Outcome of the 2025 GB Physical, Chemical and Technical Properties Guidance Survey

Outcome of survey on a GB specific guidance document for physical, chemical and technical properties for plant protection products.

Introduction

In GB the assessment of physical, chemical and technical properties for plant protection products (PPPs) is currently conducted according to this draft guidance document:

The Health and Safety Executive (HSE) conducted a survey between 6 March and 4 April 2025 to seek stakeholders views on the GB specific guidance document prior to implementation. This document provides a summary of the comments received during the survey and a response to these comments by HSE.

Screening and evaluation of the comments received

A total of 14 responses (sometimes making more than one point) were received relating to the changes in the physical, chemical and technical properties guidance document for GB. All comments received have been tabulated with reference to the section of the guidance to which the comment referred, with one row for each response. A summary of the number of comments received are provided in Table 1 and all the detailed comments are listed in Table 2, with a response by HSE. The survey stated HSE will only consider responses to the survey that specifically relate to the changes in the physical, chemical and technical properties guidance document and are relevant to the application of the guidance in GB. In the interests of transparency all comments have been reported.

Table 1: Number of comments received on the changes to the physical, chemical and technical properties guidance document for PPPs in GB

Section	Number of comments
Identity of the plant protection product (Section 1)	3

Section	Number of comments
Section 2, pages 11-15, covering Good Laboratory Practice, FAO specifications, analytical methods, test methods for physical, chemical and technical properties and ready to use preparations	7
Explosive and oxidising properties (Section 2.2)	2
Flammability and self-heating (Section 2.3)	4
Acidity/alkalinity and pH value (Section 2.4)	0
Viscosity and surface tension (Section 2.5)	1
Relative density and bulk density (Section 2.6)	1
Storage stability and shelf-life (Section 2.7)	2
Section 2.8, pages 32-35, covering CIPAC standard waters, test concentrations and adjuvants under technical characteristics of the plant protection product	2
Suspensibility, spontaneity of dispersion and dispersion stability (Section 2.8.3)	4
Degree of dissolution and dilution stability (Section 2.8.4)	1
Particle size distribution, dust content, attrition and mechanical stability (Section 2.8.5)	3
Emulsifiability, re-emulsifiability, emulsion stability (Section 2.8.6)	1
Flowability, pourability and dustability (Section 2.8.7)	1
Physical and chemical compatibility with other products including plant protection products which its use is to be authorised (Section 2.9)	1
Adherence and distribution to seeds (Section 2.10)	1
Other studies (Section 2.11)	1
Further information on the plant protection product (Section 4)	4

Section	Number of comments
Appendix 1 – requirements for the technical characteristics of the plant protection product	2
Other comments	2

Table 2: Detailed comments received on changes to the physical, chemical and technical properties guidance for PPPs in GB and HSE response

No.	Stakeholder comments	HSE comments
Identity of the plant protection product (Section 1)		
1	CRD are the regulatory authority for both GB and NI and reference is only made to assimilated regs and no comments are made between EU and GB requirements at all. It is not clear where this information is expected to be provided - Part C or will be in a new form? Reference is made only to UK REACH - does this encompass EU reach for NI products? We assume HSE will be doing 'checking' as well. It is still not clear in this guidance what is required in terms of labelling is g/L and %w/w ok only or are both needed? An example of 'A justification regarding the potential formation of any relevant impurities during the formulation process should be provided' would be helpful as this is new requirement? Does this go beyond 1107/2009 requirements? It is more like an Active Substance requirement.	The 2025 GB physical, chemical and technical properties guidance document will apply in GB only as stated on page 5 of the guidance. EU guidance (SANCO/10473/2003 – rev. 5) applies in NI. When the GB specific guidance is adopted and published on the HSE website, the website pages will provide information on which guidance should be applied to authorisation for GB and NI and where possible links will be provided to the relevant GB/EU guidance. Please note UK REACH applies to GB only. Both g/L and %w/w are required to be submitted for the evaluation. Labelling requirements are provided in the labelling handbook, a reference to this has now been added. HSE does not agree ‘a justification regarding the potential formation of any relevant impurities during the formulation process’ is a new requirement. Assimilated Regulation 284/2013 under section 1.4.3 states ‘a description of the formulation process should be provided’ and under section 5.1.1 ‘relevant impurities identified in the technical material or which may be formed during manufacture of the plant protection product or from degradation of the plant protection product during storage’. In addition, the dRR Part C template published on the HSE website states ‘insert information for any impurities of toxicological concern that can be formed’.

