



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain  
Pesticides and Biocides

## NOTE FOR GUIDANCE

*This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.*

# **Technical Guidance Note**

## **on comparative assessment of biocidal products**

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## 1.- Introduction

- (1) With a view to achieving a high level of protection of human health, animal health and the environment, the biocidal products Regulation<sup>1</sup> ("BPR" hereinafter) aims to promote the substitution of active substances (ASs) of particular concern to public health or the environment, the so-called candidates for substitution (CFSs) as defined in Article 10(1) of that Regulation. The objective of the substitution goal in the BPR is to ensure that over time the use of these substances is restricted or even replaced by better alternatives.
- (2) Accordingly, in the course of granting or renewing the authorisation of a biocidal product (BP) that contains an AS that is a CFS, it is requested to compare the BP with other authorised BPs, non-chemical means of control and prevention methods ("non-chemical alternatives" hereafter) with regard to risks they pose and benefits from their use.
- (3) As a result of such a comparative assessment, a BP containing ASs identified as CFS should be prohibited or restricted where it is demonstrated that other available authorised BPs or non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages.
- (4) The results of the comparative assessment shall be forwarded, without delay, to the competent authorities (CAs) of other Member States (MSs) and ECHA and, in the case of evaluation of an application for a Union authorization (UA), also to the Commission. The conclusions from the comparative assessment will have to be integrated in the product assessment report (PAR) and shall be taken into account when granting or renewing the product authorisation.
- (5) Considering the number of active substances that may be CFS and the variability of potential authorised BPs and non-chemical alternatives that can be involved in a comparative assessment as well as the number of elements for comparison, it can be expected that in practice this is potentially a complex and resource intensive exercise.
- (6) Therefore, it is essential that comparative assessment at product authorisation or renewal is performed within the relevant deadlines and in a way that does not jeopardize the functioning of the whole regulatory system for biocides, which has to achieve other important tasks such as the review programme of ASs and the first authorisation of all BPs placed on the EU market.

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<sup>1</sup> OJ L167 27.06.12 p.1.

## 2.- Legal basis

- (7) In accordance with Article 23(1) of the BPR, the receiving competent authority or, in the case of an evaluation of an application for a UA, the evaluating CA (eCA), shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a BP containing an AS that is a CFS in accordance with Article 10(1) of that Regulation. This also applies to the applications for product authorisation referred to in Article 91 of the BPR.
- (8) As required by Article 24 of the BPR, the Commission shall draw up Technical Guidance Notes (TGN) to facilitate the implementation of Chapter VII and, in particular, Article 23(3).

## 3.- Scope

- (9) This document provides guidance on how an eCA has to carry out a comparative assessment and how it should be investigated and demonstrated that:
  - (a) for the uses specified in the application, another authorised BP or a non-chemical alternative already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;
  - (b) the chemical diversity of the ASs is adequate to minimise the occurrence of resistance in the target harmful organism.
- (10) This document has to be read in connection with the following notes for guidance:
  - (a) CA-March14-Doc.5.4-Final<sup>2</sup>, on "Comparative assessment of biocidal products".
  - (b) CA-March14-Doc.4.4-Final<sup>3</sup>, on "Compilation of available information on approved active substances with regard to certain criteria with a view to facilitate product authorisation".
  - (c) CA-March14-Doc.4.1-Final<sup>4</sup>, on "Principles for taking decisions on the approval of active substances under the BPR".
  - (d) CA-Nov14-Doc.4.4-Final<sup>5</sup>, on "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR".

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<sup>2</sup> Available at <https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e>

<sup>3</sup> Available at <https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d>

<sup>4</sup> Available at <https://circabc.europa.eu/w/browse/c41b4ad4-356c-4852-9512-62e72cc919df>

<sup>5</sup> Available at <https://circabc.europa.eu/w/browse/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c>

- (11) This TGN may be further adapted or developed when more experience has been gained through its use.

#### **4.- Definitions**

- (12) Relevant BP: the BP subject to comparative assessment containing one or more ASs that is a/are CFS in accordance with Article 10(1) of the BPR.
- (13) Comparative assessment: Specific part of the evaluation of an application for authorisation or for renewal of a relevant BP, which aims to compare, for the intended uses specified in the application, the relevant BP with other eligible alternative authorised BPs and eligible non-chemical alternatives with regard to risks they pose and benefits from their use.
- (14) Eligible alternative BPs: Any BPs authorised in accordance with Article 17 of the BPR for some of the intended uses specified in the application of the relevant BP. BPs authorised in accordance with Article 3 or 4 of Directive 98/8/EC<sup>6</sup> (the "BPD" hereafter) shall be considered as authorised in accordance with the BPR.
- (15) Eligible non-chemical alternatives: Non-chemical means of control and prevention methods that already exist on the EU market and for which the eCA, on the basis of the available information, considers that there is robust evidence that the alternative:
- (a) does not give rise to concern in terms of safety for humans, animals or the environment and,
  - (b) has demonstrated sufficient effectiveness under field conditions.
- (16) Adequate chemical diversity: Availability of a minimum number of different "active substances/mode of action" combinations within authorised BPs, which is sufficient to minimise the occurrence of resistance in the target harmful organism(s) covered by the uses specified in the application for authorisation or renewal of the relevant BP.
- (17) Overall risk for human health, animal health and for the environment:
- (a) For BPs: The overall integration of the conclusions of the evaluation carried out in accordance with the principles set down in Annex VI to the BPR, which are relevant to demonstrate that a BP complies with the required criteria under points (iii) and (iv) of Article 19(1)(b) of the BPR.
  - (b) For non-chemical alternatives: The overall integration of the conclusions of the evaluation carried out by a CA, which is sufficient to demonstrate that the alternative does not give rise to concern in terms of safety for humans, animals or the environment.

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<sup>6</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

- (18) Significant lower overall risk for human health, animal health and for the environment: This means that an eligible alternative BP or an eligible non-chemical alternative has a significantly better profile for the human or animal health or for the environment (depending on the main concern(s) of the CFS(s) contained in the product) and not significantly worse for any of those three aspects, compared to the relevant BP.
- (19) "Significantly better/worse" profile for human health, animal health or for the environment: this means that for one of these elements, the observed differences between the relevant BP and the compared eligible alternative BPs or non-chemical alternatives are not marginal but relevant in terms of biological significance for the safety to humans, animals or the environment.
- (20) "Not significantly worse/better" profile for human health, animal health or for the environment: this means that for one of these elements, the observed differences between the relevant BP and the compared eligible alternative BPs or non-chemical alternatives are only marginal and not relevant in terms of biological significance for the safety to humans, animals or the environment.
- (21) Biological significance: for the purpose of comparative assessment, biological significance requires expert judgment and is an estimate of the biological relevance of an observed difference between two results or observations subject to comparison, with respect to whether that difference has potential consequences, affecting the functioning of and risks to humans, animals or the environment.
- (22) Outlier BP: for the purpose of the comparison to be done at Tier I-A, this means a relevant BP having a significantly worse profile for the safety of humans, animals or the environment (depending on the main concern(s) posed by the CFS(s) contained in the product) than the majority of the eligible alternative BPs authorised for a same use.
- (23) Similar risk mitigation measure (RMM), hazard or precautionary statement (H/P-statement): for the purpose of the comparison to be done at Tier I-A, this means that an alternative BP is subject to RMMs or H/P-statements that are considered to be similar in terms of effectiveness, practicability and level of restriction than those applied in the relevant BP.
- (24) Better RMM or H/P-statement: for the purpose of the comparison to be done at Tier I-A, this means that an alternative BP is subject to RMMs or H/P-statements that are considered to be more effective and/or more practical and/or less restrictive than those applied in the relevant BP. This may also include the case where the alternative BP is not subject to any RMMs or H/P-statements.
- (25) Outlier value: for the purpose of the comparison to be done at Tier I-B, an outlier value is a result (or set of results) for the relevant BP that is separated from the majority of results (or set of results) for the alternative BPs. An outlier value can be proven statistically or using expert judgment.
- (26) Sufficiently effective (for non-chemical alternatives): this means that the overall integration of the evaluation carried out by a CA concludes that the alternative

provides similar levels of protection, control or other intended effects to those of the relevant BP for the same use.

(27) Significant economic or practical disadvantage (posed by the alternative BPs or non-chemical alternatives): for the purpose of comparative assessment, it means a quantifiable major impairment of working practices or business activity leading either to:

- (a) an inability to maintain sufficient control of the target organism or
- (b) the control of the target organism at very high efforts and/or disproportionate costs.

as a consequence of the substitution in the use of the relevant BP by another alternative BP or a non-chemical alternative.

## 5.- Mapping of existing alternatives to the relevant BP

(28) This section describes how an eCA should:

- (a) Define the intended uses in the application for product authorisation or renewal and decide which ones should be subject to comparative assessment,
- (b) Identify the alternative BPs and non-chemical alternatives that are eligible for the comparison with the relevant BP.

### 5.1.- Defining the intended use(s) in the application

(29) Paragraph (a) of article 23(3) focuses the comparative assessment on the uses specified in the application of the relevant BP; hence, each intended use of the relevant BP should in principle be addressed in the comparison. However, where the outcome of the overall assessment of the application shows that some intended uses cannot be authorised due to any safety or efficacy concerns, these uses can be excluded from the comparative assessment.

