

# Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance

January 2023

# ABC

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## Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance

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## ABBREVIATIONS

AoA	Analysis of alternatives
AS	Active substance
BP	Biocidal product
BPD	Biocidal Products Directive (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)
BPR	Biocidal Products Regulation (Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products)
CAR	Competent Authority Report
CfS	(substance) candidate for substitution
eCA	Evaluating competent authority
ED	Endocrine disruptor
MSCA	Member State Competent Authority
PAR	Product assessment report
PBT	Persistent, bioaccumulative and toxic
vPvB	Very persistent and very bioaccumulative

## 1. Background and purpose of the guidance

This document aims at providing guidance primarily to applicants for approval of biocidal active substances but also to Member State Competent Authorities (MSCAs) on how to perform an analysis of alternatives to active substances being candidate for substitution (CfS) according to Art. 10(1) of the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)<sup>1</sup>. It is expected that the applicants for these substances would prepare an analysis of alternatives to support their application for approval/renewal of a biocidal active substance. The need to develop this guidance and its content was discussed on several occasions at the Biocidal Products Committee<sup>2</sup> (BPC) and at the meetings of the Member States' competent authorities for biocidal products (CA)<sup>3</sup>. The cases of the first approval or renewal of boric acid, disodium tetraborate pentahydrate and creosote showed the need for a more structured approach to the assessment of alternatives.

Among substances which are candidates for substitution, there are differences in the applicable legal provisions for the approval or renewal of active substances depending on whether they meet the exclusion criteria listed in Art.5(1) or if they only meet at least one of the criteria listed in Art. 10(1)(b) to 10(1)(f)). These regulatory differences are summarised in section 2.1. Despite these differences from a regulatory point of view, the principles pertaining to the assessment of alternatives remain the same for both types of substances and no distinction is made in terms of content of the analysis of alternative. As described below, such analyses conducted by the applicants for CfS provide a useful set of information for either the substance approval/renewal or for the biocidal product authorisation.

Conducting an analysis of alternatives at the stage of an active substance approval or renewal is recognised to be a challenging task, among others for the following reasons:

- all the intended uses of an active substance are not necessarily known;
- the level of available information related to known uses is variable, depending on the case;
- the number of uses, biocidal products and types of treated articles can be very high for certain active substances-product types;
- the eCAs (and even applicants) might have limited knowledge and expertise on the uses and the potential alternatives to the substance/use combinations;
- ECHA's database on biocidal products does not include all products available on the EU market (e.g. the ones authorised for national markets under the transitional rules), does not allow an easy extraction of specific data fields or does not contain specific information on uses;
- not all the approved active substances have been approved according to the same data

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<sup>1</sup> An active substance is considered as a candidate for substitution if any of the following criteria are met: it meets at least one of the exclusion criteria listed under Article 5(1); it is classified as a respiratory sensitiser; its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use; it meets two of the criteria to be considered as PBT; it causes concerns for human or animal health and for the environment even with very restrictive risk management measures; it contains a significant proportion of non-active isomers or impurities.

<sup>2</sup> E.g. BPC-38; BPC-42 and BPC-45 where drafts of the guidance were presented and agreed to.

<sup>3</sup> E.g. Document [CA-June22-Doc.5.4a](#) where the draft guidance was presented and [CA-Dec22-Doc.5.4a](#) describing the agreed guidance implementation timeline and steps involved.

- requirements and rules (e.g. BPD vs. BPR, presence or not of an ED assessment);
- there are differences in terms of requirements, procedures and consequences for substances meeting the exclusion criteria and the other substances candidate for substitution with regard to the availability of suitable alternatives;
- there are different types of dossiers, at different stages of the regulatory process (first approval, renewal, “backlog” dossiers), making it difficult having a single, strictly defined approach, covering all cases or having different approaches for each possible case.

Despite these limitations, an analysis of alternatives at the stage of active substance approval or renewal can provide useful information for these regulatory steps and the following. More detailed information about the uses and products is available at the product authorisation stage where more specific comparative assessments are conducted. The analysis of alternatives at the active substance approval/renewal stage is more generic by nature but should nevertheless aim at setting a high-level picture on the availability and suitability of alternatives. For this reason, it is not possible to determine clear-cut criteria regarding the suitability of alternatives at the active substance stage.

This broader picture should support the active substance approval process for substances candidate for substitution but also the subsequent product comparative assessment. The workload related to the latter could be lightened if a good quality and sufficiently detailed analysis of alternatives is provided by the applicant of the active substance. However, in several cases, based on the available information, it should not be expected that the analysis of alternatives at active substance level would lead to clear-cut conclusions on the availability of suitable alternatives for the intended uses.

This guidance provides a set of elements which can be used to assess the availability of suitable alternatives to substances meeting the exclusion criteria, and substances meeting the substitution criteria but not the exclusion criteria. It is accompanied by a template<sup>4</sup> which provides a structure for reporting this analysis. Applicants of such substances are advised to use this guidance and to submit an analysis of alternatives to their eCA as part of their application. A public version of this analysis is intended to be published on ECHA’s website (see section 2.2).

This document has been designed as a single framework guidance which allows a **flexible approach, tailored to the case** and the entity performing the analysis of alternatives (i.e. an applicant or a MSCA). It should be seen as a recommended non-mandatory framework guideline for stakeholders, providing advice on how to perform and structure an analysis of alternatives for active substances candidate for substitution. It describes the elements which, in an ideal situation, would be reported and analysed. However, it is acknowledged that it will not always be possible to address all these elements and to reach firm conclusions on all evaluation criteria.

Since the level of access to information related to the intended uses of the active substance and their potential alternatives can be very different between an applicant and an MSCA, the entity conducting the analysis of alternatives would have the opportunity to tailor the breadth and depth of the analysis, according to the case and available resources, as described below. It is not expected from the entity performing the analysis of alternatives that all these elements

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<sup>4</sup> See <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats>

would be described and assessed for each intended use in all the cases due to the likely lack of information. It would be for this entity to judge for the case in question, based on the availability of information, the available resources to conduct the assessment and the criticality of this assessment for the active substance approval/renewal or subsequent biocidal product authorisation how detailed and thorough the assessment should be.

