GB adoption of the 2023 European Food Safety Agency guidance on risk assessment for birds and mammals

Summary of key changes and stakeholder comments

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Summary of changes and GB proposals

Introduction

The EU has adopted the updated 2023 European Food Safety Authority guidance (on the EFSA website) on bird and mammal risk assessment for plant protection products (PPPs).

This replaces the 2009 EFSA guidance (on the EFSA website) and applies for applications in the EU and Northern Ireland (NI) from 1 October 2025.

Clarification regarding the use of this guidance for NI applications is provided on the HSE website in the guidance on birds and mammals – risk assessment for ecotoxicology. The updated guidance incorporates the latest scientific knowledge and new data that has become available since the 2009 guidance was published.

HSE made a detailed review of the 2023 guidance, to consider if:

- it is appropriate to Great Britain;
- amendments are required;
- alternative, independent GB guidance should be drafted for bird and mammal risk assessment.

The updated guidance has been considered by HSE in view of the UK-EU Common Understanding to work towards a sanitary and phytosanitary agreement. Until then, GB pesticide regulations and guidance continue to apply.

Key changes in guidance

The HSE review focused on changes between the 2009 and 2023 guidance, the basis for these changes, practicalities of implementation, and implications for divergence between Great Britain and Northern Ireland. Key changes identified by HSE are summarised in Appendix 1.

The fundamental risk assessment methodology remains the same, with acute and long-term/reproductive risks to birds and mammals considered. The toxicity data required are largely unchanged and the general approach to modelling exposure is unaltered.

Risk assessments conducted using the 2023 guidance satisfy the same protection goals as risk assessments conducted using the 2009 guidance and are compatible with the requirements of assimilated Regulation 1107/2009.

Databases used in calculating exposure estimates have been updated and expanded to incorporate new information that has become available. Advice on higher tier risk assessment options is also expanded, in light of experience with use of such refinements. These changes are scientifically merited and will lead to more accurate and consistent risk assessments.

Proposals for GB adoption

HSE proposed to adopt the 2023 EFSA guidance document for GB applications, with some clarification for how and when the guidance will apply to GB assessments, to reflect GB legislation. The clarifications reflect national requirements and enable practical implementation of the guidance. They are appropriate for a national regulator to determine to ensure that the same, high standards of protection continue to be met. These clarifications are explained below.

Benchmark dose

In the 2009 guidance, the standard toxicity endpoint used in long-term/reproductive risk assessment is a dose at which no adverse effects are seen (NOAEL), based on statistical comparison with the control group.

In contrast, the 2023 guidance adopts a consistent effect level of greater than or equal to 10% for setting the endpoint, and recommends the use of benchmark dose modelling (BMD) for this purpose. While this change is scientifically merited, HSE considers it impractical to routinely determine BMD10 endpoints for use in PPP evaluations, where the active substance has been reviewed to 2009 EFSA guidance.

Therefore, HSE requires the use of BMD10 endpoints (where possible) for all future GB active substance evaluations. However, for GB PPP evaluations, HSE will accept either use of BMD10 or NOAEL endpoints, depending on which guidance was followed when the active substance was reviewed.

It is noted that use of a BMD toxicity endpoint is an acceptable refinement option for risk assessments conducted to 2009 EFSA guidance.

Time weighted average factor

In both the 2009 and 2023 guidance documents, the exposure estimate used in the long-term/reproductive risk assessment incorporates a time-weighted average factor (TWA).

The 2009 guidance presumes a TWA of less than 1 can be used as standard (unless there is evidence to the contrary), while the 2023 guidance requires this to be justified, based on a detailed review of the toxicity data. This change is scientifically merited but impractical to implement for use in PPP evaluations, where the active substance has been reviewed to 2009 guidance.

HSE will apply the 2023 guidance approach for deciding use of a TWA factor for all future GB active substance evaluations. However, for GB PPP evaluations, HSE will accept use

of the TWA approach according to the guidance in place at the most recent active substance assessment. This is with the condition that, where an endpoint is set based on the median lethal dose divided by 10 (LD50/10) or effects on eggshell thickness, a TWA of less than 1 should not be used.

Secondary poisoning and drinking water

HSE considers that some areas of the 2023 guidance are not currently implementable, given they rely on guidance in other areas that has not yet been implemented. Specifically, this relates to the secondary poisoning and drinking water risk assessments, where exposure is considered through benthic invertebrates and/or soil pore water (Sections 10.2, 10.4 and 11).

The following documents provide more detail:

- Scientific report of EFSA on the 'repair action' of the FOCUS surface water scenarios (on the EFSA website);
- EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (on the EFSA website).

HSE considers that these areas of the 2023 guidance are currently not implemented for GB assessments until the corresponding guidance has also been implemented. Therefore, HSE will only determine whether these approaches should be used in GB submissions after the corresponding guidance is adopted.

Higher tier studies

Specific recommendations have been added to 2023 guidance regarding the conduct of higher tier ecological studies and field studies investigating toxic effects in focal species (Sections 6.5., 2-6., 5.5 and 7.1). These recommendations include an increase to the minimum number of sites or individuals to monitor.

It is understood that these recommendations have been developed in the context of conducting a risk assessment that is appropriate for conditions across, potentially, the whole of the EU. HSE considers that this is beyond the requirements for an assessment which considers only GB conditions. Therefore, for GB assessments, the recommendations regarding higher tier studies should be considered in a GB context, reflecting the lower diversity of conditions the assessment is required to cover.

Stakeholder views on GB adoption

HSE conducted a survey between 9 April 2026 and 1 May 2026, seeking stakeholders' views on the proposals for GB adoption of the 2023 EFSA bird and mammal guidance. The survey asked questions about potential impacts of the proposed changes to how bird and mammal risk assessments are performed for PPPs in Great Britain.

The total number of stakeholder responses received was 12. The number of respondents representing each organisational category is summarised in the following table.

Table 1: Organisation categories of respondents

Organisation category	Number of responses
Industry	5
Other	4
Contact research organisation	3
Government, academia, non-governmental organisation	0

Respondents were asked their views on changes in the guidance under a number of subject areas, corresponding with specific sections of the guidance document. They were requested to specify to what extent they agreed or disagreed with the changes in each subject area, from strongly agreeing to strongly disagreeing. The response categories used, and how HSE has converted these to a representative score, are described in the following table.

