

The Detailed Technical Sift for Plant Protection Products Guidance on Requirements

May 2024

Contents

[General Information for the Detailed Technical Sift](#)

[dRR Part B Section 1. Identity Of The Plant Protection Product](#)

[dRR Part B Section 2. Physical And Chemical Properties](#)

[dRR Part B Section 3. Efficacy](#)

[dRR Part B Section 4. Further Information On The Plant Protection Product](#)

[dRR Part B Section 5. Analytical Methods](#)

[dRR Part B Section 6. Mammalian Toxicology](#)

[dRR Part B Section 6. Mammalian Toxicology – Non Dietary Exposure](#)

[dRR Part B Section 7. Metabolism And Residues](#)

[dRR Part B Section 8. Environmental Fate](#)

[dRR Part B Section 9. Ecotoxicology](#)

[dRR Part B Section 10. Assessment of the relevance of metabolites in groundwater](#)

General Information for the Detailed Technical Sift

What are the key issues for the detailed technical sift
The application has not been submitted using the required current draft Registration Report (dRR) format. The current dRR template can be found by following this link: Draft registration reports (dRRs) for pesticide applications - Pesticides - HSE
Full formulation details are required in the application form, see link for guidance Physical and Chemical Properties (hse.gov.uk)
Reference has been made to the fact that further studies/trials reports will be available shortly. All the data to support the application must be present from the outset and cannot be submitted later. Confirmation is required whether the application should continue based only on the submitted studies. [<i>Where this is the only identified issue at the sift, HSE will contact the applicant to avoid a rejection where possible</i>]
The application has included draft reports/studies. HSE will only consider the application is complete and ready for acceptance once the final trials/study reports are submitted.
There are discrepancies in the proposed GAP (rates, earliest and latest timings, interval, uses/crops, growth stages, targets, method of application) between the draft label//application overview. These discrepancies must be clarified, confirming the correct GAP, noting that a new draft label may be required if changes are considered major.
The proposed formulation details differ from those currently authorised in the UK [<i>reference</i>]. Clarification of the formulation details is required, including whether a proposed change is intended. If necessary, revised details should be submitted.
It is stated that the application is to be supported by the use of data from a UK authorised reference product. Full authorisation details of any UK product must be provided (including the MAPP number, formulation composition where possible (outlined in Part C), material safety data sheets (MSDS) for all co-formulants in all referenced products). The details should include a comparison of the authorised uses/GAP, classification of components for the existing UK product and the requested uses/product, and make clear how the existing UK authorised product supports this application. Note, access to unprotected data can only be made by reference to one product; see link for guidance: How to apply for authorisation to market a new pesticide product - Pesticides - HSE
The product contains a candidate for substitution, and an assessment of comparative assessment and substitution must be provided in line with HSE guidance: Candidates for substitution: pesticides active substances - HSE
The application overview does not clearly outline how each area of the risk assessment is being supported for each of the intended uses. For example: whether the data are new; reference to a previous assessment or existing uses(details required), evaluation in the DAR/RAR for the approval/renewal of the active); extrapolation; or a combination of these approaches.

dRR Part B Section 1. Identity Of The Plant Protection Product

Data point	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
1.4.2 Information on the active substance (KCP1.4.2)	<p>The ISO name, CAS number, EINECS number, CIPAC number and a statement as to whether the active is present in the PPP as an ester, salt or anion or cation must be included.</p> <p>Where an active is present as a variant, information on the amount of the active moiety and variant should be stated. Information on how the identity complies with the implementing regulation is required (e.g. the implementing regulation covers the acid moiety).</p> <p>The tolerance limits for the technical material and pure active in the PPP should be stated.</p>
1.1.3 Statement of purity (and detailed information on impurities) of the active substance (s) (KCP 1.2)	<p>A clear reference is required to where the source of the active substance(s) used in the PPP was considered to be technically equivalent.</p> <p>Each active source should be deemed equivalent by GB, 5 batch data and a draft TER maybe required.</p> <p>Sources deemed equivalent by an EU Member States only applies to Northern Ireland and a RFTE application will be required.</p> <p>Pesticide active substance source changes: technical equivalence (hse.gov.uk)</p>
1.2.2 Composition of the plant protection product (PPP) (KCP 1.4)	<p>The amount of the pure and technical grade active ingredient (TGAI) in the PPP should be stated.</p> <p>Where an active is present as a variant, information must be provided outlining at what stage in the manufacturing process the variant is produced i.e. the manufacture of the TGAI or manufacture of the PPP. The amount of the variant and the 'acid moiety' should be stated. Compliance with the identity established in the implementing regulation is required.</p> <p>Information on relevant impurities is required.</p> <p>Where data have been conducted on different formulations from the one for which an authorisation is being sought, then the full composition details should also be given along with a case on why the data generated can be extrapolated to the PPP being supported for authorisation.</p>

1.2.2 Information on co-formulants (KCP 1.4.3)	<p>For each co-formulant a MSDS should be provided. The applicant should confirm that these represent the latest version.</p> <p>For each co-formulant the following information is required:</p> <ul style="list-style-type: none"> • Trade name • IUPAC name • Chemical name • CAS number • Relevant EC numbers • Structure/formula • Function
---	---

dRR Part B Section 2. Physical And Chemical Properties

Data point	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
Classification properties: Explosive properties (KCP 2.2.1) Oxidizing properties (KCP 2.2.2) Flash point (KCP 2.3.1) Flammability (KCP 2.3.2) Self-heating	<p>The classification of the PPP must be in accordance with CLP (Regulation EC (No) 1272/2008)</p> <p>The test methods applicable are outlined in the commission communication document (2013/C 95/02).</p> <p>Cases presented to address the classification properties must be robust. For the active it is acceptable to refer to data evaluated for the approval (provided data access is available) or make a case based on the chemical structure. For the co-formulants reference to the MSDS can be made.</p> <p>The HSE Guidance document for the generation of data on the physical, chemical and technical properties of plant protection products, including CLP and storage stability aspects, can be found here: https://www.hse.gov.uk/pesticides/assets/docs/crd-guidance-document.pdf</p>

Data point	What are the key issues for the detailed technical sift
<p>(KCP 2.3.3)</p> <p>Viscosity (KCP 2.5.1) and Surface tension (KCP 2.5.2)</p>	<p>Regulation (EC) No 284/2013: For liquid formulations the viscosity shall be determined at two shear rates and at 20°C and 40°C</p> <p>For liquid formulations the surface tension should be determined at the highest in use concentration.</p> <p>Regulation (EC) No 545/2011: The viscosity and surface tension is required for liquid formulations.</p> <p>In both cases; The aspiration hazard should be assessed where the hydrocarbon content of the PPP is $\geq 10\%$ - the dynamic viscosity should be determined at 40°C for this assessment.</p> <p>(Kinematic viscosity = Dynamic viscosity/density)</p>
<p>Storage Stability after 14 days at 54° C (KCP 2.7.1)</p> <p>Stability after storage for other periods and/or temperatures (KCP 2.7.2)</p> <p>Minimum content after heat stability testing (KCP 2.7.3)</p> <p>Ambient temperature shelf life (KCP 2.7.5)</p>	<p>The active content should be determined prior to and after storage. Any decrease observed must be within acceptable criteria or the decrease adequately addressed including the fate of the active and a justification of an appropriate shelf life.</p> <p>Any relevant impurities that can form or increase on manufacture or storage of the PPP must be determined prior to and after storage. For any relevant impurities not determined a case to justify their non-determination must be given.</p> <p>It should be made clear what analytical methods have been used to determine the active content and any relevant impurities (cross reference details outlined in section 5 of the dRR).</p> <p>All relevant technical properties should be determined prior to and after storage.</p> <p>It should be made clear what packaging the formulation has been stored in for the stability and shelf life studies.</p>
<p>Technical properties (KCP 2.8.1 – 2.8.7)</p>	<p>All relevant properties for the PPP must be determined or a justification given for missing data. Please see https://www.hse.gov.uk/pesticides/assets/docs/crd-guidance-document.pdf for details.</p>