It is expected that an applicant for the renewal of an active substance meeting the exclusion criteria would strive to make an analysis of alternatives which is as comprehensive as possible. Indeed, such an applicant wishing to have its substance (re)approved will have to demonstrate that at least one of the derogation criteria set in Art.5(2) of the BPR is fulfilled, in which the (non)availability of suitable alternatives is a key element.

The guidance does not indicate clear-cut criteria to decide whether an alternative is suitable since this is considered to be a case-by-case assessment, nor whether there are sufficient alternatives. This first version of the guidance describes the desired content for the analysis of alternatives but not the content for the related aspects of the derogation criteria such as Art 5(2)(b)<sup>5</sup> or Art 5(2)(c)<sup>6</sup>. For the latter criteria, the [ECHA guidance on socio-economic analysis](#)<sup>7</sup> may be considered for the establishment of justifications.

Conducting an analysis of alternatives can be done following a general standard approach. However, it remains a case-by-case assessment and should allow flexibility to best match the needs. High-level criteria for the identification and assessment of alternatives can generally be listed but it is not always possible to define detailed specific criteria for all components of the assessment. This guidance builds on other reference documents and methodologies such as the [ECHA guidance on application for authorisation under REACH](#) (ECHA, 2021), the [Commission's Technical Guidance Note on comparative assessment of biocidal products](#) (EC, 2015), the [Interstate Chemicals Clearinghouse Alternatives Assessment Guide](#) (IC2, 2017) and the [OECD Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative](#) (OECD, 2021).

This guidance is primarily aimed at:

- The applicants to support their application for approval/renewal of a biocidal active substance which is meeting the exclusion or substitution criteria
- The MSCAs willing to perform an analysis of alternatives for active substances meeting the exclusion or substitution criteria<sup>8</sup>

However, the guidance can also be used as a reference by the BPC for developing the opinions on the approval and renewal of biocidal active substances, opinions on available alternatives and as an information source for the comparative assessment of products<sup>9</sup>. It can also be used by

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<sup>5</sup> BPR Art 5(2)(b): "it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment"

<sup>6</sup> BPR Art 5(2)(c) : "not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance."

<sup>7</sup> Guidance on the preparation of socio-economic analysis as part of an application for authorisation

<sup>8</sup> Even though eCAs/MSAs do not have a legal requirement to make an analysis of alternatives *per se* in the active substance approval/renewal process they might be willing to make one themselves, e.g. as a complement to one submitted by an applicant or for other reasons.

<sup>9</sup> The comparative assessment of biocidal products prescribed in Art.23 of the BPR follows the procedure described in the Commission's Technical Guidance Note on comparative assessment of biocidal products (EC, 2015). The information on alternatives collected at the stage of active substance approval/renewal is one information source which can be used

third parties willing to submit information on alternatives during the third parties' consultations under Article 10(3).

## 2. Scope of the analysis of alternatives under the Biocidal Products Regulation

### 2.1 The regulatory context

One of the main objectives of the Biocidal Products Regulation is to ensure a high level of protection for both human and animal health and the environment from the use of biocidal products. To reach that objective, the BPR provides a set of mechanisms that aims at creating incentives to the gradual replacement of active substances identified as candidate for substitution by alternatives with a more favourable risk profile.

#### 2.1.1 Substances meeting the exclusion criteria

Article 5 of the BPR ensures that in the course of the evaluation of an application for active substance approval, active substances will be assessed against exclusion criteria which have been set to phase out substances which raise particular concerns (in the meaning of Art. 5(1)<sup>10</sup>). Active substances meeting one of Art. 5(1) criteria shall not be approved unless it is shown that at least one of the conditions set out in Art. 5(2) of the BPR is met<sup>11</sup>. For this purpose, according to Art. 6(1)(c), the applicant needs to submit evidence that Art.5(2) is applicable. Art.5(2) specifies that the availability of suitable and sufficient alternative substances or technologies shall be a key consideration when deciding on the approval of substances meeting the exclusion criteria. In this sense, the submission of an analysis of alternatives by the applicant for a substance meeting the exclusion criteria is required. The approval of active substances meeting the exclusion criteria may be approved for a maximum of five years and renewed for a maximum period of seven years (Art. 10(4) and 4(1)).

Products containing that active substance will have to be subject to a comparative assessment by the receiving/evaluating competent authority at the time of authorisation and will only be authorised if there are no suitable alternatives (Art. 23(3)). Paragraph 10 of Annex VI of the BPR also requests the competent authorities, or the Commission, to evaluate whether the conditions of Article 5(2) of the BPR can be satisfied during the evaluation of the related biocidal products.

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for this purpose, noting though that the situation might have changed between the two processes and that more specific and up-to-date information should be collected at the time of product comparative assessment.

<sup>10</sup> i.e. classified as CMR 1a or 1b, considered as endocrine disruptor or meeting the criteria for PBT or vPvB (Art 5(1)).

<sup>11</sup> Art 5 (2) (a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment; (b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; (c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

### **2.1.2 Substances which are candidate for substitution but not meeting the exclusion criteria**

When substances meet at least one of the criteria for substitution according to Art.10(1)(b) to (f) but do not meet any of the exclusion criteria (Art.5(1)/Art.10(1)(a)), a comparative assessment at biocide product level is performed by the relevant competent authority (Art.23(1)). The placing on the market of the biocidal products containing an active substance which is candidate for substitution shall be prohibited or restricted in case the comparative assessment performed following the technical guidance note referred to in Art. 24 demonstrates that suitable alternatives are available (Art. 23(3)). The submission of an analysis of alternatives by applicants for approval/renewal of such active substances is not legally required but strongly recommended to support the comparative assessment at product authorisation stage.

### **2.1.3 Regulatory challenges related to the assessment of alternatives**

As described above, an analysis of alternatives is a key component of the BPR regulatory process for substances which are candidate for substitution (substances meeting the exclusion criteria (Art.5(1)/Art. 10(1)(a) and the ones only meeting at least one of the criteria listed in Art. 10(1)(b) to (f)), either for the substance approval stage, for the authorisation of biocidal products, or the subsequent renewals. For this purpose, the submission of an analysis of alternatives by the applicants of substances candidate for substitution as part of their application is highly important.