(30) In consequence, the eCA should only consider those uses to be included in the (draft) SPC of the product, as they would have been assessed and associated with any specific RMMs that are relevant for comparative assessment.

(31) A use is the result of the combination of the elements listed below within a given product type (PT), in connection with its respective RMMs and instructions for use:

1	Product Type	e.g. PT 19
2	Where relevant, an exact description of the authorised use	e.g. Repellent
3	Target organism(s) (including development stage)	e.g. Mosquito (adult)
4	Field of use	e.g. indoor use
5	Category(ies) of users	e.g. General public
6	Application method(s)	e.g. Spraying



- (32) Each intended use should be identified as per its description under section 4.1 of the draft SPC proposed by the applicant<sup>7</sup>. The same use can also include combinations of more than one target organism, user category or field of use. See some examples below:
- (a) PT 14: Use 1: Mice – non-professionals – indoor; Use 2: mice – professional and non-professional users – indoor; Use 3: rats and mice – professional – in and around buildings, open areas and sewers.
  - (b) PT 8: Wood staining fungi – professional users – spraying – outdoor,
  - (c) PT 19: Repellent – (adult) mosquitos – general public (above 12 years) – spraying – outdoor.
- (33) Elements 1 to 5 in the above table should be considered as the critical ones in order to focus the search for eligible alternative BPs. On a case by case basis, where the eCA considers that an application method makes that the BP is used in practice for very different purposes or under very different circumstances (e.g. manual vs. automated dipping wood preservatives), some application methods could be considered as separate uses to be covered under the comparative assessment.

## ***5.2.- Eligibility criteria for alternatives to the intended use(s) of the relevant BP***

### *5.2.1 For biocidal products*

- (34) Only eligible alternative BPs ("alternative BPs" hereafter) as defined in this document should be included in the comparison with the relevant BP. Therefore, existing products placed on the market of MSs according to the national systems operating during the transitional period shall be excluded from the comparison.
- (35) Alternative BPs will have to be authorised for at least one of the intended uses<sup>8</sup> in the relevant BP, even if they are authorised for other additional different uses.
- (36) Alternative BPs can also be authorised products containing an AS which is a CFS and that have been already subject to a comparative assessment themselves or, which are being subject to a “class” comparison as described in document CA-March14-Doc.5.4-Final (e.g. at the renewal stage).
- (37) Concerning the target organisms in alternative BPs, where the relevant BP claims to act against a specific category (e.g. a specific species of ‘cockroaches’), alternative BPs authorised for a broader category of that target organism (e.g. ‘cockroaches’ in general) may be included in the comparison if they are effective against the same target organism. For some PTs such as disinfectants or preservatives, claims concerning very specific target organisms should be given

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<sup>7</sup> For consistency, applicants are invited to consult the agreed "Application codes document" for the relevant PT.

<sup>8</sup> Where an authorised use of a BP is phrased in a slightly different way to the intended use in the relevant BP, this should not prevent an eCA from considering that BP as an eligible alternative BP.

further consideration (e.g. an antibacterial claim within PT 11 does not mean an efficacy against *Legionella*).

- (38) In principle, alternative BPs requiring a different application method for a given intended use of the relevant BP should still be considered as an alternative. Where a different application method might have an impact on the practical conditions of use of the alternative BPs, this should be taken into account and may lead to the conclusions that the alternative BP is not a suitable substitute for the relevant BP because of a significant economic or practical disadvantage.
- (39) An eCA will have to search for alternative BPs in the Register for Biocidal Products (R4BP). The summary of product characteristics (SPC) created in xml format by the SPC generator tool will be fully searchable for the authorised uses, provided that the information is available in the SPC<sup>9</sup>. For mutual recognition (MR) procedures, the reference MS (RefMS) should identify alternative BPs authorised under its own market as well as under other MSs markets<sup>10</sup> (see document CA-March14-Doc.5.4-Final).

#### 5.2.2 For non-chemical alternatives

- (40) Only eligible alternative non-chemical alternatives as defined in this document should be included in the comparison with the relevant BP. This evidence should clearly be indicated in the comparative assessment report to be sent to ECHA and MSs in accordance with Article 23(2) of the BPR. In the absence of such evidence, the non-chemical alternatives should be considered as non-eligible.
- (41) In order to identify them, the eCA should look at the information collected during the public consultation carried out by ECHA in the context of the approval or renewal of an active substance which is a candidate for substitution (Article 10(3) of the BPR)<sup>11</sup>. In this context, no further public consultation at MS level should be carried out. MSs are encouraged to relay ECHA's work towards their national stakeholders and to invite them to provide feedback directly to ECHA.
- (42) Where additional information on alternatives becomes available after the active substance approval or renewal, this information should also be communicated to ECHA by using the same templates and made available to CAs so that it can also be considered in the context of the comparative assessment.

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<sup>9</sup> CAs are invited to introduce the key elements in the SPC (e.g. those in paragraph 31) of the already authorised products in the R4BP in order to allow the searches for comparative assessment. A “priority list” could be set to identify products for which the information should be introduced in R4BP first (e.g. by PT; first authorisations or products not containing a CFS). A search tool for the authorised uses within the xml SPCs generated by the SPC generator will be developed by ECHA.

<sup>10</sup> Until the R4BP is populated with searchable SPCs and ECHA can further develop the search tool, RefMSs are only requested to compare the relevant BP to the alternative BPs authorised in their territory.

<sup>11</sup> See templates indicating what information will be required from third parties about available substitutes to facilitate the assessment of the risks and benefits of the suggested alternatives in terms of safety for the human health, animal health and the environment, efficacy and economic or practical disadvantages. They are available at <http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/public-consultation-on-potential-candidates-for-substitution>

- (43) For the already approved AS/PT combinations for which a comparative assessment is necessary at the product authorisation stage, *ad hoc* public consultations in collaboration with ECHA could be carried out. In the meantime and for the purpose of the identification of eligible non-chemical alternatives, the eCA should take into account any information becoming available to them:
- (a) In the context of a public consultation for another AS for the same PT and similar uses to the already approved CFS contained in the relevant BP,
  - (b) Via comparative assessments reports concerning MR procedures of BPs belonging to the same PT,
  - (c) By any other means (on-line available information, etc...).

## **6.- Tiered approach to comparative assessment**

- (44) When carrying out a comparative assessment, eCAs should follow a tiered approach preceded by a screening phase. Tier I focuses on the comparison of the relevant BP with the alternative BPs and Tier II with the eligible non-chemical alternatives.
- (45) In principle, an eCA is expected to carry out Tier I first as the required information for comparative assessment can be easier to reach and evaluate in the case of authorised BPs (e.g. through the R4BP) than for non-chemical alternatives. This approach also relies first on BPs as they have been evaluated according to harmonized rules and for which information is easier to collect and compare.
- (46) Where no alternative BPs are available or suitable, a comparison will be made with the identified non-chemical alternatives at Tier II. Nevertheless, where an eCA is aware of an eligible non-chemical alternative which is likely to meet the required criteria of Article 23(3)(a), Tier II can be performed first.
- (47) Both at Tiers I and II, the eCA will have to follow a step wise approach to prevent unnecessary additional efforts. The eligible alternative BPs or non-chemical alternatives should present i) a significantly lower overall risk for human health, animal health and for the environment, ii) no other significant economic or practical disadvantages and iii) being sufficiently effective for the use considered. Therefore, on the basis of the available information to them, the eCAs should focus first on those elements which comparison is likely to stop the comparative assessment at the earliest stage, where appropriate.
- (48) Regarding the overall risk for human health, animal health and for the environment, the comparison should focus first on the specific area(s) of concern posed by the CFS(s)<sup>12</sup> contained in the relevant BP (e.g. health or environment).

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<sup>12</sup> This means the substitution criteria referred to in document CA-March14-Doc.4.1-Final on "Principles for taking decisions on the approval of active substances under the BPR". Other criteria will be also considered when additional guidance is developed and experience is gained in the context of the AS approval.

Where no better alternative BPs or non-chemical alternatives exist for such area(s) of concern, no further investigations would be necessary and conclusions could be reached that there is no suitable alternative.

### **6.1.- Screening phase**

- (49) The screening phase shall allow through a simple assessment to judge whether it is pertinent or not to go further into the comparative assessment and if yes, up to what level of complexity (*see flow chart 7.1*).
- (50) In accordance with Article 23(b) of the BPR, the eCA has to check first if the chemical diversity of the available ASs within the identified alternative BPs can be considered as adequate to minimise the occurrence of resistance in the target harmful organism(s) (*see section 6.1.1 below*). As a general rule, where a CA concludes that there is not an adequate chemical diversity, no further investigations should be made and the comparative assessment could therefore be finalised at this stage.
- (51) However, where the CFS in the relevant BP is targeted by the exclusion criteria<sup>13</sup>, then the interest of substitution might prevail and the relevant BP should be subject to a detailed comparative assessment according to Tier I-B (*see section 6.2.2.*), whether there is adequate chemical diversity or not. In so doing, the relevant BP could be restricted or prohibited if alternative BPs, with the same active substances - mode of action combination (e.g. anticoagulant rodenticides) but with a better profile are available. This approach would be consistent with the substitution aim established by the BPR while having limited or no impact on the potential risk of resistance.
- (52) After this initial screening phase, a tiered approach as per the flow charts described in the annexes to this document should be performed to further streamline the comparative assessment process.