Table 2: Response categories used in the HSE survey and equivalent scores

To what extent do you agree or disagree with…	HSE score
Strongly agree	5
Agree	4
Neither agree or disagree	3
Disagree	2
Strong disagree	1
Unsure	No score

The following table summarises the extent to which respondents agreed or disagreed with changes in each subject area. An average score is included for each subject area, which excludes 'unsure' responses.

Table 3: Summary of the extent of agreement or disagreement with changes in the guidance

Question	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Unsure	Average score
To what extent do you agree or disagree with the addition of the problem formulation step?	2	5	5	0	0	0	3.75
To what extent do you agree or disagree with the changes in the use of toxicity data and the effect assessment (excluding the benchmark dose)?	1	7	3	0	0	1	3.82
To what extent do you agree or disagree with the benchmark dose for active substance assessment?	0	7	2	0	3	0	3.08

Question	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Unsure	Average score
To what extent do you agree or disagree with the HSE proposal to not use the benchmark dose for product assessment in Great Britain (unless already considered for the active substance)?	8	3	1	0	0	0	4.58
To what extent do you agree or disagree with the changes in the exposure assessment for products applied as sprays or seed treatments (excluding the use or not of a time weighted average)?	1	6	3	2	0	0	3.50
To what extent do you agree or disagree with the method for determining whether a time weighted average approach is appropriate during active substance assessment?	1	4	2	4	1	0	3.00

Question	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Unsure	Average score
To what extent do you agree or disagree with the HSE proposal to not consider whether a time weighted average is suitable during product assessment in Great Britain (unless already considered for the active substance)?	8	3	0	0	0	1	4.73
To what extent do you agree or disagree with the changes to the evaluation of field effect studies and other methods that integrate exposure and effect assessment?	1	2	7	0	0	2	3.40
To what extent do you agree or disagree with the changes in the risk assessment for products applied as granules?	0	1	6	0	0	5	3.14
To what extent do you agree or disagree with the changes in the risk assessment for metabolites?	0	2	3	3	1	3	2.67

Question	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Unsure	Average score
To what extent do you agree or disagree with the changes in assessing risk to birds and mammals via bioaccumulation, biomagnification and secondary poisoning?	1	0	5	4	0	2	2.80
To what extent do you agree or disagree with the changes in assessing risk via contaminated water?	1	5	4	2	0	0	3.42
To what extent do you agree or disagree with the changes in assessing risks from formulated products, including those containing more than one active substance?	1	0	7	1	1	2	2.90
To what extent do you agree or disagree with the changes to uncertainty analysis and weight-of-evidence consideration?	1	1	5	1	1	3	3.00

Question	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Unsure	Average score
To what extent do you agree or disagree with the EFSA birds and mammals calculator tool?	1	4	0	3	3	1	2.73

For each of the questions (as specified in Table 3), respondents were also asked to summarise any comments they have regarding that particular change/subject area. Appendix 2 includes all of the comments received from stakeholders, along with HSE responses to each comment.

Final decision on GB adoption

Following a review of the feedback received from stakeholders, it has been decided to adopt the updated 2023 EFSA guidance in Great Britain, with specified clarifications for GB assessments. Adopting the updated guidance aligns Great Britain with the EU process, with the remaining differences reflecting national requirements and enabling practical implementation of the guidance. This is appropriate for a national regulator and ensures that the same, high standards continue to be met.

From 17 February 2027, any GB pesticide assessment which relies on a new bird and mammal risk assessment, must take account of the 2023 EFSA guidance. Applicants are able to voluntarily use this guidance from 17 August 2026.

The following clarifications apply to the use of the 2023 EFSA guidance in GB submissions:

- **Benchmark dose (BMD):** until the BMD for the active substance has been derived as part of the approval or renewal of approval of the active substance, the NOAEL will be used for product authorisations (unless the agreed active substance endpoint is already a BMD10).
- **Time weighted average factor (TWA):** until the TWA approach specified in the 2023 EFSA guidance has been agreed as part of the approval or renewal of approval of the active substance, product risk assessments should be conducted using the TWA approach specified in the 2009 EFSA guidance. Where the critical endpoint for the reproductive risk assessment is based on effects on eggshell thickness or is derived from an acute toxicity study, a TWA of less than 1 should not be used.
- **Secondary poisoning and drinking water:** until the corresponding guidance has also been implemented, consideration of exposure through benthic invertebrates and soil pore water is not required.
- **Field monitoring studies:** recommendations in the 2023 EFSA guidance regarding the use of higher tier studies should be considered in a GB context, reflecting the lower diversity of conditions the assessment is required to cover. The use of the Critical Appraisal Tool (CAT) approach for higher tier study evaluation is considered optional for GB submissions.
- **Metabolites:** ecotoxicologically relevant metabolites identified during the most recent active substance evaluation should be considered in GB product risk assessments, whether the active substance assessment was conducted to the 2023 or 2009 EFSA guidance.

Appendices

Appendix 1: HSE consideration of key changes in guidance

Table 4: HSE consideration of key differences between 2009 and 2023 EFSA guidance on bird and mammal risk assessment

Section	Subject	Extent of changes compared to 2009 EFSA guidance	Key changes highlighted by HSE
1	Background and terms of reference	Minor	None
2	Introduction	Minor	None
3	Risk assessment background	Minor	None
4	Problem formulation	New addition	Inclusion of an explicit problem formulation step.
5.2.6.1	Effect assessment	Minor	Additional recommendations included regarding the use of historic control data.
5.2.6.3 and Appendix D	Effect assessment	New addition	New extrapolation factors included to estimate median lethal dose (LD50) values, where there is less than 50% mortality in acute toxicity studies with mammals.
5.2.6.5 and Appendix C	Effect assessment	Minor	Includes detailed information on which mammalian endpoints are ecotoxicologically relevant for the reproductive risk assessment (which mammalian endpoints impact population abundance).
5.2.7	Effect assessment	Extensive	Use of 10% effect level to determine biological relevance and use of benchmark dose modelling to determine the 10% effect level dose (EL10).