Data point	What are the key issues for the detailed technical sift
	<p>The applicant should clearly outline the maximum and minimum in use concentrations being supported for authorisation.</p> <p>For technical properties which are concentration dependent (e.g. persistent foaming, suspensibility and emulsifiability), the concentration of the product tested for each technical property should relate to the recommended in use rates given on the label, even where other concentrations are indicated in the test method, so long as the concentration tested is within the scope of the method.</p> <p>Where data have not been generated at the recommended minimum and maximum in use rates then a robust justification should be outlined.</p> <p>For particle size, if > 1 % of particles have a diameter of < 50 µm then the impact on operators and the satisfactory application of the PPP through the application equipment must be addressed.</p> <p>The following data are required prior to an authorisation being possible for ready to use PPP in trigger sprayers:</p> <p>Evidence must be provided that the preparation may be satisfactorily applied and that this is maintained on storage (e.g. demonstration that no nozzle blockage occurs on storage). This can be achieved by demonstrating that the quantity of spray dispensed is consistent for multiple spray actions and this is maintained at interim time periods and after storage.</p>
<p>Adhesion to seeds (KCP 2.10.1)</p> <p>Distribution to seed (KCP 2.10.2)</p>	<p>For seed treatments data on the adhesion and distribution to seeds must be provided. The types of seed tested must be fully justified. The method of analysis used to determine the active on the seed should be stated and cross reference to the validation data presented in section 5 of the dRR made.</p>

dRR Part B Section 3. Efficacy

General	What are the key issues for the detailed technical sift
UK Labelling	Issues that may require further consideration of the label wording can include: the expression of the level of control, in relation to the underlying data; addition of specific UK label phrases relevant for a particular target or product type; UK resistance management.
UK Resistance Management	Consideration should be given to the relevance of any core resistance management strategy to UK conditions, adapting as necessary. For example, UK current resistance status of relevant targets; availability of alternatives; overall treatment programmes; cultural practices, specific resistance label phrases. Further general information on UK-resistance management can be found from the UK-Resistance Action Groups (UK RAGs): The Resistance Action Group (RAG) AHDB
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
Format, content, and quality of BAD/dRR	<p>The dRR and Biological Assessment Dossier (BAD) should follow the dRR Part 3 (efficacy) format for data requirements and numbering. In most cases it would be expected that a BAD will be submitted, with an appropriate concise summary in the dRR, following the dRR template guidance. All data points should be addressed appropriately, including sufficient detail on methodology and summary tables in the BAD and dRR. If the BAD and dRR are absent, have significant omissions, or considered overall poor quality (rather than a specific issue with a data point as listed below), this may result in a rejection.</p> <p>(Exceptionally, if only a small number of trials is being summarised, it may be possible to submit just one document rather than producing two, provided all relevant information is present).</p> <p>The proposed uses in the relevant GAP tables, dRR and on the proposed UK label should be identical. Specific attention should be given to individual pest uses. In addition, any discrepancies/changes to existing UK uses should be identified and addressed.</p>
Reference products used in Efficacy trials (This includes reference products used in all of the trials (preliminary,	The BAD and/or dRR must include details of the authorised uses for the reference products used. This is to determine the relevance of the reference products: whether it is authorised for the target, and has been used at the authorised rate in the MS where data were generated. The details provided can either be the whole label, or the relevant sections for the particular target in the trials. The labels/details of reference products from other countries should be translated into English.

General	What are the key issues for the detailed technical sift
MED, efficacy trials, crop safety etc.).	
Background and context	The dRR and BAD must provide the background information required to conduct an assessment. Information should be provided in line with the dRR Part B3 template. These details include an introduction, description of the active substance(s) and the mode of action, description of the PPP and its currently registered/proposed uses.
Proposed Crops/situations and targets	<p>The dRR Section 3 template (Table 3.2-4) includes a table where applicants should provide an indication on the importance of the crop/situation and economic importance of the proposed pests in each of the requested MS. (These details are usually provided in the BAD, but it is helpful to include these in the dRR itself.).</p> <p>This information should be used by the applicant when justifying both the location and number of trials submitted in support of the uses.</p>
3.2.1 Preliminary Data (KCP 6.1)	<p>This point should be covered in line with the draft Part B3 template. The data or information required for this section depends on how old or well-known an active substance it and how many active substances are within the product. If preliminary data are available it should be included with detailed descriptions (or cross-referenced if included under other data points). New active substances always require preliminary data.</p> <p>For all co-formulated products, a justification of the combination of multiple active or safener/synergistic substances is required. This can include the rationale for combining the actives, evidence on the ratio of actives, resistance management information. (MED of the co-formulated product itself are addressed under 3.2.2)</p>

General	What are the key issues for the detailed technical sift
<p>3.2.2 Minimum Effective Dose (KCP 6.2)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, particularly PP 1/225.</p> <p>MED should be addressed in at least one of the major uses. If no data/reduced data were produced against a specific target, justification must be provided to support extrapolation to those targets. Consideration should be given to the relevance of the targets on which MED has been based.</p> <p>Summary tables: Summary tables must contain sufficient detail for an evaluation to be conducted. Examples of summary tables can be found in the Part B3 template. Examples of details that should be included are EPPO climatic zone, target, number of trials, infestation in untreated control, BBCH stages, % control with the test (at different rates for MED) % control with reference products etc. Infestations and % control should include a mean, min and max value.</p>
<p>3.2.3 Efficacy tests (KCP 6.2)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards. Details of trial methodology should be provided. All of the proposed crops/uses and targets should be considered with either data or a justification that data are not required. (For example, appropriate extrapolations with reference to the EPPO Minor Use Extrapolation tables). Data should usually be presented separately for each EPPO climatic zone. EPPO PP 1/226 provides guidance on the number of trials required.</p> <p>Summary tables must contain sufficient detail for an evaluation to be conducted. Examples of summary tables can be found in the Part B3 template. Examples of details that should be included are EPPO climatic zone, target, number of trials, level of infestation in untreated control, BBCH stages, % control with the test and reference products etc. Infestations and % control should include a mean, min and max value</p>
<p>3.3 Information on the occurrence or possible occurrence of the development of Resistance (KCP 6.3)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/213. A resistance risk analysis should be conducted and should consider amongst other details the active substance, its mode of action and any evidence of resistance or cross resistance. If considered necessary, a suitable resistance management strategy should be provided.</p>

General	What are the key issues for the detailed technical sift
	Refer to UK Resistance Action Groups, and HSE specific guidance for specific strategies and any UK restrictions (see below under UK National Addenda).
3.4.1 Phytotoxicity to host crop (KCP 6.4.1)	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/135. For Herbicides, phytotoxicity will need to be considered in specific weed free selectivity trials and the test product must be applied at both N and 2N. Details on trial methodology should be provided. All of the proposed crops/uses should be considered with either data or a justification that data are not required. Data should be presented separately for each EPPO climatic zone. EPPO PP 1/226 provides guidance on the number of trials required.</p> <p>Summary tables: Summary tables must contain sufficient detail for an evaluation to be conducted. Examples of summary tables can be found in the Part B3 template. Examples of details that should be included are EPPO climatic zones, BBCH stages, number of trials with x% amount of damage for the test and reference products at both N and 2N (including maximum levels and the level of symptoms at the last assessment).</p>
3.4.2 Effect on the yield of treated plants or plant products (KCP 6.4.2)	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/135. For Herbicides, yield will need to be considered in specific weed free selectivity trials and the test product must be applied at both N and 2N. Details on trial methodology should be provided. All of the proposed crops/uses should be considered with either data or a justification that data are not required. Data should be presented separately for each EPPO climatic zone. EPPO PP 1/226 provides guidance on the number of trials required. There should be a consideration of the relationship between phytotoxicity and yield - it is useful to include the trials with significant phytotoxicity or yield reductions in a summary table to determine if there is a relationship.</p> <p>Summary tables: Summary tables must contain sufficient detail for an evaluation to be conducted. Examples of summary tables can be found in the Part B3 template. Examples of details that should be included are EPPO climatic zones, BBCH stages, number of trials, crop and variety, yield in untreated, yield at N and 2N as % of untreated for both test and reference products.</p>
3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/135 which describes the appropriate quality assessments for a range of crops. The individual assessments required for aspects of quality will be dependent on the proposed uses, and in particular the crops. Any tests should be described and summarised in tabular form if appropriate.</p>

General	What are the key issues for the detailed technical sift
	<p>EPPO PP 1/242 'Taint tests' should be followed for relevant crops.. It should be noted that a case based only on lack of residues at harvest may not acceptable because taint effects can arise from applications made at early growth stages. In addition, in certain circumstances, taint tests may also be relevant for fresh produce. <i>This is not a point of rejection, but the information must be submitted during the course of the assessment.</i></p>
<p>3.4.4 Effects on transformation processes (KCP 6.4.4)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards PP 1/243 on transformation process and (where relevant) PP 1/268 (unintentional effects on wine). It is particularly critical for major crops where transformation is a key process for the harvested crop portion, and it is considered a high risk situation. For example, a fungicide for use in cereals or vines.</p>
<p>3.4.5 Impact on treated plants or plant products or plant products to be used for propagation (KCP 6.4.5)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards. In particular, Table 1 in EPPO PP 1/135 provides a decision scheme outlining when data are required to address this issue. This should be used to justify either data provided or a reasoned case that not required.</p>
<p>Other missing information not covered under general or specific data points</p>	<p>Any missing information/data should be raised here if the lack of the data/information means it is not possible to proceed with the assessment</p>
<p>3.5.1 Impact on succeeding crops (KCP 6.5.1)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/207. A theoretical risk assessment should be conducted and if there is considered to be a potential for negative effects, field trials should be conducted. Data or a justification of its absence should be provided to support all of the following crops proposed on the label - or if no restrictions are proposed, data/ a</p>