One of the challenges of assessing chemical alternatives under the BPR is the fact the regulatory (first) approval or renewal process of some potential alternatives might not have been completed at the stage of drafting the analysis of alternatives or at the stage of its evaluation by competent authorities. Therefore, the regulatory status (approved/non-approved) and characteristics (e.g. hazard/risk, efficacy) of these potential alternatives is uncertain, leading to uncertainty in the assessment of these chemical alternatives. This issue is recognised and should be mentioned, where relevant, in the analysis of alternatives for the concerned substances.

A different issue affects the non-chemical alternatives: these are not subject to the same approval process as the active substances under the BPR, which may lead to uncertainties regarding some of their features such as their efficacy or risk profile.

Whether a potential alternative is an active substance or not, where these are provided by private companies, the availability on the market of these alternatives may vary over time, depending on the regulatory and market conditions. These uncertainties have an impact on the analysis of alternatives; however, it should be kept in mind that these analyses reflect the situation at the moment of their elaboration based on the information available and that this situation may change in the future. The competent authorities take these elements into account when evaluating the analyses of alternatives.

## **2.2 The process: submission of an analysis of alternatives and third parties' consultations**

If the applicant knows or suspects by that its active substance is a candidate for substitution (either meeting the exclusion criteria (Art. 10(1)(a) or meeting only at least one of the criteria listed in Art. 10(1)(b) to (f)), it is strongly encouraged to submit an analysis of alternatives

covering all the indented uses (to the extent possible) following this guidance and template as part of their dossier for active substance approval/renewal, including a public version which would be published during the consultation referred to in Art.10(3)<sup>12</sup>.

Submitting this information as part of the applicant's dossier will facilitate the collection of information on alternatives during the interested third parties' consultations (see below)<sup>13</sup>. In this regard, it is important that the public version of the analysis of alternatives which is intended to be published has minimum redacted (blacked out) confidential information, if any. Confidential information can instead be reported in a slightly more generic, non-confidential manner. Any confidentiality claim should be duly justified<sup>14</sup>.

In the active substance approval/renewal process, two types of interested third parties' consultations are distinguished, depending on the type of substance:

### **2.2.1 Substances which are candidate for substitution according to Art. 10(1)**

If during the approval process of an active substance, the evaluating competent authority identifies an active substance as a potential candidate for substitution, before submitting its opinion on the approval or renewal of the active substance to the Commission, ECHA will launch a consultation on the active substance in question (Art.10(3) of the BPR). This applies to applications for approval or for renewal of approval of active substances, including review programme substances.

The consultation gathers relevant information on the availability of alternatives to the active substance in question. Information on the availability of potential alternatives is highly important to support the comparative assessment that is required for the authorisation of biocidal products containing the active substance (considered as a candidate for substitution). Information is sought on potential alternatives (chemical and non-chemical) for the targeted organisms and intended use. Chemical alternatives might have similar or different modes of action and application methods than the substance candidate for substitution, or be active substances allowed for the same PT but without known products on the market for the same use (potential candidates to develop alternative products for the intended use). Any information on alternatives under development is also welcome.

To best take into account the collected information on alternatives in the substance evaluation process this consultation under Art.10(3) of the BPR should take place as early as possible, preferably as soon as the applicant's dossier is received, with the publication of the public version of the analysis of alternatives provided by the applicant<sup>15</sup>. This AoA will help interested third

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<sup>12</sup> with the applicant's consent as there is no legal requirement to publish such a document.

<sup>13</sup> In absence of an analysis of alternatives submitted by the applicant, if a MSCA has performed one, it could be published as part of the third parties' consultation referred to in Art.10(3). If no analysis of alternatives is available at all, only basic information on the Cfs and its intended use would be published to collect information on alternatives (see agreed document CA-Dec22-Doc.5.4)

<sup>14</sup> see Appendix 1 for more details. Note that a non-public version of the analysis of alternatives may be requested by third parties under the Access to Documents Regulation No 1049/2001. The author of the document will be consulted regarding possible confidentiality claims as part of that process.

<sup>15</sup> The applicant should base its analysis (including the risk assessment) on the most relevant information. In absence of finalised assessments by the competent authorities/BPC the applicant should use other relevant and pertinent information at its disposal. Since the peer review would not be finalised when the AoA is published, the outcome of the

parties in providing targeted comments based on the information already provided by the applicant.

Based on the applicant's information provided in the application dossier, the comments received during the consultation and other sources of information, the evaluating MSCA (eCA) will describe and evaluate the availability of alternatives to the use of the substance candidate for substitution (CfS) in its draft opinion to the BPC for the approval or renewal of the active substance.

### **2.2.2 Substances meeting the exclusion criteria (Art.5(1)/Art. 10(1)(a))**

For substances meeting the exclusion criteria, to decide if the active substance may be approved or not, an additional consultation<sup>16</sup> is organised by the Commission to collect information on whether the conditions for derogation set out in Article 5(2) of the BPR are satisfied. This consultation generally takes place after that the opinion of the BPC on the approval/renewal of the active substance is sent to the Commission.

Interested parties are invited to contribute to the consultation to collect valuable information for the decision-making process, in particular on whether any of the derogation criteria listed under Art. 5(2) are met (negligible risk, essentiality of the use, disproportionate negative impact on society of a non-approval) but also with relevant additional or updated information on the existence or absence of suitable alternatives. In the case of substances meeting the exclusion criteria, in addition to an analysis of alternatives (as comprehensive as possible), it is essential that the applicant provides solid justifications in relation with the conditions for derogation under Article 5(2) of the BPR to support its application for the approval of the substance.

## **2.3 What is in alternative to a biocidal active substance**

As a first step, it should be carefully considered if there is a real need for the technical functionality provided by the active substance under consideration to prevent or control a serious danger to human health, animal health or the environment and/or if there are other ways of achieving the same goal. If it is considered that the functionality is still needed or that other methods, practices or end-product material changes could be envisaged, alternatives will have to be searched for and assessed. When looking at potential safer alternatives, the options should be looked at widely, such as substances and non-chemical alternatives that could be used.