Section	Subject	Extent of changes compared to 2009 EFSA guidance	Key changes highlighted by HSE
5.2.9	Effect assessment	New addition	Added consideration of risks to migratory birds from neurotoxic effects of pesticide active substances.
5.3.3	Effect assessment	Moderate	Modification to the approach for using a geometric mean LD50 where multiple acute toxicity studies are available.
6.1	Exposure assessment	New addition	Discussion on the use of toxicokinetic/toxicodynamic (TKTD) models in bird and mammal risk assessment.
6.1.4	Exposure assessment	Extensive	Revised approach for determining whether toxic effects could be due to short-term exposure, and hence whether a time weighted average factor (fTWA) of less than 1 can be used in reproductive risk assessments for birds and mammals.
6.2.1 and Appendix I	Exposure assessment	New addition	For PPPs applied as sprays, consideration of risks to birds and mammals in off-crop environments.
6.2.2 and Appendix E	Exposure assessment	Moderate	There are differences in crop groupings and shortcut values for exposure calculations are no longer included.
6.2.3 and Appendix F	Exposure assessment	Moderate	Updated data on body weight and proportion of food items in the diets of model species are included.
6.2.4 and Appendix J	Exposure assessment	Moderate	Updated data on initial residue values in food items are included for use in exposure calculations. The geometric mean is used, rather than the median, to characterise the central tendency of these datasets.
6.2.6 & Appendix L	Exposure assessment	Moderate	The use of deposition values in the exposure assessment is revised. Crop interception values align with FOCUS (2014) guidance.

Section	Subject	Extent of changes compared to 2009 EFSA guidance	Key changes highlighted by HSE
6.3 and Appendix M	Exposure assessment	Minor	Addition of a default fTWA value for seedlings.
6.5.2-6.5.5	Exposure assessment	Extensive	Inclusion of new recommendations for the conduct of field studies and their interpretation, such as the required crop coverage in the study area.
6.5.8	Exposure assessment	Extensive	Inclusion of default foraging areas to contextualise risks to birds and mammals from PPPs applied as seed treatments.
6.5.9	Exposure assessment	New addition	Inclusion of a step comparing new Tier 3 refinements with findings from previous studies, using a historic database.
7.1	Integrated exposure and effect assessment	Moderate	Inclusion of new recommendations for the conduct of field effect studies and their interpretation.
7.3	Integrated exposure and effect assessment	Moderate	Expanded consideration of the use of population models in bird and mammal risk assessment.
8 and Appendix Q	Granules	Moderate	Addition of the scenario ‘ingestion of granules when seeking seeds as food’ and removal of the scenario ‘ingestion of granules as part of soil uptake.’ Additional guidance for assessing risks from granules via residues in food items and from fast dissolving granules is also included.
9	Metabolites	Extensive	Expanded and updated guidance for assessing risks from metabolites, following a stepwise approach.

Section	Subject	Extent of changes compared to 2009 EFSA guidance	Key changes highlighted by HSE
10.2	Secondary poisoning	Moderate	Revised approach to assessing risks to birds and mammals via consumption of earthworms, using a 7-day TWA soil concentration and following the 'pore water' approach.
10.4	Secondary poisoning	New addition	Addition of scenarios for benthic invertebrate-eating birds and mammals.
11	Contaminated water	Minor	Additional guidance on which uses require consideration of the leaf scenario and inclusion of soil pore water approaches.
12	Formulations	New addition	For PPPs containing multiple active substances, mixture assessments are added for secondary poisoning and contaminated water exposure routes. Formulation and active substance toxicity data are compared to determine a model deviation ratio (MDR).
13	Uncertainty analysis and weight of evidence	Moderate	Revised guidance for considering and presenting uncertainties associated with higher tier risk assessments.
14	Risk mitigation	Minor	None
15	Calculator tool	New addition	A new calculator tool is available for conducting risk assessments for PPPs applied as sprays or as seed treatments.

Appendix 2: Stakeholder comments and HSE responses

Addition of a problem formulation step – Section 4 of the EFSA guidance

Number	Stakeholder comment	HSE response
1	The problem formulation step formalises an already implicit process. It may improve transparency and clarity of the risk assessment framework. The step is considered useful, particularly for clarifying exposure scenarios where risks to terrestrial vertebrates can be excluded.	HSE agrees with this comment and the benefits of explicit inclusion of a problem formulation step in the risk assessment.
2	This was not formally noted but was in fact generally done in the past. Section 4 just makes the process clearer.	It is agreed that this addition formalises points that have been previously considered in PPP risk assessments, but in a more transparent manner.
3	It contextualises and structures in a step-wise approach the already known and commonly used information about when and how to perform a prospective RA for b+m.	Read response 2.
4	We broadly agree with the addition of the problem formulation step, which operates overall as a backdrop to the risk assessment scheme implemented through the guidance document. It is also useful to confirm specific application types where routes of exposure to terrestrial vertebrates is precluded. However, we would suggest that the titling of the problem formulation could be misinterpreted as a pesticide formulation, rather than the ‘problem’ of assessing risk generally.	HSE agree it is important to not mistake problem formulation with pesticide formulation. Read response 1.
5	It's unclear what value the problem formulation has on the overall assessment. How much will this be considered in the overall assessment and what impact will it have? Does this	HSE considers the key benefit of the inclusion of the problem formulation step to be that it transparently focuses the risk assessment on relevant routes of exposure at the earliest stage. It is acknowledged that this could impact

Number	Stakeholder comment	HSE response
	not only add to the volume of work for regulators to assess?	workloads but it is considered that for most PPPs this step should be relatively quick and there will be elements that will be common across multiple PPPs. Where a PPP is more unusual, in terms of properties, application methodology etc., this step will be more time consuming but will save time at subsequent steps in the risk assessment, as non-relevant routes of exposure will be eliminated from further assessment.

Changes in the use of toxicity data and the effect assessment (excluding benchmark dose) - Section 5 and Appendices B-D of the EFSA guidance

Number	Stakeholder comment	HSE response
6	The 2023 guidance strengthens the focus on ecological and population relevance in effect assessment. Multigeneration and developmental mammalian studies are regarded as most relevant, while other endpoints should inform hazard understanding without dominating ecotoxicological conclusions unless population relevance is demonstrated. Isolated organ effects, in the absence of clear adversity or population relevance, should therefore not automatically be considered ecotoxicologically relevant. Concerns remain regarding potential overreliance on expert judgement and inconsistencies in this judgement. The revised guidance has the potential to improving consistency, transparency, and scientific defensibility of endpoint selection - provided expectations are aligned early in the regulatory process (for example via pre-submission discussions). We agree with the addition of an extrapolation factor for acute toxicity to mammals.	HSE agree that the guidance helps focus the effects assessment on parameters that are ecologically relevant and which could impact populations. It is acknowledged that there will still be a requirement for evaluators to exercise expert judgement regarding endpoint selection but it is difficult to see how this can be avoided entirely and the guidance will promote greater consistency and transparency. It is also agreed that the inclusion of extrapolation factors for acute mammal toxicity studies is positive and aligns with the approach for acute toxicity to birds.
7	Despite the guidance provided, deciding and justifying the ecological relevance of reproductive/long-term effects in mammals would always require expert judgment and lot of discussions	Read response 6.

