Technical Agreements for Biocides Analytical Methods, Physico-Chemical Properties and Physical Hazards (APCP)

Version 4.2, April 2024

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Date	Change
18/12/2023	Insertion of 4.4 Insertion of 5.2 and 5.2.1 Insertion of 8, 8.1, 8.1.1
20/03/2024	Editorial amendments in 7.3 Addition of second paragraph in 3.1.3 (WG IV 2023)

1. Introduction

The Technical Agreements for Biocides (TAB) intends to provide in a concise format the general agreements of the Working Groups (WG) which have not yet been included in any other BPR related guidance documents. However, citations from other guidance documents are included to highlight the concept under discussion. This version includes issues until WG II 2022, as well as those parts of the Manual of Technical Agreements (MOTA v.6) of the Biocides Technical Meeting (TM) that were still deemed valid and relevant.

This document is intended to cover the technical and scientific WG agreements that have general relevance and to create a general database of questions where an agreement has already been reached. Relating to the assessment of individual active substances and biocidal products, only agreements of general relevance have been included.

The TAB is publicly available at the ECHA website.

The answers presented in the document are those agreed by the WG. They are not the official view of ECHA or the Commission.

The TAB is not a legally binding document. It is not an authoritative source of information, and when in doubt, the original documents cited should always be consulted. The main sources for the TAB are the adopted minutes of the WG (and the preceding document MOTA), and in all cases, a reference is given to the WG meeting or the TM where the agreement was reached. Nevertheless, it is highly advisable to follow the TAB recommendations to prevent referrals, WG discussions and possible non-approvals and non-authorizations.

2. Procedure

The TAB is a living document that will be updated over time with new additions.

The WG identifies agreements as new TAB entries in the course of its discussions. If an agreement is identified as a new TAB entry, a text proposal will be drafted by the owner of the respective agenda point unless differently agreed in the meeting.

A suggestion for a new TAB entry can also be proposed by any WG member or the SECR spontaneously as an agenda item for agreement in a WG meeting. If agreed, a refined text proposal will be drafted by the requester unless differently agreed in the meeting.

The text proposal is reviewed by the WG in a subsequent meeting to agree on the concrete wording. The subject matter should not be re-discussed.

To maintain consistency with previous practice, the reference meeting will be the meeting at which the issue has been discussed and/or the TAB entry has been identified, not the meeting in which the final text is agreed.

The TAB is applicable immediately unless specified otherwise.

SECR will update the TAB document regularly whenever new text has been agreed and publish the document.

(WG II 2023)

3. Active substances

3.1. Reference specification and reference source

3.1.1. Reference source under the Biocidal Products Regulation (BPR) (EU) No 528/2012

In summary, the following definitions have been agreed:

- A source is defined by the following information:
  - the applicant
  - the manufacturer
  - the manufacture location/plant location
  - the manufacturing process

- The specification is set by the applicants and should in general be derived from a 5-batch analysis. Quality control data might be used to refine or support the specification set by the applicant. In specific cases, it might be possible to refer to specifications set by other pieces of legislation (see 3.1.4). Nevertheless, these specifications need to be supported by analytical data.

- Reference specification can be defined as the specification compared to the test substance used in the provided studies and adjusted by the experts of toxicology, ecotoxicology and chemistry taking into account the content of the different constituents in the (test) substance. Hence, it can be regarded as a scientific refinement of the specification.

  - The experts can narrow or expand the specification using quality control data, the composition of the test substance or expert judgement using the physico-chemical, toxicological and eco-toxicological properties of the substance. A sound scientific justification should always be provided when the reference specification deviates from the specification.

  - There should always be one reference specification for one application. This also applies for an application, which includes several applicants, e.g. task forces. In cases of several applicants with their own active substance dossier, the reference specification with the lowest purity is taken for the inclusion in the Union list.

  - Reference source is the combination of a source and the set reference specification considering the provided studies (including the composition of the test substance). Each applicant (including consortia and task forces) might have its own reference sources.

(WG II 2014, WG III 2014, WG II 2015)

3.1.2. Reference specifications based on other pieces of legislation, European Pharmacopoeia or EN norms

The reference specification can also be set by referring to other pieces of legislation, e.g. food additives, European Pharmacopoeia or EN norms. In these cases, the reference has to be clearly identified with the exact title and year (date of issue). It has to be highlighted that also these reference specifications have to be confirmed by providing 5-batch analyses. The specification should repeat the criteria which are used in other pieces of legislation, European Pharmacopoeia or EN norms, and measurements of the substance from the source (manufacturing location) should demonstrate that the substance fulfils these criteria. When relevant, it should be justified why the norm is applicable (e.g. link to the relevant PT and uses).

In cases where the substances are listed in the European Pharmacopoeia and the manufacturing sites are certified according to the procedure of the European Pharmacopoeia a 5-batch analysis is not required. As the requirement for a 5-batch analysis can be considered to be covered by the certification procedure for including the manufacturing site into the European Pharmacopoeia. Therefore, in such cases the submission of certificates of analysis together with proof that the manufacturing site is certified are considered sufficient.

It has to be highlighted when a reference to other (legal) frameworks is made all parameters listed in this framework must be complied with. For example, the Commission Regulation (EU) No 231/2012 laying down specifications for food additives includes the entry E 260 Acetic acid which specifies the content of acetic acid and other parameters as boiling point, specific gravity, test for acetate, solidification point, non-volatile residue, formic acid, formates and other oxidisable substances, readily oxidisable substances, arsenic, lead and mercury; all these parameters must be determined and comply with the values indicated in this piece of legislation.

(WG IV 2016, WG I 2017, WG VII 2018)

3.1.3. Number of reference sources

The CAR can include as many (reference) sources as complying with the reference specification. However, these sources must be included in the CAR for approval of the active substance. All sources, which are not included in the CAR but used for biocidal products, must apply for the assessment for technical equivalence to ECHA before they can be used for product authorisation.

In case of several sources for one active substance dossier (e.g. a task force), one specification which captures all sources should be set. This is done by considering the specification for each source independently and combining the "worst case" concentrations of the active substance and the impurities to achieve the specification, i.e. lowest content of active substance and highest content of impurities. Note that all impurities should be stated in the specification, even if only present in one source. This specification is the basis to set the reference specification.

(WG III 2016, WG IV 2023)

3.1.4. Reference specification for UVCB substances

The constituents of UVCB substances are not subdivided into main-constituents and impurities, thus the purity of UVCB substances is always 100%. Nevertheless, the identities of the constituents and their content must be provided. The content of each constituent should be provided as a range which is based on the 5-batch analyses, its mean value ± 3 times the standard deviation.

(WG III 2021)

3.2. Substance composition and 5-batch analysis

3.2.1. GLP requirement for 5-batch analysis

The 5-batch analyses including the method development and validation of the method shall be conducted by a GLP certified laboratory. In cases the study was not conducted under the GLP requirements (e.g. for dossiers submitted under the BPD), quality control data need to be presented to support the analysis.