2	Maybe it makes sense to keep the reference to the guideline generic? e.g., "SANCO/10597/2003 in its latest revision?"	Revision numbers for guidance documents have been included to add clarity on what guidance documents apply in GB.
3	On page 10 it is stated that safety data sheets should be up to date. It would be appreciated, if a more concrete age would be stated like not older than one or two years.	Assimilated Regulation 284/2013 states 'Safety data sheets pursuant to Article 31 of Regulation (EC) No 1907/2006 shall be provided'. An age limit for safety data sheets is not provided in the guidance as there is no legal requirement for a supplier to update a safety data sheet unless there are relevant changes.
Section 2, page 11-15, covering Good Laboratory Practice, FAO specifications, analytical methods, test methods for physical, chemical and technical properties and ready to use preparations		
4	CRD need to be clear in the text if there are divergences from EU or GB requirements - CRD must already internal guidance for evaluators who are evaluating on behalf of GB and NI?	The guidance applies in GB only and therefore will not cover divergence between requirements in the EU and GB.
5	FAO specification proposal: Plant protection products should comply with relevant FAO specifications. FAO specifications apply to a single active substance and its formulations covered by the specified formulation types, but not to formulations with multiple active substances. If developed under the new procedure, FAO specifications apply only to the products of manufacturers whose data has been evaluated. Therefore, if an FAO specification exists, any deviation from it shall be described in detail and justified.	HSE partially agrees with the proposed text. The guidance has been updated with the following text: 'Plant protection products should comply with relevant FAO specifications. FAO specifications for formulations generally apply to a single active substance and specified formulation types. If developed under the new procedure, FAO specifications apply only to products of manufacturers whose data have been evaluated. Therefore, if an applicable FAO specification exists, any deviation from it shall be described in detail and justified.'
6	On page 13, the updated guidance for analytical methods is SANTE/2020/12830 rev. 2. In addition, on page 15, the reference needs updating too.	SANTE/2020/12830 rev. 2 has not been adopted in GB and therefore no update is required to the reference. Please also see comments under row 2.

7	Under sub-section “Chemical assay for physical and chemical properties” SANTE/2020/12830 rev. 1 guidelines are referenced instead of rev. 2. EC methods A.3, A.9, A.10, A.11, A.12, A.15, A.16, A.17 & A.21 are no longer part of the latest revision of EU Reg (EC) 440/2008. If the assimilated regulation 440/2008 is planned to get an update accordingly, the respective EC methods reference would lead nowhere (though Commission Communication 2023/C 344/02 and 01 still list these EC methods).	See reply to comment 6 regarding revision number of SANTE/2020/12830. The update to the EU Regulation 440/2008 does not apply in GB. The 2025 GB physical, chemical and technical properties guidance document aligns with the legislation that currently applies in GB (Assimilated Regulation 440/2008). This includes the EC methods along with other test methods. If amendments are made to Assimilated Regulation 440/2008, the guidance will be updated accordingly.
8	Analytical methods – we welcome this inclusion	Noted.
9	Ideally, the guidance should no longer try to link the EEC A.XX tests to the UN / CLP system, even if still referenced in what are now older EU CP regulatory texts such as the 2013/C 95/02. Or else guidance should clearly recommend utilizing only UN RTDG & MTC processes / test method options for relevant phys-chem data points to align with Global + GB Dangerous Goods and CLP classification requirements.	See reply to comment 7
10	(EC)No. 440/2008 referencing – to update to newer version of (EC) No. 440/2008	See reply to comment 7
Explosive and oxidising properties (Section 2.2)		