#### **6.1.1.- Chemical diversity assessment**

- (53) Article 23(b) of the BPR refers to the adequate chemical diversity of the available active substances as one of the two sine qua non conditions to be met in order to allow a restriction in the intended uses or the prohibition of the relevant BP as a result of comparative assessment.
- (54) Therefore, conclusions should be reached by the eCA on whether the chemical diversity of the available ASs within the identified alternative BPs can be considered as adequate to minimise the occurrence of resistance in the target harmful organism(s).
- (55) This availability of ASs should be also looked at taking into account the different user categories, so that chemical diversity is adequate in BPs authorised both for

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<sup>13</sup> A list containing information on the exclusion and substitution criteria agreed in document CA-March14-Doc.4.1-Final (Principles for taking decisions on the approval of active substances under the BPR) that are met by active substances on which an approval decision has been taken will be made available on Circabc and periodically updated by ECHA (*see document CA-March14-Doc.4.4*).

professional and non-professional users. An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.

#### *6.1.1.1.- Active substances/mode of action combinations*

- (56) As per the definition of adequate chemical diversity, a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection. Theoretically, the use of two different "active substances/mode of action" combinations would be the minimum number enabling that goal. However, if resistance appears to one of the combinations and the other is used systematically, resistance to the other remaining combination will be developed or selected soon.
- (57) Therefore it is proposed that as a general rule, at least three different and independent "active substances/mode of action" combinations should remain available through authorised BPs for a given use (e.g. mice – non-professionals – indoor<sup>14</sup>) in order to consider that the chemical diversity is adequate.
- (58) Where an eCA considers that the above general rule and/or a rotation strategy is not applicable for some PTs or some specific uses, the consideration of whether the available "active substances/mode of action" combinations can be seen as an adequate chemical diversity to minimise the occurrence of resistance should be assessed on case by case basis in accordance the principles set in Annex VI to the BPR regarding the effects on target organisms.

#### **6.2.- Tier I. Comparison to eligible alternative BPs**

- (59) At Tier I, comparison will first be made with other alternative BPs, to confirm whether or not some of these BPs fulfill the requirements of Article 23(3)(a)<sup>15</sup>. The comparative assessment should be conducted at different degree of details depending on the hazard properties of the CFS contained in the relevant BP:
- a) Tier I-A: This tier will have to be followed where the relevant BP does not contain a CFS meeting the exclusion criteria in Article 5(1) of the BPR. Under this tier, the comparison will be based on elements that are available at SPC level and to which eCAs can have access through the R4BP. Those elements could be risk or hazard-based (e.g. RMMs and/or hazard or precautionary statements).

Tier I-A will enable the eCA to conclude that substitution of the relevant BP by alternative BPs will not be appropriate. Therefore, comparative assessment should move to Tier II in order to compare the relevant BP with the eligible non-chemical alternatives. However, in cases where substitution will be identified as a possibility, a more detailed assessment of comparative risk shall be undertaken under Tier I-B.

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<sup>14</sup> E.g. Alphachloralose, corn-cob and anticoagulant rodenticides.

<sup>15</sup> Any eligible alternative BPs should be considered as being sufficiently effective, so no further investigation should be made on this criterion.

- b) Tier I-B: This tier will have to be followed where the relevant BP contains a CFS meeting the exclusion criteria in Article 5(1) of the BPR or where substitution is identified as a possibility at Tier I-A. At Tier I-B, the eCA must carry out a detailed comparison in terms of risk for human health, animal health and the environment by looking at information available in the product assessment report (PAR) level and to which eCAs can have access through the R4BP.

#### **6.2.1.- Tier I-A - comparison of elements available at SPC level**

- (60) The main goal of Tier I-A is to conclude whether substitution of the relevant BP by alternative BPs will be or not to be appropriate and then move to Tier I-B or Tier II, accordingly (*see Annex 7.2*).

##### *6.2.1.1 Assessment of significant lower overall risk for human health, animal health and the environment*

- (61) In order to streamline the process further and avoid unnecessary work, investigations should be oriented to conclude whether, for the specific area(s) of concern posed by the CFS(s), the relevant BP can or cannot be considered as an outlier with regard to the alternative BPs; in other words, whether or not the possibility for substitution exists.

##### 6.2.1.1.1 Key elements for comparison

- (62) As per document CA-March14-Doc.4.1-Final<sup>16</sup>, only the RMMs and H/P-statements associated to the following substitution criteria listed in Article 10(1) of the BPR will have to be compared at Tier I-A:
- (a) Respiratory sensitiser and
  - (b) Two out of the three P/B/T properties.
- (63) When carrying out the comparison the eCA should consider the following elements:
- (a) Effectiveness, practicability and level of restriction of the RMMs<sup>17</sup> and H/P-statements,
  - (b) Remaining risks after implementation of the proposed RMMs and P-statements.

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<sup>16</sup> Criterion (f) in Article 10(1) of the BPR (i.e. significant proportion of non-active isomers or impurities) is now considered for taking decisions on the approval of AS under the BPR (as per document CA-Nov14-Doc.4.4-Final). However, this criterion can be considered as irrelevant in terms of triggering any specific RMMs or P-statements to be considered at Tier I-A.

<sup>17</sup> See in Annex 7.2.1.a an example of ranking for RMMs intended to mitigate human health concerns at the workplace (in line with Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work).

#### 6.3.1.1.2. Criteria for significant differences

- (64) At Tier I-A stage and for the purpose of concluding whether or not the relevant BP is an outlier, it might be difficult to define a pre-established set of criteria to make decisions regarding the number or the relevance of the RMMs and H/P-statements on which the relevant BP and the alternative BPs may differ.
- (65) Therefore, the eCA when reaching such conclusion can make use of expert judgement on a case by case basis, while not losing consistency and transparency. The reasoning supporting such investigation and the associated conclusion will have to be clearly explained in the comparative assessment report.

#### 6.2.1.1.3 Conclusion

- (66) Where the comparison at Tier I-A shows that better alternative BPs exist for such area(s) of concern in terms of RMMs or H/P-statements, the CA can consider the relevant BP as an outlier and therefore move to Tier I-B for further investigations on those better alternatives only (*see example in Annex 7.2.1*), provided that the alternative BPs do not pose any significant practical or economic disadvantage.
- (67) Where no better alternative BPs are found for such area(s) of concern in terms of RMMs or H/P-statements, the CA can conclude that the relevant BP is not an outlier and therefore there is not a possibility for substitution. Comparative assessment should move to Tier II then (*see example in Annex 7.2.1*).

#### 6.2.1.2 Assessment of significant economic or practical disadvantages

- (68) The eCA will have reach a conclusion on whether or not the alternative BPs present any significant economic or practical disadvantages compared to the relevant BP for a given use (*see flow chart in Annex 7.2.2*).
- (69) Article 23(3)(a) of the BPR is silent on whether this assessment should focus on the disadvantages for the relevant users of the BPs or for society in general. In the context of comparative assessment at the product authorisation or renewal stage, it is proposed that the assessment of the practical and economic disadvantages is only focused at user level and not in terms of a wider socioeconomic analysis<sup>18</sup>, which would be almost impossible to manage within the procedural timelines.
- (70) A two-step approach is proposed for the two elements to be investigated under this section:
  - (a) Identifying any economic or practical disadvantages linked to the substitution by the alternative BPs,
  - (b) Deciding whether or not the identified disadvantages are significant in accordance with the definition provided by this document, as only those that are significant would prevent the eCA from proposing a restriction or the ban of the relevant BP. In other words, some non-significant disadvantages can be acceptable and could be balanced against other

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<sup>18</sup> Unless required by the AS approval.

expected benefits of the alternative BPs for the human/animal health or the environment.

#### 6.2.1.2.1 Identifying any economic or practical disadvantages

- (71) The eCA should be able to identify any disadvantages associated to the substitution by the alternative BPs either by:
- (a) In-house or external independent expertise on the different sectors or industrial processes concerned by the use subject to comparative assessment. This identification can be based, among other sources, on the information collected in the context of the public consultation carried out in accordance with Article 10(3) of the BPR.
  - (b) Conducting *ad hoc* narrow consultations with consumer and/or sector-specific stakeholder organisations at EU/national level, which must be compatible with the relevant procedural timelines.
- (72) Concerning the practical disadvantages, the following kinds of disadvantages affecting the technical feasibility of substitution should be identified:
- (a) Any adaptations or changes in the technology<sup>19</sup>, process, procedure or device, modification of end product or other solutions necessary to replace the relevant product (e.g. the requirement for new/additional equipment, risk mitigation measures, energy, personnel changes and training needs, raw materials, waste, etc.).
  - (b) Any other disadvantages in terms of compliance with legislation on worker safety, relation with community, etc.
  - (c) Any delayed time for effect or higher amounts of alternative BPs needed to achieve the control of the target organism.
- (73) Regarding the economic disadvantages, the eCA should identify any direct and/or indirect costs associated with the transitioning to the alternative BP. Where possible, economic disadvantages should be presented in connection with the different practical disadvantages identified above. The sources of data and its quality and reliability, the assumptions and uncertainties in the methodology of analysis and their impact on the conclusions of the assessment should be clearly justified in the comparative assessment report.
- (74) In order to contribute further to this identification process, the application for product authorisation/renewal of the relevant product may also contain a critical review of the information on alternatives collected by ECHA in the context of the public consultation referred to in Article 10(3) of the BPR. For CFS on which an approval decision has already been taken, the public consultation referred to in Article 10(3) will only be carried out at the time of the renewal of the AS approval. For those cases, the above-mentioned critical review should cover the

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<sup>19</sup> This can be especially significant where the use of the relevant BP involves *in situ* installations.



alternative BPs knowledge of which is available to the applicant at the time of the submission of the application<sup>20</sup>.