General	What are the key issues for the detailed technical sift
	<p>justification should be provided to support this. Cultivation methods such as ploughing can be proposed to reduce the impact on following crops. Any tests should be described and summarised in tabular form.</p> <p>(Please note that for the UK there is a specific requirement to address the use of sequences or mixtures of ALS inhibiting herbicides. For full details, refer to the UK National addenda guidance, link below).</p>
<p>3.5.2 Impact on other plants including adjacent crops (and tank cleaning) (KCP 6.5.2)</p>	<p>This point should be covered in line with the draft Part B3 template and the EPPO standards, in particular EPPO PP 1/256. A theoretical risk assessment should be conducted and if there is considered to be a potential for negative effects, field trials should be conducted. Data or a justification of its absence should be provided to support the safety to adjacent crops. Any tests should be described and summarised in tabular form.</p> <p>Sufficient data (or justification for its absence) should be submitted to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops. (See EPPO PP 1/292).</p>
<p>3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)</p>	<p>Consideration of this section is only usually required at a National level, for example when specific claims have been made on the National label (usually for an insecticide) e.g. '<i>Compatible with IPM programmes</i>'. Applicants may need to submit relevant National addendum. (If claims are made on the UK label, see UK section). Cross reference to the ecotoxicology section of the dRR should be sufficient, and/or details of any assessments made in the effectiveness trials.</p>
<p>3.6 Other/special studies (KCP 6.6)</p>	<p>The level of data or information required in this section will depend on the type of product/active substance. Many of these issues will relate to specific claims or wording on National labels, and should be addressed in National addenda. This section should refer to relevant EPPO standards, where available, or for UK uses any relevant UK specific guidelines. The types of issues may include biological compatibility, convenience tank mixes and sequences, proposed label, rainfastness claims, justification of water volumes and the impact of environmental conditions on the efficacy of the product.</p>
	<p>For certain active substances, there are statutory restrictions encompassing all products. For example, the total number of applications of any product containing the relevant active substance on a crop. Full details on UK Resistance label phrases and statutory restrictions are in HSE Efficacy guidelines: 601, 602, 603, 606, 611 and 617) at Efficacy Evaluations and Guidelines (hse.gov.uk)</p> <p>Where the proposed UK GAP conflicts with these restrictions, an amended GAP will be required. The application will be rejected and a revised GAP required.</p>

General	What are the key issues for the detailed technical sift
	<p>For UK-only requested uses, it may be necessary to provide further justification for the relevance of the generated data to UK conditions (agronomic, pest biology, environmental conditions etc.). Relevant details are provided in EPPO PP 1/278, PP 1/241 and PP 1/269.</p> <p>The proposed GAP should also reflect UK circumstances, in terms of crop, pest and agronomic practice. An explanation and comparison of proposed uses with any existing relevant UK authorisations may also be relevant, and require further justification. Any proposed discrepancies must be explained.</p>
	<p>Applicants should refer to HSE Efficacy guidance document: '<i>Efficacy Assessments: UK Product labelling and National issues/addenda</i>', available at: Efficacy Data and Information - Concise summary (hse.gov.uk). It is drafted as a UK National Addendum dRR B3, with appropriate UK-specific information under the relevant associated data points. (For all other points, reference should be made to the core dRR B3). The guidance covers:</p> <ul style="list-style-type: none"> • UK label wording scheme describing differentiating the expected efficacy of the product, based on the underlying data assessed in the regulatory trials. • Specific efficacy label phrases associated with certain product types and/or active substances. • The limited number of cases for specific product types or proposed uses, where UK specific issues may need addressing, possibly with the submission of specific data. • Overview of UK Resistance Management
	<p><u>Unless</u> the request is for a UK-only authorisation, deficiencies in relation to UK-specific issues will be addressed as further points of clarification and the application accepted (provided there are no core issues identified above). Where the request is for a UK-only authorisation, and the deficiencies are considered significant the application may be rejected. Examples might include: the relevance of the GAP and requested uses to the UK; requirement to consider statutory resistance management restrictions, discrepancies between requested GAP and relevant authorised product.</p>

dRR Part B Section 4. Further Information On The Plant Protection Product

Data point	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
4.1 Packaging and compatibility with the preparation (KCP 4.4)	<p>Full details of the proposed packaging should be outlined with a clear indication of the composition of the material in contact with the PPP.</p> <p>Where several types of packaging are proposed then extrapolations between different packaging is possible. Details are outlined in the HSE Guidance document for the generation of data on the physical, chemical and technical properties of plant protection products, section 2.11, which can be found here: HSE PPP Phys/Chem Guidance, 2018 for details.</p> <p>NB – An authorisation in the UK on the basis of accelerated storage data only is possible, and a data requirement for continued authorisation can be set to fully address the stability of the packaging.</p>

dRR Part B Section 5. Analytical Methods

Data point	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections

<p>5.2.1.1 Determination of active substance and/or variant in the PPP (KCP 5.1.1)</p>	<p>The validation data must comply with the criteria set out in SANCO 3030/99 rev. 5 with any deviations being fully justified. This guidance document can be found here: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.</p> <p>If the validation data have been generated on a different formulation then full composition details must be outlined in part C of the dRR. A justification to extrapolate the validation data generated to the PPP for which authorisation is sought must be outlined.</p>
<p>5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)</p>	<p>Validation data must comply with SANCO 3030/99 rev. 5 which can be found here: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.</p> <p>Under Regulation (EC) No 284/2013:</p> <p>Monitoring methods are required for all relevant impurities regardless of whether they need to be included or not in the storage stability studies. Where a method is required for a relevant impurity then confirmation of identity is also a relevant validation parameter.</p>
<p>5.2.2 Methods for the determination of residues (pre-registration methods) (KCP 5.1.2)</p>	<p>Validation data must comply with SANTE/2020/12830: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes</p> <p>Under Regulation (EC) No 545/2011:</p>

	<p>A full description and analytical validation data are not required under regulation (EC) No 545/2011 for all pre-registration methods. However, some specific studies may require full details and validation data for the methods used to collect data. This includes (but is not limited to) the following examples:</p> <ul style="list-style-type: none"> • Data to support seed loading • Residue trials <p>Under Regulation (EC) No 284/2013:</p> <p>Full details and supporting validation data for all methods[†] used to generate data in all areas of the risk assessment must be provided.</p> <p>[†]Currently it is the UK's position that this requirement would only apply to new studies and not studies already accepted for an authorisation. However, this issue is under discussion.</p>
<p>5.3.2 Description of analytical methods for the determination of residues (post-registration monitoring methods)</p> <p>(KCP 5.2)</p>	<p>Validation data must comply with SANTE/2020/12830: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes</p> <p>Clear details of the methods available to support each of the following matrices must be provided:</p> <ul style="list-style-type: none"> • Plants (should support all matrices for which an authorisation is being sought) • Products of animal origin • Soil • Water (drinking or ground water and surface water) • Air • Body fluids and tissues <p>Where reference is made to the data assessed for approval/renewal then this must be clearly stated with brief details of the method available e.g.</p> <ul style="list-style-type: none"> • HPLC-MS/MS methods regarded as fully validated for two ion transitions for high water crops and high acid crops with an LOQ of 0.01 mg/kg

	<ul style="list-style-type: none"> HPLC-MS method validated for three ions on soil with an LOQ of 0.01 mg/kg with a data gap identified for further accuracy data. <p>Where a method is not required then this should be stated and a reason clearly outlined.</p>
--	---

dRR Part B Section 6. Mammalian Toxicology

Requirements	What are the key elements checked as part of the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
Toxicological information on the active substances (dRR B6, 6.2.1 and B7)	<p>Toxicological information on the active substance(s) should include:</p> <p>Classification of the active substance(s):</p> <ul style="list-style-type: none"> Proposed classification should be consistent with the GB MCL list (for GB applications) or the EU harmonised classification (for NI applications). Where mandatory/harmonised classification is not available, the classification proposal presented in the GB MCL Technical Report or Agency Opinion, RAC Opinion, and/or the outcome of the active substance assessment (e.g. EFSA conclusion), as appropriate. Differences between GB and EU classifications, and any potential implications for GB and NI authorisations, should be highlighted. <p>Reference values for the active substance(s): the AOEL, AAOEL (if applicable, or a surrogate, dRR Part B6), ARfD and ADI (dRR Part B7). These values are agreed at the active substance approval and are not re-considered for assessment of PPPs; the agreed reference values must be used in all instances.</p>
Hazard assessment (dRR A, B6 and C)	<p>The submitted hazard assessment should include details of:</p> <ul style="list-style-type: none"> The basis for the proposal for human health hazard classification and labelling of the product. This may include the method(s) used to meet the data requirements of Regulation 284/2013 (section 7.2), including consideration of alternative methods to vertebrate testing (such as the calculation method of CLP, read-across of data, or in vitro methods). Consideration of other human health hazards (e.g. carcinogenicity, mutagenicity, reproductive toxicity, STOT SE and STOT RE) which should be assessed using the calculation method of CLP.

Requirements	What are the key elements checked as part of the detailed technical sift
	<ul style="list-style-type: none"> - Details of the components (active substances, safeners, synergists, agonists and co-formulants) in the formulated product - including concentrations (Part C) and hazard classification in accordance with CLP, for all components. <p>If the calculation method of CLP has been relied upon, the following should be provided:</p> <ul style="list-style-type: none"> - Details of the classification calculations (in Part C) in accordance with the criteria described in the guidance on the application of CLP. <p>If studies conducted in vertebrate animals have been relied upon, the following should be provided:</p> <ul style="list-style-type: none"> - Justification of the steps taken to avoid animal testing and the need for vertebrate studies conducted after the implementation of Regulation 1107/2009. Further information on testing on vertebrate animals is available on the HSE website Pesticide Toxicology guidance (hse.gov.uk) and Toxicology – Active Substances (hse.gov.uk) and Toxicology - Plant Protection Products (hse.gov.uk) <ul style="list-style-type: none"> - Confirmation that the test substance is the same as the formulated product for which authorisation is sought (i.e. same names or codes used), or information to explain differences. <p>If read-across to data/information on a similar formulation has been relied upon, the following details should be provided:</p> <ul style="list-style-type: none"> - Details (full composition and SDS for the co-formulants) of the formulation for which read-across has been made (in Part C). If such information is not available an explanation must be provided. - A comparison of the formulations, including the impact of any differences in formulations on the toxicology assessment (in Part C). <p>The hazard assessment (the basis for the proposal and conclusions) must be consistent throughout the dRR.</p>
Classification and labelling (dRR A, B6 and C)	<p>The proposal for classification and labelling should be:</p> <ul style="list-style-type: none"> - Consistent with the information submitted to meet the data requirements and any other available information.