Number	Stakeholder comment	HSE response
8	The amendments and new additions to the effect assessment section better reflect relevance to natural populations. In particular the expanded relevance of certain long-term mammalian studies and collected endpoints should aid in consistency of long-term endpoint setting. We agree with the addition of an extrapolation factor for acute toxicity to mammals.	Read response 6.

Use of benchmark dose endpoints in the long-term risk assessment - Section 5.2.7 of the EFSA guidance and HSE proposal to not use the benchmark dose for product assessment in Great Britain (unless already considered for the active substance)

Number	Stakeholder comment	HSE response
9a	We strongly agree with the HSE proposal to only conduct BMD analysis at the next relevant (renewal of) approval of an active substance. Such analysis is purely based on active substance data so should be consistent between product registration assessments under the same active substance approval period. Additionally, it is incredibly time consuming and requires access to the source studies, which are held only by the data owner so such analysis cannot be fully conducted by other registrants with only data access.	HSE understands the concern raised regarding access to studies and acknowledges that determining BMD10s for required studies and parameters will be time consuming. These are key reasons why HSE is proposing to only determine BMD10 endpoints at the active substance evaluation stage (except where proposed as a refinement option for a PPP). It is understood that it will not always be possible to derive a robust BMD10 and that there will be circumstances where NOAEL endpoints will have to be used instead.

Number	Stakeholder comment	HSE response
9b	Whilst we agree with the principle of moving to a consistent effect level for long-term hazard characterisation and this is aligned with, for example, aquatic guidance. However, we foresee two problems with the use of BMD10 endpoint derivation: 1) Many studies are not sufficiently designed for benchmark dose derivation and so the reliability of BMD10 values can be low. The guidance attempts to overcome this by setting wide limits of reliability which is a questionable approach. 2) The 10% effect level seems to be arbitrary in its selection given it is irrespective of the long-term effect seen. For example, various papers have previously identified larger than 10% reductions in adult bodyweight as of low to no ecological relevance. Ideally some further consideration should be made into the relevant BMD critical effect value (effect percentage) for broad effect types.	The use of a 10% effect level endpoint in long-term risk assessment ensures greater consistency between risk assessments conducted with different active substances. The 10% effect endpoints use all of the available data and are less influenced by dose selection and differences in statistical methods compared to NOAEL endpoints. Therefore, HSE considers the use of a consistent effect level in risk assessment to be preferable. It is acknowledged that different endpoints measured in toxicity studies will vary in their significance for wild bird and mammal populations. However, to address this issue would require additional research and specifically designed population models that are not currently available.
9c	Finally, we would point to the need for additional guidance on proper methodologies and processes for the overall BMD analysis activity. We note that CropLife Europe have proposed a ‘toolbox’ approach which is logical in the prior analysis and ‘filtering’ of studies and effects which would possibly be critical and suitable for BMD analysis. Some corresponding guidance and/or training provided by competent authorities would be greatly beneficial for correct and consistent methodology across applicants and evaluators.	HSE understands the need for additional guidance on BMD calculation methodologies and is open to providing training on this topic to applicants in future, once sufficient experience has been gained applying this aspect of the guidance. HSE would also consider any proposals from stakeholders regarding practical implementation of this approach.

Number	Stakeholder comment	HSE response
10	It is impractical for individual applicants to generate BMD10 values for product assessments, this would lead to increasing workloads for applicants and HSE's Chemicals Regulation Division, and potentially different endpoints from the same data sources, with limited evidence that this helps to achieve protection goals. This is something that should only be done at active substance level (approval/renewal) by the main notifier.	Read responses 9a-c.
11	BMD modelling is complicated and requires all raw data so should only be done for the active substance to avoid different values being generated for different products.	Read responses 9a-c.
12	Agree that BMD should be the preferred approach for setting the reproductive endpoints for use in the risk assessment for birds and mammals as it makes use of the whole data set (dose response data). However, the implementation of this approach is still an area to explore my both industry, consultancy agents and regulatory authorities. Definitely agree that BMD endpoints should be set/agreed at active substance level!	Read responses 9a-c.

13	Among CropLife members there is broad agreement that benchmark dose (BMD) modelling, and in particular the BMD10 concept, is scientifically sound in principle and offers clear theoretical advantages over NOAEL-based approaches, including use of the full dose-response dataset, interpolation between dose levels, and improved statistical characterization of uncertainty. It is additionally in line with the use of a 10% threshold for biological relevance of effects. BMD modelling is highly resource-intensive, requiring access to raw study data, extensive data extraction, modelling, and expert evaluation, with limited potential to increase conservativism. It is proposed that BMD analyses should therefore focus on ecologically relevant endpoints likely to drive risk assessment, rather than being applied indiscriminately to all measured parameters. There are serious concerns over the available tools, including the EFSA online platform and associated R packages, which are widely viewed as not yet fit for regulatory use, due to limitations in documentation, transparency, version control, archiving, and usability. A validated, regulatory-grade tool and clearer guidance on methodologies, study selection, endpoint filtering, and decision criteria are considered essential prerequisites. Consequently, a phased and pragmatic implementation is supported, limiting mandatory BMD analysis to active substance approval or renewal, where consistent endpoints can be agreed at EU level and applied across product assessments in Great Britain. During	The proposed HSE approach for GB product applications is intended to support practical and pragmatic implementation of BMD endpoints in bird and mammal risk assessment. HSE acknowledges the concerns raised regarding available tools for performing BMD analysis and share the desire for a validated, regulatory-grade tool. We are happy to have ongoing discussion as this issue evolves. Also read responses 9a-c.

Number	Stakeholder comment	HSE response
	any transition period, previously agreed NOAELs should remain valid, with the possibility of BMD10 being used as a weight-of-evidence input, rather than as a default Tier 1 endpoint. Overall, we support the direction of travel toward BMD10, provided implementation is proportionate, harmonised, and underpinned by clear procedures, appropriate tools, and regulatory guidance.	
14	Current OECD guidelines for long-term vertebrate studies are not designed for the calculation on BMD. In the vast majority of cases, the data is not fit for this purpose, and although this can be identified easily, EU MS have indicated that BMD analysis should be performed in its entirety before coming to that conclusion. Will this also be the case for HSE?	If an applicant wishes to makes a reasoned case argument that BMD analysis for a particular parameter is either not possible for technical reasons or is not required as the parameter is clearly not sensitive, such a case would be considered by HSE. Also read responses 9a-c.
15	It is not always possible to calculate BMD using currently available data because the studies were not designed for it, and BMD calculation methods can be debated. Sometimes BMD can be calculated for some endpoints but not all - what then? Therefore, it seems inappropriate to push for BMD unless suitable data are available for all active ingredients (which would take decades and has welfare issues).	Read responses 9a-c and 14.