11	Do you want to add some specific text regarding a negative EC result, ie in line with page 14? Negative EC test result– UN test method is not required. It is assumed the same result will be obtained using the UN test method	HSE doesn't consider it necessary to add additional text to individual sections as this is already covered on page 14. The individual sections also reiterate in case of a positive result with EC test method, the appropriate UN test method is required to confirm classification.
12	"If data for explosive properties is not available on the SDS (Which SDS? co-formulant/tech a.s./formulation) or the SDS states 'not explosive' but no test result has been provided to support this statement, these cannot be regarded as negative test results. In this case, SDS' cannot be used to support the justification the product is not explosive". In the SANCO/10473/2003 – rev 5 document it is stated "by reference to the MSDS for all of the co-formulants and active substance, which demonstrate that they are not explosive)". Where "Not explosive" is stated on the SDS, that should be sufficient information for all co-formulants. When we test the formulation itself, we will have the necessary test results or justification, but not for coformulants. The same comment applies to oxidising properties too.	In section 2.2. on page 17 of the 2025 GB physical, chemical and technical properties guidance it states 'it may be acceptable to make reference to the SDS' for the active substance and all co-formulants to demonstrate they are not explosive'. Therefore, this text refers to the active and co-formulant SDS', not the specific formulation SDS. HSE disagrees that a statement of 'not explosive' on a SDS is sufficient when no test result has been provided to support the statement on the SDS. HSE do not expect applicants to test the individual co-formulants for explosive/oxidising properties, but the manufacturer or supplier of the co-formulant may have tested and included the information on the SDS. In this case SDS can be relied upon to make a case the formulation does not require classification as explosive/oxidising. It is noted a case for non-classification as explosive/oxidising can also be made based on the structure of the active substance and co-formulants in the formulation without reference to the SDS.
Flammability and self-heating (Section 2.3)		

13	Do you want to add some specific text regarding a negative EC result, ie in line with page 14? Negative EC test result– UN test method is not required. It is assumed the same result will be obtained using the UN test method	See reply to comment 11
14	EC methods A.15 and A.16 are no longer part of the latest revision of EU Reg (EC) 440/2008. If the assimilated regulation 440/2008 is planned to get an update accordingly, the EC method A.15 & A.16 reference would lead nowhere (though Commission Communication 2023/C 344/02 and 01 still list EC methods A.15 & A.16 as well). ISO/IEC 80079-20-1:201 is currently the guideline method listed in Reg (EC) 440/2008 for auto-ignition temperature (liquids, gases).	See reply to comment 7
15	Please double-check, if in Table 5 the criterium of category 2 (a) is correct. Shouldn't it be "Wetted zone does stop fire for at least 4 minutes"?	Noted, the guidance has been checked and updated.

16	Explanation of use of EEC A.16 a preliminary self-heating test and confusion with Grewer Oven test: This is essentially as per SANCO/10473/2003 –rev.5. Whilst what is stated in relation to the use and limitations of the EEC A.16 test is fundamentally correct (though test should no longer be relevant), the way EEC A.16 is utilised as a preliminary test could be better explained (whilst EEC A.16 is titled “self-ignition”, the data positive is the point at which the sample temperature reaches 400°C, not necessarily the oven, and does not mandate only an ignition event as a positive). The Grewer Oven Test (broadly like EEC A.16 but referenced in the UN RTDG MTC and CLP whilst EEC A.16 is not), is subsequently also annotated as a screening test for UN Test N.4. However, this is more prescriptive of the sample / oven temperature differential that triggers a positive for further evaluation of self-heating classification criteria. In which case, considering the EEC A .16 also being only a preliminary screening test as per its wording, it is unnecessary to list two screening assessments which are broadly doing the same thing under different regulatory mechanisms in the same guidance. This can then lead to confusion.	HSE is not requesting data from both screening tests; the guidance provides examples of acceptable methods for self-heating that applicants can use.
Viscosity and surface tension (Section 2.5)		
17	Surface tension: we agree with the alignment with method A5. SANCO/10473/2003 – rev 5 needs to be corrected	Noted.