#### 6.2.1.2.2 Input assessment and conclusion

- (75) Looking at the definition of significant economic or practical disadvantages provided by this document, the eCA should reach a conclusion on whether or not the identified disadvantages lead to either:
- (a) An inability to maintain sufficient control of the target organism or
  - (b) The control of the target organism at very high efforts and/or disproportionate costs.
- (76) Concerning the inability to maintain a sufficient control of the target organism, the eCA will have to investigate whether or not the use of the alternative BP(s) leads to such an inability. As far as the control of the target organism can be achieved, some potential disadvantages in terms of time needed for effect, amounts to be used, higher (while affordable) costs or less practical applications methods should, in principle, not be considered as significant.
- (77) Regarding the control of the target organism at very high efforts and/or disproportionate costs, the eCA will have to investigate whether or not the substitution by the alternative BP(s), while ensuring the control of the target organism, is not feasible from an economic point of view. This means in practice that some higher but proportionate costs should, in principle, not be considered as a significant disadvantage.
- (78) When reaching a conclusion on this section, the eCA will also have to make use of expert judgement on a case by case basis, provided that robust justification is available in the comparative assessment report (e.g. data, statements from user sectors, etc.).

#### 6.2.1.3 Overall conclusion of Tier I-A

- (79) On the basis of the overall investigation carried out at Tier I-A, the eCA will be recommended to move to:
- (a) Tier I-B, where:
    - the relevant BP is an outlier and a more detailed comparison with the alternative BPs has to be conducted in terms of the overall risk for human health, animal health and the environment and
    - the alternative BPs do not pose any significant economic or practical disadvantages.

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<sup>20</sup> Where further information is gathered during the evaluation (e.g. in an *ad hoc* consultation as mentioned in paragraph 71(b)), the eCA may make this information available to the applicant at an earlier stage than the draft PAR referred to in Article 30(3)(b) of the BPR.

- (b) Tier II, where:
- the relevant BP is not an outlier in terms of risk for human health, animal health and the environment or
  - the alternative BPs pose any significant economic or practical disadvantages.

#### **6.2.2.- Tier I-B – detailed comparison**

- (80) The main goal of Tier I-B is to conclude whether or not substitution of a relevant BP (either containing a CFS meeting the exclusion criteria or being considered as an outlier at Tier I-A) by alternative BPs would be appropriate and, if not, move to Tier II (*see Annex 7.3*).

##### *6.2.2.1 Assessment of significant lower overall risk for human health, animal health and the environment*

- (81) In order to streamline the process and avoid unnecessary work, investigations should be oriented to conclude whether, for the specific area(s) of concern posed by the CFS(s), the associated values or ratios of the relevant BP can or cannot be considered as an outlier value with regard to those values available in the PAR of the alternative BPs.

##### 6.2.2.1.1 Key elements for comparison

- (82) As per documents CA-March14-Doc.4.1-Final and CA-Nov14-Doc.4.4-Final, only data available in the PAR associated to the following exclusion/substitution criteria will have to be compared:
- (a) Concerning human or animal health:
- CMR properties (exclusion criterion),
  - ED properties (exclusion criterion),
  - Respiratory sensitiser (substitution criterion).
- (b) Concerning the environment:
- PBT properties (exclusion criterion),
  - Two out of the three P/B/T properties (substitution criterion).
- (c) Concerning the identity of the substance<sup>21</sup>:
- Significant proportion of non-active isomers or impurities (substitution criterion).

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<sup>21</sup> When addressing this criterion, the eCA might have to decide whether to consider human health or environmental elements.

- (83) The detailed comparison can focus on elements from a qualitative to a more quantitative nature. Comparison of quantitative values (e.g. PEC/PNEC ratios and risk characterisation ratios) should be approached with particular attention and be subject to expert judgement by taking into consideration, on a case by case basis, the following elements:
- (a) The risk assessments of the alternative BPs might have been based on previous guidance documents, exposure models, etc.
  - (b) Risk assessments are generally only refined as far as is necessary to demonstrate a safe use. Different refinements may have been applied in some situations, making difficult a 'like for like' comparison.
  - (c) The exposure patterns of the alternative BPs for the same use should be similar, as it can affect how the PNEC was derived, how was the PEC calculated, what type of human health effects are considered (e.g. predominating local versus systemic, etc...).

#### 6.2.2.1.2. Criteria for significant differences

- (84) At Tier I-B the comparison of the relevant values/data in the PAR concerning the above-mentioned elements will be oriented to conclude whether or not the values of the relevant BP are outlier values in accordance with the definition provided by this document as well as the associated biological significance to them; that is whether the observed difference between two results or observations has any potential consequences regarding the risks to humans, animals or the environment.
- (85) When carrying out the above investigations, the eCA can make use of expert judgement on a case by case basis, while not losing consistency and transparency. The reasoning supporting such investigations and conclusions will have to be clearly explained in the comparative assessment report.

#### 6.2.2.1.3 Conclusion (*see example in Annex 7.3*)

- (86) Where the compared value is not considered to be an outlier value, no further investigations should be carried out as it can be concluded that the alternative BPs have not a significantly better profile than the relevant BP; that is, that the observed differences are only marginal and are not relevant in terms of biological significance for the safety to humans, animals or the environment.
- (87) Where such a value is considered to be an outlier value, the eCA can reach the conclusion that the alternative BPs have a significantly better profile and therefore, further investigations should be carried out to confirm whether or not the alternative BPs are not significantly worse for any of those three aspects, compared to the relevant BP (i.e. the observed differences are only marginal and not relevant in terms of biological significance).
- (88) Should it be the case, it can be concluded that the alternative BPs have a significantly lower overall risk for human health, animal health and the environment.

#### 6.2.2.2 Assessment of significant economic or practical disadvantages

- (89) Where the relevant BP has been subject to Tier I-A, the eCA would have already reached the conclusion that the alternative BPs do not pose any significant economic or practical disadvantages.
- (90) Where the relevant BP contains a CFS meeting the exclusion criteria, the eCA will have to follow the approach described in section 6.2.1.2 of this document.

#### 6.2.2.3 Overall conclusion of Tier I-B

- (91) Where the comparison at Tier I-B shows that the alternative BPs either:
  - (a) Have not a significantly better profile for the specific area(s) of concern than the relevant BP or,
  - (b) Pose any significant economic or practical disadvantages,no further investigations should be carried out and comparative assessment must move to Tier II.
- (92) Where the comparison at Tier I-B shows that the alternative BPs:
  - (a) Have a significantly lower overall risk for human health, animal health and the environment and,
  - (b) Do not pose any significant economic or practical disadvantages,the eCA can conclude that there are suitable alternative BPs and decide to restrict any of the intended uses in the application for authorisation, not authorise, amend or cancel, where appropriate, the relevant BP.

### 6.3.- Tier II - comparison to eligible non-chemical alternatives

- (93) The main goal of Tier II is to conclude whether or not substitution of the relevant BP by an eligible non-chemical alternative would be possible and, if not, either to conclude the comparative assessment or to move to Tier I when Tier II has been performed first (*see Annex 7.4*).
- (94) According to the principle referred to in paragraph 47 and with a view to streamline the comparison, the eCA should look first at the criteria concerning the effectiveness or the economic or practical disadvantages linked to the non-chemical alternative and, at a later stage, at the safety criteria as they might be more difficult to compare. In cases where it might be easier to do, the eCA may however start the comparison by looking at the safety criteria first.

#### 6.3.1. Assessment of "sufficiently effective"

- (95) A limiting factor when comparing the relevant BP to non-chemical alternatives can be the lack of available agreed standards, as most of them are not subject to a pre-marketing authorisation regime.

- (96) When looking at the efficacy of the non-chemical alternatives, for the use(s) subject to comparative assessment, the eCA should follow a step wise approach:
- (a) Step 1: use the criteria applied to BPs, where relevant,
  - (b) Step 2: use criteria within the relevant legislation or technical standards (if any) applicable to the non-chemical alternative(s),
  - (c) Step 3: use expert judgement.

#### 6.3.1.1 Effects on target organisms

- (97) The eCA should also consider any effects on target organisms linked to the use of the non-chemical alternative in accordance with the principles set in Annex VI to the BPR. Where the non-chemical alternative is intended to be used against vertebrate harmful organisms, particular attention should be paid to:
- (a) The potential selection of any behaviour affecting the effectiveness of the alternative in the future (e.g. aversion to traps in neophobic rodents),
  - (b) The conditions under which death occurs (e.g. unnecessary suffering, etc.).

#### 6.3.1.2 Conclusion

- (98) The eCA should reach a conclusion on whether or not the non-chemical alternatives are sufficiently effective as defined in this document; that is, the alternative provides similar levels of protection, control or other intended effects to those of the relevant BP for the same use.
- (99) For that purpose, the eCA should make use of expert judgement based on scientific evidence and biological significance, which will have to be clearly explained in the comparative assessment report.

#### 6.3.2 *Assessment of significant economic or practical disadvantages*

- (100) The eCA will have to follow the approach described in section 6.2.1.2 of this document.
- (101) A conclusion should be reached on whether or not the relevant BP by the non-chemical alternatives have any significant economic or practical disadvantages.