Number	Stakeholder comment	HSE response
16	BMD is a valuable tool and from a scientific point of view more appropriate for tox endpoints than using NOELs (if the dataset is suitable). Hence, while I understand and appreciate the aim of having consistent evaluations, particularly regarding such critical points such as endpoint setting, BMD models should still not be ignored on product level if available (could be used, for example, as weight of evidence approach).	For GB product submissions, if an applicant chooses to use a BMD10 in their risk assessment prior to such an endpoint being determined in an active substance review, in order to refine a failing risk assessment, then the BMD10 would be considered by HSE. Also read responses 9a-c.

Changes in the exposure assessment for products applied as sprays or seed treatments - Section 6, Appendices E-P and Annexes A-F of the EFSA guidance

Number	Stakeholder comment	HSE response
17	We welcome the update to residues per unit dose (RUDs) etc, which are based on much larger datasets than the previous guidance version. However, it must be acknowledged that some default exposure parameters are still based upon limited historical data sets and so are more suitable to refine with additional or more specific information from the applicant.	HSE agrees that updating the databases for parameters such as RUD is beneficial, with more data included and the reliability of the data assessed. It is acknowledged that, where datasets are still limited, it may be possible to refine parameters, where new relevant and reliable data are available to support such a refinement.

Number	Stakeholder comment	HSE response
18a	The 2023 EFSA guidance introduces a substantial increase in complexity, with a greater number of exposure scenarios, and generic species, which may be challenging to relate to real species and field conditions and for which the ecological representativeness is not always transparent. For example, we do not understand why there is a small granivorous and small omnivorous mammal in the bare soil scenario with the same body weight, ie why are there two different diets for the proposedly same species? We appreciate that the revised framework introduces methodological updates to exposure assessment for spray and seed treatment uses, including revised RUD values based on more extensive and recent datasets than those used previously. However, it must be acknowledged that some default exposure parameters are still based upon limited historical data sets, and so are more suitable to refine with additional or more specific information. An example is the addition of the medium herbivorous mammal in cereals during BBCH stages 30-39. In the 2009 guidance cereals in these growth stages were not considered attractive feed for medium herbivorous mammals, which also resulted in a lack of residue data for this scenario in the collection from Lahr et al. Our recommended approach to increase realism is to use the RUD data for this scenario from Ebeling et al. (2026).	HSE recognises that the expanded range of scenarios and model species in the 2023 EFSA guidance compared to the 2009 EFSA guidance increases the complexity and time required to perform risk assessments. It is anticipated that use of the calculator tool will help minimise this impact. HSE will also explore whether a narrower range of model species can be identified that are relevant for risk assessment in Great Britain. Also read response 17.

Number	Stakeholder comment	HSE response
18b	Concerns are also expressed regarding the proportionality and feasibility of crop- and scenario-specific assessments for minor crops. There are some relatively minor crops, which are now defined as specific crop category. For many companies, it would not be worth investing in crop-specific higher tier data for these crops, because of their relatively small market value. Overall, we support the updated parameters in principle, while highlighting the need for simplification, clearer justification, and flexibility in the application of conservative defaults and higher tier data.	Regarding minor crops, HSE will consider applicant's proposals to extrapolate risk assessments from major crops to minor crops, where justified, particularly when higher tier data are available. Also read response 17.
19	Spray applications: Swift from generic focal species concept with representatives of real species (EFSA 2009) to the concept of feeding guilt (EFSA 2023) might be initially a bit tricky – also considering the increased number of relevant Tier 1 scenarios with EFSA 2023. The guidance for seed treatments in EFSA (2023) more clear compared to EFSA (2009) although refinement options lack details.	It is acknowledged that further clarity on refinement options for seed treatment applications would be beneficial. To this end, HSE is exploring whether additional advice can be made available to applicants regarding generic refinements (i.e. not active substance specific) for GB applications. Also read responses 18a and b.

New method for determining whether a time weighted average can be used - Section 6.1.4, Appendix H of the EFSA guidance and HSE proposal to not consider whether a time weighted average (TWA) is suitable during product assessment in Great Britian (unless already considered for the active substance)

Number	Stakeholder comment	HSE response
20a	CropLife members acknowledge the scientific rationale of the time weighted average (fTWA) concept and welcome EFSA's effort in the 2023 guidance to provide a structured approach for determining fTWA applicability at the active substance level. However, there is broad agreement that the proposed decision framework remains ambiguous and highly subjective, relying heavily on expert judgement. A key concern is that most underlying toxicity studies are not designed to determine whether observed long-term effects are driven by short-term peak exposure or true long-term exposure, resulting in persistent uncertainty. For metabolites in particular, long-term studies are not required so the fTWA cannot be assessed. The scientific justification for moving from a default fTWA consideration in EFSA 2009 to a mandatory justification in EFSA 2023 is lacking, which may introduce additional conservatism without clear benefit and may exclude useful exposure refinements based on residue dissipation data.	The new approach for determining whether a TWA of less than one can be used is considered beneficial, since it is based on examination of the available toxicity dataset, rather than a default assumption. It is acknowledged that this will reduce the number of substances where residue decline refinements are possible in the long-term risk assessment, however this is considered scientifically justified. HSE does have some concerns regarding the practicality and clarity of the approach, as written in the guidance, and the potential for uncertain conclusions to be reached. Therefore, a project has been commissioned to test the methodology, with the aim of providing recommendations to help with implementation of this aspect of the guidance by applicants and regulators. The specific concern over use of the TWA approach for metabolites is also noted. Read response 33 for further consideration of metabolites.

