Summary of changes to the physical, chemical and technical properties guidance document for plant protection products in GB

Section 1: Identity of the plant protection product

Section	Key changes to the guidance
1.1 Applicant	No changes.
1.2 Producer of the plant protection product and the active substance(s)	Reference to SANCO/10597/2003-rev. 10.1 added for additional sources of active substances.
1.3 Trade name or proposed trade name and producer's development code number of the preparation if appropriate	No changes.
1.4 Detailed quantitative and qualitative information on the composition of the plant protection product	Key changes include reference to the GB Pesticides Approvals Register, updated text for variants and an additional section for unacceptable co-formulants.

Section 2: Physical, chemical and technical properties of the plant protection product

Section	Key changes to the guidance
Good Laboratory Practice (GLP)	A list of properties that are required to be to GLP has been added. No change to the GLP requirements.
FAO specifications	New section.

Section	Key changes to the guidance
Analytical methods	Updates to bring the text in line with the latest revisions of the guidance documents, SANCO/3030/99 rev. 5. and SANTE/2020/12830 rev. 1.
Test methods for physical, chemical and technical properties	Text clarified for EC and UN methods but the requirements remain the same. Additional text to clarify other flashpoint test methods can be used for classification. Reference to CIPAC methods no longer supported has been updated.
Ready to use preparations	Formulation code AL added for ready to use preparations.
2.1 Appearance	No changes.
2.2 Explosive and oxidising properties	Updates to the text to align with the latest UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11 rev. 8 e.g. decomposition energy and decomposition onset temperature results. Definitions added for positive EC test results. Further information added to clarify when safety data sheets can be relied upon for the active substance and co-formulants to determine if a formulation is not explosive/oxidising.
2.3 Flammability and self-heating	Updates to the text to align with the latest UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11 rev. 8. Definitions added for positive EC test results for flammability. Further information added to clarify when safety data sheets can be relied upon for the active substance and co-formulants to determine if a formulation is not flammable/self-heating. Additionally, for self-heating classification criteria in line with Assimilated Regulation 1272/2008 have been added and details of screening studies.

Section	Key changes to the guidance
2.4 Acidity/alkalinity and pH value	OECD test guideline No. 122 added and clarified water types to be used to prepare the 1% dilution.
2.5 Viscosity and surface tension	Significant changes to the viscosity text to clarify the requirements. Definitions added for Newtonian and non-Newtonian liquids. For surface tension additional text has been added for if the highest in-use concentration exceeds 1 g/L in line with the test method.
2.6 Relative density and bulk density	Additional text to note density may also be required at 40ºC to calculate kinematic viscosity if the formulation contains at least 10% of a substance which has been classified as a Category 1 aspiration hazard.
2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	Additional text to clarify the requirements for relevant impurities before and after storage e.g. the relevant impurity content should not increase above the maximum allowed level in the formulation and data is always required for relevant impurities before storage. The packaging requirements for ambient, accelerated and low temperature storage stability have been clarified. Information provided on label amendments e.g. protect from frost and shake before use. Low temperature storage stability is required for all liquid formulations. Therefore, the text in the current guidance stating ‘protect from frost’ on the product label may be acceptable *in lieu* of cold stability test data has been removed. Ambient temperatures updated to reflect GB only.

Section	Key changes to the guidance
2.8 Technical characteristics of the plant protection product	Updates to the latest revisions of test methods and where relevant updates to test concentrations. Tap water added for the wet sieve test. Additional section for adjuvants.
2.8.1 Wettability	No changes.
2.8.2 Persistent foaming	No changes.
2.8.3 Suspensibility, spontaneity of dispersion and dispersion stability	Updates to CIPAC methods and methods guidance (SANTE/2020/12830, rev. 1) and acceptability limits added for re-suspensibility. Additional guidance added for spontaneity of dispersion if the preparation contains more than one insoluble active substance and MT 174 is used (gravimetric assay).
2.8.4 Degree of dissolution and dilution stability	Acceptable limit for MT 196 added.
2.8.5 Particle size distribution, dust content, attrition and mechanical stability	Key changes include updates to CIPAC methods and new text for hardness and integrity. For particle size distribution, where more than 1% of particles (w/w) are below 50 µm, inhalation toxicity should be addressed. The current guidance states an inhalation study may be required.
2.8.6 Emulsifiability, re-emulsifiability, emulsion stability	Label advice added if separation is observed.
2.8.7 Flowability, pourability and dustability	Update to CIPAC method.
2.9 Physical and chemical compatibility with other products including plant protection products which its use is to be authorised	Additional information added to clarify convenience and positive tank-mixes. No change to requirements.

Section	Key changes to the guidance
2.10 Adherence and distribution to seeds	Change in requirement for active substance loading if a preparation contains two or more active substances. Data is required for all active substances in the preparation for active substance loading. Additional text added to clarify requirements if new uses are requested for seed treatments.
2.11 Other studies	New sections for water soluble packaging, droplet size and disintegration of tablets.

Section 4: Further information on the plant protection product

Section	Key changes to the guidance
Effectiveness of cleaning procedures	Reference to the latest methods guidance added, SANTE/2020/12830 rev. 1.
Packaging	Key changes include recognition that SL formulations can be aqueous or organic based, clarification of seepage data requirements (ambient data required) and additional information for trigger packs.

Appendix 1: Requirements for the technical characteristics of the plant protection product

Section	Key changes to the guidance
All formulation types	Row for relevant impurity content (if applicable) added to all formulation types. Data is required before storage and data/case after storage for relevant impurities. Updates to CIPAC methods to latest revisions.
1.1 - 1.14 Common liquid preparations	Particle size distribution requirement added before storage for suspension concentrates in line with Assimilated Regulation 284/2013. No other changes to other common liquid preparations.
2.1 - 2.11 Common solid preparations	Information on water soluble bags in note 1 in the current guidance has been moved to section 2.11 other studies in the new guidance. The properties required to be generated with aliquots of an aqueous solution of the bag material have been added to the tables in Appendix 1. Information on how tablet dose uniformity should be determined has been added for all tablet formulations. Additional text for hardness and integrity has been added for tablets for direct application (DT) and water dispersible tablets (WT). For water soluble tablets (ST), the wet sieve requirement has been removed as the wet sieve test is already covered by CIPAC MT 196.

Section	Key changes to the guidance
3.1 - 3.5 Seed treatments	The Heubach test has been added to Appendix 1 for adherence to seeds for seed treatment formulations to be in line with the text of the current guidance. For emulsions for seed treatments (ES), the low temperature stability requirements have been updated in line with the latest FAO manual – the volume of separation of particulate or oily matter shall not be greater than 0.3 mL. Water soluble powders for seed treatment (SS) formulation code has been removed from the new guidance.
4.1 - 4.6 Miscellaneous	Fogging concentrates, hot fogging (HN), cold fogging (KN) – droplet size has been added as an additional requirement. The formulation code AL has also been added if a formulation is intended to be applied as a hot and cold fog.