In general, different types of alternatives can be defined, however, the function is the starting point<sup>17</sup>. Starting a search for alternatives from the technical function performed by the substance to substitute rather than its chemical structure and the associated risks is key to allowing a wider range of substitution solutions. Rather than focusing on similar chemical drop-in substitutes, which often have similar toxicity profiles, this approach – known as 'functional substitution' –

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peer review might affect the risk assessment performed in the AoA. If this is the case, it should be reflected in the BPC opinion.

<sup>16</sup> See <https://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations>

<sup>17</sup> See section 3.2.2 for details on how to describe the function of the active substance

helps to avoid regrettable substitution and can lead to process and product innovation opportunities (Tickner et al. 2015), Alternatives may include chemical substitutions, alternative materials, changes to the product process or product redesign to eliminate a particular chemical. The widest range of possible alternatives should be researched, including emerging technologies (IC2, 2017)<sup>18</sup>, keeping in mind that the alternatives have to be considered from a user perspective.

Applied to biocidal active substances, an alternative can be defined as follows<sup>19</sup>:

### Box 1: Definition of an alternative

An alternative to a biocidal active substance is a means able to replace the function that the active substance performs.

The alternatives can be **chemical substances<sup>1</sup> or non-chemical alternatives** (non-chemical means of control and prevention methods).

Non-chemical alternatives can be e.g. physical means of achieving the same function of the biocidal active substance or means that remove the need for the biocidal active substance function altogether. These could be organisational procedures, preventive measures, a device, changes in a product manufacturing process, changes in the end-product<sup>2</sup>, changes in the material of the end-product (e.g. steel pole instead of wooden pole), etc.

<sup>1</sup> biocidal active substances, including micro-organisms, as described in Article 3(1)(c) of the BPR or non-biocidal active substances. Even though active substances approved under the BPR should be the focus, other active substances can be included in the AoA if relevant and possible (e.g. substances in the Review Programme). Including them in the AoA could provide useful insight on potential upcoming alternatives, noting that a full evaluation according to the BPR prescriptions has not been performed yet.

<sup>2</sup> "End-product" is used in the context of this guidance as a generic term describing the final "object" of interest, which can be a treated article or, other types of objects of similar nature.

The full consideration of the availability of suitable non-chemical alternatives in an analysis of alternative to a substance is key. This is also true in the area of biocides for which a limited number of active substances are approved under the BPR, and for which, at product level, a sufficient chemical diversity is required for a given use<sup>20</sup>. Therefore, non-chemical alternatives

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<sup>18</sup> In the context of the present guidance, it is suggested to only report non-confidential information at a general level under section 3.3.1.2 Research and development. These emerging technologies would not be part of the assessment since these are not considered available yet. The purpose is to provide a general picture of the ongoing developments and R&D.

<sup>19</sup> The grey box below is a definition in general of what could be understood as an alternative to a biocidal active substance. This does not mean that it is possible in all (or most) cases to list and assess all these elements. However, it clarifies that when considering alternatives, a broad mind should be adopted and not considering chemical alternatives only.

<sup>20</sup> At biocidal products level, a comparative assessment of biocidal products has to be performed 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. One of the criteria for considering that suitable chemical alternatives are available is the presence of an adequate chemical diversity, i.e. the availability of at least three different and independent "active substances/mode of action" combinations within authorised BPs for a given use, considered to be sufficient to minimise the occurrence of resistance in the target harmful organism(s). However, for substances meeting the exclusion criteria, the relevant BP could be restricted or prohibited if

can play a crucial role in controlling a pest, in complement or as replacement of the use of biocidal substances.

The purpose of an analysis of alternative under the BPR is to determine whether there are suitable alternatives to the use of an active substance candidate for substitution (CfS) as defined according to BPR Article 10.

Under REACH application for Authorisation, a suitable alternative is defined as (ECHA, 2021):

**Suitable alternative:** *Includes any alternative to the Annex XIV substance for the use applied for, which is safer<sup>21</sup> (i.e. entailing a lower risk for human health or the environment) and technically and economically feasible in the EU (i.e. not in abstracto or in laboratory conditions or under conditions that are of exceptional nature). Furthermore, it must be available from the perspective of production capacities of alternative substances, or from the perspective of feasibility of the alternative technology, and in light of the legal and factual requirements for putting them into circulation.<sup>22</sup> See also the note of the European Commission of 27 May 2020 on "Suitable alternative available in general & Requirement for a substitution plan"<sup>23</sup>.*

By analogy to the suitability criteria developed under the REACH applications for authorisation process, an adapted definition of a suitable alternative to a biocidal active substance under the BPR can be defined as follows:

### Box 2: Definition of a suitable alternative

An alternative to an active biocidal substance is considered a **suitable alternative** for a given intended use if it is fulfilling the three following criteria:

- **Safer**, i.e. it reduces the risk to human health, animal health and the environment, and
- **Technically and economically feasible** for the users in the EU (including efficacy), and
- **Available**, from the perspective of production capacities of alternative substances, or of feasibility of the alternative technology, and in light of the legal and factual requirements for placing them on the market.

The above definitions are consistent with the criteria addressed at biocidal product level in regard to the comparative assessment of biocidal products where Article 23(3)(a) of the BPR indicates: "for the uses specified in the application, another authorised biocidal product or a non-chemical

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alternative BPs, with the same active substances - mode of action combination (e.g. anticoagulant rodenticides) but with a better profile are available (see paragraph 51 of the Technical Guidance Note (EC, 2015).

<sup>21</sup> REACH recital 73 and paragraph 72 of the General Court's judgments in case T-837/16. Judgment of the case T-837/16, Kingdom of Sweden v. European Commission, 7 March 2019, ECLI:EU:T:2019:144. Available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=211428&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=14256428>

<sup>22</sup> Article 55 of REACH and paragraphs 72 and 73 of the General Court's judgments in case T-837/16.

<sup>23</sup> Available at [https://echa.europa.eu/documents/10162/13637/ec\\_note\\_suitable\\_alternative\\_in\\_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1](https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1)

*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".* However, since at the stage of active substance approval/renewal stage not all the uses are known or assessed in detail, it is likely that the assessment of the risks of the alternatives focuses on the hazard and potential for exposure, and that the technical and economic feasibility is assessed at a more generic level than what would be done at the stage of product authorisation.