Requirements	What are the key elements checked as part of the detailed technical sift
	<ul style="list-style-type: none"> - Consistent between all documents (Label, dRR A, B6). <p>In accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.</p>
Safety data sheets (SDS)	<p>SDS for all co-formulants, including any alternative trade names, must be submitted. The classification and labelling for alternative co-formulants should be identical, or worst-case classification and labelling should be used to determine the hazard classification of the product</p> <p>SDS for all co-formulants in other formulations to which read-across is proposed should be provided.</p> <p>SDS should be:</p> <ul style="list-style-type: none"> - In English. - In compliance with the GB/NI format (i.e. according to Annex II and articles 31 & 32 of Regulation (EC) 1907/2006 REACH) <p>Less than 2 years old (based on revision or release date). For SDS older than 2 years, a statement confirming that it is the most recent version is acceptable.</p>
Toxicological evaluation of groundwater metabolites (dRR B6 and B10; see also section 10 in this DTS document below)	<p>The evaluation of groundwater metabolites should be in line with the SANCO guidance document (221/2000 Rev 11; 21/10/21): pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr-rev11.pdf (europa.eu)</p> <p>The submitted assessment(s) need to be appropriate for the groundwater levels predicted by the applicant.</p>
Dermal absorption	<p>Dermal absorption values must be provided in accordance with the appropriate EFSA Guidance on dermal absorption (2012; http://www.efsa.europa.eu/en/efsajournal/pub/2665 or 2017; https://www.efsa.europa.eu/en/efsajournal/pub/4873).</p> <p>If studies have been relied upon, the following should be provided:</p> <ul style="list-style-type: none"> - Study report(s). - Study summary, including interpretation of the results according to the appropriate EFSA Guidance on dermal absorption. This should include both text and supporting calculations; if the BfR template has been used to support calculations, this should also be submitted.

Requirements	What are the key elements checked as part of the detailed technical sift
	<p>If studies conducted in vertebrate animals have been relied upon, the following should be provided:</p> <ul style="list-style-type: none"> - Justification of the steps taken to avoid animal testing (i.e. use of in vitro alternatives) and the need for vertebrate studies conducted after the implementation of Regulation 1107/2009. <p>If data on a similar formulation have been relied upon, the following should be provided:</p> <ul style="list-style-type: none"> - A formulation comparison according to the EFSA guidance (section 6.2). <p>Where relying upon dermal absorption studies that have been previously relied upon (i.e. for the representative product for the active substance approval process, or a previous application before renewal), the existing data should be interpreted according the EFSA guidance that applies for the new application.</p> <p>If the product label / GAP includes a use of the product as a dilution, dermal absorption values must be proposed to cover the extremes of the in-use dilutions.</p>
Combined exposure	<p>Where the PPP contains two or more active substances the potential for combined toxicity must be addressed. For the toxicology assessment, a consideration of combined toxicity with respect to the operator, worker, resident, bystander assessment (i.e. against the AOEL).</p> <p>For renewal applications under Article 43, combined exposure does not need to be considered until all actives within the formulation have been renewed.</p> <p>-</p>
Skin sensitisers	<p>For formulated products that are classified for skin sensitisation, all in-use dilutions according to the GAP must not present an unacceptable risk to residents or bystanders, i.e. all in-use dilutions must not meet the criteria for classification for skin sensitisation in accordance with Regulation 1272/2008.</p>

Non Dietary Exposure dRR Part B Section 6. Mammalian Toxicology – Non Dietary Exposure

Data point	What are the key issues for the technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
6.6.2 Operator exposure (KCP 7.2.1)	<p>Operator exposure must be estimated using the following guidance: 2022 EFSA Exposure Guidance</p> <p>For scenarios not included in the guidance the advice in the data requirements handbook should be followed: Non-dietary human exposure (hse.gov.uk)</p> <p>Justification must be provided for any deviation from the default values in the guidance supported by submission of data used to derive alternative values.</p>
6.6.3 Measurement of operator exposure	<p>Where specific data are referred to these should conform to the recommendations for designing, conducting and assessing higher tier field studies as detailed in the following guidance:</p> <p>2022 EFSA Exposure Guidance</p> <p>Justification must be provided for any deviation from the guidance.</p> <p>A case must be provided as to how these data are more relevant to the proposed use than the existing data supporting the online EFSA OPEX Model.</p> <p>The following points should be addressed: GLP; analytical methods; and representativeness of subjects, equipment; application method, applied material, and task duration should also be demonstrated.</p>
6.6.4 Worker exposure (KCP 7.2.3)	<p>Worker exposure must be estimated using the following guidance where relevant:</p> <p>2022 EFSA Exposure Guidance</p> <p>For scenarios not included in the guidance the advice in the data requirements handbook should be followed: Non-dietary human exposure (hse.gov.uk)</p> <p>Multiple applications, crop entry activities prior to harvest, and harvesting activities where workers may contact treated surfaces must be addressed.</p> <p>Justification must be provided for any deviation from the default values in the guidance supported by submission of data used to derive alternative values.</p>

Data point	What are the key issues for the technical sift
	<p>For protected crops the potential exposure TC value assuming no protection from clothing should be used as a first tier estimate for exposure to re-entry workers.</p> <p>Where use of disposable personal protection gloves are required to reduce exposure to re-entry workers, the assessment must reflect Regulatory update 24/2014 'New arrangements for the use of personal protection gloves to reduce skin exposure in re-entry work after application of plant protection products to crops':</p> <p>http://webarchive.nationalarchives.gov.uk/20151023155227/http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/PPE-gloves-reg-up-2014.htm</p> <p>Information should be provided to confirm that the use of splash resistant single use gloves is a feasible and practical risk mitigation measure to protect all groups of re-entry workers entering treated crops; and there is a reasonable expectation of compliance through employers and the self-employed understanding their duties, under the 'Health and Safety at Work Act' and the 'Control of Substances Hazardous to Health Regulations'</p>
<p>6.6.4.2 Refinement of generic DFR value (KCP 7.2)</p>	<p>Where specific data are referred to these should conform to the recommendations for designing, conducting and assessing higher tier field studies as detailed in following guidance:</p> <p>2022 EFSA Exposure Guidance</p> <p>Justification must be provided for any deviation from the guidance. The following points should be addressed:</p> <ul style="list-style-type: none"> • GLP; analytical methods; number of sites/samples; representativeness of crop; growth stages; application method, applied material, and weather conditions.
<p>6.6.4.3 Measurement of worker exposure</p>	<p>Where specific data are referred to these should conform to the recommendations for designing, conducting and assessing higher tier field studies as detailed in the following guidance:</p> <p>2022 EFSA Exposure Guidance</p> <p>Justification must be provided for any deviation from the guidance. The following points should be addressed:</p>

Data point	What are the key issues for the technical sift
	<ul style="list-style-type: none"> GLP; analytical methods; and representativeness of subjects, equipment; application method, applied material, and task duration should also be demonstrated.
6.6.5 Bystander and resident exposure (KCP 7.2.2)	<p>If an AAOEL is set then a bystander assessment is required in addition to a resident assessment. In other cases the resident assessment protects bystanders.</p> <p>Bystander and resident exposure must be estimated following guidance where relevant:</p> <p>2022 EFSA Exposure Guidance</p> <p>For scenarios not included in the guidance the advice in the data requirements handbook should be followed: Non-dietary human exposure (hse.gov.uk)</p> <p>Justification must be provided for any deviation from the default values in the guidance supported by submission of data used to derive alternative values.</p>
6.6.5.2 Measurement of bystander and/or resident exposure	<p>Where specific data are referred to these should conform to the recommendations for designing, conducting and assessing higher tier field studies as detailed in the following guidance:</p> <p>2022 EFSA Exposure Guidance</p> <p>Justification must be provided for any deviation from the guidance.</p> <p>A case must be provided as to how these data are more relevant to the proposed use than the existing data supporting the online EFSA OPEX Model.</p> <p>The following points should be addressed:</p> <ul style="list-style-type: none"> GLP; analytical methods; and representativeness of subjects, equipment; application method, applied material, and task duration should also be demonstrated.
6.6.6 Combined exposure	<p>Where the PPP contains two or more actives, there must be a consideration of the need to conduct combined risk assessments for operators, workers, residents and bystanders.</p>

dRR Part B Section 7. Metabolism And Residues

General	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
MRLs	<p>In Table 7.2-9 and 7.2.12 it is important to outline the MRLs required to accommodate the proposed GAP for plants and products of animal origin and the current GB (for GB) and EU (for NI) MRLs in force. The implementing regulation that amends Regulation (EC) No 396/2005 with the current MRLs should be stated.</p> <p>In addition, any future potential MRLs the applicant is aware of (e.g. in a published article 12 RO) should also be stated.</p> <p><u>New MRL required</u></p> <p>As outlined on the HSE website an applicant must clearly outline in the submission (cover letter, application overview) that a new MRL is required.</p> <p>GB uses</p> <p>For details on what to include in your application please refer to the HSE website: New MRLs.</p> <p>NI uses</p> <p>There are separate rules for Northern Ireland (NI). Please refer to the HSE website for further details: MRLs in Northern Ireland.</p>
Guidance documents for residues	The data requirements applied in the residues assessment will be those that were applied to the relevant approval/renewal of the active substance.