(WG IV 2014 and WG V 2015)

3.2.2. Age of 5-batch analyses

In general, the age of a 5-batch analysis shall not exceed 5 years based on the date of analysis; the date of manufacture of the batches shall also not exceed 5 years. In cases where the age of the 5-batch analysis is in the range of 5 to 10 years a justification has to be provided by the applicant (e.g. quality control data) to support the results of the 5-batch analysis and to proof that the batches are still representative for the manufacturing process and that the proposed specification still applies. 5-batch analyses conducted more than 10 years ago cannot be accepted and shall be replaced by a new 5-batch analysis.

According to the current approach, to calculate the age of 5-batch analyses, the date of submission of the draft CAR to ECHA for the accordance check is considered.

(WG III 2014, WG IV 2015 and WG I 2021)

3.2.3. 5-batch analysis is not possible due to annual production

In cases where a complete 5-batch analysis cannot be provided as one batch is manufactured per year only, the reference specification is set on the analytical data of the substance produced at the pilot plant. The company has to apply for the assessment of technical equivalence to ECHA when 5 batches are available. Nevertheless, the set reference specification has to be matched.

(WG V 2017)

3.2.4. Quality control data (QC)

When submitting QC the following issues have to be considered:

- Period of monitoring/age of the data: not older than 5 years.
- Frequency of monitoring and data points: all batches of the time period (<5 years) that can be summarised with the number of data, the maximum and minimum of the measured values. However with the possibility to request all (raw) data.
- What should be monitored: minimum purity, the content of significant impurities and the content of the relevant impurities; in case this information is not measured and therefore not available, a new 5-batch analysis might be requested.
- Outliers: outliers should be considered carefully on a case-by-case basis; blending might be possible or discarding of those batches.
- Quality system: in-house methods or general production methods are acceptable, that need not to be fully validated and specific. Validation data of the analytical method must be available and might be requested from the applicant.

(WG III 2016)

3.2.5. Certificates of analysis (CoA)

In general, the CoA should cover two blocks of information, administrative information and technical information.

The administrative information shall include:

- Header (Certificate of analysis)
- Name and address of the supplier or manufacturer
- Name and address of the manufacturer
- Name and address of the manufacture location/site
- Name and address of the testing laboratory
- Date, printed names and signature(s) of analysts
- Date, printed names and signature(s) of approver
- Date of analyses
- Lot/Batch number and size
- Date of Manufacture
- Product code or number
- Expiration date of the analysed substance

The technical information shall include:

- IUPAC-, CAS-, ISO- (if available) and general name of the substance analysed
- EC- and CAS-number of the substance analysed
- Appearance of the test material (e.g. powder including particle size)
- Stability and storage statement
- Name of the test, used analytical instruments and method applied (including analytical, physical and physico-chemical tests)
- Test result (which should include the chemical composition of the substance, at least the content of the active substance and relevant impurities.)
- Acceptance criteria (e.g. product specification)

(WG IV 2015)

3.2.6. Reference specification for active substances containing solvent

The substance definition according to Article 3(2) of the BPR is excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. In cases where the solvent cannot be removed from the substance without affecting its stability or changing its composition, the solvent is part of the active substance and its reference specification.

Nonetheless, the reference specification is set as dry weight but it also includes the solvent(s) without specifying a concentration value. Consequently, the exchange of the solvent requires

the assessment of technical equivalence.

Solvents in technical concentrates (TK) are not considered as part of the active substance. In consequence, such solvents in TKs of the substance require assessment at product authorisation.

In case where the solvent is used as stabilizer, the stabilizing effect has to be demonstrated experimentally, e.g. by chromatographic analyses or based on literature data, and a specification should be set for the solvent.

(WG V 2017 and WG II 2018)

3.2.7. Solvents used for extraction

Solvents that are used as extracting agent for plant extracts are not part of the substance' composition unless the solvent is necessary to stabilise chemically the constituents of the extract or cannot be removed without affecting the composition. They however need to be considered when identifying the active substance in terms of the manufacturing process (e.g. "Chrysanthemum cinerariaefolium extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbondioxide").

In this context, it should be noted that the extraction agents are also often used as a diluent for gaining a certain company grade of their products. As a consequence the actual concentrations of the extract constituents (and their properties) are diluted. Therefore the reference specification is set as described in 3.2.6.

(WG V 2017 and WG II 2018)

3.2.8. Additives to preserve the stability of the active substance

Additives that are needed to preserve the stability of the active substance are regarded as part of the substance according to Article 3(2) of the BPR. Therefore, these additives belong to the substance' composition and the reference specification. The stabilising effect of the additive must be experimentally demonstrated, e.g. by analysis with and without additive. In particular cases, it might be acceptable that the applicant provides a solid scientific sound justification. The justification has to be evaluated case-by-case and the acceptance of the waiving justification depends on the specific structure and property of the active substance.

(WG IV 2021)

3.2.9. Calculation method to derive the theoretical dry weight specification

The dry weight composition needs to be calculated and included in the CAR. For Union list inclusion, it was agreed that the REACH guidance for identification and naming needs to be followed and the purity should refer to the dry matter. For the Union list inclusion, the actual content of the substance is to be considered.

Following considerations need to be taken into account:

- 5-batch analyses are to be performed on the technical concentrate and not on the dry material since the data should reflect what it is actually manufactured. The purified material is to be used for determination of the physico-chemical properties.
- The dry weight can be calculated with the method of calculations:

$$CDWn\ (\%) = \frac{Cn(concentration\ in\ TK)\ (\%)}{\Sigma\ Cn\ (concentration\ in\ TK\ without\ solvent)(\%)} * 100\ \%$$

CDWn = dry weight concentration of constituent "n"

OR

$$content\ active\ (TC, dry)\left(\frac{g}{kg}\right) = \frac{measured\ value\ (TK)\left(\frac{g}{kg}\right)}{sum\ of\ measured\ values\ except\ solvent\ in\ \left(\frac{g}{kg}\right)} * 1000\frac{g}{kg}$$

- Solvents and additives. Additives are constituents of substances, which do not contribute to the naming of the substance, but they have to be considered for the substance composition. Therefore, a change of an additive triggers a technical equivalence assessment. Solvents, which are not needed for stabilisation of the substance or can be removed without affecting the substance composition, should be not considered for the substance composition.

(WG II 2014, WG III 2014)

3.2.10. Minor concentration isomers (<10% w/w)

According to the REACH guidance for identification and naming of substances, a mono-constituent substance is a substance in which one constituent is present at a concentration of at least 80% w/w and which contains up to 20% w/w of impurities. A substance as manufactured that contains an individual isomer at >80% w/w is considered a mono-constituent substance. All other isomers present in the substance at <10% w/w are generally considered impurities, unless it can be demonstrated that these isomers contribute to the efficacy of the substance. Isomers that are present at <10% w/w and make a contribution to efficacy of the substance can be considered as "minor isomers" in order to differentiate them from general process impurities. However, the information about the efficacy of each individual isomer might not always be available or difficult to generate. In such cases, the eCA should consult the working group members case by case to decide on the most appropriate name. ISO names can only be used if the isomeric composition described in ISO definition of the substance is met. Consistency with other legislations (REACH, CLH, and PPP) should be taken into account for the naming of active substances.