Initiating the analysis on the basis of the technical function of the substance allows a broader range of substitution options. However, additional considerations are key to ensure that uses for which suitable alternatives are available are properly identified. These are described in the box below and are further described in the relevant sections of this guidance.

### **Box 3: The importance of defining the scope of the uses**

There might not exist a single alternative suitable to cover the full spectrum of intended uses of the CfS (no "one size fits all" alternative). However, different alternatives might be able to replace several of these intended uses. Therefore, to ensure that uses for which suitable alternatives are available are properly identified:

1. the list of alternatives considered in the assessment should be broad enough;
2. the intended uses of the CfS should be appropriately defined (narrowly enough)
3. the criteria or threshold values to assess the suitability of the alternatives should not be over-prescribed but tailored to the real needs for each intended use (i.e. can be different for each intended use).

This guidance describes below recommended steps and set of information for identifying potential alternatives and determining their suitability.

## **3. Content and structure of the analysis of alternatives**

This chapter describes the content and structure of the analysis of alternatives. The ability to address certain components of the analysis of alternatives depends on whether the entity conducting the analysis is an applicant or a competent authority. If a competent authority conducts the analysis of alternatives, it is likely more challenging for them to collect certain information which are normally best known by the substance manufacturers and downstream users. In this case, it is anticipated that the information provided in certain sections is less comprehensive than what an applicant is expected to provide.

Applicants are advised to submit analysis of alternatives which are as comprehensive as possible, including a public version for publication, covering the different intended uses. The breadth and depth of the analysis should be tailored to the case and available resources. It is however acknowledged that it will not always be possible to address all these elements.

### 3.1 Scope of the assessment and overview of the approach

Setting the scope of an analysis of alternatives is critical given that this is the step where is determined:

- (a) the level of stakeholder engagement intended to be undertaken;
- (b) the goals and principles underlying the project; and
- (c) the precise assessment criteria used for assessing the alternatives

Setting the scope also involves establishing boundaries for the assessment. This helps to focus resources and outline a plan to assess alternatives. It includes a description of the intended uses and representative biocidal and treated articles/end-products, hazard endpoints, exposure pathways, life cycle segments, and technical functionality/performance attributes that need to be considered.

The scope of the analysis, the methodology and process followed will depend on the entity conducting the analysis (e.g. a manufacturer of an active substance or a competent authority) and the case at hand. As described above, it is expected from an applicant for an approval or renewal of an active substance which is candidate for substitution<sup>24</sup> that the analysis of alternatives is performed more thoroughly, with involvement of the relevant stakeholders, covering all the intended uses to the extent feasible, so that a fuller picture is provided to the competent authorities for the opinion and decision making. In contrast, if a competent authority performs the analysis, it is expected to be more focused on the key elements.

In the case of applicants, involvement of stakeholders at an early stage of the process is key in collecting information on alternatives.

Transparency in the process of making the analysis of alternatives is also a key requirement to ensure its credibility. Assumptions, data sources, data quality, decisions, etc., should be documented and explained.

As indicated earlier, as a first step, it should be carefully considered if there is a real need for the technical functionality provided by the active substance under consideration and/or if there are other ways of achieving the same goal. This assessment needs to be reported in the analysis of alternatives (see section 3.2.2)<sup>25</sup>. When looking at potential safer alternatives, the options should be looked at widely, such as substances and non-chemical alternatives that could be used.

The process of analysis of alternatives involves:

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<sup>24</sup> both for substances meeting one of the exclusion criteria and the ones only fulfilling one of the criteria listed in Art.10(1)(b) to (f))

<sup>25</sup> The assessment of the need for the technical functionality provided by the active substance is linked to the "essentiality" criterion of the derogation condition described in Art. 5(2)(b) for substances meeting the exclusion criteria and can be documented separately by the applicant as part of its overall argumentation regarding Art. 5(2) conditions. However, since the assessment of the need for the technical functionality of a substance is the very first step of an analysis of alternatives, it is included in this AoA guidance and is applicable not only for substance meeting the exclusion criteria (Art.10(1)(a)) but also to the other substances candidate for substitution (Art.10(1)(b) to f)).

- **identifying potential alternatives** to the active substance under consideration on the basis of the functional requirements for the identified uses and representative biocidal products and treated articles/end-products;
- **assessing the suitability and availability** of potential alternatives, on the basis of their **technical and economic feasibility and overall reduction in risk** to the environment, human and animal health; and
- to the extent feasible, determining the **actions and timescales** that may be required to make available suitable alternatives.

The active substance approval or renewal process under the BPR focuses on the active substance and not on the related biocidal products (which are assessed separately under product authorisation) and all the uses are not necessarily known at that stage. However, a well-conducted analysis of alternatives at the active substance approval/renewal stage needs to address to the extent feasible all the foreseen intended uses and the characteristics of representative biocidal products and treated articles/end-products (if relevant) since they are usually directly relevant for assessing the suitability of the alternatives<sup>26</sup>.

This more comprehensive analysis would allow the applicant to demonstrate the non-availability of suitable alternatives for several intended uses and for the competent authorities to have a broader set of information to evaluate the alternatives both at the stage of active substance approval/renewal and, later on, at the stage of product authorisation during the comparative assessment<sup>27</sup>. Therefore, it is important to include in the analysis such representative biocidal products<sup>28</sup>, treated articles/end-products for each intended use.

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<sup>26</sup> E.g. Wood preservatives: the biocidal product (e.g. a liquid mixture to be applied on wood) and the treated article/end-product (the piece of wood to be protected) can both have characteristics which are relevant for assessing the alternatives.

<sup>27</sup> Even though an applicant might be tempted to focus on one intended use to demonstrate the absence of suitable alternatives and therefore calling for the active substance approval/renewal, the competent authorities might disagree with the applicant's assessment, putting at risk their application. Therefore, from an applicant's perspective, the analysis of alternatives for the different foreseen intended uses can provide a broader picture and a more solid argumentation regarding the non-availability of suitable alternatives for several intended uses.

