90} is greater than 100 days.

[56] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, pp. 85–152.

Example 3a: Identification of DT_{90} for the a.s., non-SFO kinetics

Step 1: Same as in Example 2, look up the DT_{50} and Kinetics (Method of calculation) in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3/9.3.1)'.

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT50 (d): 139 days (slow phase), k1 = 0.022, k2 = 0.005, tb = 33.24 in the tool ESCAPE v. 2 Kinetics: HS Field or Lab: non-normalised worst case from field studies.
Application data	Crop: lettuce/chicory Depth of soil layer: 10 cm and 15 cm (soil incorporation) Soil bulk density: 1.5g/cm3 % plant interception: pre-sowing or pre-planting therefore no crop interception Number of applications: 1 Interval (d): - Application rate(s): 1440 g a.s./ha

Result of step 1 in Example 3a: $DT_{(50)}$ for a.s., non-SFO kinetics: **139 days***.

*If the DT_{50} is already greater than 100 days, the second step can be skipped. However, for illustrating the general approach, the step 2 is reported also for this example.

Step 2: In the sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)', compare the initial $PEC_{(s)}$ with the $PEC_{(s)}$ at 100 days.

PEC(s) 10 cm incorp. (mg/kg)	Single application Actual	Single application Time weighted average
Initial	0.96	-
Short term 24 h	0.939	0.950
2 d	0.919	0.939
4 d	0.879	0.919
Long term 7 d	0.823	0.890
28 d	0.518	0.717
50 d	0.427	0.602
100 d	0.333	0.490
Plateau concentration (20 cm)	0.049 mg/kg after 2 yr	
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)	1.009 mg/kg	

If the $PEC_{(s)}$ at 100 days is greater than 10% of the initial $PEC_{(s)}$, the DT_{90} is > 100 days.
Result of step 2 in Example 3a: 0.333 mg/kg corresponds to 35% of the initial $PEC_{(s)}$ of 0.96 mg/kg.

Conclusion: Tier 1 studies are triggered as the DT_{90} is greater than 100 days.

The alternative option for identifying the DT_{90} is shown in Example 3b.

Example 3b: Identification of DT_{90} for the a.s., non-SFO kinetics

An approach similar to Example 2 can be applied:

Step 1: Look up the DT_{50} and Kinetics (Method of calculation) in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)'.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 4.5 d Kinetics: FOMC (α=0.6; β=2;) Field or Lab: Field
Application data	Crop: hops lettuce (biennial application) lettuce (annual application)

Result of step 1 in Example 3: $DT_{(50)}$ for a.s., non-SFO kinetics: **4.5 days.**

Step 2: Look up the DT_{50} identified in step 1 in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'Rate of degradation field soil dissipation studies (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.2.1)'.

The DT_{90} value corresponding to the DT_{50} used in the PEC soil calculation is the relevant value to decide whether tier 1 studies are triggered.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

....

Field studies

parent	**Aerobic conditions**									
Soil type (bare soil)	**Location (country or USA state)**	**pH[1]**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90} (d) actual**	**χ2**	**Method of calculation**	**DT_{50} (d) Norm.**	**χ2**	**Method of calculation**
Clay loam	Italy	7.4	0-30	4.1	91	7.1	FOMC	4.5	1.2	FOMC

Result of step 2: DT_{90} is 91 days.

Conclusion: Tier 1 studies are not triggered as the DT_{90} is less than 100 days.

In case of doubts, residues assessor may seek assistance of experts in the field of assessment of fate and behaviour into the environment to identify the appropriate DT_{90}.

B.3. DT_{90} in soil for soil metabolites

The same procedure as described for a.s. can be applied to the identification of the DT_{90} of the significant metabolites. An example for the identification of the relevant DT_{90} of metabolites with SFO degradation kinetics is provided below (Example 4). For metabolites following other degrading kinetics, the same approach should be applied.

Example 4: Identification of DT_{90} for significant metabolites (degradation following SFO kinetics)

Step 1: Look up the DT_{50} and Kinetics (Method of calculation) in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)'.

Metabolite X11438848 Method of calculation	FOCUS standard PECsoil Molecular weight relative to the parent: 0.795 DT_{50} (d): 54 days Kinetics: SFO Field or Lab: representative worst-case from lab studies
Application data	Application rate assumed: 14.7 g/ha (assumed X11438848 is formed at a maximum of 62.2% of the applied dose)

Result step 1: 54 days, SFO kinetics.

Step 2: Calculation of DT_{90} by multiplying the DT_{50} with 3.32, as SFO kinetic is applicable.

$$DT_{90} = 54\ d \times 3.32 = 179\ d.$$

Conclusion: Tier 1 studies are triggered as the DT_{90} is greater than 100 days.

B.4. DT_{50} in soil for active substances

For calculating of the accumulation factor for persistent active substances which follow SFO kinetics, the DT_{50} needs to be used (See **Equation 10** in Section 5.3.4.3). An example how to identify this input value is presented below.

Example 5: Identification of DT_{50} for a.s. (degradation following SFO kinetics) for calculating f_{acc}

Step 1: Look up the DT_{50} and Kinetics (Method of calculation) in the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)'.

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT_{50} (d): 846.6 days Kinetics: SFO Field or Lab: non-normalized worst case from field studies.
Application data	Crop: cereals Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 Number of applications: 2 Interval (d): 14 % plant interception: 80/80 Application rate: 2 x 150 g a.s. ha^{-1}

Result: DT_{50} = 846.6 days.

$$f_{acc} = \frac{e^{-\frac{\ln 2}{DT50}\Delta t}}{1 - e^{-\frac{\ln 2}{DT50}\Delta t}}.$$

Result for Δt = 365 days, facc = 2.87

B.5. Calculation of the seasonal effective application rate (A_{eff}) for the critical GAP

In Section 5.3.4, the guidance document describes how the application rate for rotational crop field studies (Tier 2) is calculated for the relevant GAPs. In example 6, the approach is illustrated for a critical GAP of 3 applications of 100 g/kg ha, with an interval of 21 days, with crop interception rates of 35%, 55% and 85%. The A_{eff} is calculated according **Equation 5**, the seasonal effective application rate is derived according to **Equation 6**.