General	What are the key issues for the detailed technical sift
	<p>Information on the transitional arrangements for applying data requirements is outlined in the guidance document SANTE/11509 /2013– rev. 5.2. This is available at the following link: Guidelines on Active Substances and Plant Protection Products (europa.eu)</p> <p>Regulation (EC) No 545/2011 The residues data applicable are those outlined in Regulation (EC) No 544/2011 – and this is referenced in the subsequent sections. The guidance relevant to the assessment are the Lundejn guidance available on the EU commission website: http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</p> <p>NB – For any MRL assessment where a dietary burden calculation for livestock is required then the OECD feeding tables must be applied.</p> <p>Regulation (EC) No 284/2013 The residues data applicable are those outlined in Regulation (EC) No 283/2013 – and this is referenced in the subsequent sections.</p> <p>The guidance relevant to the assessment are the OECD guidance which are available at the following link: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-5-other-test-guidelines_20745796</p>
7.2.1 Stability of residues (KCA 6.1)	<p>It must be clearly outlined how the available data support the proposed uses and all components of the residue definition:</p> <ul style="list-style-type: none"> • The data must cover the crop matrices being supported. • For new residue trials the maximum length of storage for each crop should be stated so it is clear that these time periods are supported by the available data. • All components and analytes in the risk assessment and monitoring residue definitions as applicable must be addressed.

	<ul style="list-style-type: none"> The analytical method(s) used should be satisfactorily validated in accordance with the SANTE/2020/12830, which can be found here, and a summary of the validated method included in section 5 of the dRR.
7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)	<p>The available plant metabolism data must be suitability representative of the crop group, application method, rate and PHI for the proposed uses</p> <p>The agreed residue definitions (for risk assessment and monitoring) should be stated. Any deviations from the agreed residue definitions should be stated and justified.</p>
7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)	<p>The data must cover the proposed uses, appropriate plant back intervals and the proposed application rates.</p> <p>The agreed residue definitions (for risk assessment and monitoring) should be stated. Any deviations should be stated and justified.</p>
7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)	<p>The nature of the residue on processing must be assessed.</p> <p>Under Regulation (EC) No 283/2013, these data are necessary when residues are found in the consumable part of the crop (≥ 0.01 mg/kg).</p> <p>Under Regulation (EC) No 544/2011, these data are usually necessary when residues are found > 0.1 mg/kg).</p> <p>A clear statement on the need for processing for each crop should be stated.</p>
7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)	<p>If relevant to the proposed uses and the resulting dietary burden of livestock then livestock metabolism data will be required.</p> <p>The agreed residue definitions (for risk assessment and monitoring) should be stated. Any deviations should be stated and justified.</p> <p><u>Triggers for livestock data</u></p> <p>Regulation (EC) No 544/2011; Residues ≥ 0.1 mg/kg (DM) in the diet of livestock.</p> <p>Regulation (EC) No 283/2013; > 0.004 mg/kg bw/day (DM) in the diet of livestock.</p>
7.2.3 Magnitude of residues in plants (KCA 6.3)	<p><u>Details of how the use is supported</u></p> <p>It must be clear how each use is being supported. A summary of the trials data available to support each GAP should be given and the individual residue trial values, any conversion factors used (monitoring to risk</p>

assessment), STMR, HR and MRL required for the proposed GAP should be stated. In this summary the source of all parts should be clear whether trials are new data submitted or previously evaluated trials (DAR, EFSA Conclusion, existing UP assessment, new data (e.g. Smith et al., 2014)).

It must be clear how the trials data comply with the residue definitions for risk assessment and monitoring. Conversion factors used (monitoring to risk assessment and their derivation should be clearly stated). Any deviations must be clearly presented and fully justified.

Use of overdosed trials

Where overdosed trials have been used a justification for their use should be outlined.

If the proportionality principle has been applied sufficient information should be outlined to show how it has been applied and the residues obtained in the trials and the resulting residues at the N rate given. Note it is not applicable to use the proportionality principle when the PHI is a varying factor, and caution needs to be made with multiple applications. If there can be time dependent variations, use of the proportionality principle might not be appropriate.

Extrapolations

If extrapolations have been relied upon these should be clearly stated on a crop by crop basis. The use of different formulation types should also be justified if the PHI is relatively short (up to 7 days).

Extrapolations must be in accordance with the extrapolations guidance document. The following guidance document applies in GB:

- EC, 2017, Guidance Document, Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/VI/95 Rev. 10.3) available [Technical guidance for the extrapolation of residue trials for plants and residues data for products of animal origin to support the authorisation of PPP and setting of MRLs in Great Britain - Pesticides - HSE](#)

The following guidance document applies in EU, relevant to NI, assessments:

- [Guidelines - Maximum Residue levels - European Commission \(europa.eu\)](#)

Air assisted applications

Where the proposed GAP is an all over spray (e.g. to pome fruits, stone fruits, fruiting vegetable) then the in use concentration of the spray solution for each trial, the water volumes and amount applied per hectare for each trial should be clearly outlined. An assessment as to how the data support the proposed in use concentrations should be made, also considering the water volumes recommended for use.

7.2.3 Magnitude of residues in plants (KCA 6.3)

<p>(Continued)</p>	<p><u>Data not relevant to the UK</u></p> <p>Uses not relevant to the UK application should be removed from the dRR unless they are required e.g. forming part of the MRL assessment or data from the SEU required (and suitable) to complete the data set of trials.</p> <p><u>Analytical methods</u></p> <p>The analytical methods used in the new trials should be clearly indicated (using the company specific code for the analytical method) with the details and validation data outlined in section 5 (this part, section 5, can either include details of the new method and/or new validation data in full or reference to a previous UP assessment of the method and validation data for relevant crop matrices).</p> <p>The procedural recoveries for all new trials should be summarised in the residues section.</p> <p><u>Previous assessments</u></p> <p>Where reference is made to a previous evaluation then this must have been conducted to uniform principles (UPs) e.g. evaluation for the approval/renewal of the active or a previous product assessed to UP. Sufficient information must be given to allow an assessment of the trials data available to be easily made.</p> <p>NB - It is not sufficient to refer to the MRL compilation dossier or the EFSA RO on the article 12 review – these evaluations are not necessarily conducted to uniform principles and data protection is not addressed in the MRL review.</p>
<p>7.2.4 Magnitude of residues in livestock: Dietary burden of livestock and livestock feeding studies (KCA 6.4.1-6.4.3)</p>	<p>The feeding tables used (OECD or SANCO) should be stated.</p> <p>NB - where the data requirements outlined in Reg. 283/2013 are applicable to the active assessment then the OECD feeding tables must be used. The OECD feeding tables should also be applied where an article 10 MRL submission will be required and this includes uses on animal feed items. In other cases the SANCO feeding tables can be applied.</p> <p>Input values must be clearly defined (e.g. taken from the trials presented in the submission, the article 12 MRL review, a recent article 10 reasoned opinion and must take into account residues in rotational crops if relevant).</p>

	<p>Any processing factors used should be clearly outlined and justified.</p> <p>The maximum and median dietary burdens should be presented. The resulting residues (for risk assessment and MRLs) for products of animal origin must be clearly outlined.</p> <p><u>Triggers of livestock data</u> Regulation (EC) No 544/2011; Residues ≥ 0.1 mg/kg (DM) in the diet of livestock and livestock metabolism data demonstrate that residues of ≥ 0.01 mg/kg may occur.</p> <p>Regulation (EC) No 283/2013; >0.004 mg/kg bw/day (DM) in the diet of livestock and livestock metabolism data demonstrate that residues of ≥ 0.01 mg/kg may occur.</p>
<p>7.2.5 Magnitude of residues in processed commodities (KCA 6.5.2 – 6.5.3)</p>	<p><u>Outline the need for processing data for each crop</u> For each crop being supported it should be stated if processing data are required and if not the reason the magnitude of residues in processed commodities are not required. Where data are required it should be stated what data are available.</p> <p>The highest residue found in the consumed commodities arising from use at the GAP should be clear in this section for each of the intended uses.</p> <p><u>Triggers for processing data</u> Regulation (EC) No 544/2011: Residues > 0.1 mg/kg. Regulation (EC) No 283/2013: Residues ≥ 0.1 mg/kg.</p> <p>NB – under some circumstances magnitude of residue studies may be required even when residues are <0.1 mg/kg (e.g. pesticide has a high acute toxicity, the ADI is low, toxicological relevant metabolites formed on processing, the significance of the processed commodity in the diet)</p> <p>Deviations from the above ‘triggers’ should be explained taking account of the considerations in the data requirements regarding the circumstances for when data are required.</p>
<p>7.2.6 Magnitude of residues in representative succeeding crops</p>	<p><u>Outline the need for rotational crop data</u> Does the magnitude of residues in rotational crops need to be considered? If not, the reason should be outlined e.g. crop is not rotated, rotational crop metabolism study shows for the proposed application rates residues will be < 0.01 mg/kg.</p>