Number	Stakeholder comment	HSE response
20b	Regarding product assessment in Great Britain, we largely agree with HSE's proposal not to reassess fTWA applicability at product level unless already addressed for the active substance, as fTWA decisions are driven by substance-specific toxicity data and should therefore be assessed consistently at active substance approval or renewal. We strongly suggest flexibility for checks of underlying data in all cases, including those in which chronic endpoints are defined on the basis of acute studies (LD50/10) or eggshell thickness is affected in the presence of maternal toxicity, to avoid unnecessary conservatism. We would like to make aware of the fact that discussions on the topic of fTWA evaluations are ongoing at EU level. CLE provided a position paper on the topic to the members of the PAI group which is included for information. The next opportunity to exchange with company experts on this topic will be at the next SETAC EU in Maastricht (19 May 2026).	The agreement with the HSE proposal regarding implementation of the TWA approach for GB products is noted. Read responses 25 and 26 regarding LD50/10 endpoints.
21	The EFSA 2023 decision method is too subjective. A submitter may consider that fTWA is appropriate but regulators may disagree. No fTWA suddenly negates the possibility of refinement using residue decline studies.	Read responses 20a and b.
22	I agree with HSE's Chemicals Regulation Division's proposed approach to use the TWA in product assessments until an active substance level evaluation has shown that it is not appropriate to use it.	Read responses 20a and b.

Number	Stakeholder comment	HSE response
23	If BMD modelling is not considered on product level, I fully agree that TWA suitability should not be assessed on product level either to stay consistent. Otherwise the active substance toxicity data package would need to be re-assessed in detail on product level anyway.	It is agreed that it is most efficient to consider BMD modelling and TWA suitability at the same stage, given it involves examination of the same data package.
24	fTWA applicability should definitely be assessed/decided at a.s. level together with the BMD analysis as data sets to be checked are more or less the same. Harmonisation and consistency among different PPP authorizations at different MSs/authorities is also crucial.	Read response 23.
25	We agree that fTWA should not be assessed at product level, but disagree with the HSE proposal that in all cases where the LD50/10 is used in the avian assessment fTWA is not justified. Please refer to the last sentence of paragraph 2 on Page 62 of the guidance. Even where the LD50/10 is used if not effects were seen in the study the fTWA is justified.	Where the LD50 is an unbound ‘greater than’ value, HSE would generally not use an LD50/10 endpoint in the long-term risk assessment, given there is no positive indication this endpoint is below the BMD10 or NOAEL.

26	The possibility to not assume long-term exposure = long-term effects for certain types of effect does have scientific logic in some situations but is still somewhat arbitrary as prescribed in the guidance document. Unfortunately, many studies are not suitably designed to fully determine whether it is short or long-term exposure causing such effects. Our concern is that the criteria of the guidance document may lead to instances of unnecessarily conservative risk assessment, whilst also removing possibility of exposure refinement (via DT50 information for example). We strongly agree that assessment of fTWA applicability should in almost all cases be undertaken at the next (renewal of) approval of the active substance. This is best done in conjunction with the BMD analysis as it requires detailed evaluation of the long-term toxicity dataset. It also allows for any increased conservatism caused by removal of fTWA assumption to be considered alongside a more precise long-term endpoint (BMD10). However, we would recommend that some addition, clear guidance be provided as to how long-term endpoints above the most critical (lowest) should be considered, in case the combination of endpoint and fTWA applicability causes an overall critical risk assessment. HSE's proposal to exclude fTWA applicability under product assessments is 'where an endpoint is set based on the LD50/10 or effects on eggshell thickness'. We would ask HSE to confirm that the LD50/10 criterion is applicable to both birds and	HSE can confirm that the LD50/10 is only considered for potential use in the long-term risk assessment for birds, not mammals. Additionally, extrapolated LD50/10s and geometric mean LD50/10s can be considered when comparing the LD50/10 and reproductive toxicity endpoints. Also read responses 20a and b, and 23.

Number	Stakeholder comment	HSE response
	mammals, and whether the LD50/10 consideration can make use of extrapolated endpoints and/or geometric mean endpoints where multiple acute toxicity tests are available.	

Changes to the evaluation of field effect studies and other methods that integrate exposure and effect assessment - Section 7 and Annex G of the EFSA guidance

Number	Stakeholder comment	HSE response
27	We acknowledge that additional guidance on the integration of exposure and effects assessment, including field effect studies, addresses a recognised need. However, there is concern about the practicality and proportionality of the proposed approaches. Requirements such as the '30% rule' and the use of the CAT are considered difficult to apply in practice. Some of the changes are insufficiently justified, and especially the CAT approach is considered to be of limited added value, while the increased procedural complexity risks constraining expert judgement in higher-tier assessments. Overall, stakeholders support a GB-specific, pragmatic implementation of higher-tier assessments focused on relevance to GB conditions, with field studies used as a final and targeted refinement step, supported by clearer guidance on study design, interpretation, and the appropriate role of expert judgement.	Specific recommendations have been added to the 2023 EFSA guidance regarding the conduct of higher-tier ecological studies and field studies investigating toxic effects in focal species (Sections 6.5., 2-6., 5.5 and 7.1). These recommendations include an increase to the minimum number of sites or individuals to monitor. They have been developed in the context of conducting a risk assessment that is appropriate for conditions across the whole of the EU. HSE considers that this is beyond the requirements of an assessment which considers only GB conditions, hence for GB assessments these recommendations will be considered in a GB context, reflecting the lower diversity of conditions the assessment is required to cover. HSE will explore whether additional guidance can be provided to applicants on this subject in future, in light of experience gained applying this aspect of the new guidance. The use of the CAT approach for higher tier study evaluation is considered optional for GB submissions.

Number	Stakeholder comment	HSE response
28	Appreciate the detailed discussion on population models and enclosure studies as valuable tools for regulatory ERA. However, for field effect studies (but also ecological studies, for example on PT) some of the new requirements are very challenging/unrealistic due to practical limitations (for example landscape, site selection, number of species tested, sample size, control fields for acute effects).	Read response 27.
29	The evaluation of higher tier effect studies has become more demanding under the new guidance document, which is also expected to affect the extent to which industry can rely on already existing studies. In many cases, alternative refinement options are therefore likely to be preferred. Nevertheless, I still agree with the introduction of relevance and reliability evaluation of field effect studies using CATs.	Read response 27.
30	Additional instruction on the design, conduct and interpretation of field-effect studies is appreciated within the guidance document. However, we consider such studies only of use as a final step of refined investigation and limited to only specific situations.	Read response 27.

Changes in the risk assessment for products applied as granules - Section 8 and Appendix Q of the EFSA guidance

Number	Stakeholder comment	HSE response
31	No experience with kind of assessment yet.	Noted. It is understood that the need to conduct bird and mammal risk assessments for PPPs applied as granules is relatively uncommon.
32	There has not been a substantive change in the risk assessment framework for products applied as granules, including meaningful refinement options, for example where rapid decline is assumed. A dedicated transparent calculator is missing.	It is agreed that the changes are not substantive and that an available calculator tool for granule applications would be useful.