The seasonal effective application rate can be re-calculated to a soil concentration according to **Equation 1**. In the graphical presentation, the contributions of the three applications are presented. The orange line gives the estimated soil concentration correlating to the seasonal effective application rate.

Example 6: Calculation of A_{eff} for critical GAP in an annual crop

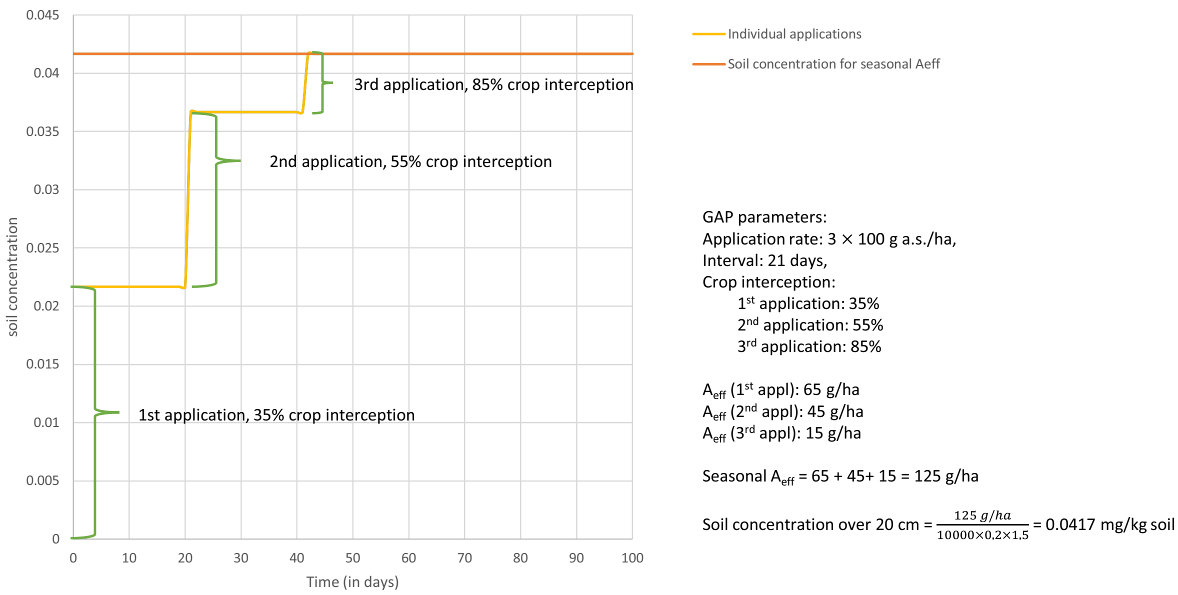

Figure B.1: Calculation of seasonal effective application rate

Result for Example 6: Seasonal A_{eff} = 125 g/ha;

This seasonal A_{eff} corresponds to a soil concentration (expressed over 20 cm) of 0.0417 mg/kg soil (represented by the orange line).

In the figure below, the actual soil concentration derived by soil modelling is presented, considering the degradation of the a.s. between the individual applications; the example was calculated for a DT_{90} of the a.s. of 200 days (blue line). This illustration demonstrates that the calculated A_{eff} (and the corresponding soil concentration, orange line) is overestimating the maximum soil concentration that is expected under practical conditions (grey line). The difference between the orange and the grey line will decrease with higher DT_{90} values for the a.s., as the decline between the applications will have less effect.

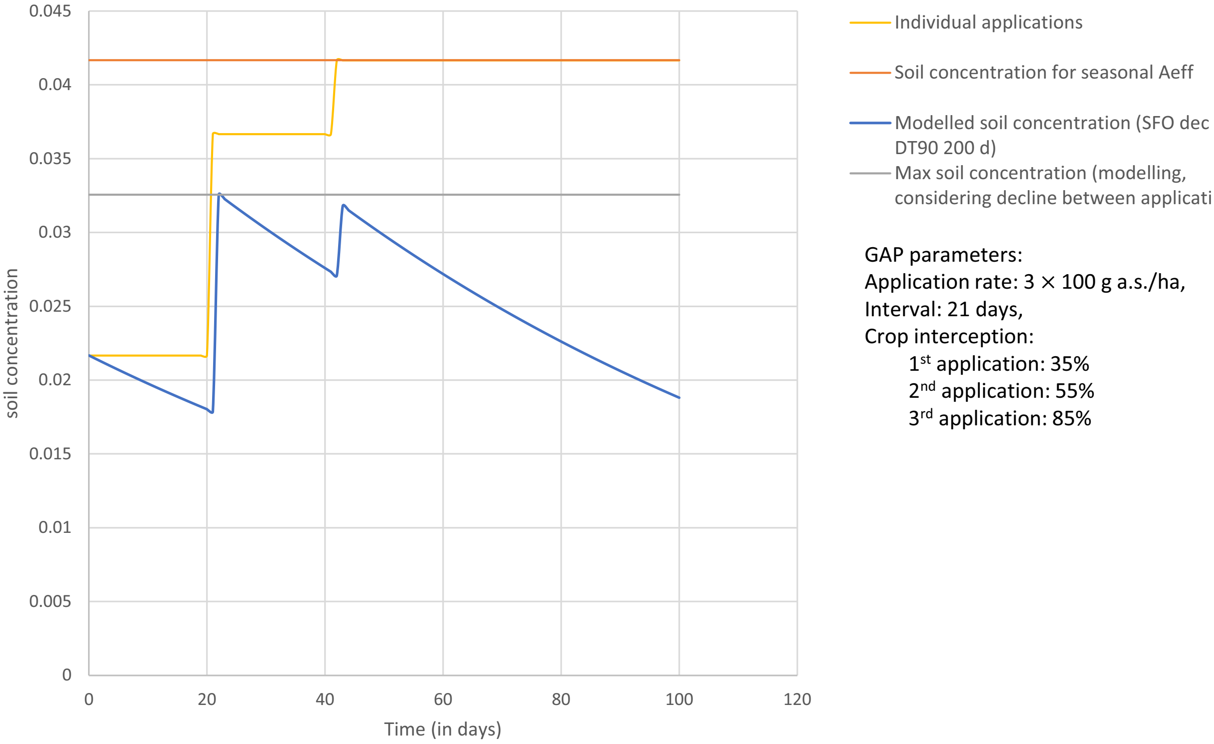

Figure B.2: Comparison of calculated soil concentration corresponding seasonal effective application rate and soil concentration of a.s. derived by modelling