(TM II 2011, WG IV 2017)

3.2.11. Redefinition of active substances

In case where an active substance requires a redefinition according to Article 13 of Commission Delegated Regulation (EU) No 1062/2014, the following procedure was agreed:

- The eCA and applicant discuss and agree on the redefinition of the substance.
- The eCA initiate an early working group discussion (APCP) for the redefinition.
- The applicant is invited to the early WG discussion.

- During the early working group discussion, member states, applicant and ECHA can exchange their views and agree/disagree on the redefinition of the active substance.
- In case of disagreement, the active substance is not redefined.
- In case of agreement, the eCA informs officially ECHA about the redefinition after the working group meeting.
- ECHA updates the Registry.
- ECHA publishes the invitation to take over the role of participant.

(WG III 2016)

3.2.12. Commodity Chemicals

A legally binding definition of and selection criteria for commodity chemicals are not available. However, the CA-document 'Management of product authorisation for in situ cases' (CA-July19-Doc.4.1-Final (As amended by CA-Dec20-Doc.4.14, CA-March21-Doc4.10 and CA-Dec21-Doc. 4.6)) explains the term 'commodity chemical' as follows: "Well-known and widely used REACH registered industrial chemical not marketed for biocidal purposes." Thus, this definition shall apply to active substances and precursors used to generated active substances in situ.

(WG IV 2021)

3.2.13. Active substances that may allow reduced analytical information for active substance identification

The information requirements according to Annex II to the BPR apply to all active substances. However, the eCA may initiate an e-consultation for certain well-known substances for getting agreement on the required analytical information and whether the available results are sufficient to characterise the active substance. In cases where reduced information is sufficient or an alternative approach for setting the reference specification is acceptable, this procedure is also to be followed if an application for the assessment of technical equivalence will be submitted to ECHA. Further, active substances supplied by alternative suppliers, listed on the Article 95 list, must be approved as technically equivalent. It is the responsibility of the applicant for biocidal product authorisation that the used source is traceable.

(WG II 2017)

3.3. Technical equivalence and chemical similarity

3.3.1. Chemical similarity checks for the evaluation of multiple dossiers of the same active substance

For the evaluation of multiple dossiers of the same active substance, the assessment of chemical similarity is not regarded as necessary as the applicants have to provide their own complete and compliant data packages, which allow individual evaluations of the active substance. Hence, the applications refer to their own reference sources. Therefore, a chemical similarity check is not necessary as sufficient information is provided to support the approval of the active substance. However, in such cases more than one reference specification might be acceptable. It has to be noted that a combined CAR and list of endpoints needs to be provided by the eCA.

(WG II 2014)

3.4. Naming of (active) substances

3.4.1. General rules

As a general principle, the REACH guidance for identification and naming of substances should be applied for the naming of active substances as agreed at the CA meeting in 2007 (CA-March07.Doc.4.1.1). However, in cases where constituents with a content of <10% contribute to the activity of the substance, these constituents may also be considered for the naming of the active substance. In such cases, the eCA should consult the working group members case by case to decide on the most appropriate name.

(WG IV 2017)

3.4.2. ISO names

An ISO name can only be used if the ISO definition of the substance is met. ISO names of active substances are internationally recognised and used. Hence, a modification of an ISO name should be proposed carefully with consultation of the applicant. Generally, existing ISO names should be used as far as possible. However, in exceptional cases a change of an ISO name might be necessary.

3.4.3. Naming of glass substances

The name of glass substances should be based on the element(s) responsible for efficacy and the network formers of the glass with the addition "glass". The network modifiers are not contributing to the substance' name but they should be included in the reference specification.

Examples: silver borophosphate glass, silver phosphoborate glass, silver zinc phosphate glass

(WG II 2018)

3.4.4. Active substances are named according to their dry form

Regardless of the presence of solvent in the active substance, the name for the active substance will always be derived from the (theoretical) dry form.

The CAR should give clear information on the actual test substance.

(TM V 2007)

3.4.5. Consideration on experimental results of assessed physical and chemical properties, hazards and respective characteristics of the active substance under TC/TK

As mentioned in point 3.4.4, if an active substance is not available in a stable dry form and the solvent(s) cannot be removed, the applicant has to provide an explanation why data on the dry form cannot be generated. Consequently, experiments to assess physical and chemical properties, hazards and respective characteristics can be performed on the active substance as manufactured (TK form), which includes the solvent(s).

(WG II 2023)

4. Physical and chemical properties

4.1. General issues

4.1.1. Categorization of the physico-chemical properties

The physico-chemical properties should not be categorized. For example, water solubility cannot be expressed verbally, based on threshold values: very slightly soluble – slightly soluble – moderately soluble – readily soluble. Instead of verbal descriptions, actual values should be used in the report, avoiding terms like "high" or "low" as far as possible.

(TM I 2006)

4.1.2. Use of literature

The 'Introduction to guidance on the Biocidal Products Regulation Part A: Information requirements Volumes I – IV Version 1, March 2022 lists requirements for the use of public literature data. The criteria have been further specified as follows:

- Journals can be used if
  - The exact method is given
  - The purity of the test substance is indicated
  - The results are given and discussed
- Handbooks can be used for noncritical endpoints (density, melting- and boiling point)
- Data of Safety Data Sheets (SDS) **are not accepted**

Further, it was highlighted if different literature sources have conflicting results/data for an endpoint, a test on this endpoint or further explanation has to be submitted.

Literature referring to analytical methods can be used as long as it includes complete and sufficient information on the validation and its parameters.

(WG III 2017)

4.1.3. Use of FAO manual on development and use of FAO and WHO specifications for pesticides, 3rd revision, March 2016, and second edition, 2022

The ECHA's Guidance on the BPR: Volume 1 Parts A+B+C refers to the 2010 version of the FAO Manual. However, the 2016 and 2022 versions of the FAO Manual are available which include revised/new CIPAC methods. The impact of the revised CIPAC methods on the results of the studies was not investigated yet, which could impact the choice on which version to follow. However, from initial considerations it seems that results will not be significantly impacted.

It was agreed to allow applicants to follow the 2016 and 2022 FAO Manual when choosing the relevant CIPAC methods. However, studies performed according to the 2010 version should still be accepted, as this is the one mentioned in the ECHA guidance.

(WG VI 2018)

4.2. Surface tension

The trigger value for surface activity has been set to 60 mN/m at 20 ºC. This value is in accordance with the cut-off value of 60 mN/m as stated in point A.5 of COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). In this regulation, it is stated "Considering that distilled water has a surface tension of 72.75 mN/m at 20 °C, substances showing a surface tension lower than 60 mN/m under the conditions of this method should be regarded as being surface-active materials." The method described is based on OECD test guideline 115.