<sup>28</sup> The focus can be on biocidal products authorised under the BPR. However, considering that still many products are available on the market of EU Member States under the transitional measures, if useful information is available on these, they can be included in the AoA since they can provide useful insight on potential alternatives, underlying though their particular regulatory and evaluation status.

**Box 4: Sustainability aspects, beyond chemical safety**

Beyond the potential reduction of overall risk of using an alternative, broader sustainability criteria can play a role in identifying the most appropriate alternative.

The OECD guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative (OECD, 2021) describes the following:

*The concept of sustainable chemistry includes a broader set of environmental, social, and economic factors beyond the molecular design focus of green chemistry. These include "upstream" and "downstream" chemical or product impacts, resource depletion, circularity, energy use, climate change potential, environmental justice considerations, and worker and community health and well-being. These considerations can form a critical part of the decision about a preferred alternative and are first identified at the scoping stage of an assessment. Sustainability attributes or trade-offs associated with a chemical choice are often considered in the context of a product's lifecycle (or footprint). In addition to hazard and exposure, life-cycle approaches take into account energy use and resource consumption at all points of the lifecycle: raw material extraction, manufacturing, use, and end-of-life management. [...] (OECD, 2021).*

For instance, an alternative could be considered safer, available, technically and economically feasible but could lead to a much higher energy or raw material use over the entire end-product life cycle (e.g. a biocide-treated wood article vs. a plastic, concrete or steel alternative end-product not requiring to be treated with a biocide).

*Evaluating potential impacts of concern along the life cycle and end-of life (recycling) [...] for each alternative could lead to improved decision-making that minimizes potential trade-offs between toxicity and other sustainability attributes. (OECD, 2021)*

This OECD guidance describes ways to address these broader sustainability criteria in an analysis of alternatives. In the context of the present guidance on analysis of alternatives to CfS, to reach the objectives of the BPR aiming at a high level of safety and to avoid a too cumbersome process, it is suggested to focus the assessment primarily on the overall reduction of risk of the alternatives compared to the CfS in relation with the hazard endpoints which makes the active substance a candidate for substitution under Article 10 or the BPR (see section below on risk reduction). However, if significant broader sustainability concerns are identified, they can be reported (and assessed to the extent feasible) in the analysis (e.g. under the "Other information" or "Reduction of overall risk" sections of a given alternative, as appropriate). The identification of these concerns and related trade-offs will help the decision-maker in formulating its judgement on the suitability of the alternative.

The process for the analysis of alternatives can be a stepwise approach, considering different aspects of an alternative's feasibility, risks and availability separately and bringing these together in a final decision. However, it is more likely that all these aspects will be considered simultaneously. Further to this, and more specifically when it is an applicant conducting the analysis, involvement of stakeholders within and outside the supply chain, and especially downstream users will not be a single process in advance of selecting potential alternatives for further investigation, but rather it will be iterative, with continued interactions and information

gathering at each stage of the process.

The IC2 Alternatives Assessment Guide (IC2 2017) describes three different approaches that can be used to assess the different components of an analysis of alternatives:

### 1. Sequential framework

The alternatives from the initial list are assessed in consecutive steps, starting with hazard assessment, followed by performance, cost and availability, exposure and any additional assessment modules. At each step the less favourable alternatives are discarded and the preferred alternatives emerge at the end of the process.

### 2. Simultaneous framework

The alternatives from the initial list are assessed simultaneously for all assessment modules (hazard, performance, cost and availability, exposure, any additional elements). A multi-parameter analysis is then performed to select the preferred alternatives.

### 3. Hybrid framework

This framework is the combination of the sequential and simultaneous frameworks. The hazard and performance assessment are performed first in sequence, resulting in a first set of preferred alternatives. This set of alternatives is then assessed for the other modules (cost and availability, exposure, any additional elements) and a multi-parameter analysis is performed to select the final list of preferred alternatives.

It is up to the assessor making the analysis of alternatives to decide which approach is the most appropriate to their case. The relative importance of the different components of the analysis will be different in each case. For example, it may be clear that a potential alternative does not represent a reduction in risk as compared to the CfS. In this event, there is no need for a detailed analysis of the technical and economic feasibility of this alternative. However, the decision criteria and reasons for concluding on the (non)suitability of an alternative for a certain assessment component should be clearly described and justified by the author of the analysis. At biocidal products authorisation stage, competent authorities apply a tiered approach as described in the Technical Guidance Note on comparative assessment of biocidal products (EC, 2015) to assess alternatives. A tiered approach (e.g. the sequential framework described above) can also be taken to conduct an analysis of alternatives at active substance level.