B.6. Identification of the seasonal effective application rate (A_{eff}) for representative use assessed in the peer review

For accumulating a.s. that do not follow SFO kinetics (see Section 5.3.4.4), the seasonal effective application rate (A_{eff}) reported in the LoEP for the representative use assessed in the peer review is required to calculate the application rate for field studies studies.

Example 7 illustrates how the A_{eff} is identified in the LoEP.

Example 7: Calculation of seasonal effective application rate for representative use assessed in the peer review

Step 1: In the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)', look up the application data which were used in the $PEC_{(s)}$ calculation for the a.s.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): k1 = 0.00810; k2 = 0.00023 Breakpoint (tb) = 53 d (DT50 = 1235 d) Kinetics: HS model Field or Lab: worst case, non-normalised DT50 from field dissipation studies (German trial).
Application data	Crop: wheat, rye, barley, triticale, oats Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 50% (BBCH 25-69) Number of applications: 1 Interval (d): n/a Application rate(s): 250 g as/ha (Maximum total dose)

Result of step 1: Application rate for cereals: 1 × 250 g/ha, at BBCH 25–65 (50% crop interception rate).

Step 2: Calculate the seasonal effective application rate for representative use using **Equation 6** (see Section 5.3.3).

$$\text{Seasonal } A_{eff}(g/ha) = \sum_{i=1}^{n} A \times \left(1 - \frac{CIR}{100}\right)$$

Result for example 7: Seasonal A_{eff} = 125 g/ha

B.7. Identification of the plateau $PEC_{(s)}$ for accumulating a.s. for the representative GAP assessed in the peer review

The soil plateau concentration (plateau $PEC_{(s)}$, in some LoEP it is also referred to as background or steady state level)[57] is required to calculate the application rate for rotational crop field studies for accumulating a.s. that do not follow SFO kinetics (see Section 5.3.4.4). The proposed approach is illustrated in Example 8.

[57] The terminology used in the LoEP for this parameter may cause confusion, since different terms are used to describe this parameter. It is therefore recommended that more attention is paid to use consistent terminology in the LoEP for describing the accumulated soil background concentration (Recommendation 7).

Example 8: Identification of the soil plateau concentration for the parent a.s.

Step 1: In the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)', look up the Plateau/background concentration (which reflects the concentration over a soil horizon of 20 cm).

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.167		-	
Short term 24h	0.165	0.166	-	-
2d	0.164	0.165	-	-
4d	0.161	0.164	-	-
Long term 7d	0.157	0.162	-	-
28d	0.133	0.149	-	-
50d	0.111	0.137	-	-
100d	0.108	0.123	-	-
Plateau concentration	Plateau = **0.31 mg/kg** (over 20 cm mixing depth) . Peak plateau concentration = **0.48 mg/kg** (over 20 cm depth + 1 application in 5 cm). Plateau reached after 40 years. Based on max. total dose of 250 g a.s/ha with 50% interception and worst case field DT50 (non-normalised, HS kinetics).			

Result for example 8: Background PEC$_{(s)}$ = 0.31 mg/kg

B.8. Identification of the PEC$_{(s)}$ for accumulating metabolites (reflecting the representative GAP assessed in the peer review)

The PEC$_{(s)}$ for metabolites is required for the calculation of the theoretical concentration for soil metabolites and the application rate for soil metabolites when they are directly tested in rotational crop field studies (see Section 5.3.8.2). The example below illustrates how to derive this end point from the LoEP (NB: the PEC$_{(s)}$ reflects the PEC$_{(s)}$ for the critical GAP assessed in the peer review, representing a soil horizon of 5 cm.)

Example 9: Identification of the $PEC_{(s)}$ for metabolites

Step 1: In the LoEP, Section 4, Environmental fate and behaviour, sub-section 'PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3/9.3.1)', look up the table for the respective metabolite (in this example Metabolite X12483137).

Metabolite X12483137 Method of calculation		FOCUS standard PECsoil Molecular weight relative to the parent: 0.87 DT_{50} (d): 478 days Kinetics: SFO Field or Lab: representative worst-case from lab studies			
Application data		Application rate assumed: 2.89 g/ha (assumed X12483137 is formed at a maximum of 11.1 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)		**Single application Actual**	**Single application Time weighted average**	**Multiple application Actual**	**Multiple application Time weighted average**
Initial		0.004		0.008	
Short term	24h	0.004	0.004	0.008	0.008
	2d	0.004	0.004	0.008	0.008
	4d	0.004	0.004	0.008	0.008
Long term	7d	0.004	0.004	0.008	0.008
	28d	0.004	0.004	0.007	0.008
	50d	0.004	0.004	0.007	0.007
	100d	0.003	0.004	0.007	0.007
Plateau concentration		0.010 mg/kg after 2 years			

Result for example 9: initial $PEC_{(s)\ (5cm)}$ = 0.004 mg/kg

The initial PEC(s) for 20 cm soil depth is derived by dividing the initial $PEC_{(s)(5cm)}$ by a factor of 4.