#### 6.3.3. *Assessment of significantly lower overall risk for human health, animal health and the environment*

- (102) As for alternative BPs, the investigations should be oriented to reach a conclusion regarding the specific area(s) of concern posed by the CFS(s) in the relevant BP (e.g. human health or environment), and then to verify that the risk profile for the other area(s) is not significantly worse.

#### 6.3.3.1 Key elements for comparison

- (103) As for the efficacy related issues, the lack of available agreed standards would be a limiting factor when comparing the safety of the relevant BP to non-chemical alternatives.

- (104) When looking at the safety of the non-chemical alternative(s), the eCA should follow a step wise approach:
- (a) Step 1: use the criteria applied to BPs, where relevant,
  - (b) Step 2: use criteria within the relevant legislation or technical standards (if any) applicable to the non-chemical alternative(s),
  - (c) Step 3: use expert judgement.

#### 6.3.3.2. Criteria for significant differences

- (105) The conclusions reached by the CA should make use of expert judgement based on scientific evidence and biological significance, which will have to be clearly explained in the comparative assessment report.

#### 6.3.3.3 Overall conclusion

- (106) Where the comparison of the above elements shows that the observed differences are only marginal and are not relevant in terms of biological significance for the safety to humans, animals or the environment, it can be concluded that the non-chemical alternative does not have a significantly better profile than the relevant BP.
- (107) Where the eCA can reach the conclusion that the non-chemical alternative has a significantly better profile for the human health, animal health or the environment (i.e. the observed differences are not marginal but relevant in terms of biological significance), further investigations should be carried out to confirm that the non-chemical alternative is not significantly worse for the other areas, compared to the relevant BP (i.e. the observed differences are only marginal and not relevant in terms of biological significance).
- (108) Should it be the case, it can be concluded that the non-chemical alternative has a significantly lower overall risk for human health, animal health and the environment.

#### 6.3.4 Overall conclusion of Tier II

- (109) Where the comparison at Tier II shows that the non-chemical alternatives either:
- (a) Are not sufficiently effective or,
  - (b) Pose any significant economic or practical disadvantages or,
  - (c) Have not a significantly lower overall risk for human health, animal health and the environment than the relevant BP,

no further investigations should be carried out and comparative assessment can be concluded. Where Tier II has been performed first, comparative assessment should then move to Tier I.

- (110) Where the comparison at Tier II shows that the non-chemical alternatives:
- (a) Are sufficiently effective and,

- (b) Do not pose any significant economic or practical disadvantages and,
- (c) Have a significantly lower overall risk for human health, animal health and the environment,

the eCA can conclude that there are suitable non-chemical alternatives and decide to restrict any of the intended uses in the application for authorisation, not authorise, amend or cancel, where appropriate, the relevant BP.

#### **6.4.- Overall conclusion. Comparative assessment report**

##### *6.4.1 Legal basis and purpose of the comparative assessment report*

- (111) In accordance with Article 23(2) of the BPR, the results of the comparative assessment shall be forwarded, without delay, to the CAs of other MSs and ECHA and, in the case of evaluation of an application for a UA, also to the Commission<sup>22</sup>.
- (112) With a view to submit the above-mentioned results in a harmonised format, the eCA should make use of the template for a comparative assessment report ("the report" hereinafter) provided for in Annex 7.5 to this document. At the end of the evaluation process, a summary of the information included in the report will have to be included in the PAR of the product<sup>23</sup>.
- (113) The eCA shall submit the report to the Coordination Group (CG) Secretariat ([biocides-coordination-group@echa.europa.eu](mailto:biocides-coordination-group@echa.europa.eu)), which will store the report in a confidential folder under the CG Interest Group of Circabc. The CG Secretariat will inform the other MSs (via the CG contact points) and the Commission of any new report made available by eCAs. The availability of such reports for all MSs will contribute to share information on alternatives as well as to maintain consistency and ensuring equal treatment among different applications.

##### *6.4.2 Content of the report*

- (114) The report will provide an overview of the assessment carried out by the eCA, the data, information and other elements, in particular expert judgement, taken into account when reaching a conclusion for the different/relevant steps of the process:
  - (a) Mapping of existing alternatives to the relevant BP,
  - (b) Screening phase,
  - (c) Tier I-A – comparison of elements available at SPC level,

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<sup>22</sup> In the context of MR procedures, the eCA can however inform the CMSs whether a comparative assessment going beyond the screening phase is going to be done, so that CMSs can start, where appropriate, its own supplemental work at national level before the 90-day MR phase (see document CA-March14-Doc.5.4-Final).

<sup>23</sup> See section 10 of the PAR template, available at <https://circabc.europa.eu/w/browse/d345f2fd-9425-4027-b483-e148e3a179ca>

- (d) Tier I-B – detailed comparison,
  - (e) Tier II – comparison to non-chemical alternatives.
- (115) The report will also include the final recommendation from the eCA in terms of restricting any of the intended uses in the application, not authorising, amending or cancelling, where appropriate, the relevant BP. The eCA will provide a short justification concerning the criteria in Article 23(3) of the BPR that are met by the alternative BPs or non-chemical alternatives supporting such recommendation:
- (a) Adequate chemical diversity in authorised BPs,
  - (b) Significantly lower overall risk for human health, animal health and the environment of existing alternatives,
  - (c) For non-chemical alternatives, being sufficiently effective,
  - (d) No significant economic or practical disadvantages.
- (116) It has to be noted that a recommendation to restrict or prohibit an otherwise compliant BP based on a comparative assessment should be considered to have the burden of proof. In other words, if the outcome of the comparative assessment is not sufficiently conclusive to conclude that the criteria of Article 23(3) of BPR are met, the recommendation would be in the line of authorising or renewing the relevant BP for 5 years in accordance with Article 23(6) of the BPR<sup>24</sup>.
- (117) A recommendation to restrict or prohibit the relevant BP can be made even when an alternative BP is only authorised in other MS or a non-chemical alternative is only available in other MS. It is indeed expected that the decision would then create an incentive for those alternatives to be made available on the market of the MS(s) having decided upon such restriction or prohibition during the 4-year period established in Article 23(7) of the BPR. At the worst, if no alternative is placed on the market by the end of this period, the CA could still review the restriction or prohibition date to avoid a situation where the chemical diversity would no longer be adequate or alternatives not available.

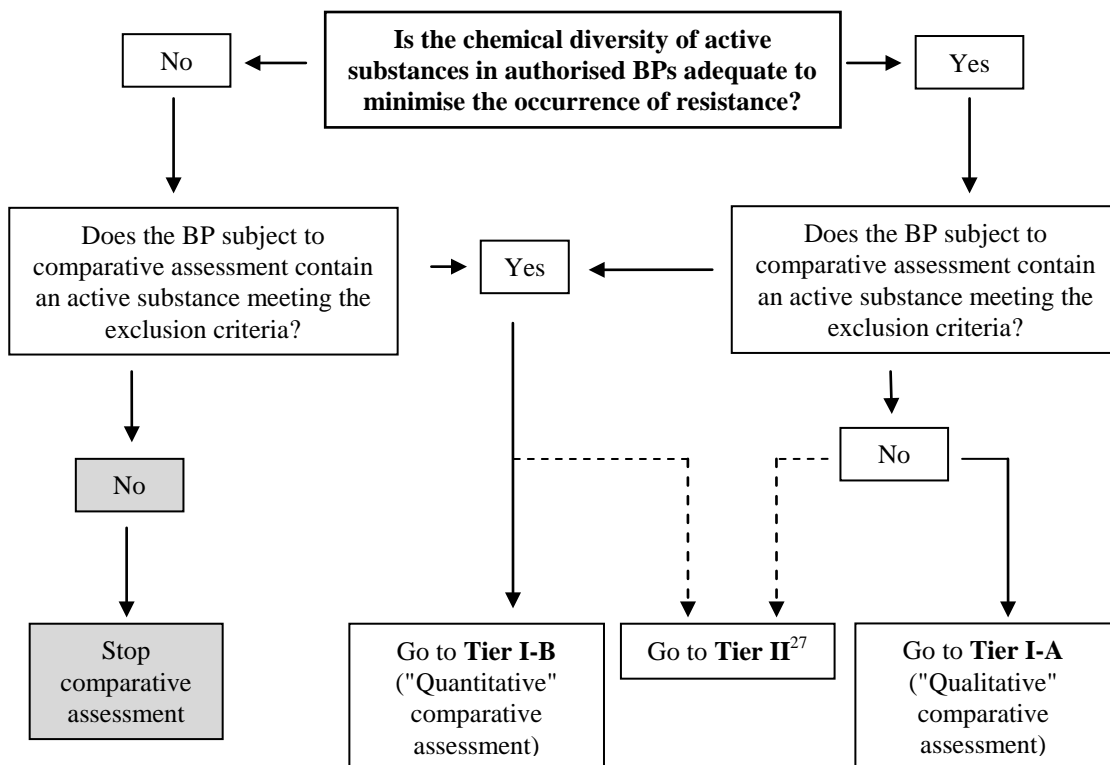
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<sup>24</sup> It has to be noted that according to Article 23(7) of the BPR a decision to restrict or prohibit the relevant BP shall only take effect 4 years after that decision.