(TM III 2011, TM IV 2012)

4.3. Physical state (at 20 °C and 101.3 kPa)

The physical state shall be determined in accordance with the definitions given in Annex I, Part 1 of the CLP Regulation. Expert judgement can be used based on e.g. the composition or, for mixtures, the presence of thickeners. However, in case of doubt, appropriate test data shall be provided (e.g. vapour pressure and (initial) melting point) to allow proper determination.

The guidance for the application of the CLP criteria provides a way forward if it would not be possible to determine a specific melting point for a certain substance or mixture (i.e. viscous substances or mixtures). Such a substance or mixture must be regarded as a liquid, and thus not a solid, if:

- the result of the ASTM D 4359-90 test, as amended, indicates 'liquid' or;
- the result of the test for determining fluidity (penetrometer test), prescribed in section 2.3.4 of Annex A of ADR, indicates 'not pasty'.

In order to allow proper determination and to properly address the endpoint, at least one of the aforementioned tests shall be performed if it would not be possible to determine a specific melting point for a certain substance or mixture.

(WG II 2023)

4.4. Odour (at 20 °C and 101.3 kPa)

This paragraph shall only apply when no (historical) data is readily available for a substance and, thus, new testing would be required to cover the data requirement under the BPR.

For the interpretation of ECHA's Guidance on the BPR: Volume 1 Parts A+B+C (Version 2.1, March 2022), substances shall be regarded as hazardous by inhalation when they meet one or more of the below criteria:

- their classification, according to CLP, consists of one or more of the following hazard classes, regardless of the category in which they have been classified within each of these hazard classes:
  - Acute toxicity (inhalation)
  - Respiratory sensitization
  - Mutagenicity
  - Carcinogenicity
  - Toxic for reproduction

- Specific target organ toxicity (single and/or repeated exposure), but only if it is conclusively proven that the inhalation route causes the hazard or if the route causing the hazard has not yet been conclusively proven
- Aspiration hazard

- they are assigned one or more of the following supplemental hazard statements:
  - EUH071
  - EUH203, but only when linked to inhalation
  - EUH204, but only when linked to inhalation
  - EUH205, but only when linked to inhalation
  - EUH207
  - EUH208, but only when linked to inhalation
  - EUH212
- new testing would cause the operator to be exposed to particles <50 µm

Note: The same interpretation shall apply to mixtures, yet in this case the classification of the mixture shall be considered.

(WG IV 2023)

5. Methods of detection and identification

5.1. General issues

5.1.1. Validation of the analytical methods used to support environmental studies

Analytical methods used to support environmental studies have to be validated in order to ascertain that the method is suitable for the purpose. In case that a specific method is not validated a scientific sound justification need to be provided to conclude whether the method is acceptable for the purpose.

(TM I 2004)

5.1.2. Stereo isomers

The analytical method for the active substance shall be specific or highly specific to analyse each individual stereo isomer of the substance. Therefore, the stereo isomers should be analysed by chiral chromatographic method. In case of racemic mixtures, an analysis of the optical rotation may be acceptable.

(WG IV 2015)

5.2. Analytical methods for monitoring purposes

5.2.1. Animal and human body fluids and tissues

The terms "toxic" and "very toxic" are referring to Directive 67/548/EEC and should be

understood as documented in Annex VII of the CLP Regulation. The current entry in the ECHA Guidance on BPR, Vol I :

> *"Where an active substance is classified as **toxic** or **very toxic**, validated analytical methods must be submitted which allow determination of the active substance at the NOAEC.*
> *Residue definition*
> *Active substances classified as **toxic** or **very toxic** are considered to be the relevant residues in human body fluids and tissues. [...]"*

should be now interpreted in the meaning of:

"*Where an active substance is classified as **Acute Tox. 1 to 3** or **STOT 1**, validated analytical methods must be submitted which allow determination of the active substance at the NOAEC. ".*
Residue definition
*Active substances classified as **Acute Tox. 1 to 3** or **STOT 1** are considered to be the relevant residues in human body fluids and tissues. [...]"*

Let it be understood that the methods can be required for substances other than the ones classified as *Acute Tox. 1 to 3 or STOT 1*, should the toxicological experts conclude that monitoring methods in body fluids are relevant.

(WG IV 2023)

6. Biocidal Products

6.1. Composition of biocidal products

6.1.1. Non-active substances (co-formulants)

The chemical identity of co-formulants must be specified. It must be clearly indicated whether a co-formulant is a substance or mixture. In cases where the co-formulant is a mixture at least the components that are relevant for classification and labelling must be indicated with their identity and content and, if available, the identity of the component in a mixture that is responsible for the function of the co-formulant.

(WG VI 2017, WG II 2023)

6.1.2. Formulation chemistry of biocidal products

Information on the formulation process of biocidal products is not a data requirement under the BPR. However, it is useful for a better understanding of the composition and the formulation chemistry of the products to provide such information. Therefore, applicants would be well advised to provide details on the formulation chemistry and the possible interaction between components of the biocidal products. In particular, the functions of the non-active substances and their role in the biocidal products should be explained. If a chemical reaction is part of the formulation process of a biocidal product, information about residual starting material and side-products of the reaction in the final product should be provided.

(WG IV 2020)

6.1.3. In situ generation – presence of non-active substances/co-formulants in the precursor(s)

Co-formulants/non-active substances can be present in a precursor or mixture with precursors

applied to the generation process of the active substance. However, the function and the purpose of these non-active substances/co-formulants must be explained in detail for understanding whether the non-active substances are involved in any reaction during and after the generation process. Theoretical and experimental data should be provided for demonstrating that the non-active substances/co-formulants are not reacting during and after the generation process, thus their concentrations remain stable before and after the in situ generation of the active substance.

(WG III 2021)

6.1.4. Iodate in biocidal products: use as redox agent

Iodate (IO_3^-) and iodide (I^-) can be present as co-formulants in biocidal products containing iodine as active substance (a.s.). The function of these substances, usually designated as stabilisers within biocidal products, is not always adequately described. Therefore, further explanation is needed on the status of these two compounds within the scope of iodine containing product authorisations.

In the context of this document, the following two cases are explained for iodate (and iodide) present as co-formulants in true products:

1. Biocidal products formulated with: IO_3^- + I_2 , but no I^- present

The biocidal product is formulated with iodine (a.s.) and iodate (co-formulant) but no iodide is present. Iodine reduces over time, to a certain extent, to the degradation product iodide. Iodate and iodide (re)form iodine by a redox-reaction, which results in a stable iodine concentration in the biocidal product. A concentration increase of iodine in the biocidal product might be temporarily observed. It should be noted that no impact on the efficacy is expected. Therefore, iodate is regarded as a co-formulant acting as redox agent.

2. Biocidal products formulated with: IO_3^- + I^- + I_2

The biocidal product is formulated with iodate, iodide (co-formulants) and iodine (a.s.). Several chemical reactions may occur in parallel and can be described as:

a) Iodine (I_2) is reduced to iodide ($2I^-$);

b) Iodate and iodide react in a redox reaction to iodine.