$PEC_{(s)(20cm)}$ = 0.004 (in mg/kg)/4 = 0.001 mg/kg

The application rate for the metabolite should be calculated according to **Equation 14**.

The adjustment for the critical GAP assessed (compared to the GAP of the representative use) is done according to **Equation 12**.

B.9. Scaling of results of rotational crop field studies if soil concentration of metabolites was lower than expected

Scaling of rotational crop studies in case the soil concentration of metabolites was lower than expected, need to be carefully considered. The following information needs to be available:

- What is the reference soil concentration of the metabolite used for deriving a scaling factor (modelled soil concentration or $PEC_{(s)}$)? This information is required to calculate the scaling factor. Using $PEC_{(s)}$ as reference soil concentration is leading to a high level of conservatism (See example below). When the reference soil concentrations are derived by soil modelling, the relevant soil types used in the study should be considered. When the reference soil concentration is derived by soil modelling, it is important to consider the soil type and the metabolic pattern typical for the soil type.
- Formation and degradation kinetics for metabolites: The soil concentration of metabolites changes over time. The formation rate of a metabolite and consequently the peak soil concentration but also the time when the peak concentration occurs depends on the soil type.
- Plant metabolism: Is the soil metabolite under assessment also formed by in the crop (metabolite identified in primary crop metabolism)? What is the degradation pathway of the soil metabolite in the crop? This information would be required to decide which components of the residues in the plant should be scaled/should not be scaled as they have a different origin than the soil metabolite.

Example 10: Calculation of theoretical scaling factors by comparing measured soil concentrations with PEC(s) – Limitations and related uncertainties

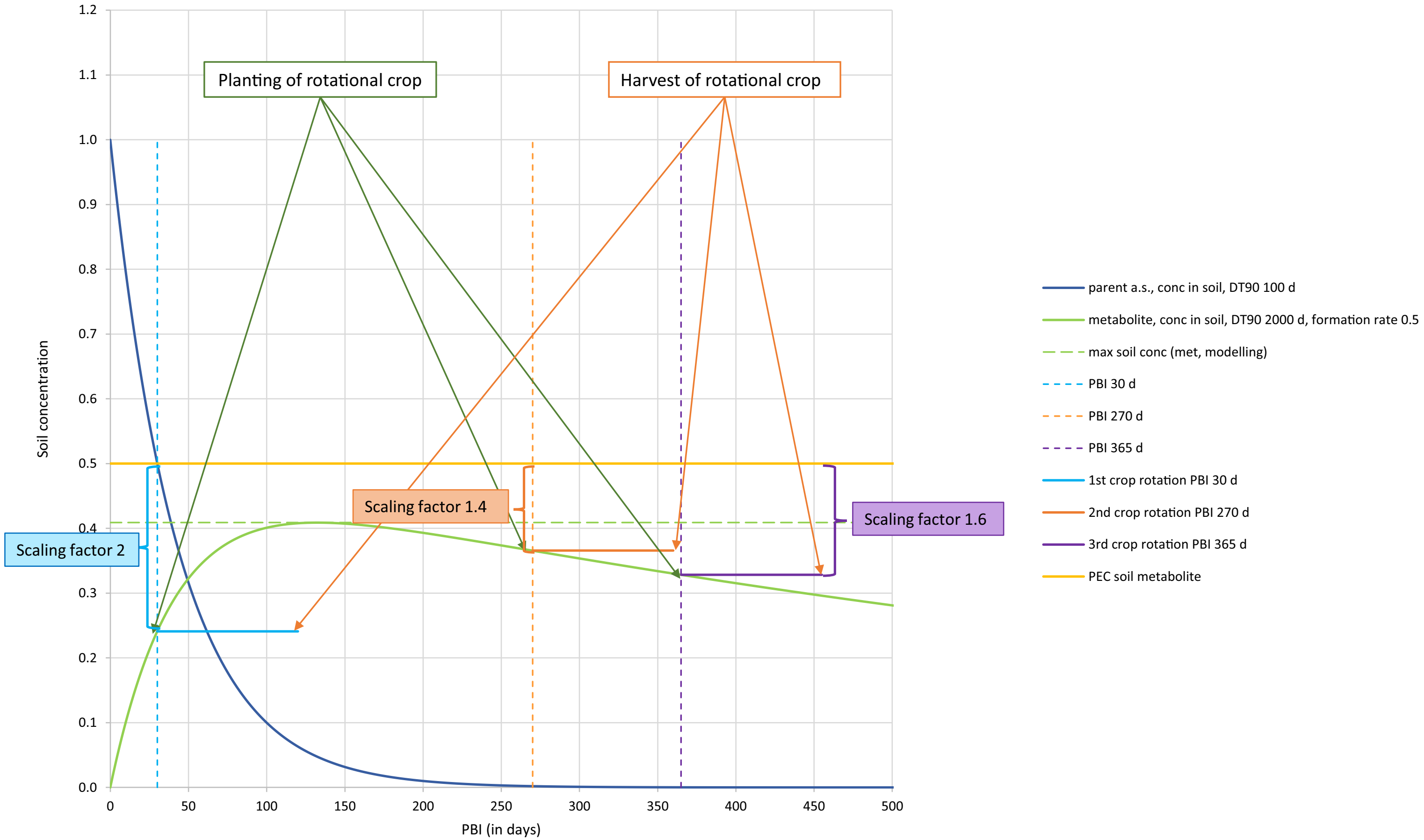

Figure B.3: Calculation of theoretical scaling factors by comparing soil concentration of metabolite at time of planting of rotational crops (PBI 30 d, 270 d and 365 d) with $PEC_{(s)}$

The theoretical scaling factors at the different time points are 2, 1.4 and 1.6.

Applying these scaling factors to the residues measured in rotational crops will lead to a significant overestimation, in particular for PBI 30 days, as the soil concentration increased and at the time of harvesting the crop of the first crop rotation, the peak soil concentration was reached.