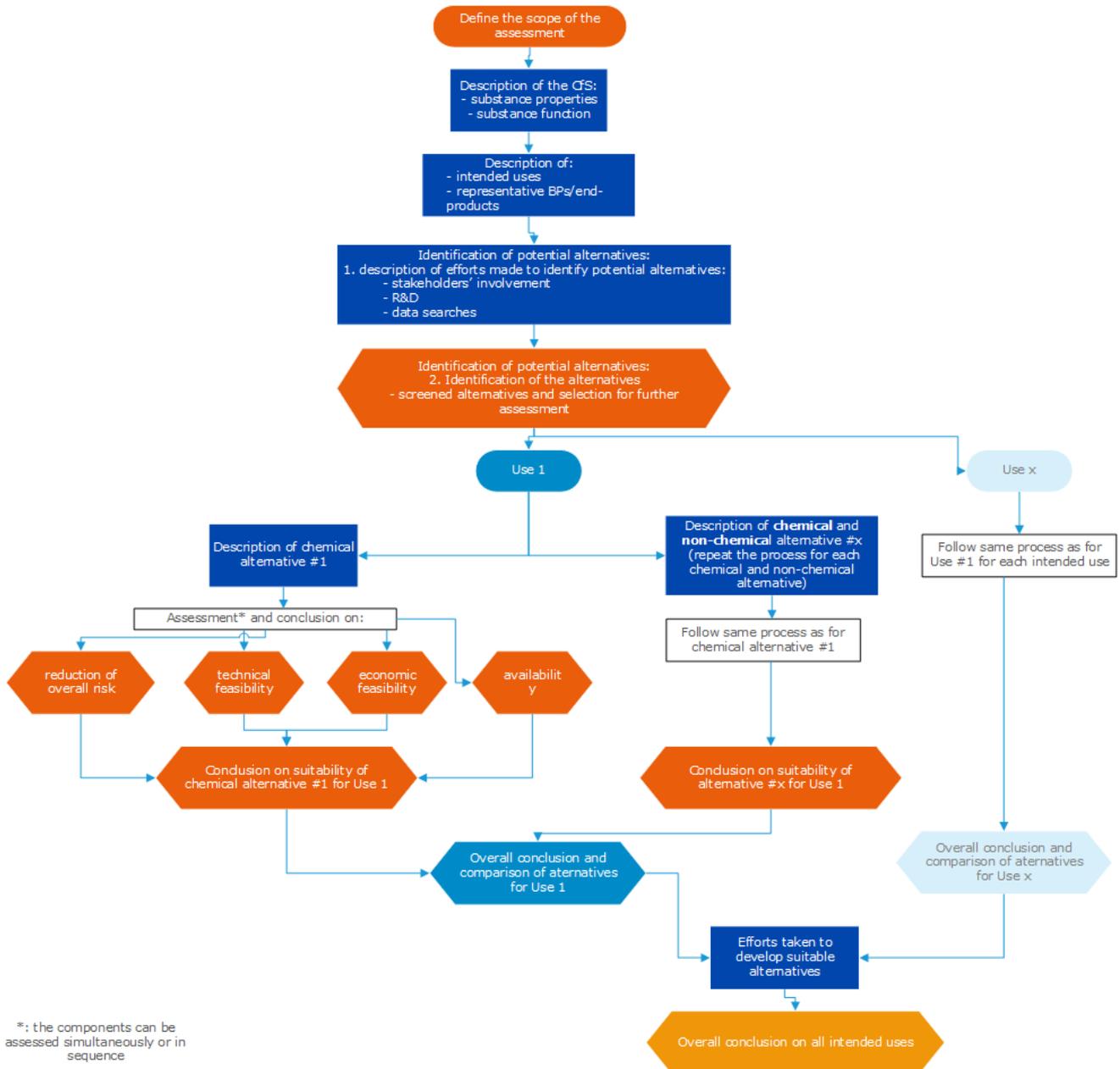
#### **Box 5: Methodologies for analysing alternatives and real cases examples**

Several methodologies and guidance material exist on analysing alternatives or some components of the analysis. However, the main components are generally similar and are described in the present guidance on alternatives to biocidal active substances.

For additional references, the [OECD substitution toolbox](#) provides a large compilation of methodologies, tools and other resources relevant to chemical substitution and analysis of alternatives, including e.g. [ECHA's Guidance on the preparation of an application for authorisation](#) (ECHA, 2021), the [Interstate Chemicals Clearinghouse Alternatives Assessment Guide](#) (IC2, 2017), the [OECD Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative](#) (OECD, 2021). Also, [ECHA's substitution webpages](#), selected [examples](#) of analysis of alternatives under REACH applications for authorisation, and ECHA's [online training on analysis of alternatives](#) are useful resources to consider.

Figure 1 describes a possible stepwise approach for conducting the analysis of alternatives.

**Figure 1: Stepwise approach for conducting the analysis of alternatives**



## 3.2 Analysis of the substance function(s), types of uses, technical requirements and markets for the products

### 3.2.1 Identification and properties of the substance candidate for substitution

The substance identity of the active biocidal substance for which the analysis of alternatives is performed should be clear. This section should summarise the most relevant substance identifiers, physical properties, hazard classifications and hazard concerns, Product Types and the list of intended uses<sup>29</sup>.

Regarding the substance identity and main properties, the following pieces of information can be provided, if applicable and feasible:

#### *Chemical substances*

##### Substance identity:

- ISO name, IUPAC name or equivalent
- CAS and EC number
- Molecular and structural formula
- Molecular mass

##### Physico-chemical properties:

- Appearance
- Melting point
- Boiling point
- Temperature of decomposition
- Vapour pressure
- Henry's Law constant
- Relative density
- Solubility in water
- Partition coefficient (n-octanol/water) and its pH dependency

##### Hazard properties:

- Harmonised classification according to CLP
- PBT/vPvB or ED properties
- Hazard properties having led the active substance to be considered as a candidate for substitution under Article 10 of the BPR

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<sup>29</sup> Please refer to the ECHA Guidance for identification and naming of substances under REACH and CLP for more details on how to identify a substance: [https://echa.europa.eu/documents/10162/23036412/substance\\_id\\_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d](https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d)

### *Micro-organism*

#### Identity:

- Common name of the micro-organism
- Taxonomic name and strain

#### Biological properties:

- General information on the micro-organism
- Development stages/life cycle of the micro-organism
- Hazard properties having lead the micro-organism to be considered as a candidate for substitution under Article 10 of the BPR

## **3.2.2 Description of the function provided by the CfS active substance**

As indicated in previous sections, a good understanding of the substance function is the starting point to look for other ways of performing that function with a wide range of possible options<sup>30</sup>.

In this section a description of the following information should be indicated:

- what the active substance is doing (task) and how (mode of action);
- a summary of its efficacy towards the target organism(s)<sup>31</sup>;
- other useful functions than the biocidal action that the active substance might have;
- the necessary conditions under which the function(s) is(are) performed
- are there features of the treated articles/end-product that determine the requirement for use of the substance? Would using a different article or a different material for the article eliminate the need for the active substance?<sup>32</sup>
- is there a real need for the functionality delivered by the substance?
  - if it is possible to eliminate the CfS without substitution while maintaining the function of the end-product/article, finding an alternative is not necessary<sup>33</sup>. A description and justification for the need for the technical functionality provided by the CfS should be provided;
  - are there are other ways of achieving the same goal or the possibility to completely eliminate the need for the CfS via adaptation of production processes or materials, i.e. would the use of non-chemical methods (non-chemical means of control and prevention methods) eliminate the need for the active substance? (e.g. by using a different process to manufacture the end-product or by changing the material used to manufacture the end-product). These potential non-chemical alternatives should be part of the assessment in addition to the potential chemical alternatives.