Iodate and iodide (re)form iodine by a redox-reaction, which results in a stable iodine concentration in the biocidal product. A slight concentration increase of iodine in the biocidal product might be temporarily observed due to involvement of iodate and iodide in this reaction. It should be noted that no impact on the efficacy is expected. Therefore, iodate and iodide are regarded as co-formulants acting as redox agents.

For both co-formulants, the risk assessment of the biocidal product should take into account the maximum theoretical concentration of all iodine sources (meaning iodine and iodate and/or iodide that can be converted to iodine equivalents). However, in case unacceptable risks have been identified as a result of the consideration of total dietary intake of iodine (including co-formulants) due to the use of biocidal products, it is not considered appropriate to take risk management decisions in isolation with respect to the biocidal product.

Conclusion

Within the scope of applications for authorisation of iodine containing products, iodate and iodide as above explained are considered co-formulants with the function redox agents.

(BPC-24)

6.2. Physical, chemical and technical properties

6.2.1. Storage stability

6.2.1.1. Consideration about the storage stability tests

According to the article 18(a) ("…the promotion of best practices as a means of reducing the use of biocidal products to a minimum") of the BPR and annex VI, paragraph 77 ("…in order to assess if the recommended dose is the minimum necessary to achieve the desired effect ") of the BPR, overdosing is not acceptable and there are no criteria on overdosing available.

Due to the complexity of the different groups of UVCB substances, the assessment should be done case-by-case. It has to be highlighted that for UVCB substance not only the analytical data should be considered but also other parameters such as the analytical finger-print, physico-chemical properties, toxicity and eco-toxicity data may be used along with efficacy data after storage.

(WG I 2016)

6.2.1.2. Monitoring methods for relevant impurities, metabolites, degradation products and SoCs during storage tests

In cases where relevant impurities or SOCs are generated during product storage or their concentration is increased during storage, a determination of the content of the relevant impurities or SoCs before and after the storage stability test is required. Consequently, a fully validated analytical method is needed for those species.

An explanation should be provided in cases where the increase of a relevant impurity or SoC initially present in a product is not expected during storage. In these cases, they do not need to be included in the storage stability/shelf-life study and no validated analytical method is required.

(WG V 2015)

6.2.1.3. Transportation and storage on-site before use of the biocidal product

The question was raised which requirements apply to biocidal products that are stored on-site before use.

It should be differentiated between

a. storage of a biocidal product for supply and
b. storage of a biocidal product at the premises of the user of the biocidal product.

The latter is in the responsibility of the user who shall follow the instructions provided with the biocidal product. Biocidal products that are stored for supply have to comply with the information requirements included in Annex III to the BPR. In this context, it was noted that silos and tanks used on-site as containers before use are not regarded as packaging material and need not to be considered for long-term storage testing. This also apply for tanks used for transportation only.

(WG III 2019 and WG I 2022)

6.2.1.4. Peracetic acid (PAA) – storage stability tests

Peracetic acid is approved as an active substance in equilibrium with acetic acid and hydrogen peroxide. Therefore, the equilibrium components play an important role for the content peracetic acid. Consequently, it is not sufficient to monitor the content of PAA only but the content of hydrogen peroxide and acetic acid must also be monitored. Therefore, the storage stability tests (accelerated and long term) must include analyses and results thereof of PAA, hydrogen peroxide and acetic acid. When setting the shelf-life of the biocidal products all three components must be taken into account and shall not degrade by >10%. If so, further information and/or testing might be required, e.g. degradation products, efficacy tests.

(WG I 2022)

6.2.1.5. Data requirements regarding storage stability tests

In accordance with Annex III to the BPR, accelerated storage test(s) and long-term storage test(s) at ambient temperature are both data requirements. Hence, these must be provided or addressed when an authorisation application is submitted. The 'CG-53-2022-07 AP 14.1 Shelf-life setting at PA-vf'-document (September 2022), details the timelines and considerations, clearly distinguishing between national/union and simplified authorisation applications, regarding the submission of these tests in order to allow their timely and complete assessment.

It should be noted that although ECHA's Guidance on the BPR: Volume 1 Parts A+B+C (Version 2.0, May 2018) includes a reference to GIFAP (Croplife International) monograph no. 17 (Croplife, 2009) as primarily leading Guidance for storage stability tests, the decisions in the document 'CG-53-2022-07 AP 14.1 Shelf-life setting at PA-vf'[1]-and 'Post-authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation'[2] overrule the Croplife document.

6.2.1.6. Accelerated storage test

In accordance with ECHA's Guidance on the BPR: Volume 1 Parts A+B+C (Version 2.0, May 2018), if it can be clearly demonstrated that the biocidal product will not be subjected to temperatures above 30ºC during storage then accelerated storage data might not be required.

6.2.1.7. Shelf-life

A decision tree based approach, based on the applicable guidance, is used for the assessment of the shelf-life of biocidal products. The approach takes into account the storage stability data which was made available to the evaluating competent authority (or reference member state) in accordance with the provisions of the 'CG-53-2022-07 AP 14.1 Shelf-life setting at PA-vf'-document (September 2022).

It was decided at the CG meeting that the common practice of setting a provisional shelf-life based on accelerated data and requiring the full long-term storage stability studies as post-authorization requirement will not be accepted anymore. Hence, the shelf-life will be set based on the available data from the long-term storage stability studies and extrapolation from results of the data at elevated temperatures to two years at ambient temperatures cannot be accepted

[1] https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/f78774d6-9695-4803-a322-efd16ff42483/CG-53-2022-07%20AP%2014.1%20Shelf-life%20setting%20during%20PA_vf.docx

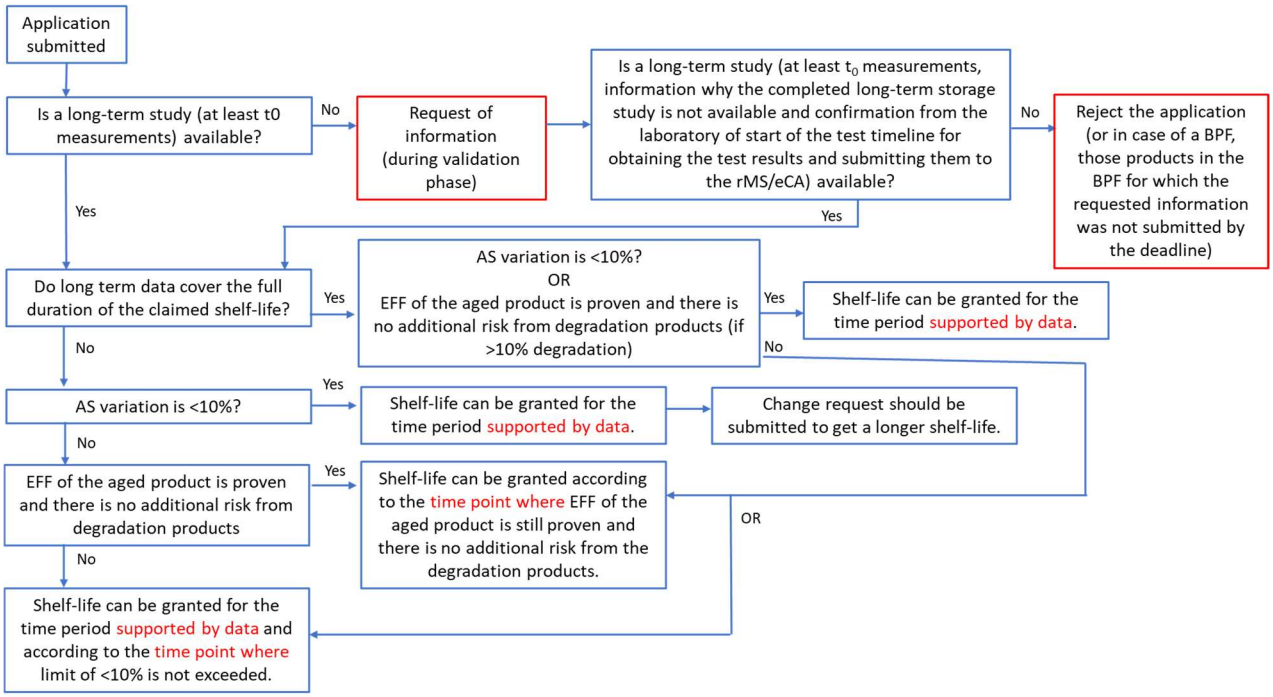
[2] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