<p>(KCA 6.6.2)</p>	<p><u>Relevant crops and plant back periods</u> Data should be available on a cereal, a root and tuber vegetable and a leafy crop for appropriate plant back periods (typically 30, 90 and 365 days).</p> <p>It should be clearly outlined how the proposed application rates compare to the application rates investigated in the rotational crop studies. An estimate of the residues from the field studies for the N rate should be outlined.</p> <p><u>Plateau concentration</u> If annual applications of persistent active substances result in higher plateau concentrations in soil than a single application, the plateau concentration shall be taken into account.</p> <p>NB - The draft OECD guidance on rotational crops proposes that the plateau concentration needs to be considered where the DT₉₀ > 500 days and the DT₅₀ > 150 days.</p> <p><u>Positive residues in rotational crops</u> If positive residues are obtained then the impact of these on the dietary burden of livestock, MRLs and consumer exposure must be addressed. Where relevant appropriate plant back intervals must be proposed.</p> <p>NB – plant back restrictions must be based on the available data. In addition, they cannot be used to negate the need to generate data (e.g. animal metabolism data).</p>
<p>7.2.7 Other / special studies</p>	<p>If relevant for applications made after the 1 January 2020 and being assessed according to the data requirements outlined in Reg. No. 283/2013 a consideration of the potential for residues in bee products is required (Annex 6.10.1).</p> <p>Technical guidelines on how this data requirement should be addressed can be found in the 'Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey' (SANTE/11956/2016 rev. 9, 14 September 2018)</p>
<p>7.2.8 Estimation of exposure through diet and other means</p>	<p>For the UK, consumer intake assessments should be conducted using PRIMo and the UK specific models. These models can be found here:</p>

(KCA 6.9)	<ul style="list-style-type: none"> * EFSA PRIMo model * Consumer Exposure (hse.gov.uk) * Consumer Exposure (hse.gov.uk) <p>Input values must be clearly defined and must take into account residues in rotational crops if relevant.</p> <p>Any processing factors used should be clearly outlined and justified.</p> <p>Where the PPP contains two or more actives there must be a consideration of the need to conduct a combined risk assessment been made?</p> <p><i>(NB – if a combined risk assessment is required the dRR implies that only a combined acute assessment is required. For the UK a chronic combined risk assessment is also required).</i></p>
------------------	---

dRR Part B Section 8. Environmental Fate

Data point	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections
Clarity of GAP 8.1.	<p>Applications must clearly state the use pattern (GAP) including the following information (where appropriate): crop types, earliest and latest growth stages, timings of application (month/season), number of applications, application rate (g a.s/ha), interval, application method, and crop interception.</p> <p>If the application method involves any additional information which could influence the exposure assessment, such as banded applications, or split doses, this must be clearly explained with the use pattern table.</p> <p>Where the product is not intended for use on an annual basis this must be made clear in the use pattern table, label, and the dRR.</p> <p>Within each environmental compartment it must be clear what use pattern has been used for the modelling, including all the use pattern specific inputs given above.</p>

Data point	What are the key issues for the detailed technical sift
	<p>Where a single use pattern has been selected to represent the risk envelope for multiple uses in a particular environmental compartment this must be clearly explained in the dRR</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Clarity of GAP for microbial products</p>	<p>In addition to the details given in Clarity of GAP above –</p> <p>For microbial pesticides, it may also be appropriate for you to include the dose in units such as CFU / ha (colony forming units / ha). However, it is noted that there may be other ways of expressing the dose. The units should be consistent with the dose expression used in the approval of the active substance.</p> <p>As approval is usually at species and strain level, you must specify the approved species and strain used in the product.</p> <p>If for any reason you consider that the taxonomic classification of microorganisms has been amended since approval of the the organism, resulting in a change in the name of the species /strain, please provide adequate evidence of this.</p>
<p>Risk envelope</p> <p>8.7 / 8.8 / 8.9</p>	<p>If proposing a risk envelope approach in any environmental compartment, please clearly explain the rationale for the risk envelope use pattern selected. Ensure you consider factors such as: crop type, application rate, method and timing of application, crop interception, earliest and latest application timings, soil types and relevant FOCUS scenarios (e.g. GB/NI applicable GW scenarios) etc</p> <p>Risk envelope suitability for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>Clarity of endpoints used in modelling and provision of example output</p> <p>8.7 / 8.8 /8.9.</p>	<p>Applicants should clearly show the inputs used for modelling in each compartment. For FOCUS ground water it is required to provide an example input and summary output file from each FOCUS model used (PEARL, PELMO, MACRO, PRZM), ideally the files for the run which resulted in the highest PEC would be provided.</p> <p>Where metabolites are predicted to occur in groundwater, input and output files for the metabolites should be provided as well as those for the active substance.</p>

Data point	What are the key issues for the detailed technical sift
	<p>Where metabolites in complex degradation pathways are observed it must be clear how all metabolites have been modelled, for example if a primary metabolite is modelled as parent in order to obtain results for a secondary metabolite</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Justification of new endpoints:</p> <p>General</p> <p>8.7.1 / 8.8.1 / 8.9.1</p>	<p>Endpoints from the approval of the active substance should be used, and this should be clear in the report.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Justification of new endpoints:</p> <p>Use of confirmatory data endpoints:</p> <p>8.7.1 / 8.8.1 / 8.9.1</p>	<p>If endpoints are available from an assessment of confirmatory data, and noted by the EU procedure, these must be used, unless existing assessments using previously agreed EU endpoints are more protective. (i.e. The confirmatory data process results in less conservative endpoints AND the already agreed EU endpoints provide an acceptable assessment). Justify the approach taken.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Justification of new endpoints:</p> <p>New active substance or metabolite data.</p> <p>8.7.1 / 8.8.1 / 8.9.1</p>	<p>Where any additional active substance and metabolite data are provided it must be demonstrated that these data are essential to support the authorisation. In addition, it is essential to demonstrate clearly how the new endpoints have been derived. It must also be demonstrated that there is a right to access the data which generated new endpoints.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Justification of new endpoints:</p>	<p>New guidance relating to active substance and metabolite endpoints that was not in place at the time of the approval of the active substance should not be applied.</p>

Data point	What are the key issues for the detailed technical sift
<p>Endpoints and Guidance- applying new guidance to active substance and metabolite endpoints:</p> <p>8.7.1 / 8.8.1 / 8.9.1</p>	<p>For example, do not recalculate the geometric K_{oc} when the approval of the active substance was for the arithmetic K_{oc}.</p> <p>However, the exception to this would be where it can be demonstrated that application of new guidance is <u>essential</u> to support the safe use for the proposed product. In such cases, adequate justification must be provided; and the presentation of a 1st tier assessment with existing agreed endpoints and a 2nd tier assessment applying the later guidance.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>Justification of new endpoints:</p> <p>Modelling metabolites where there are multiple potential endpoints for use for the parent substance:</p> <p>8.7.1 / 8.8.1 / 8.9.1</p>	<p>Where there are multiple potential endpoints for use for the parent (e.g. pH dependence for the DT50), the values to use when modelling the parent may differ from the value to use when modelling the metabolite. The approach and endpoints used in the approval of the active substance should be used, or any post approval assessment that modified this approach. If the approach departs from this, robust justification should be provided.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>PEC calculations for microbial products</p>	<p>Where the product contains a microbial rather than a chemical active substance the approach to PEC calculations requires careful explanation and justification.</p> <p>In the majority of cases the approach undertaken for active substance approval should be followed. If there is no quantitative exposure or risk assessment in the approval of the active substance, a justification should be provided as to why it is acceptable that no quantitative exposure or risk assessment is required for the product.</p> <p>If appropriate, refer to any post approval authorisation assessment where a different approach to that taken in the approval of the active substance was followed.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>

Data point	What are the key issues for the detailed technical sift
<p>PEC soil</p> <p>8.7</p>	<p>PECsoil calculations should be provided for the use pattern which results in the highest soil loading (justification for which use pattern results in the highest soil loading should be shown).</p> <p>If use pattern contains alternative applications such as banded applications the PECsoil should still be determined based on the full amount reaching the soil.</p> <p>The input parameters used for the calculations must be clearly shown.</p> <p>Soil (hse.gov.uk)</p>
<p>PECsoil accumulation</p> <p>8.7</p>	<p>If soil DissT90 is > 365 days for active substance or metabolite PECsoil accumulation values should be provided.</p> <p>The accumulation depth must be suitable for the crop under consideration. A depth of 20cm is appropriate for potatoes and other root crops where ploughing is involved at harvest. 20cm is also applicable when incorporation to such a depth is included at the time of application. For all other situations, 5cm tillage depth must be applied.</p> <p>Soil (hse.gov.uk)</p>
<p>PEC groundwater</p> <p>8.8</p>	<p>Simulations should be conducted for all crops included in the critical use pattern (GAP) table, or for the critical use pattern IF justification as to why it is the critical use is also provided.</p> <p>A justification must be provided for the application timings modelled, ensuring that they cover the worst case for both the parent active substance and the metabolites.</p> <p>Where new modelling is required, modelling for the appropriate use patterns using FOCUS PEARL 4.4.4 and PELMO 5.5.3 should be provided.</p> <p>MACRO modelling is required if</p> <ul style="list-style-type: none"> A) NI and GB product: the crop is parameterised for scenario Châteaudun, unless the PEC_{GW} values calculated with FOCUS PEARL and FOCUS PELMO are far below the trigger of 0.1 µg/L (e.g. <0.001 µg/L). B) GB product: The substance has a KOC >100ml/g <p>Groundwater (hse.gov.uk)</p>