The degradation pathways of an active substance can be much more complex than in the example presented above (e.g. sequential formation of soil metabolites, soil metabolites formed by cleavage of a precursor molecules, degradation following different degradation kinetics different behaviour in different soil types). In addition, once a soil metabolite is taken up by the roots of rotational crops, the soil metabolite are subject to further metabolisation in plants.

Hence, an analysis would be required to decide which metabolites in plants are clearly resulting from a certain soil metabolite (precursor in the metabolic pathway) and therefore might need to be scaled, if the precursor soil metabolite was not in the expected range. If a sequential degradation pathway cannot be established between a soil metabolite and the plant metabolite, scaling of residue concentrations found in plants is leading to an additional, high uncertainty.

B.10. Representativeness of rotational crop studies with respect to soil metabolites

Soil metabolites are sufficiently addressed by rotational crop studies performed with the application of the parent a.s. to soil, if the peak soil concentration of the respective metabolite was formed during the duration of the study. Hence, an assessment of the formation/degradation kinetics of the soil metabolite is required to decide whether rotational crop studies performed with the parent are enough or whether additional studies are required. Results of soil analysis are also a useful source of information to be taken into account, but with some limitations, as the limited number of sampling points does not allow to describe the formation/degradation kinetics adequately.

In the following example, an analysis was performed for a simple case, where the a.s. and the metabolite degrade following SFO; the parent a.s. is a direct precursor of the metabolite. No other metabolites are formed. The degradation/formation kinetics for different DT_{90} of the a.s. and the metabolite are presented in figures, to illustrate whether the metabolite has formed during the rotational crop study to a sufficient degree.

Example 11: Formation of soil metabolites in rotational crop study, depending on the ratio of DT_{90} for a.s. and metabolite

The table below gives an overview on the cases presented in Figures B.4–B.11, based on the DT_{90} of the a.s. and the metabolite.

Table B.1: DT_{90} for soil metabolites and parent a.s.; metabolites expected to be sufficiently addressed/not sufficiently addressed

			Active substance: Degradation rate		
			Fast	**Medium**	**Slow**
			DT_{90} < 100 d	**DT_{90} between 100 and 365 d**	**DT_{90} > 365 d**
Significant soil metabolite: Degradation rate	**Medium**	DT_{90} between 100 and 365 days	DT_{90} met < DT_{90} a.s Not applicable	DT_{90} met < DT_{90} a.s. Figure B.6 Soil metabolite sufficiently addressed[a]	DT_{90} met < DT_{90} a.s. Figure B.9 Soil metabolite sufficiently addressed[a]
			DT_{90} met > DT_{90} a.s. Figure B.4: Soil metabolite sufficiently addressed[a]	DT_{90} met > DT_{90} a.s. Figure B.7 Soil metabolite is sufficiently addressed[a]	DT_{90} met > DT_{90} a.s. Not applicable
	Slow	DT_{90} > 365 d	DT_{90} met < DT_{90} a.s. Not applicable	DT_{90} met < DT_{90} a.s. Not applicable	DT_{90} met < DT_{90} a.s. Figure B.10 Soil metabolite sufficiently addressed[a]

			Active substance: Degradation rate		
			Fast	**Medium**	**Slow**
			$DT_{90} < 100$ d	**DT_{90} between 100 and 365 d**	**$DT_{90} > 365$ d**
			DT_{90} met > DT_{90} a.s. Figure B.5 Soil metabolite not sufficiently addressed (accumulation of soil metabolite following multiannual use)	DT_{90} met > DT_{90} a.s. Figure B.8 Soil metabolite not sufficiently addressed (accumulation of soil metabolite following multiannual use)	DT_{90} met > DT_{90} a.s. Figure B.11 Soil metabolite not sufficiently addressed (accumulation of soil metabolite following multiannual use)

(a): The soil metabolites are sufficiently addressed, as the peak soil concentration of the respective metabolite was formed during the duration of the study.

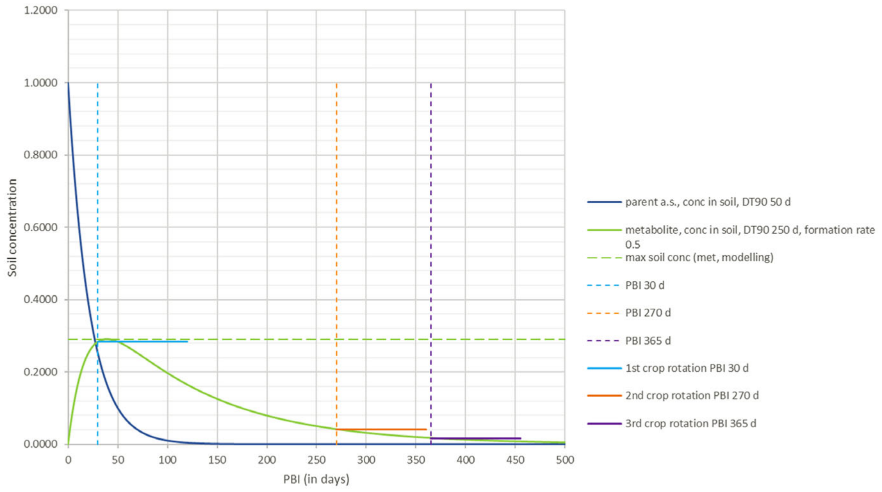

Figure B.4: DT_{90} parent 50 d, DT_{90} metabolite 250 d, soil metabolite is sufficiently addressed