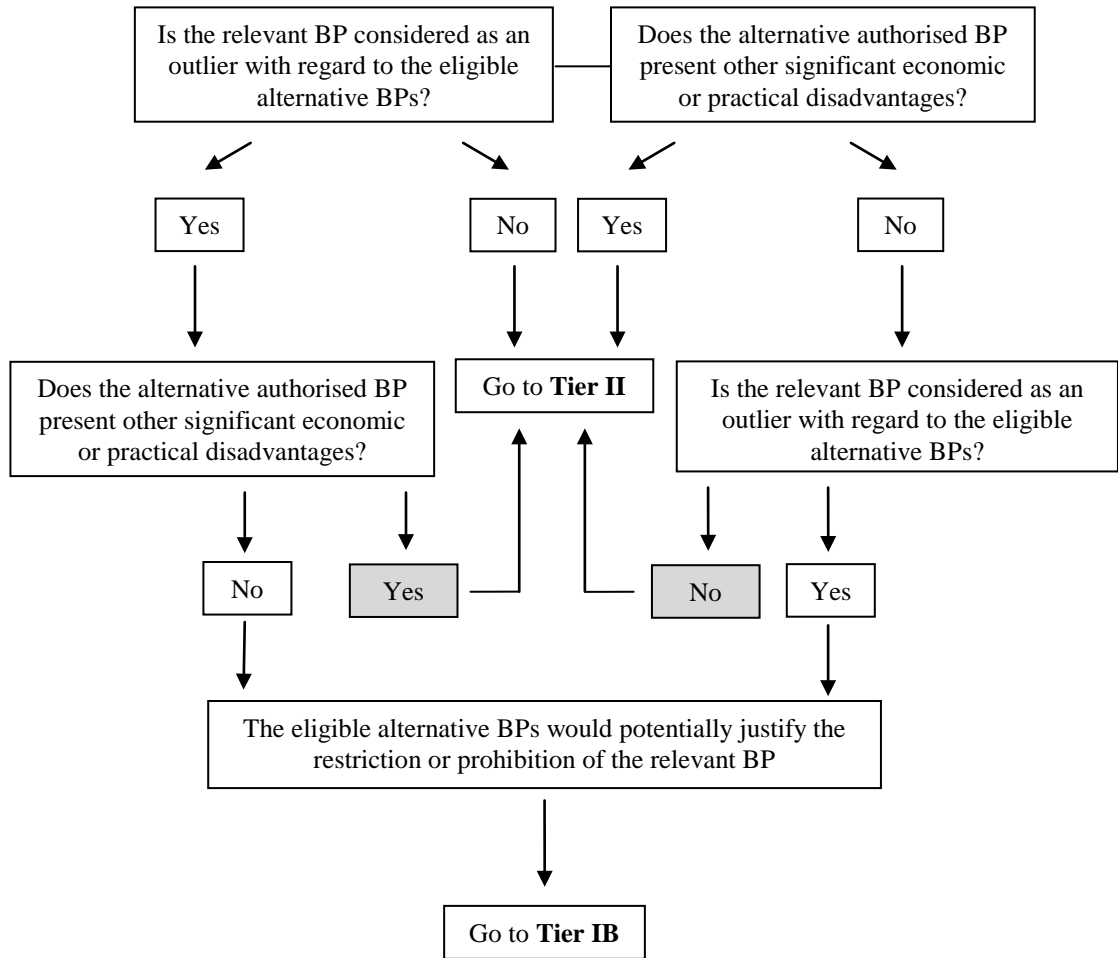
## 7.- Annexes

### 7.1.- Flow chart for the screening phase



<sup>27</sup> Where a CA is aware of an eligible non-chemical alternative which is likely to meet the criteria required by Article 23(3)(a) of the BPR, Tier II can be performed first (see paragraph 46 of this document).

**7.2.- Flow chart for Tier I-A**



## 7.2.1 – Examples of how to identify an outlier BP at Tier I-A

PT 8 use: Wood staining fungi – professional users – indoor – brushing.

RMMs and H/P-statements in the relevant BP linked to the substitution criterion met by the CFS contained therein	Do alternative BPs have better RMMs or H/P-Ss?			Overall conclusion at Tier I-A: Is the relevant BP an outlier?
	BP1	BP2	BPn	
<b>Respiratory sensitiser (RS)</b>				
RMM1 - wear respiratory protection	yes <sup>a</sup> (none)	yes (none)	yes (none)	There are alternative BPs which are not classified as RS and that can be used even without wearing respiratory protection. Thus, the relevant BP seems to be an outlier <sup>28</sup> and substitution might be possible.  → Go to Tier I-B for a more detailed comparison.
PS 261 ( <i>Avoid breathing dust/fume/gas/mist/vapours/spray</i> )	yes (none)	yes (none)	no <sup>b</sup> (PS 261)	
PS 285 ( <i>In case of inadequate ventilation wear respiratory protection</i> )	yes (none)	yes (none)	yes (none)	

<sup>a</sup> A "yes" means that the alternative BP either has no RMM or H/P-statement, or has a better RMM or H/P-statement, as appropriate.

<sup>b</sup> A "no" means that the alternative BP has the same, a similar or even more restrictive RMM or H/P-statement, as appropriate.

PT 8 use: Wood staining fungi – industrial user – indoor – automated dipping.

RMMs and H/P-statements in the relevant BP linked to the substitution criterion met by the CFS contained therein	Do alternative BPs have better RMMs or H/P-Ss?			Overall conclusion at Tier I-A: Is the relevant BP an outlier?
	BP1	BP2	BPn	
<b>Two of the P/B/T criteria (e.g. P&amp;T)</b>				
RMM1-P: only for use at industrial sites which are soil-banded.	no <sup>a</sup> (same)	yes <sup>b</sup> (none)	no (more restrictive)	The alternative BPs have the same or similar RMMs to protect the environment. Thus, the product does not seem to be an outlier and it can be concluded that substitution is not possible.  → Tier I-B is not necessary.  → Go to Tier II for a comparison with the identified eligible non-chemical alternatives.
RMM2-P: treated timbers to be stored under cover & recovery system in place	no (similar)	no (same)	no (same)	
RMMn-T: Safe disposal- avoid contact with fresh waters	yes (none)	no (same)	no (similar)	

<sup>a</sup> A "no" means that the alternative BP has the same, a similar or even a more restrictive RMM.

<sup>b</sup> A "yes" means that the alternative BP either has no RMM or a better RMM.

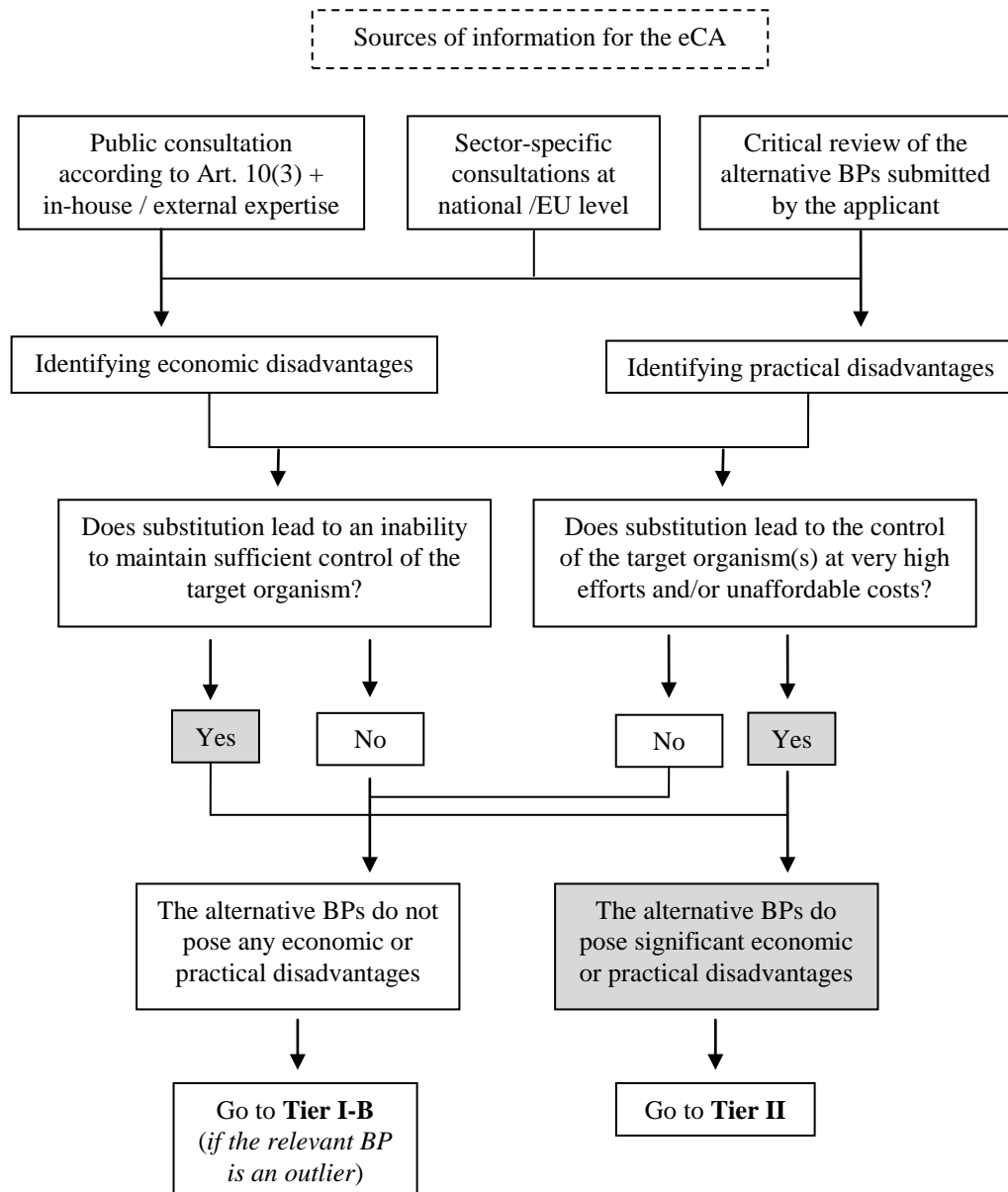
<sup>28</sup> The relevant BP can still be considered as an outlier where there is one or more alternative BPs that can also qualify as an outlier compared to the rest of alternative BPs, provided that the latest constitute a majority group.