Data point	What are the key issues for the detailed technical sift
<p>PEC groundwater</p> <p>Assessment of relevance of groundwater metabolites</p> <p>8.8</p>	<p>If metabolites are indicated at levels >0.1 ug/L a relevance assessment must be provided (see section B10).</p> <p>Groundwater (hse.gov.uk)</p>
<p>PEC surface water spray drift</p> <p>8.9</p>	<p>Calculations should be conducted for all crops included in the critical use pattern (GAP) table, unless a robust justification is provided that the use patterns modelled are protective of the use patterns which have not been modelled.</p> <p>Specific spray drift exposure assessment should be provided for the parent and for all ecotoxicologically relevant metabolites formed in water. Where appropriate, model early and late PECsw spray drift.</p> <p>The inputs used for modelling should be clearly shown (noting that water dissipation values can be used in GB/NI assessments instead of DegT50).</p> <p>Surface water and sediment assessments for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>PEC surface water sediment</p> <p>8.9</p>	<p>PECsed values should be provided unless adequate justification is provided to explain why they are not needed. This can include reference to the available ecotoxicology endpoints</p> <p>If PECsediment accumulation was considered during approval of the active substance it should be considered at product level.</p> <p>Where the sediment DT90 is available and is longer than 1-year PECsed accumulation should be determined. IF a DT50 / DT90 value is not available but there is an observed “lack of decline” in sediment it is considered reasonable to utilise a default of 1000 d as a first tier assessment.</p>

Data point	What are the key issues for the detailed technical sift
	<p>Spray drift surface water exposure assessments, pesticides (hse.gov.uk) Surface water and sediment assessments for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>PEC surface water</p> <p>Spray drift for protected / permanent protection with full enclosure uses</p> <p>8.9</p>	<p>‘Protected’ uses include polytunnels with sides which can be removed / rolled up. Use within these structures are treated the same as outdoor use with associated drift requirements.</p> <p>‘Permanent protection with full enclosure’ refers to solid glasshouse and uses within these structures do not require spray drift assessment. However; exposure via drainflow should be assessed if the crop is grown directly in soil, or if growing media can be disposed of onto agricultural drained land.</p> <p>Protected uses: Environmental fate guidance for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>Disposal or transplanting of growing media: environmental fate considerations for pesticide registrations in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>PECsw Spray drift</p> <p>Drift reduction technology (DRT)</p> <p>8.9</p>	<p>Either DRT or standard spray drift calculations must be provided (and NOT both). Where both have been supplied but DRT is stipulated on the label, only the DRT assessment will be evaluated. If DRT is not stipulated on the label only standard spray drift will be validated.</p> <p>If DRT is required on the label then the PECsw spray drift must be determined for DRT.</p> <p>Spray drift surface water exposure assessments, pesticides (hse.gov.uk)</p>
<p>PEC surface water drainflow</p>	<p>Calculations should be conducted for all crops included in the critical use pattern (GAP) table, unless a robust justification is provided that the use patterns modelled are protective of the use patterns which have not been modelled.</p> <p>The application timings modelled must be justified, ensuring that they address the worst case for both the parent active substance and the metabolites.</p> <p>If the crop can be grown on drained soils then an assessment is required of potential surface water exposure via drainflow.</p>

Data point	What are the key issues for the detailed technical sift
	<p>Where a quantitative assessment is required, PECsw drainflow results for the parent and ecotoxicologically relevant metabolites formed in both soil and water (noting that the approach for each is different) is required.</p> <p>The inputs used for modelling should be clearly shown.</p> <p>When required to address the ecotoxicology assessment, applicants should provide PECsed drainflow values for parent and for all ecotoxicologically relevant metabolites formed in soil or water or sediment.</p> <p>When the GAP includes multiple applications use the peak PECsoil to derive a pseudo application rate for parent PECsw but use the maximum total dose approach for soil formed metabolites.</p> <p>Surface water and sediment assessments for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>First tier drainflow calculation for pesticides registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>PEC surface water drainflow</p> <p>HTDF</p> <p>8.9</p>	<p>If first tier drainflow modelling results in PECsw drainflow results which exceed the aquatic RAC the applicant should either provide higher tier drain flow (HTDF) modelling, or specify mitigation or restrictions required.</p> <p>It must be demonstrated that the correct aquatic organisms groups have been considered in the HTDF modelling, and that the correct triggers/approaches have been used.</p> <p>In addition, if the product contains more than one active substance, assessment of the combined drainflow may be required.</p> <p>Where possible the need for higher tier modelling will be identified during the detailed technical sift. Otherwise, it will be highlighted during the course of the environment/ecotoxicology assessments.</p> <p>Surface water and sediment assessments for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>First tier drainflow calculation for pesticides registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>Fate and behaviour in air</p>	<p>A justification must be provided if it is considered that exposure via air is not of concern. As a first tier this should be in line with the approach taken within the Active substance approval process.</p>

Data point	What are the key issues for the detailed technical sift
8.10	<p>If the approval for the active substance raised a specific issue with respect to exposure of the air, the implications for atmospheric exposure from the requested use pattern must be taken into consideration.</p> <p>Consideration should be given to potential for long range transport, AND to short range transport and deposition.</p> <p>Air (hse.gov.uk)</p>
<p>General issues:</p> <p>Surrogate crops</p>	<p>A clear justification must be provided for the choice of surrogate crop (e.g. for use in FOCUS groundwater models, or for crop interception).</p> <p>The justification should include a description of the growth habit and size of both the desired crop and the surrogate crop at the time of product application, so that it can be determined if the choice of surrogate crop is appropriate.</p> <p>Environmental Fate and Behaviour (hse.gov.uk)</p>
<p>General issues:</p> <p>Broad crop categories</p>	<p>A clear justification for the input parameters used in exposure assessments (e.g. crop interception) must be provided when the crop category is very broad e.g. ornamentals</p> <p>Ornamental crops: Environmental fate considerations for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p>
<p>General issues:</p> <p>Disposal of growing media</p>	<p>Determination of environmental exposure following the disposal of growing media onto land must be considered for all container grown crops.</p> <p>In addition, the transplanting of container grown crops onto land must also be considered as a source of exposure.</p> <p>Disposal or transplanting of growing media: environmental fate considerations for pesticide registrations in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>Protected uses: Environmental fate guidance for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>Ornamental crops: Environmental fate considerations for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p>

Data point	What are the key issues for the detailed technical sift
<p>General issues:</p> <p>Protected use</p>	<p>It must be clear what types of structures are being referred to when discussing protected crops. The exposure assessment for fully enclosed permanent glasshouse structures differs greatly from that for polytunnels.</p> <p>For permanent protection with full enclosure the growing media should be specified as the exposure assessment and the labelling requirements differ dependant on the growing media</p> <p>For further information, refer to SANCO/12184/2014 – rev. 5 – 27 January 2015: (8b3db10c-005d-4e1e-b2f7-1d426aa23c93_en (europa.eu))</p> <p>This guidance document explains clustering and ranking of emissions of active substances of plant protection products, and transformation products of these active substances, from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments.</p> <p>Protected uses: Environmental fate guidance for pesticide registration in Great Britain and Northern Ireland (hse.gov.uk)</p> <p>Crop Definitions List NOV 20 for PDF (hse.gov.uk)</p>
<p>General issues:</p> <p>Disposal of growing media</p>	<p>An assessment based on the disposal of compost onto land, following the use of compost for crops grown under protection, should be provided.</p> <p>Disposal or transplanting of growing media: environmental fate considerations for pesticide registrations in Great Britain and Northern Ireland (hse.gov.uk)</p>

dRR Part B Section 9. Ecotoxicology

General	What are the key issues for the detailed technical sift
Part A	Part A must be consistent with the outcomes in individual dRR Part B sections

Study reports and summaries	Is there a submitted study report and robust study summary for all data relied on? (a list of studies/papers relied on should be summarised in the appendix of Part B)
Ecotoxicology	Is there a summary of the risk assessment for all non-target organism groups?
Ecotoxicology Classification	Has environmental classification been conducted according to CLP?
Formulation studies	If the formulation studies submitted have not tested the product under assessment – has a case for comparability/extrapolation of the data to support this product been provided? (should be provided in the Part C, Formulation studies and combined risk assessment in ecotoxicology - Pesticides - HSE advises on extrapolation consideration)
GAP	Has the correct critical GAP been identified and clearly presented? (The GAP should include the crop, maximum single application rate in g a.s/ha, number of applications, minimum interval between applications, BBCH range)
Data point	What are the key issues for the detailed technical sift
9.2 Effects on birds (KCP 10.1.1)	Have EU/GB agreed endpoints been used in the risk assessment for the active substance(s)? If not has additional data been submitted to support a refinement of the endpoint? (Please note that further consideration of a study already evaluated and concluded on at Annex I is not acceptable)
9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)	Has the correct guidance document been used (currently EFSA, 2009)? (should be the current guidance document at the time of application submission)
	Has an acute risk assessment been provided for the active substances(s) and proposed critical product GAP?
	Has a long-term risk assessment been provided for the active substances(s) and proposed critical product GAP?