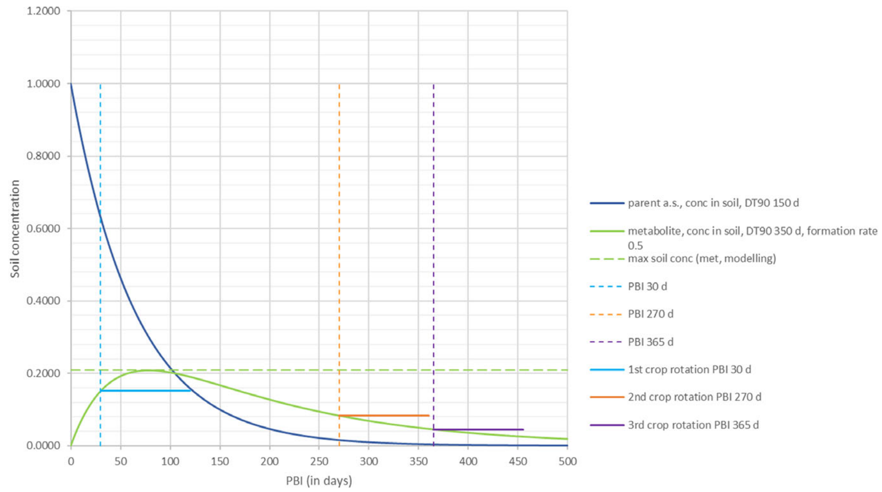

Figure B.6: DT_{90} parent 150 d, DT_{90} metabolite 350 d, the soil metabolite is sufficiently addressed

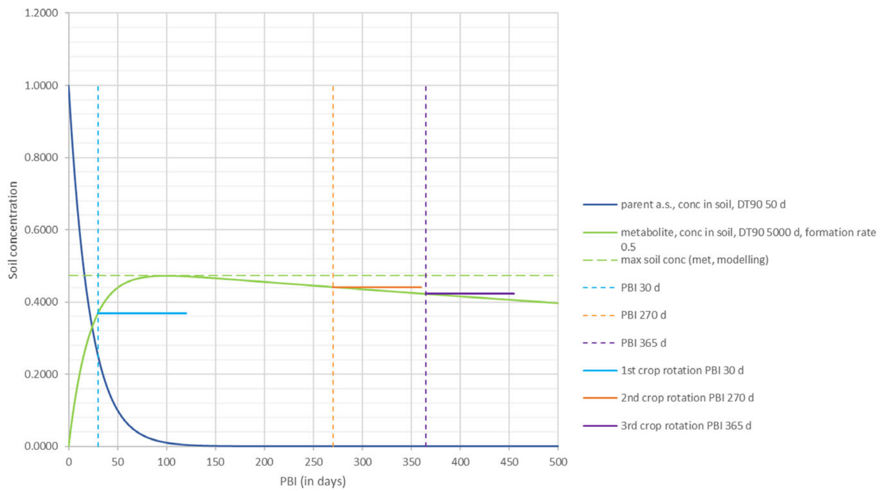

Figure B.5: DT_{90} parent 50 d, DT_{90} metabolite 5000 d (accumulating metabolite), the soil metabolite might not be sufficiently addressed, since accumulation following multiannual use is not represented

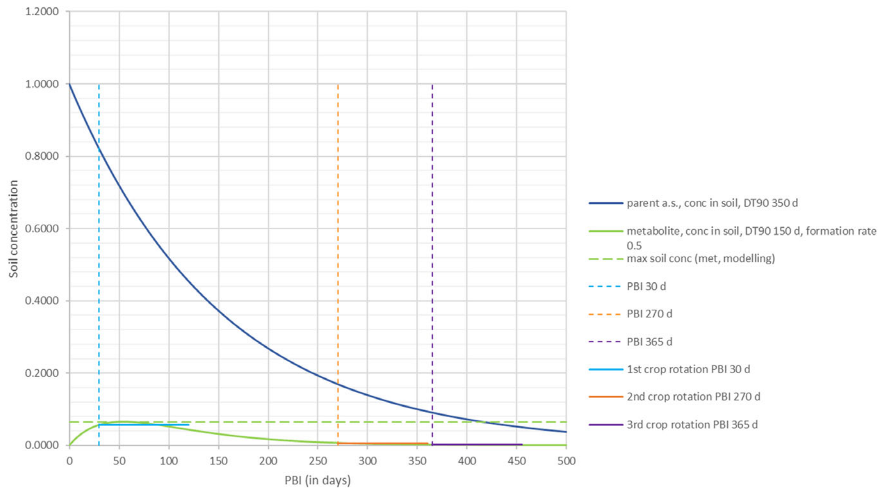

Figure B.7: DT_{90} parent 350 d, DT_{90} metabolite 150 d, the soil metabolite is sufficiently addressed

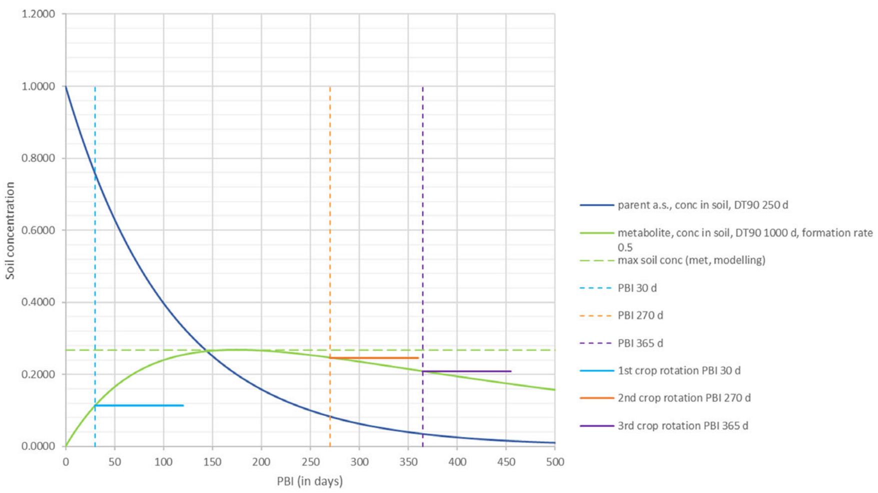

Figure B.8: DT_{90} parent 250 d, DT_{90} metabolite 1000 d (accumulating metabolite), the soil metabolite might not be sufficiently addressed, since accumulation following multiannual use is not represented