anymore.

Due to differences in procedure and existing prior agreements between Member States, two distinct decision trees were made: one for national/union authorisation applications and one for simplified authorization applications.

It should be noted that these decision trees essentially deal with variations in content of the active substance(s)[3] measured during storage stability tests. However, for simplified authorisation applications, shelf-life can also be addressed based on efficacy data on fresh and aged samples (CG-30-2018-11 AP 7.2. E-c - Storage stability simplified authorisation). Nonetheless, hereunder is a non-exhaustive list of cases where these decision trees might not be directly applied:

- If the level of relevant impurities is higher than the defined value in assessment report of the active substance.
  How this should impact the shelf-life should be dealt with on a case-by-case basis depending on the impact of these relevant impurities on the toxicological and eco-toxicological assessment.
- If significant variation of physico-chemical and technical properties would appear during storage.
  How this should impact the shelf-life should be dealt with on a case-by-case basis depending on the biocidal product(s) and its use(s).
- If the biocidal product(s) is/are (a) bait product(s).
  The shelf-life must also be supported by palatability. Refer to efficacy data requirements and respective guidance.



[3] The OECD guideline and the Manual on development and use of FAO and WHO specifications for pesticides states that the decrease of the active substance should not be more than 5%, whereas a 10% threshold for degradation was agreed and applied previously under the BPD. Under the BPR, it was agreed that the 10% threshold should be applied (WG II 2017).

Figure 1 Shelf-life decision tree for national/union authorisation (CG-53).

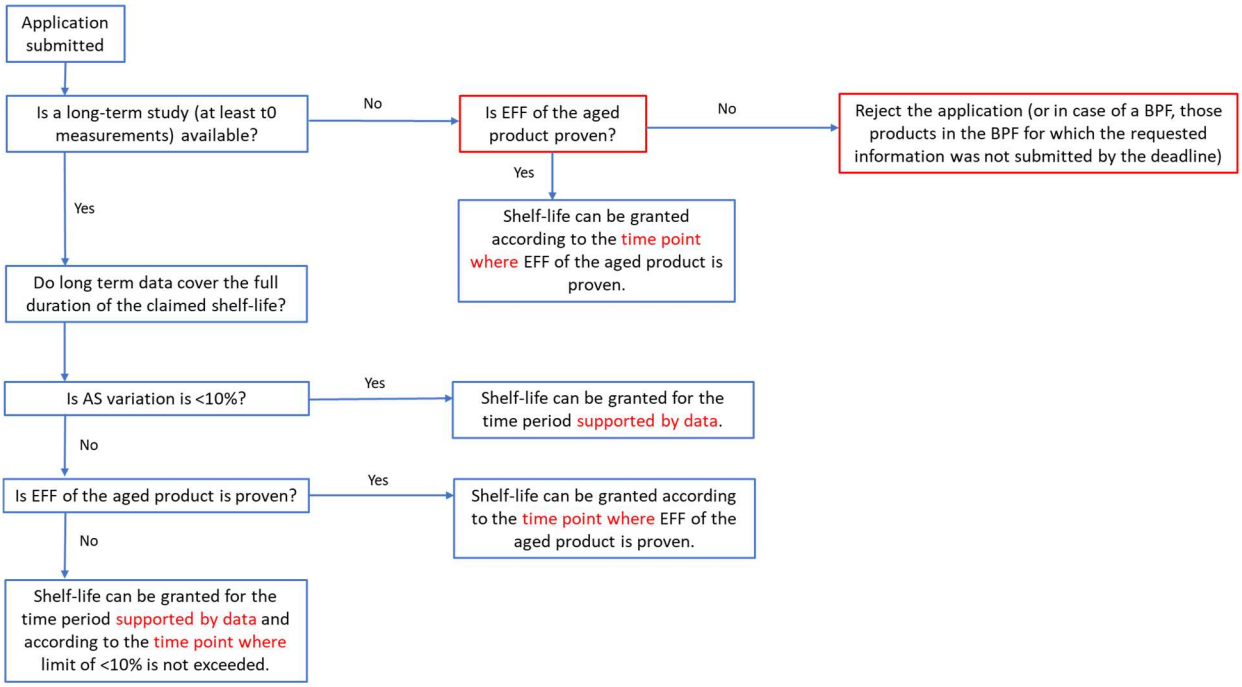


Figure 1 Shelf-life decision tree for simplified authorisation (CG-53).

6.2.2. Mass median aerodynamic diameter (MMAD)

The guidance on the BPR, Information requirements, Volume I section 2.6.5.6 provides unclear information about the situation when the MMAD must be determined. It is stated: "The particle size distribution of powder biocidal products and granules must be addressed … For all powder biocidal products and biocidal products that are applied in a manner that generates exposure to aerosols, particles or droplets then the MMAD (mass median aerodynamic diameter) must be determined." Hence, it remains unclear under which situations the MMAD must be determined.

All of the following criteria must be fulfilled if the determination of the MMAD will be waived:

1. The product is not sold together with a spraying device, applicable for solid and liquid products;
2. The MMAD is not required as an input parameter for the human exposure assessment;
3. The MMAD is not relevant to demonstrate efficacy.

In cases where the pressure of a packaging can change upon storage, MMAD should be provided before and after storage (e.g. AE formulations).

(WG VII 2018)

7. Physical hazards and respective characteristics

7.1. Waiving justifications for not testing on physical hazards – general considerations

7.1.1. Generic waiving statements

Generic waiving statements are not acceptable as they are not addressing the specific composition of biocidal products and active substances and the correlated chemical structures. Although, generic statements can introduce a waiving justification but substance- or product specific justifications must be included in scientifically sound waiving justifications.