	Has a secondary poisoning assessment been provided for the active substances(s) using GB&NI PECs (if triggered)?
	Has a drinking water assessment been provided for the active substances(s) and proposed critical product GAP?
	If there are >1 active substance, has a combined acute and reproductive risk assessment been provided? as detailed in Formulation studies and combined risk assessment in ecotoxicology - Pesticides - HSE
	If a higher tier assessment is required – are all refinements either supported by submitted data or have been previously agreed during the EU/GB approval for the active substance(s)?
	If a higher tier assessment is required – have focal species been proposed and justified? Has relevance to the GAP been justified? Has relevance for GB/NI been considered?
	If a higher tier assessment is required – has residue decline proposed as a refinement? If so has the relevance of the trials for GB&NI and proposed GAP been justified (i.e. climate, agricultural landscape, tested GAP)?
9.5 Effects on aquatic organisms (KCP 10.2)	Have EU/GB agreed endpoints been used in the risk assessment for the active substance and the metabolites? If not have additional data been submitted to support a refinement of that endpoint? (please note that further consideration of a study already evaluated and concluded on at Annex I is not acceptable)
	For any new aquatic studies submitted do analytical results of the study support the expression of endpoints (i.e. nominal/initial measured/mean measured concentrations)?
	Has the correct guidance document been used (i.e. EFSA 2013)? (should be the current guidance document at the time of application submission)

	Have GB/NI specific PEC _{sw} values for spray drift and drainflow been used in the risk assessment?
	<p>Has the risk to all relevant aquatic organism groups and exposure timescales been assessed?</p> <p>Have all ecotoxicologically relevant metabolites been included in risk assessment?</p>
	Related to the above: If relevant for the substance(s) and/or metabolites has the risk to sediment-dwellers been assessed considering exposure via sediment?
	<p>Has a higher tier drainflow assessment been triggered for any of the actives in the formulated product? If so have the number of exceedance events been considered for the aquatic organism group for which an acceptable risk has not been demonstrated at first tier? Reference should be made to current Environmental fate models (hse.gov.uk)</p> <p>(For aquatic plants and algae, there must be no more than 60% of exceedance years in each scenario. The risk is acceptable if there are no more than 18 years out of 30 exceeding the RAC based on first tier data.</p> <p>For aquatic invertebrates and fish there is a lower limit threshold value. The risk is acceptable if there are no more than 10% of exceedance years in each scenario. This equates to no more than 3 years out of 30 exceeding the RAC.)</p>
	Has an assessment (or case) been provided for the risk from the formulated product and critical GB/NI GAP?
	Has any risk mitigation required for GB/NI authorisation been clearly identified? Is it line with HSE guidance?
	If multiple species data are relied on, is the method and Assessment Factor used in line with EFSA, 2013?
	Has a mesocosm been used? If so, has the endpoint and Assessment Factor used been fully justified? (i.e. is it in line with what was agreed at Annex I or in line with EFSA, 2013?).

9.5 Effects on aquatic organisms (KCP 10.2) (Continued)	(If the mesocosm has been used to address the risk via drainflow then there should be consideration of exposure profiles – to demonstrate whether the exposure in the mesocosm is representative of that expected in the field).
	If the product contains > 1 active substance: Has an assessment (or case) been provided for the risk from the formulated product (including the risk from exposure to combined active substances.)? Current formulation guidance Formulation studies and combined risk assessment in ecotoxicology - Pesticides - HSE outlines the approaches to be taken.
9.6 Effects on bees (KCP 10.3.1)	Have EU/GB agreed endpoints been used in the risk assessment for the active substance(s)? If not has additional data been submitted to support a refinement of that endpoint? (Please note that further consideration of a study already evaluated and concluded on at Annex I is not acceptable)
	Has the correct guidance document been used (currently SANCO, 2002 referencing EPPO scheme, 2002b)? (Should be the current guidance document at the time of application submission.)
	Has an acute contact risk assessment been provided for the active(s), formulated product and proposed critical product GAP?
	Has an acute oral risk assessment been provided for the active(s), formulated product and proposed critical product GAP?
	If a higher tier assessment is required – are the study guidelines and the guidance document used for the assessment stated? Do the studies match GAP?
9.7 Effects on arthropods other than bees (KCP 10.3.2)	Has the correct guidance document been used (currently ESCORT II, 2001)? (should be the current guidance document at the time of application submission)
	Is the proposed GAP for pre-emergence of the crop or early post-emergence? If so and there is more than a single application, PER _{soil} exposure should be calculated and an in-field risk assessment conducted. (PER _{soil} calculated using the MAF values in Appendix III of ESCORT II)

	<p>Has a first tier in-field and off-field risk assessment been provided using glass plate toxicity studies?</p> <p>(If glass plate studies and a HQ assessment have not been provided then it is assumed that the tier 1 assessment for in-field and off-field would not demonstrate an acceptable risk and therefore extended laboratory studies would be required for the 2 indicators species plus 2 additional species. If these extended studies have been provided then glass plate studies are not required. If not then the assessment is not considered to be sufficient and a data gap would be applicable).</p> <p>If a higher tier risk assessment is required for the in-field and/or off-field risk – has it been provided and is it in accordance with the methodology of ESCORT II?</p> <p>If a higher tier MAF refinement using soil/foliar DT₅₀ data for the substance has been provided- has this been justified? (By use in a previous HSE agreed assessment, EU country assessment or justified by submitting new data?)</p> <p>Is any proposed mitigation for an off-field risk in line with current HSE guidance on risk mitigation? Ecotox risk mitigation labelling-2015.pdf (hse.gov.uk) (i.e. 5m buffer zone for field crops)</p>
<p>9.8 Effects on non-target soil meso-and macrofauna (KCP 10.4)</p>	<p>Have EU/GB agreed endpoints been used in the risk assessment for the active substance(s) and metabolites? If not has additional data been submitted to support a refinement of that endpoint? (Please note that further consideration of a study already evaluated and concluded on at Annex I is not acceptable.)</p> <p>Has the correct guidance document been used (currently SANCO, 2002)? (Should be the current guidance document at the time of application submission.)</p>
<p>9.9 Effects on soil microbial activity (KCP 10.5)</p>	<p>For soil meso- and macrofauna studies: If the Log P_{ow} of the active(s) is >2 and studies have been conducted in artificial soil, has the correction factor been applied to the endpoints? (This correction factor should be used regardless of the organic matter content of the soil – unless natural soil and full justification etc.)</p>

	Has a risk assessment been provided for all substances (active(s), ecotoxicologically relevant metabolites and formulated product) and critical proposed GAP?
	If >1 active substance in the product, has a consideration of the combined risk been provided for these organism groups?
	If a higher tier risk assessment is required – are the refinements supported by new data or are they previously agreed? (e.g.EU or GB -agreed for the active substance)
9.10 Effects on non-target terrestrial plants (KCP 10.6)	If there are EU/GB agreed active endpoints, have these been used in the risk assessment for all uses?
	Has the correct guidance document been used (currently SANCO, 2002)? (Should be the current guidance document at the time of application submission.)
	If considered necessary, has a tier I assessment been conducted?
	If necessary, has a tier II deterministic/probabilistic assessment been conducted (with at least 6 species)?
	If a HC ₅ has been calculated - has it been demonstrated that the data belongs to the same sensitivity distribution? (Via goodness of fit test results, visual inspection of the response curve.)
	If the risk is not resolved, has further assessment been provided to address this risk? Or appropriate risk mitigation added?

dRR Part B SECTION 10. Assessment of the relevance of metabolites in groundwater

What are the key issues for the detailed technical sift

Applicant has provided PEC_{gw} calculations at Section B.8.8 in FOCUS scenarios relevant to GB/NI and in Section B.10 has addressed the relevance of any metabolite(s) predicted to reach 0.1 µg/l or above in groundwater in those scenarios, in accordance with guidance described in SANCO 221/2000 rev.10 for the following steps:

STEP 1: Exclude degradation products of no concern [*fate*]

STEP 2: Quantification of potential groundwater contamination [*fate*]

STEP 3: Hazard Assessment. Identification of relevant metabolites

Stage 1 – Screen for biological activity [*efficacy*]

Stage 2 – Screen for genotoxicity [*toxicology*]

Stage 3 – Screen for toxicity [*toxicology*]

STEP 4: Exposure Assessment – ‘Threshold of concern’ approach [*toxicology*]

STEP 5: Refined Risk Assessments for Non-Relevant Metabolites [*toxicology/ chemistry*]