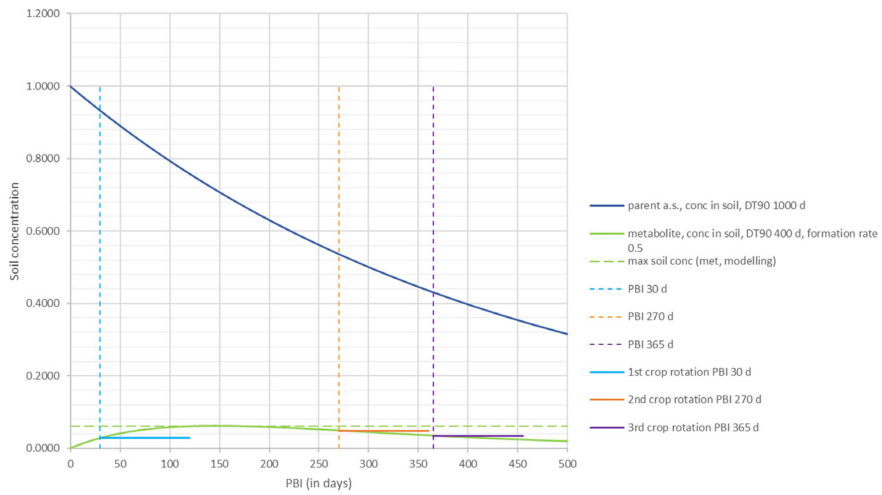

Figure B.10: DT_{90} parent 1000 d, DT_{90} metabolite 400 d, the soil metabolite is sufficiently addressed

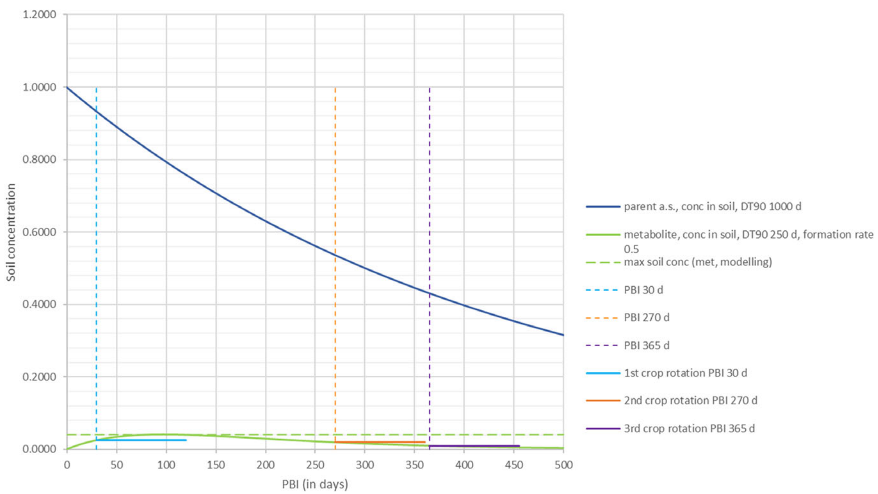

Figure B.9: DT_{90} parent 1000 d, DT_{90} metabolite 250 d, the soil metabolite is sufficiently addressed

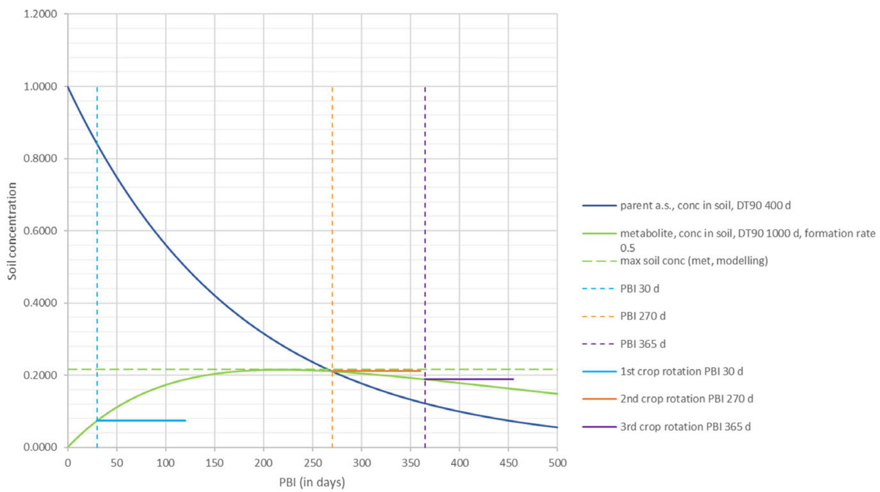

Figure B.11: DT_{90} parent 400 d, DT_{90} metabolite 1000 d, the soil metabolite might not be sufficiently addressed since accumulation following multiannual use is not represented

B.11. Identification of the input values for the risk assessment of residues in rotational crops and for livestock dietary burden calculation (STMR/HR)

The following example illustrates how to derive the risk assessment values (HR/STMR) from rotational crop studies (tier 3) in crops belonging to the super crop group 'Leafy vegetables and Brassica' (see Section 6.4.2). In the example, the residue concentrations reported for mature leaves of lettuces, spinaches, head cabbages, cauliflower and immature leaves of lettuces and spinaches are presented for the different subgroups and the different PBIs. The HR and STMR values derived are then extrapolated to the remaining food commodities according to Table A.6.