Relative density and bulk density (Section 2.6)		
18	Density: *CIPAC methods can be referenced: CIPAC MT 3.1, MT 3.2, MT 3.3 and/or CIPAC MT 203 (provisional, see: CIPAC Homepage under Status new methods / CIPAC_MT_-_Superseded_Methods_v3_2025-03-22.pdf)*	Noted. The guidance has been updated to add in the following density methods: CIPAC MT 3.1, 3.2, 3.3 and 203. HSE will also conduct a periodic review to check the test methods are still valid and update these where necessary.
Storage stability and shelf-life (Section 2.7)		
20	A temperature of higher than 18-22 °C would reflect a worse case, right? Should this not be clarified? Is it enough to monitor the content of the impurities during accelerated storage or should it be done in both the accelerated and the ambient temperature storage study? This is not clear in the current draft revision. There is a spelling error under "accelerated testing", line 8 should read: "under the provision that shelf-life…"	A temperature of higher than 18-22°C may reflect worst case. However, where the storage tests are not conducted under typical conditions then the temperature during the storage period must be justified appropriate to the climatic conditions of GB (18-22°C). The content of relevant impurities should be determined before and after accelerated and ambient storage unless a scientific case can be provided that the relevant impurities will not form upon storage. Section 2.7 under the side-heading relevant impurities (page 28) has been updated in the guidance to clarify the requirement is for accelerated and ambient storage. HSE has checked the guidance for a spelling error.

21	Ambient testing (shelf life): proposal for rewording to avoid ambiguity of the meaning of “test” which should refer to “storage test” but not “test, e.g. pH test”.: “Real-time and ambient temperature testing is performed under ‘normal conditions’, usually over a period of two years. The results produced give a more accurate description of the likely properties and do not require extrapolation. ~~However, such storage tests require a prolonged testing period. These tests are also ,~~ Though such storage tests are ~~the most~~ appropriate in producing information on the stability of the packaging for a product, they require a prolonged testing period. ~~These tests are also ,~~ The storage tests should be conducted at ambient temperature. Storage temperatures must reflect the maximum and minimum temperatures likely to be experienced in a warehouse, farm store or garden store for amateur products. Where storage tests are not conducted under typical storage conditions then the temperature used during the storage period must be justified, appropriate to the climatic conditions of GB (18-22°C) and recorded in the study.”	HSE accepts the proposed text to clarify storage tests vs other tests. The guidance has been updated.
Section 2.8, pages 32-35, covering CIPAC standard waters, test concentrations and adjuvants under technical characteristics of the plant protection product		
22	The line breaks between “3” and “g in 250 mL” in the dilution stability entry.	Noted, the guidance has been updated.

23	Persistent foam: GB requirement (highest and lowest recommended concentration) greater the FAO & SANCO/10473/2003 – rev 5 requirements – can you please provide reasoning for requesting also the lowest recommended use concentration?	HSE recognises the lowest recommended concentration is not required in the FAO manual. However, the highest recommended concentration does not necessarily represent worst case when an anti-foam is present in the formulation. A case can be submitted in lieu of data at the lowest in-use concentration.
Suspensibility, spontaneity of dispersion and dispersion stability (Section 2.8.3)		
24	The updated guidance for analytical methods is SANTE/2020/12830 rev. 2. Please can this be updated on page 37 and page 38?	See reply to comment 6.
25	This section is not really clear: For MT 174, only gravimetric assay should be used, no matter if there is only 1 active or at least 2 insoluble actives? But, for suspensibility, the chemical assay should be used if there are at least 2 insoluble actives? Why mention this under Spontaneity of Dispersion then? Would it not make sense to keep that separate to avoid confusion? Is not revision 2 of SANTE/2020/12830 is currently in force?	CIPAC MT 174 only describes gravimetric assay, there is no option for chemical assay in the CIPAC method for water dispersible granules. The current guidance states chemical assay is required if there are multiple insoluble active substances which contradicts the CIPAC method, therefore, the guidance was updated to clarify what to do in this situation. Gravimetric assay is acceptable using MT 174 for multiple actives providing suspensibility data is available using chemical assay. The guidance text has been updated (see comment in row 26). Revision 2 of SANTE/2020/12830 has not been adopted in GB and therefore revision 1 applies at this time.