**7.2.1.a – Example of ranking for RMMs intended to mitigate human health concerns at the workplace with regard to the level of restriction associated to each RMM (in line with Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work)**

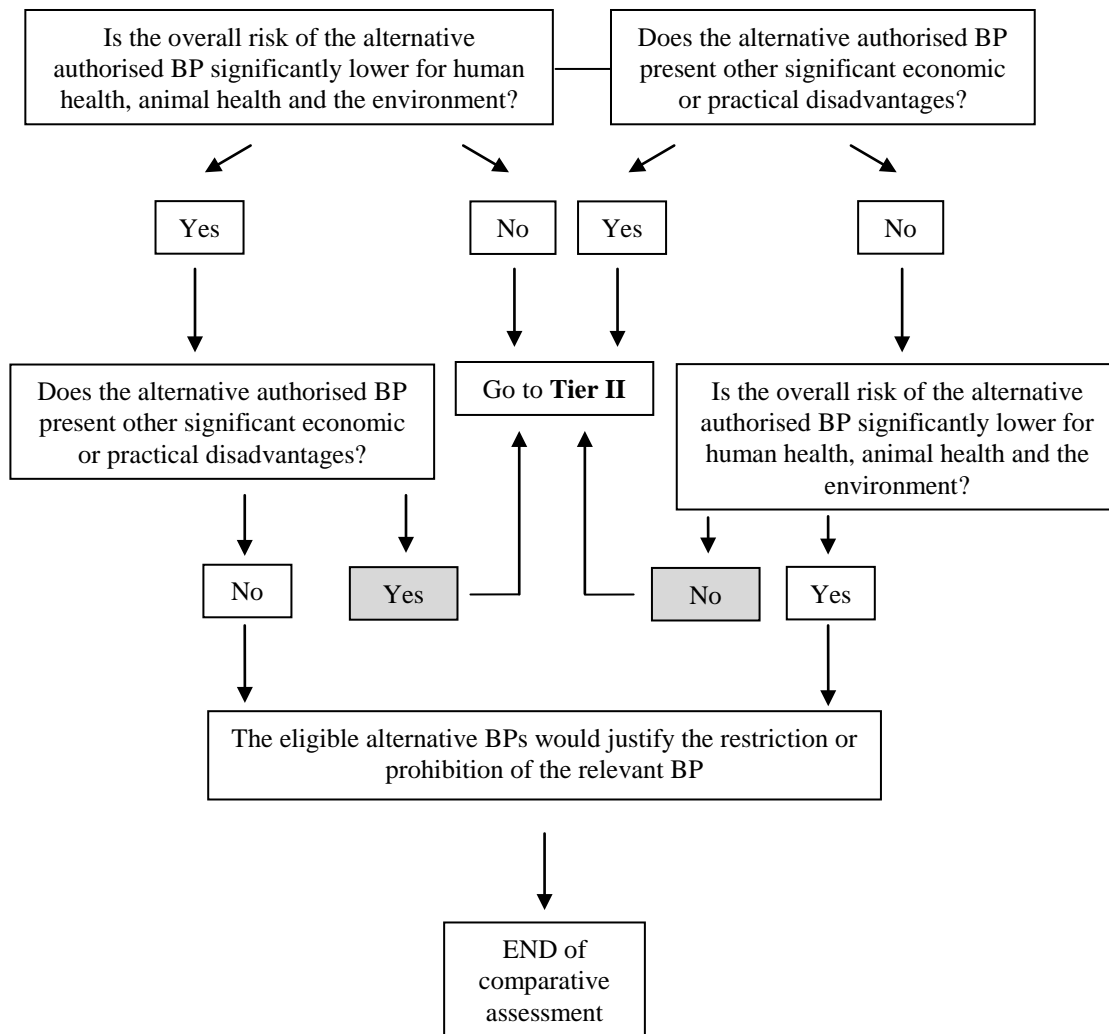
<b>Examples of RMM</b>	<b>Less restrictive</b>	<b>Medium restrictive</b>	<b>Very restrictive</b>
<b>1. Substitution</b> <sup>29</sup>	-	<ul style="list-style-type: none"> <li>• Substitution of the use (<i>not applicable</i>)</li> </ul>	<ul style="list-style-type: none"> <li>• Substitution of the hazardous substance (<i>not applicable</i>)</li> </ul>
<b>2. Engineering / Technical measures</b>	<ul style="list-style-type: none"> <li>• Intrinsically safe packaging.</li> </ul>	<ul style="list-style-type: none"> <li>• Special application device (e.g. nozzle of a certain diameter),</li> <li>• Special equipment (e.g. long spraying lance, lockable bait boxes, etc.),</li> <li>• Technical room ventilation (e.g. definite air exchange rate).</li> </ul>	<ul style="list-style-type: none"> <li>• Isolated working area by construction measures,</li> <li>• Closed system,</li> <li>• Extraction hood.</li> </ul>
<b>3. Organisational measures</b>	<ul style="list-style-type: none"> <li>• Instruction, training.</li> </ul>	<ul style="list-style-type: none"> <li>• Professionals, only,</li> <li>• Outdoors, only</li> </ul>	<ul style="list-style-type: none"> <li>• Trained, specialised professionals, only,</li> <li>• Certificate of competence.</li> </ul>
<b>4. PPE</b>	<ul style="list-style-type: none"> <li>• Gloves (Cat. III),</li> <li>• Safety goggles,</li> <li>• Safety boots.</li> </ul>	<ul style="list-style-type: none"> <li>• Protective coverall (type 4-6),</li> <li>• Rpe: particle filter (ffp1-2)</li> </ul>	<ul style="list-style-type: none"> <li>• Protective coverall (type 1-3),</li> <li>• Rpe: gas mask, mask with particle filter class 3 / ffp3, scba etc.</li> </ul>

<sup>29</sup> This example is not applicable to authorised biocidal products authorised for a given use.

**7.2.2 – Flow chart for the assessment of any economic or practical disadvantages at Tier I-A**



### 7.3.- Flow chart for Tier I-B



**7.3.1 – Examples of how to assess at Tier I-B whether the alternative BPs have a significantly lower overall risk for human health, animal health and the environment**

PT 8 use: Wood staining fungi – professional users – indoor – brushing.

CFS = Respiratory sensitiser; substitution might be possible according to Tier I-A.