Examples of unacceptable waiving justifications are without further explanations:

- study scientifically not necessary
- the study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties
- the dye contains azo groups but in such small amount which is considered to be insignificant
- the study does not need to be conducted because none of the components of the biocidal product family has explosive properties.
- the biocidal product is an aqueous solution
- the SDS does not indicate any physical hazards
- the substance is not classified, neither self-classified nor harmonised

(WG III 2021, WG II 2022)

7.1.2. Safety Data Sheets (SDS)

The waiving justifications with regard to physical hazards include very often references to safety data sheets (SDS) and the information provided therein. However, this information must be carefully considered and used as it is observed that the quality of this information is often not meaningful or reliable. Statements as 'not flammable' or 'not explosive' are not results but conclusions of possible results. It is not known for what reason(s) the conclusion was made and the capability of the substance(s) in a mixture to induce (certain) positive test results cannot be estimated. Consequently, such information cannot be used to support waiving of physical hazard testing. It should also be noted that statements on the SDS as 'not available', 'no information' or omitting information cannot be regarded as negative test results. In such cases the information is simply not available and cannot be considered for supporting the waiving of physical hazards.

In case data originating from an SDS are used as supporting evidence in a more elaborate waiving justification, at least an SDS with the indication of test results and applied test method of the relevant physical hazard test is required.

(WG III 2021, WG II 2022)

7.1.3. Harmonised classification

In cases where reference to a harmonised classification is made, the index number of the harmonised classification according to Annex VI to CLP Regulation must be provided. In this context it must be highlighted that missing classifications for (certain) physical hazard classes shall not be interpreted that the substance is not classified. In such cases it is the responsibility of the applicant to provide experimental tests or scientific sound waiving justifications. It should also be highlighted that the information requirements according to Annex II and Annex III to the BPR are still applicable even if the substance has a harmonised classification. Thus tests or scientific sound waiving justifications for all physical hazard classes must be provided by the applicant.

(WG III 2021, WG II 2022)

7.1.4. Chemical structure/composition of the active substance and biocidal product

7.1.4.1. Chemical structure

The guidance for the application of the CLP criteria provides the possibility to screen for chemical groups/functional groups that are associated with certain physical hazards. There are also examples of functional groups indicated in the guidance which may indicated physical hazards of inorganic materials. The Guidance on the Application of the CLP criteria (V 5.0, July 2017) and the Manual of Tests and Criteria (MTC) (Rev.7 (2019) and Amend.1 (2021)) provide a non-exhaustive list of functional groups that are indicative of e.g. explosives or self-reactive substances and mixtures. Bretherick's Handbook of Reactive Chemical Hazards provides details on functional groups and it might be consulted if a functional group is not included in the MTC or CLP guidance. In general, waiving due to the chemical structure might be justified but must include all functional groups of the structure In case of doubt or there is no information on the functional group(s) of the structure is available, the screening procedure should be continued or testing initiated.

In case of structural alerts of constituents present in the active substance or components included in the biocidal product, the alerts have to be seen in the context of entire chemical structure(s) and their concentrations. Thus, even low concentrations of constituents and components that show alerts may trigger a physical hazard. Therefore, applicants must provide a scientific sound justification, why a low content of alerting constituent(s)/component(s) is/are not triggering physical hazards for their individual biocidal product. In cases where a solid justification based on composition cannot be provided, the screening procedure for the respective physical hazard should be followed further according to the CLP criteria. In addition, it should be noted that the full composition must be considered and the constituents/components shall not be considered in isolation. Consequently, the following steps must be taken into consideration when waiving due to functional groups is applied:

1. With regard to biocidal products, there must be sufficient information on the composition of each co-formulant available for basing the waiving justifications on functional groups of the co-formulants. In cases where the compositions of co-formulants are incomplete or unknown, testing is unavoidable as even low concentrations of constituents may trigger physical hazards. In this context it should be highlighted that all constituents of substances/constituents of co-formulants with a content of ≥0.1% must be identified and known.

2. Information about substances can only be used if the applicant for product authorisation is the data owner or has a letter of access (LoA) to the data or if the information is in the public domain.[4]
3. The entire structures of all constituents and co-formulants must be taken into account, thus all functional groups of constituents of the active substance, and where applicable of co-formulants must be listed.
4. Analyses for each functional group must be provided why or why not it is regarded as a reactive group that cause physical hazard(s).
5. Analyses of the content of each constituent that may have reactive groups and its overall contribution to the physical hazard(s) must be provided.
6. The impact of solvent(s) present in the biocidal products must be investigated and a threshold concentration(s) where the possible physical hazard(s) starts to be suppressed must be derived.

Note: active substances do normally not contain solvents but in cases where it cannot be removed from the active substance the same approach applies.

(WG III 2021, WG II 2022)

7.1.4.2. Composition of the active substance and biocidal product

- The active substance is normally well-defined in its composition due to the requirement of 5-batch analysis and corresponding reference specification. Thus, the qualitative composition should be sufficient for considering waiving due to structural alerts where appropriate and possible.
- The composition of formulations/mixtures are normally described by the name of the individual ingredient / component without knowing the (exact) composition of them. The safety data sheets (SDS) are normally indicating only the purity or the content of relevant constituents but only in rare cases the full composition. If the complete qualitative composition of the formulations/mixtures is not known, waiving based chemical structure cannot be considered.
- Constituents of a substance or components of a mixture may have an indication for physical hazards or even classified for physical hazards. Thus, there is the possibility that the substance or mixture should also be classified. However, it is unknown which concentration of these constituent/components would trigger a positive test result. Therefore, it should be carefully considered whether waiving is justified (see also section 7.1.2).
- Presence of water: high concentrations of water can have a phlegmatizing effect but it is difficult to derive a threshold to totally suppress physical hazards. This should be

[4] To be understood as any information published in scientific literature or in electronic format (on internet). Conversely, the term "public domain" in copyright protection suggests that the information is not copyright protected anymore and may be normally used for free (e.g. the term of the copyright protection has already expired, information in certain open public repositories etc.). However, it is always advisable to enquire on the actual status of the "public domain" and to check respective copyright clauses. Applicants should be cautious in respecting copyright and should not automatically copy published studies, even if the publication itself has been lawfully acquired or accessed, without first having ascertained that the information may be lawfully used for the registration purposes. In case of published studies, it is recommended to check conditions of their use for regulatory purposes. (Guidance on Data Sharing, v. 4.0, p. 45)

dealt with case-by-case.

(WG III 2021, WG II 2022)

7.1.5. Waiving due to experience in use and handling of the active substance or biocidal product

Waiving of physical hazard testing based on experience in use and handling of the active substance and the biocidal product is possible. However, it should not be forgotten that physical hazards are based on specific designed methods which include specific test conditions and evaluation procedures. Therefore, the experience in use and handling must be comparable with the test method of the required test. Waiving justifications must include such comparison and applicants must explain why the experience in use and handling provides the same results as the test. Otherwise, a solid scientific justification must be provided why the test method(s) would not provide a different result than the experience in use and handling.

In addition, the test on corrosion to metals can be waived when the experience in use and handling results in a classification of the BP or the active substance. A proposed "non-classification" must be supported by testing.