Changes in the risk assessment for metabolites - Section 9 of the EFSA guidance

Number	Stakeholder comment	HSE response
33	We agree that assessment of ecotoxicologically relevant metabolites should be performed primarily at active substance evaluation or renewal in combination with residue definition to ensure harmonised conclusions applicable across all products. It is recommended to include in the product submission a short confirmation/argumentation, why the active substance evaluation is applicable also to the product. There is strong concern that the EFSA 2023 approach introduces unnecessary complexity and excessive conservatism, particularly through combining generic parent RUDs with worst-case, substance-specific metabolite ratios, which can significantly overestimate realistic exposure. In addition, thresholds for toxicological coverage of metabolites are considered unrealistic given study design limitations, as studies were originally intended for consumer safety and not ecotoxicological internal exposure assessment, risking overly conservative and scientifically disproportionate risk assessments. For metabolites for which a long-term risk assessment is needed (for example if they are more toxic than the parent), the fTWA cannot be assessed as, according to Regulation 283/2013, long-term studies are not required.	HSE considers that identification of ecotoxicologically relevant metabolites should occur during the active substance evaluation. For GB PPPs, HSE will consider ecotoxicologically relevant metabolites identified during the most recent evaluation of the active substance, whether the active substance assessment was conducted to the 2023 or 2009 EFSA guidance. HSE consider that the approach in the 2023 EFSA guidance for assessing risks from metabolites is clearer and follows a stepwise approach. This should lead to more consistent evaluations and decision making. It is noted that in previous active substance submissions to HSE, deficiencies have been regularly identified in how metabolites have been evaluated by applicants. HSE will explore providing training for applicants on consideration of metabolites in bird and mammal risk assessment.

Number	Stakeholder comment	HSE response
34	The assessment of metabolites under the new guidance is leading to the introduction of new endpoints at product level. In some cases as many as eight new metabolites are being identified due to inadequate historical data and alignment between Absorption, distribution, metabolism, and excretion (ADME) studies and crop residues. This is introducing new endpoints at product level which has been rejected so far by HSE for fTWA and BMD.	Read response 33.
35	On the one had appreciate more guidance and that this topic is properly addressed, but parts of the new metabolite risk assessments are way too complex and confusing, which will just lead to inconsistencies in submitted risk assessments and evaluations. Link to TWA applicability due to forced AUC approach is not scientifically reasonable if, for example, just the max metabolite levels are used as refinement.	Read response 33.
36	Clear and straightforward scheme although many points still need EFSA's clarifications.	Read response 33.
37	We appreciate the clarity of the step-wise presentation for metabolite risk assessment.	Read response 33.

Changes in assessing risk to birds and mammals through bioaccumulation, biomagnification and secondary poisoning - Section 10 and Appendix R of the EFSA guidance

Number	Stakeholder comment	HSE response
38	We agree that secondary poisoning assessments can be performed in cases where suitable and scientifically robust models are available. But for earthworm-eating species following the pore-water approach and for benthic-invertebrate eating species, a risk assessment cannot be performed until corresponding GB-relevant exposure guidance is updated and clearly defined. At this stage, exposure cannot be calculated in Great Britain. Also, in EU the relevant guidance (PERSAM for soil and FOCUS repair for surface water) has not yet been implemented. Additionally, we would like to make HSE aware of the fact that changes to the selected model species from the old guidance to EFSA 2023 are insufficiently justified. The EFSA 2023 approach relies on model species with unclear ecological realism, for example small birds feeding on fish/benthic invertebrates.	Until suitable methodology for assessing exposure is adopted in Great Britain, risks to earthworm-eating species via pore water and risks to benthic invertebrate-eating species will not be considered for GB submissions. If/when such methodology becomes available, HSE will consider these aspects of the guidance further at that stage.
39	The new scenario for secondary poisoning via benthic invertebrates needs further consideration. What mammals are relevant for this scenario (and are they found in the UK)?	Read response 38.
40	Pore water approach (earthworm-eaters) and benthic organism-eating aspects cannot currently be adopted. We agree with HSE's proposal not to adopt these aspects of the assessment until corresponding exposure guidance is updated and adopted for Great Britain.	Read response 38.

Changes in assessing risk via contaminated water - Section 11 and Appendix S of the EFSA guidance

Number	Stakeholder comment	HSE response
41	It is appreciated that exposure via soil-formed metabolites is possible for contaminated puddle water, so this is now explicitly in scope of the assessment. The retention of a screening step is appreciated but would preferably incorporate 'effective' maximum application rather than just total application rate.	It is agreed that the addition of consideration of risks from soil metabolites via consumption of puddle water is scientifically justified. HSE consider that it is appropriate to use the total dose application rate, rather than the effective application rate, in the screening step calculation, for simplicity. The effective application rate can still be used if a full quantitative risk assessment is triggered.
42	Good that soil metabolites are clearly addressed in the new guidance document. No critical changes compared to the previous methodology.	Read response 41.
43	We do not agree with the EFSA 2023 approach of directly using pore water predicted environmental concentration (PEC) values (top 1 cm soil) as a surrogate for puddle water exposure, as pore water is not accessible to birds and mammals unless diluted by rainfall, and the removal of an explicit dilution term (present in EFSA 2009) is considered unrealistic and overly conservative.	Until suitable methodology for assessing exposure is adopted in Great Britain, the pore water approach will not be considered for GB submissions. If/when such methodology becomes available, HSE will consider this aspect of the guidance further at that stage. HSE acknowledges the respondents comment that the approach is unrealistic due to the lack of explicit consideration of dilution by rainfall.

Changes in assessing risks from formulated products, including those containing more than one active substance - Section 12 of the EFSA guidance

Number	Stakeholder comment	HSE response
44	It is currently unlikely that sufficient data will exist to determine MDR for long-term toxicity to birds and mammals and the guidance does not appear to describe how this can be accounted for in long-term combined risk assessments. Furthermore, the use of MDR seems limited to account for indications of more-than-additive toxicity, whereas it would be appropriate to also adjust combined risk assessment for less-than-additive toxicity being demonstrated (MDR less than 0.3) using equation 56 of the guidance document. We would further propose that where experimental data is available on a mixture, that this should be considered in preference for mixture risk assessment being more representative of true mixture toxicity compared to estimated values. The consideration of mixture risk for exposure via drinking water and secondary poisoning is new compared to the previous (2009) guidance. We appreciate that combined exposure could occur via these routes, but the guidance offers no assessment approach beyond simple dose addition. Further approaches may be needed and so should be developed, or at least reasonable additional considerations provided, for example time course to peak exposure per-substance, toxic mode of action differences.	HSE agrees that in many cases formulation data will either not be available or not be sufficiently reliable to allow a robust MDR to be determined, and HSE would not support the generation of new data for this purpose. Generally, HSE would expect to see active substance toxicity data used in combined risk assessments for birds and mammals, rather than formulation toxicity studies. It is expected that risks from PPPs containing multiple active substances will generally be considered at the product evaluation stage. HSE will review the need to update existing guidance on combined risk assessment for GB applications (Formulation studies and combined risk assessment in ecotoxicology) in light of the 2023 EFSA guidance.