26	MT 174 Dispersibility of water dispersible granules proposal: “For the determination of spontaneity according to MT 174, gravimetric assay is prescribed by the method. Where there is more than one insoluble active substance present in the preparation, gravimetric assay is acceptable for MT 174, but the suspensibility using MT 184.1 should be generated by chemical assay.”	HSE accepts the proposed text. The guidance has been updated.
27	Would it be possible to mention that the concentration is in terms of product? I have seen dossiers were the test has been done in terms of active concentration. Also, the latest CIPAC suspensibility method is CIPAC MT 184.1, and this states the concentrations as 0.1 to 10%. The draft presented mentions CIPAC 184 throughout, surely the latest method should be quoted? Also, could be highlighted that spontaneity for granules is the gravimetric test (MT 174) and that MT 160 is not suitable for spontaneity of granules - seen dossiers that used the wrong method. The idea of the granule spontaneity is that the spontaneity of the whole formulation is determined (the break-up of the granule) rather than spontaneity of the active substance.	The product concentrations that should be tested are listed on page 34 in Table 9 rather than in each individual section. The table heading has been updated to make it clear this refers to product concentrations. The latest CIPAC method for suspensibility is MT 184.1 which is referenced in the 2025 GB physical, chemical and technical properties guidance. HSE agrees the concentrations in scope of the method for MT 184.1 are 0.1 to 10%. These are stated in Table 9 of the guidance. The guidance states ‘for the determination of spontaneity according to MT 174, gravimetric assay is prescribed’. In addition, it states MT 160.1 is for liquid formulations forming suspension on dilution with water and MT 174 is for water dispersible granules. Therefore, HSE does not consider any updates to the text are required.
Degree of dissolution and dilution stability (Section 2.8.4)		

28	Can't see the acceptable limit for MT 196 in the guidance.	Please refer to page 38 for the acceptable limit for MT 196 in the guidance.
Particle size distribution, dust content, attrition and mechanical stability (Section 2.8.5)		
29	There is a line break between “75” and “µm sieve”	The guidance has been checked and no update is required.
30	Wet sieve: DC formulation: GB requirement (before and after storage) greater than FAO & SANCO/10473/2003 – rev 5 (before storage only), however we agree with GB requirement.	Noted.
31	Particle size distribution: Proposal Inhalation “Where more than 1% of particles (w/w) are below 50 µm, then particle size of this dust should be determined by an appropriate method, e.g., CIPAC MT 187.” Justification: toxicological requirements should not be referenced to in phys-chem data requirements.	Toxicological requirements are referenced in the current guidance document so this is not a new addition. The current guidance states ‘an inhalation study may be required’ and the 2025 GB guidance states ‘inhalation toxicity should be addressed’. The change to the guidance is to reflect that studies may not be required and inhalation toxicity may be addressed by other means. HSE recognises the text could be clearer and has updated the guidance to ‘the potential of inhalation toxicity should be addressed’.
Emulsifiability, re-emulsifiability, emulsion stability (Section 2.8.6)		
32	Formulation types: EW & ME we agree with the determination of emulsion stability after low temperature storage. New CIPAC 36.4 will be presented June 2025 with several changes	Noted.
Flowability, pourability and dustability (Section 2.8.7)		

33	CIPAC MT 148.2 has superseded MT 148 & MT 148.1	Noted, the guidance has been updated.
Physical and chemical compatibility with other products including plant protection products which its use is to be authorised (Section 2.9)		
34	"Any convenience tank-mix must be supported by physical and chemical compatibility data, whether specific products are named or not." Clarification is required as to exactly what is required to be submitted to HSE for convenience tank mixes and what data should be available only at the manufacturer. Proposal for Convenience Tank mix: "Any recommendation for convenience tank-mix should be supported." (full stop, no details)	All tank mixtures should be supported by physical and chemical compatibility data. However, once the first tank mixture is authorised for any product containing that active substance, HSE will accept a compatibility assurance statement (CAS) and do not need to see the physical and chemical compatibility data. However, the data must be available for submission if requested by HSE. As this is stated in the guidance HSE does not consider any changes to the guidance for physical and chemical compatibility are required.
Adherence and distribution to seeds (Section 2.10)		
35	Tests should be carried out on seed from each crop or crop group on which the preparation is proposed for use. Extrapolations may be accepted from one seed type to another based on comparable seed size, shape and surface morphology. "The seed loading should be a determination of the active substance content of the seeds, and a validated method of analysis should be used. Where a preparation contains two or more active substances analysis of only one of the active substances should be justified."	HSE considers data is required on each active for seed loading. This aligns with the EU approach in SANCO/10473/2003 rev. 5.
Other studies (Section 2.11)		