(WG III 2021, WG II 2022)

7.2. Corrosion to metals

Corrosion to metals is so complex that the evaluation of a mixture cannot be extrapolated from similar behaviour of components of a mixture. However, if one component of a mixture is corrosive to metals the mixture is likely to be corrosive to metals as well. Testing the actual mixture is therefore highly recommended.

No test is required if the test item does not contain:

- halogens
- acids
- bases
- complexing agents

and

- if the test item is in the pH range between 5.5 and 8.5.

All above mentioned points **must be fulfilled**.

The following aspects are important:

- The interaction or reactions of ingredients play a role, i.e. the possible reaction products are to be considered
- Water content of organic substances: drop formation may occur during testing and the increase of concentration, causing localized corrosion.
- Classification is also required when the classification criteria of the corrosion rate of 6.25 mm/a are not met, but the criteria for localized corrosion are met
- Products containing corrosion inhibitors must be tested over the whole period of four weeks, since consumption of the corrosion inhibitor can lead to a retarding effect and thus to a possible underestimation of corrosive properties if the test is conducted for

only one week.

- For products containing reactive or unstable corrosive components (e.g. hydrogen peroxide or organic peroxides such as peracetic acid) these substances may be decomposed before the end of the test period. In these cases, a replacement of the test solution with fresh product in appropriate intervals should be carried out. Alternatively, analysis that shows that the composition of the test item at the end of the test period has not changed, should be provided.

Waiver examples which **are not acceptable**:

- Not applicable. The products are not transported or stored in steel or aluminium containers.
- Not applicable because the products do not contain substances classified as corrosive to metals.
- The commercial packaging types which are in contact with the biocidal product do not include metal containers.

(WG II 2018, WG II 2022)

7.3. Using DSC for waiving explosive properties and self-reactive substances

The measurement of the Differential Scanning Calorimetry (DSC) can be used as waiving justification of the end-points "explosives" and "self-reactive substances". However, quality gaps of these measurements have led to unacceptance of the test and the waiving justification. Therefore, certain conditions must be considered when conducting this measurement in the context of possible waiving of the hazard classes "explosives" and "self-reactive substances".

In chapter 20.3.3.3 of the UN Manual of Tests and Criteria (7th revised edition, 2019) some important aspects are already addressed:

- "The material of the sample vessel may influence the result"
- "Evaporation of constituents will lower the exothermicity (sealed sample vessels should normally be used)"
- "When differential scanning calorimetry is used, the heating rates should normally be in the range of 2 to 5 K/min"

The second point of special importance is the presence of water or other low-boiling solvents in a substance or biocidal product. In these cases, the unavoidable use of sealed sample vessels will lead to a significant pressure rise inside the crucible.

It should be noted that it is not possible to calculate back an endothermic evaporation utilizing the evaporation enthalpy of a solvent if e.g. an open sample was used.

In addition the following key points should be considered by the conducting laboratory when using DSC to assess explosive and self-reactive properties:

- The conducting laboratory should be clearly informed about the purpose of the measurement.
- Use sealed, high-pressure (HP) rated crucibles (up to 15 MPa and 22 MPa). Inert High Pressure (HP) DSC crucible is recommended by ASTM E537 for thermal stability hazard evaluation.

- Avoid unsealed or "hermetic" crucibles: hermetic (or crimped) aluminium crucibles are ubiquitous for other DSC measurements and used open, with a pierced lid, or hermetically sealed with a press. These crucibles are inappropriate for hazard assessment.
- Carefully consider the crucible materials of construction and interactions with your chemistry – avoid non-inert metals (Al) and polymer O-rings. Stainless steel or gold-plated crucibles are considered suitable.
- Representative samples should be taken.
- Sample preparation under inert conditions if required (purge gas: nitrogen).
- For best results, use the slowest practical heating rate: Heating rate of 2 to 5 K/min.
- Sometime, "rupture" of a DSC crucible is not obvious. Always check the mass loss after DSC run. Sample mass loss greater than 10% will be considered as rupture and the data will be discarded.
- Ruptures can potentially damage the Instrument, so do NOT overload tested sample: typical sample weight 5 – 10 mg.

Reporting:

- Exothermic decomposition energy: negative value; unit: J g-1
- If stated as "exothermic", the negative sign should be omitted.
- All exothermic decompositions with onset temperatures up to 500 °C must be considered and summed up.
- Report the equipment type, heating rate and exact crucible type.
- Precisely define the metrics used (e.g. onset temperature determined via extrapolation) to avoid confusion.

In addition it should always be considered whether other screening methods are possible or even preferable, e.g. calculation of oxygen balance or SADT determination. Regarding the latter, it should be noted that in 2021 the 1st Amendment to the UN-MTC (ST/SG/AC.10/11/Rev.7/Amend.1) was published, in which the information about test series H (SADT determination) has been updated.

(WG I 2022, WG II 2022)

7.4. Classification of hydrogen peroxide as oxidizing liquid

Classification limits for hydrogen peroxide concentrations differ between the CLP and the ADR (UN RTDG). The CLP regulation requires testing specifically for hydrogen peroxide however, for hydrogen peroxide it is known that the test method for oxidising liquids is not suitable and gives false results and therefore, the CLP Regulation mentions that experience overrules test results for oxidizing liquids (only in case of positive result experience).

It was agreed in the CG to use 'experience' from the transport regulation and for CLP follow the same classification limits. These limits are:

- H2O2 <8% Not Oxidising Liquid
- H2O2 8% to <20% Oxidising Liquid, Packing Group III, UN2984
- H2O2 20% to 60% Oxidising Liquid, Packing Group II, UN2014

- H2O2 >60% Oxidising Liquid, Packing Group I, UN2015

(WG II 2019, WG IV 2019, WG III 2021, CG 54 September 2022, WG II 2023)

7.5. Flammable liquids

For biocidal products, flashpoint measurement can be waived if:

- The water content is >80% and
- No flammable components are present.

The content of flammable components is irrelevant. Hence if one component is flammable is present, even in very low concentration, the flash point must be determined.

(WG II 2022)

8. Methods of detection and identification

8.1. Analytical methods for monitoring purposes

8.1.1. Animal and human body fluids and tissues

The current entry in the ECHA Guidance on BPR, Vol I:

> *"[...] Components of the biocidal product classified as **toxic** or **very toxic** are considered to be the toxicologically relevant components. They must be analysed for monitoring purposes if human exposure cannot be excluded."*

should be now interpreted in the meaning of:

"Components of the biocidal product individually classified as Acute Tox. 1 to 3 or STOT 1 are considered to be the toxicologically relevant components. If they contribute to the classification of the biocidal product as Acute Tox. 1 to 3 or STOT 1 (i.e. only when they are identified as SoC), then a method for their monitoring in body fluids and tissues should be requested".

Let it be understood that the methods can be required for components other than the ones classified as *Acute Tox. 1 to 3 or STOT 1*, should the toxicological experts conclude that monitoring methods in body fluids are relevant.

(WG IV 2023)