Number	Stakeholder comment	HSE response
45	We disagree with the introduction of the model deviation ratio (MDR) as a default element of combined risk assessment for formulated products, as it is considered scientifically insufficiently supported and likely to lead to overly conservative outcomes. Key concerns include the unsuitability of acute formulation studies for reliable MDR derivation, unclear justification for the proposed threshold of 3, unsupported extrapolation from acute mammalian data to chronic bird and mammal risk, and lack of guidance on interpretation or follow-up of high MDR values. We therefore do not support adoption of the MDR approach and recommend continued use of the existing UK national formulation guidance (HSE, 2022).	Read response 44.
46	Previous ability to check if one a.s. was driving the risk assessment was useful.	If it can be demonstrated that one active substance (or metabolite) is driving the risk assessment, HSE would not require further consideration of the combined risk.
47	The guidance appears to state that for products containing multiple active substances, if one active substance is not suitable for use of TWA of less than1, then it should not be applied to any of the active substances in the product. No reasoning for this is given in the guidance. This is overly conservative, not scientifically justified and may significantly increase costs for companies developing products.	HSE agrees that it should be considered on an individual active substance basis whether a TWA of less than 1 can be used for that active substance (even as part of a combined risk assessment).

Changes to uncertainty analysis and weight-of-evidence consideration - Section 13 of the EFSA guidance

Number	Stakeholder comment	HSE response
48	We acknowledge that the 2023 EFSA guidance further formalises uncertainty analysis and weight-of-evidence considerations, but there is broad agreement among CropLife members that the practical usability, regulatory consequences, and added value remain unclear. The process is seen as highly formalised, subject to interpretation, and rarely requested or applied in practice, raising doubts about how it will be consistently implemented and used in decision-making.	HSE consider that for higher tier risk assessments, an evaluation of uncertainties and/or weight of evidence can help characterise the risk and can aid with risk communication. The uncertainty table used in the 2023 EFSA guidance is simpler and clearer than in the 2009 EFSA guidance.
49	Understand the general logic behind these assessments, but often seems very redundant to the actual risk assessment. If used by HSE, should at least be made clearer that this is not an applicant task but will be done by the evaluator.	It is agreed that uncertainty analysis and/or weight of evidence consideration should be performed by the regulator, rather than the applicant.
50	Historically this part of the guidance was seldom applied by risk assessors.	See responses 48 and 49.

Addition of the EFSA birds and mammals calculator tool - Section 15 of the EFSA guidance

Number	Stakeholder comment	HSE response
51	We broadly welcome the principle of having a calculator tool to support bird and mammal risk assessment. However, there are concerns over the current EFSA online calculator and we believe that the current EFSA tool is not fit for regulatory use. Key concerns include its black-box nature, limited transparency of default input parameters, unresolved bugs and errors, and poor traceability and reproducibility due to non-transparent version updates that can lead to different outcomes for the same assessment. The availability of a stable, validated, and fully transparent tool is essential, either through a consolidated EFSA version or a GB-specific alternative provided by HSE. The latter would allow HSE to influence further development and handling of errors.	HSE acknowledge the concerns raised regarding the EFSA online calculator tool. HSE is not able to provide an alternative GB-specific tool, but will explore options to assist applicants with their submissions.

Number	Stakeholder comment	HSE response
52	We generally welcome the availability of a calculator tool to aid in risk assessment. However, there are some concerns over the current EFSA online calculator tool. Firstly, this is an EU/EFSA tool, so HSE have no direct influence over its development or any identified errors with the tool. It should therefore be carefully considered by HSE how such errors are identified and addressed during the course of evaluations. Similarly, HSE should clarify how it will handle the evaluation of assessments performed under previous versions of the tool, as regular updates are currently being made. The tool is also not currently comprehensive to cover all aspects of the bird and mammal risk assessment. Finally, it is questioned whether HSE will require applicants to provide input and/or output files for the tool in support of GB submissions.	HSE will check bird and mammal risk assessments using the version of the EFSA calculator tool available at the time of evaluation. It is anticipated that any changes in outputs between versions of the tool used in preparing and evaluating the dossier would result from the correction of errors, hence it is appropriate to use the updated version. Where this has any impact on the outcome of the risk assessment, applicants will be given opportunity to respond and update their assessments (we would provide this at the earliest opportunity and would retain the option for the standard request for information in addition). The submission of input/output files to HSE for use in the calculator tool is encouraged. Also read response 51.
53	Not transparent and so tedious to use.	Read response 51.
54	I generally agree with the tool being a useful addition. However, the lack of transparency and communication over change/version control is a concern. The tool often is slow or does not work, and bugs are still present even though it is now in use for EU submissions.	Read response 51.

Number	Stakeholder comment	HSE response
55	It is a terrible tool - does not work well, crashes, does not allow all options, and is black box. An Excel spreadsheet calculator is much easier (for long-term risk assessment at least - the acute is a bit more complicated due to the new method of MAFac calculation). I recommend HSE's Chemicals Regulation Division make their own calculator, which could be simplified by only containing GB-relevant scenarios.	Read response 51.
56	The tool is currently not fit for purpose. The version control log is inadequate and does not fully detail the dates and details of the changes made. Significant errors are arising from the tool including DT50 values not being considered in Tier 2 calculations, incorrect diets assigned to focal species. Combined assessment with metabolites not working, inability to always generate Tier 1 report.	Read response 51.
57	The calculator tool is difficult to use and also it can easily time out and data entry can be lost more easily.	Read response 51.
58	Still not working correctly. Very time consuming to work with and not convenient. Browser-based and click-heavy interface (instead of spreadsheet-based such as the Northern Zone calculator, for example) with online-only functionality is also a clear downside.	Read response 51.

Number	Stakeholder comment	HSE response
59	Not always possible to reproduce tool results when the calculations are done manually; because of frequent tool version updates, results may differ significantly between different versions and this is an issue in case of dossier submissions using previous tool versions.	See response 51.

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