Example 12: Derivation of risk assessment values from rotational crop studies, super crop group Leafy vegetables and brassica (HR/STMR values) for consumer dietary risk assessment

Tier 3 crop group/ matrix	Subgroup	Crop code	Commodity - name	PBI 1	PBI 2	PBI 3	HR	STMR	Comment	Extrapolation of HR and STMR
Leafy vegetables and brassicas/ **mature leaves**	1	251020	Lettuces	0.92; **2.47**	0.37; 0.95	0.2; 0.63	2.47	0.87	For leafy vegetables, subgroup 1, the data on lettuces and spinaches are combined to derive the HR for this subgroup (highest HR among the different PBIs was identified for PBI 1). The STMR at PBI 1 was used for the chronic RA.	The HR and STMR from subgroup 1 were extrapolated to escaroles and chards
		252010	Spinaches	0.14; 0.81	0.17; 0.33	0.1; 0.13;				
	2	242020	Head cabbages	0.1; 0.15; 0.20; **0.35**	0.07; 0.14; 0.18; 0.21	0.05; 0.05; 0.15; 0.25	0.35	0.18	For subgroup 2, data were only available for head cabbage. The HR at PBI 1 was the highest among the three PBIs tested. This HR is used for the acute dietary risk assessment. The STMR of PBI the same PBI (PBI 1) was selected for the chronic RA.	The HR and STMR from subgroup 2 were extrapolated to Brussels sprouts and kales
		243020	Kales	-	-	-				
	3	241010	Broccoli	-	-	-			Subgroup 3: HR and STMR from PBI 1 were identified as the relevant risk assessment values.	The HR and STMR from subgroup 3 were extrapolated to broccoli
		241020	Cauliflowers	0.09; 0.15; 0.19; **0.23**	0.03; 0.03; 0.04; 0.04	<0.025; 0.025; 0.03; 0.03	0.23	0.17		
Leafy vegetables and brassicas/ **immature leaves**	1	251020	Lettuces	0.36; 2.3	0.25; 0.78	0.38; 0.16	3.2	0.52	For leafy vegetables, subgroup 1, the highest HR was identified at PBI 2 (HR for acute RA). The STMR at PBI 2 was used for the chronic RA.	The HR and STMR from subgroup 1 were extrapolated to
		252010	Spinaches	2.4; 2.7	0.16; **3.2**	0.6; 0.7				

Example 13 should illustrate how to derive the input values for the livestock dietary burden calculation (see Section 6.4.2, step 3).

Example 13: How to derive the input values for the dietary burden calculation of livestock

Tier 3 super crop group[(a)]	Crop	Part of the crop analysed	Results (at PBI with highest results)	HR	STMR	Extrapolation of HR and STMR to feed items included in dietary burden calculator
Root and tuber vegetables	Carrots	Roots	2× < 0.01, 0.02, 0.022	0.022	0.015	Carrot culls, swede roots, turnip roots, sugar beet (dried pulp, enssiled pulp, molasses)[(b)]
	Carrots	Leaves/ tops	4× < 0.01	< 0.01	< 0.01	Beet (mangel), beet, sugar (tops)
	Potatoes	Roots	3× < 0.01, 0.015	0.015	< 0.01	potato culls, potato (process waste, dried pulp)[(b)]
Leafy/ brassica vegetables	Kale	Mature crop	4× < 0.01	< 0.01	0.01	Cabbage, heads (leaves), kale (leaves/forage)
Cereals	Barley	Forage	2× < 0.01, 0.01, 3× 0.012, 0.15, 0.16	0.16	0.012	Barley, oat, rye, wheat (forage) Oat, triticale, wheat (hay)[(b)] Alfalfa, clover, lespedeza, trefoil, vetch (forage)[(c)] Alfalfa, clover, lespedeza, trefoil, vetch (hay)[(b),(c)]
	Barley	Grain	3× 0.02, 0.023, 0.25, 0.031, 0.45, 0.05	0.05	0.024	Barley, oat, rye, triticale, wheat (grain) Cereal based by-products (except by products of corn)
	Barley	Straw	0.15, 0.3, 0.33, 0.45; 0.47, 0.6, 0.6, 0.7	0.7	0.46	Barley, millet, oats, rice, rye, triticale, wheat (straw)
	Maize	Grain,	0.015, 0.018, 3× 0.02, 0.026, 0.3, 0.31	0.31	0.02	Corn, field (grain, millet (grain), sorghum (grain), corn (by-products)[(b)]
	Maize	Forage	0.01, 0.013, 0.018, 0.02, 0.021, 0.028, 2× 0.03	0.03	0.02	Corn, field, millet, sorghum (forage) Alfalfa, clover, lespedeza, trefoil, vetch (forage)[(c)] Alfalfa, clover, lespedeza, trefoil, vetch (hay)[(b), (c)]
Oilseeds/ pulses	Soybean	Forage	0.03, 0.034, 0.04, 0.041, 0.12, 0.15, 0.18, 0.19	0.19	0.08	Soybean forage (green), soybean silage Soybean hay (fodder)[(b)] Alfalfa, clover, lespedeza, trefoil, vetch (forage)[(c)] Alfalfa, clover, lespedeza, trefoil, vetch (hay)[(b),c)]
	Soybean	Seeds	0.02, 0.03, 4×0.05, 0.1, 0.11	0.11	0.05	Soybean, (seeds) Soybean, rape, cotton, flaxseed, lupin, safflower, sunflower (meal)[(b)] Soybean (hulls)[(b)]
	Beans	Forage	3×0.04, 0.05	0.05	0.04	Alfalfa, clover, lespedeza, trefoil, vetch (forage)[(c)]

Tier 3 super crop group[(a)]	Crop	Part of the crop analysed	Results (at PBI with highest results)	HR	STMR	Extrapolation of HR and STMR to feed items included in dietary burden calculator
						Alfalfa, clover, lespedeza, trefoil, vetch (hay)[(b),(c)]
	Beans	Seeds	2× < 0.01, 0.03, 0.035	0.035	0.02	Beans, dry seeds, cowpea, lupin, pea, (seeds)

(a): Crops relevant for dietary burden calculation.
(b): An appropriate processing factor needs to be used to recalculate from the unprocessed to the processed feed item.
(c): The dietary burden calculation should be performed with the highest/most appropriate value among the forages (barley, maize, soybean or bean forage).

Annex A – Outcome of the public consultation on the draft guidance document on the assessment of pesticide residues in rotational crops

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2023.8225.