36	There is still no addressal of Corrosive to Metals as CLP classification relevant to PPPs. It is hard for applicants to know if they need to address this point here.	Corrosive to metals is not a data requirement in Assimilated Regulation 284/2013. Therefore, HSE does not routinely require data to address corrosive to metals. However, if the applicant considers corrosive to metals data is necessary for the correct classification of the product the data should be submitted to HSE.
Further information on the plant protection product (Section 4)		
37	For effectiveness of tank cleaning procedures, clarification over whether a justification would be accepted instead of providing a validated method would be beneficial.	Please refer to the guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (SANTE/2020/12830, rev. 1) for method validation requirements for effectiveness of tank cleaning procedures.
38	Is not revision 2 of SANTE/2020/12830 is currently in force? It should be specified if the analytical method has to follow all requirements for methods for risk assessment (table 5 without extraction efficiency) or only the limited scope section 4.1.5. It should be explicitly stated that accelerated storage data is not accepted to support seepage, as it seems this is the case.	Refer to reply for comment 6 for revision number of SANTE/2020/12830. The guidance document is not intended to cover method validation requirements. Please refer to SANTE/2020/12830 rev. 1 for method validation requirements for effectiveness of cleaning procedures. HSE agrees it should be stated that accelerated seepage data is not sufficient to support authorisation. The guidance has been updated to add clarity.
39	It would be helpful if CRD could highlight the changes instead of having to go line by line between old and new guidance.	A summary of the key changes to the guidance will be published when the guidance is adopted to inform stakeholders of relevant changes for GB.

40	The method guideline on page 51 needs updating to SANTE/2020/12830 rev. 2	Refer to reply for comment 6.
Appendix 1 – requirements for the technical characteristics of the plant protection product		
41	Again it would be helpful if CRD highlighted the difference and also distinguished between GB and EU requirements.	A summary of the key changes to the guidance will be published when the guidance is adopted to inform stakeholders of relevant changes for GB. The guidance document is for GB only and therefore does not cover NI/EU requirements.
42	Section 4.1-4.6: How does this droplet size requirement apply if the fogging only takes place in closed rooms? Fogging equipment that is representative of the actual conditions is not expected to be the standard inventory of labs and usually has to be provided by study Sponsors.	Recent assessments have highlighted the importance of droplet size for fogging concentrates. HSE recognises it isn't possible to cover all situations in the guidance and therefore if the droplet size isn't relevant for a product a robust case can be submitted.
Other comments		

43	Could highlight if pH after storage needs GLP. As a technical characteristic GLP is needed for pH. pH is the only storage test that has a GLP requirement. Some companies may do a GLP study for GLP phys chem endpoints, then run all storage trials not to GLP - that would be a cheaper option. Would be good to understand that a non-GLP storage study would be completely acceptable if there was a GLP study for the essential phys chem bits (surface tension, pH, viscosity, etc....). It is noted that GLP does not mean the science is good (GLP = what was said in the study plan was done, the science can be rubbish and it is still GLP compliant). I would say that ISO compliant studies are of better quality than most GLP studies, as ISO audits the scientific reasoning of the methods.	GLP is required for pH before and after storage. Please refer to page 11-12 and 29 of the 2025 GB guidance document for a summary of the properties that are required to be to GLP. GLP is not an overall requirement for storage stability studies, but certain individual tests need to be conducted to GLP and therefore it may be advantageous to carry out all tests in the storage stability studies to GLP. Therefore, a non-GLP storage study would be acceptable provided a GLP study was available for the individual tests which require GLP. Please note pH is not the only storage test that is required to be to GLP. There is no change in the GLP requirements between the current and updated guidance. Please note it is a legal requirement to conduct regulatory safety studies in accordance with principles of GLP.
43	The guidance has much better layout and is easier to read. The new guidance needs to highlight by colour or bolding or other means any new requirements from the old guidance. The new guidance needs to address whether requirements are GB or NI (EU) or both and where the two diverge - this will become more important as divergence may increase. The cover of the guidance states 'GB' so are you going to being out 'NI' guidance then? It would be good to have this regularly updated.	To ensure the guidance document is clear and easy to read HSE is not able to highlight changes from the current guidance by colour/bolding text. However, a summary of the key changes to the guidance will be published when the guidance is adopted to inform stakeholders of relevant changes for GB. Please note this guidance document is for GB only and therefore does not cover NI. For NI, the following EU guidance applies: SANCO/10473/2003-rev.5.