Case 1

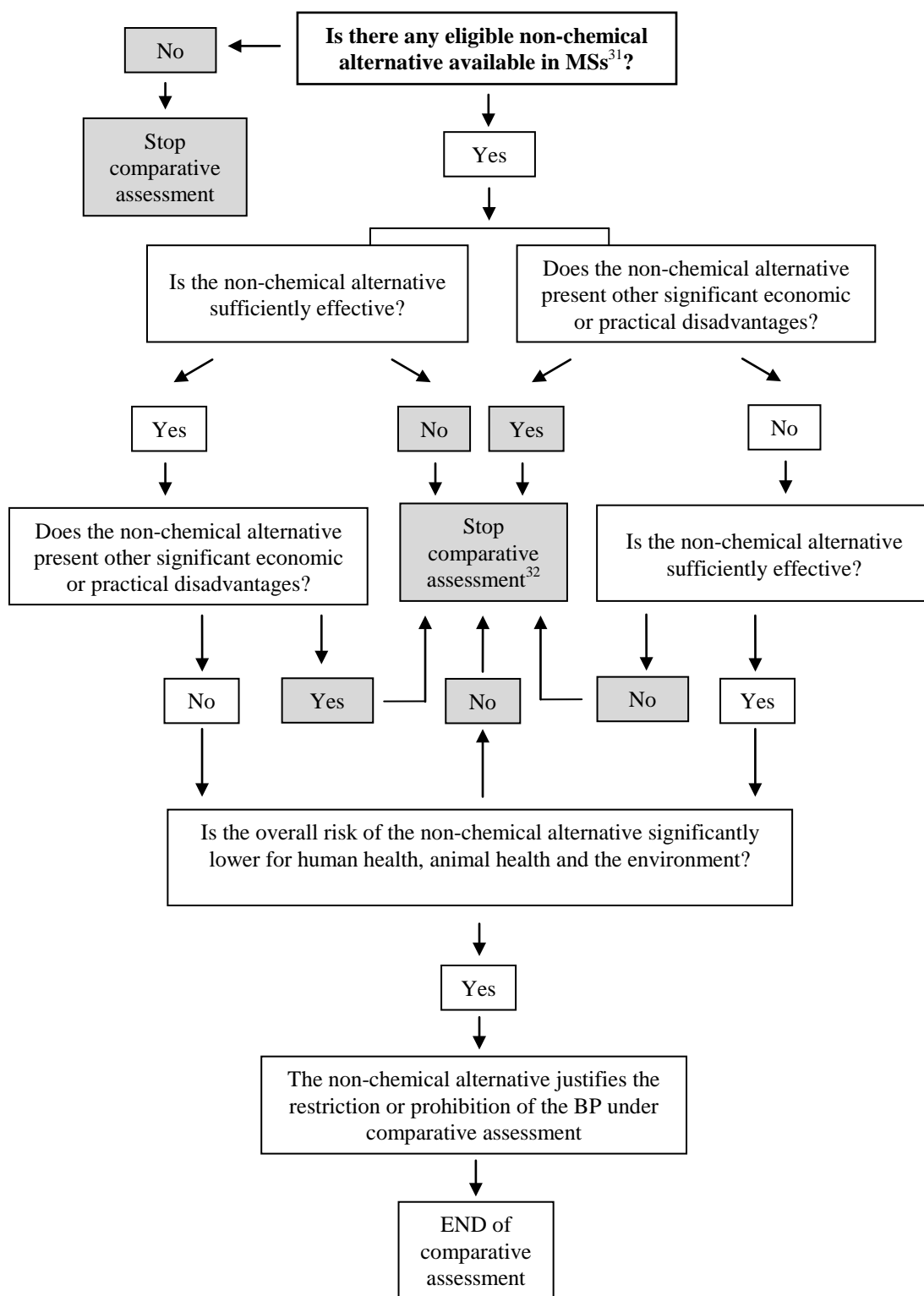
Data values in the PAR of the relevant BP	Do alternative BPs have similar values/data in the PAR <sup>30</sup> ?			Overall conclusion concerning whether the alternative BPs have a significantly better profile for HH values/data related to respiratory sensitisation
	BP1	BP2	BPn	
<b>HH relevant values/data</b>				
Value 1	yes	yes	yes	→ The relevant BP has not outlier values, so the alternative BPs have not a significantly better profile than the relevant BP; that is, the observed differences are only marginal and are not relevant in terms of biological significance for the safety to humans. → <b>No further investigations &amp; move to Tier II.</b>
Value 2	yes	yes	yes	
Value n	yes	no (worse)	yes	

Case 2

Data values in the PAR of the relevant BP	Do alternative BPs have similar values/data in the PAR <sup>30</sup> ?			Overall conclusion concerning whether the alternative BPs have a significantly better profile for HH values/data related to respiratory sensitisation
	BP1	BP2	BPn	
<b>HH relevant values/data</b>				
Value 1	yes	no (better)	no (better)	→ The relevant BP has outlier values, so the alternative BPs have a significantly better profile than the relevant BP; that is, the observed differences are not only marginal and are relevant in terms of biological significance for the safety to humans. → <b>Investigate other values/data in the alternative BPs to see if they are not significantly worse for the animal health or the environment.</b>
Value 2	no (better)	no (better)	no (better)	
Value n	no (better)	yes	no (better)	
Data values in the PAR of the relevant BP	Do alternative BPs have similar values/data in the PAR <sup>30</sup> ?			Overall conclusion concerning whether the alternative BPs have a significantly lower overall risk for human health, animal health and the environment
	BP1	BP2	BPn	
<b>AH relevant values/data</b>				
Value 1	yes	yes	yes	→ The alternative BPs are not significantly worse for the animal health or the environment than the relevant BP; that is, the observed differences are only marginal and are not relevant in terms of biological significance for the safety to animals or the environment. → <b>Alternative BPs have a significantly lower overall risk for human health, animal health and the environment.</b>
Value 2	yes	yes	yes	
Value n	yes	yes	yes	
<b>ENV relevant values /data</b>				
Value 1	yes	yes	yes	
Value 2	yes	yes	yes	
Value n	yes	yes	yes	

<sup>30</sup> Where the answer is "no", the eCA should indicate whether the observed value/data in the alternative product is better or worse.

## 7.4.- Tier II. Comparison to non-chemical alternatives



<sup>31</sup> As identified in the context of the public consultation referred to in Article 10(3) of the BPR (or becoming available since the active substance approval/renewal) and meeting the eligibility criteria set in section 5.2.2 of this document.

<sup>32</sup> Where a CA decides to perform Tier II first in accordance with paragraph 46 of this document and no suitable alternative is found, comparative assessment shall not be ended but redirected to Tier I.



## **7.5.- Template for the comparative assessment report**

### ***1. Application administrative details:***

Procedure: UA/NA/NA-MRP/NA-MRS/NA-SP

Purpose: Authorisation/renewal

Case Number in R4BP:

Evaluating Competent Authority:

Applicant:

(Prospective) Authorisation holder:

### ***2.- Administrative information of the BP/BPF***

Trade name(s):

Product type(s):

Active substance(s):

### ***3.- Intended uses for the relevant BP in the application***

List of intended uses:

### ***4.- Mapping of existing alternatives to the relevant BP***

4.1.- Identified eligible alternative BPs

4.2.- Identified eligible non-chemical alternatives

### ***5.- Screening phase***

5.1.- Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.

5.2.- Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but can benefit from derogation in accordance with Article 5(2) of the BPR.

5.3.- Conclusion of the screening phase: Stop comparative assessment / Go to Tier I-A / Go to Tier I-B / Go to Tier II.

### ***6.- Tier I-A***

6.1 For each use of the relevant BP, a description of the investigations and the outcome of the comparison for:

- Risks for human health, animal health and the environment,
- Significant economic or practical disadvantages.

6.2 Conclusion of Tier IA: Go to Tier I-B / Go to Tier II.

### ***7.- Tier I-B***

7.1.- Description of alternative BPs included in the detailed comparison

7.2.- For each use of the relevant BP, a description of the investigations and the outcome of the comparison for:

- Risks for human health, animal health and the environment,
- Significant economic or practical disadvantages.

7.3.- Conclusion of Tier I-B: End of comparative assessment / Go to Tier II.

## **8.- Tier II**

8.1.- For each use of the relevant BP, a description of the investigations and the outcome of the comparison for:

- Risks for human health, animal health and the environment,
- Sufficiently effective,
- Significant economic or practical disadvantages.

8.3.- Conclusion of Tier II: End of comparative assessment / Go to Tier I.

## **9.- Overall conclusion**

Final recommendation from the eCA in terms of restricting any of the intended uses in the application, not authorising, amending or cancelling, where appropriate, the relevant BP.

## **7.6.- List of references to comparative assessment in the BPR**

### **Recital (15)**

In the course of granting or renewing the authorisation of a biocidal product that contains an active substance that is a candidate for substitution, it should be possible to compare the biocidal product with other authorised biocidal products, non-chemical means of control and prevention methods with regard to risks they pose and benefits from their use. As a result of such a comparative assessment, a biocidal product containing active substances identified as candidates for substitution should be prohibited or restricted where it is demonstrated that other authorised biocidal products or non-chemical control or prevention methods that present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages. Appropriate phase-out periods should be provided for in such cases.

### **Article 23. Comparative assessment of biocidal products**

1. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).
2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.
3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment, performed in accordance with the technical guidance notes referred to in Article 24, demonstrates that both of the following criteria are met:
  - (a) for the uses specified in the application, another authorised biocidal product or a non chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;
  - (b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.
4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.
5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying the criteria for determining when comparative assessments involve

questions better addressed at Union level and the procedures for such comparative assessments.

6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years.

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect four years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

#### **Article 24. Technical guidance notes**

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 22(2) and 23(3).

#### **Article 30. Evaluation of applications**

1. The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

#### **Article 31. Renewal of a national authorisation**

2. The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

#### **Article 48. Cancellation or amendment of an authorisation**

1. Without prejudice to Article 23, the competent authority of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that:

- (a) the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;
- (b) the authorisation was granted on the basis of false or misleading information; or
- (c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

#### **Article 91. Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC**

Notwithstanding the first paragraph, the following shall apply:

- where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5(1) is met, the biocidal product shall be authorised in accordance with Article 19;
- where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

## 7.7.- List of abbreviations and acronyms

**AH:** animal health.

**AS(s):** active substance(s).

**BP(s):** biocidal product(s).

**BPD:** biocidal products Directive.

**BPR:** biocidal products Regulation.

**CA(s):** competent authority(ies).

**CFS(s):** candidate(s) for substitution.

**CMR:** carcinogenic, mutagenic, toxic for reproduction.

**CG:** Coordination Group.

**eCA:** evaluating CA.

**ECHA:** European Chemicals Agency.

**ED:** endocrine disrupting properties.

**ENV:** environment.

**HH:** human health.

**H-statement:** hazard statement.

**H/P-S; H/P-statement:** hazard or precautionary statement.

**MS(s):** Member State(s)

**MR:** mutual recognition procedure.

**PAR:** product assessment report.

**PBT:** persistent, bioaccumulative, toxic properties.

**PEC:** predicted effect concentration.

**PNEC:** predicted non-effect concentration.

**PT(s):** product type(s).

**P-statement:** precautionary statement.

**R4BP:** Register for Biocidal Products.

**RefMS:** reference MS.

**RMM(s):** risk mitigation measure(s).

**SPC:** summary of product characteristics.

**TGN:** Technical Guidance Notes.

**UA:** Union authorisation procedure.