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<sup>30</sup> See e.g. [Tickner et al. 2015](#) for more details and examples for defining the function of the substance, assessing the need for it and looking at the broader range of substitution options.

<sup>31</sup> E.g. to the extent known, from the applicant's dossier or active substance assessment report, if available.

<sup>32</sup> Details of required technical specifications should be provided in section "Description of the technical requirements that must be achieved by the product(s) and treated articles"

<sup>33</sup> E.g. is a disinfectant really needed in a hand soap to be used by the general public in households? If not, this active substance can simply be eliminated from the hand soap without significantly affecting its overall sanitisation properties.

If the above information varies among the different intended uses, it should be described per intended use. The methodology, data sources (preferably obtained from trusted, independent sources), assumptions made, uncertainties should be presented and justified.

### 3.2.3 Intended uses, representative products and treated articles

A more detailed description of the foreseen intended uses of the CfS active substance is necessary to identify potential alternatives to each of these uses and further assess their suitability. Even if at the stage of active substance approval/renewal all the intended uses are not necessarily known, it is advised that the applicants investigate this issue in detail to be able to describe and assess the different foreseen intended uses to support their argumentation that no feasible alternatives are available for several uses<sup>34</sup>. This would support the competent authorities to have a broader set of information to evaluate the alternatives both at active substance and, later on, at biocidal product level during the comparative assessment.

The following information should be provided to the extent feasible:

- Overview
  - Overview of the intended uses of the active substance, the types of biocidal products<sup>35</sup> in which it is used and the related treated articles/end-products<sup>36</sup>
- Markets and supply chains<sup>37</sup>
  - the market sectors for these biocidal products and treated articles/end-products (e.g. professional, general public),
  - countries/regions where the biocidal products, treated articles/end-products are commercialised,
  - volumes involved (active substance, biocidal products, treated articles/end-products) and the economic value,
  - which are the main producers and users,
  - market trends
- Application methods and rates, risk mitigation measures for each intended use (how is the active substance used in the biocidal products, treated articles/end-products)

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<sup>34</sup> Taking into consideration the fact that competent authorities might disagree with the applicant's conclusion on the non-availability of alternatives, which would put the applicant's application under risk if only one intended use has been assessed by the applicant in its AoA.

<sup>35</sup> Only biocidal products authorised under the BPR or under the transitional measures.

<sup>36</sup> These intended use descriptions and categorisations will be used in the section on suitability and availability of alternatives (each alternative assessed per intended use).

<sup>37</sup> To the extent the information is known and not breaching competition law. Ranges can be provided if precise figures are confidential. There is no need to provide detailed information as the aim is to have a general picture of the market to understand the context and the importance of the use of the AS. More detailed information and analysis on this topic can be provided separately in a socio-economic analysis. Basic high-level information can often be available e.g. from business sector associations public data, open literature, biocidal product factsheets from ECHA's website. More detailed information can also be obtained from paying market research consultancies.

- Combinations with other active substances, if relevant

In addition to the information above, for a given product type (PT), the core identification elements of an intended use can be summarised in a table. An example is indicated in the Technical Guidance Note on comparative assessment of biocidal products, section 5.1 (EC, 2015):

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

As stated in the same technical guidance note, if an application method makes that the biocidal product 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.

As described in section 2.3 box 3, the way the intended uses are defined is key in identifying alternatives. This can be shown with the following example: an active substance CfS used for PT18 against specific insect species might have suitable alternatives for the insect species present in continental Europe but not for the tropical species present in overseas territories of the EU. In this case, two separate intended uses should preferably be defined (use against continental species and use against tropical species) and taken as a basis for the analysis of alternatives. This information would provide useful input for the comparative assessment at the biocidal product authorisation stage.

While performing the analysis of alternatives, the existence of suitable alternatives for certain sub-uses within a given intended use might be revealed, calling then for the need to redefine the intended use to segregate the ones where suitable alternatives are available. In practice, the definition of intended uses is often an iterative process based on several aspects, including the availability of suitable alternatives<sup>38</sup>.

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<sup>38</sup> Similar considerations take place under the REACH application for authorisation process. See e.g. the guidance on How to develop use descriptions in applications for authorisation, available at [https://echa.europa.eu/documents/10162/13566/uses\\_description\\_in\\_auth\\_context\\_en.pdf/14b5f647-1778-47de-8178-2e2dad170424](https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf/14b5f647-1778-47de-8178-2e2dad170424)

### **3.2.4 Description of the technical requirements that must be achieved by the product(s) and treated articles**

For each foreseen intended use, the requirements that must be met by representative biocidal products, treated article/end-product to achieve a similar or acceptable level of technical feasibility (including efficacy) compared to the ones using the CfS should be described as much as possible.

These technical requirements (e.g. efficacy towards the target organism, usability in a certain temperature range, compatibility with a certain material) will be the basis for assessing the technical feasibility of the alternatives.

To the extent feasible, these requirements and corresponding values should be listed, including tolerances (i.e. an acceptable range) for the product(s), treated articles/end-products or process concerned.

If applicable, the additional requirement such as the ones below can be listed:

- Regulatory or legal requirements for technical acceptability (e.g., maximal regulatory limits or regulatory approval by national authorities);
- Internationally recognised standards for technical performance (e.g., EN or ISO standards);
- Certification requirements.

If several industrial/market sectors are concerned and if they have different technical requirements, the discussion should reflect this variety.

As indicated earlier, it is key that the criteria or threshold values selected to assess the suitability of the alternatives should not be over-prescriptive but tailored to the real needs for each intended use (i.e. the specifications can be different for each intended use).

## **3.3 Identification of potential alternatives**

### **3.3.1 Description of efforts made to identify potential alternatives**

#### 3.3.1.1 Stakeholder involvement<sup>39</sup>

For the author of the analysis of alternatives to properly identify and assess potential alternatives, involvement of stakeholders within and outside the supply chain of the applicant is a key step. This allows to:

- Better understand the exact uses of the biocidal active substance and therefore understand its function;

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<sup>39</sup> This refers to the involvement of stakeholders conducted during the elaboration of the analysis of alternatives and not to the consultation run by ECHA as per Article 10(3) of the BPR or to collect information whether the conditions for derogation set out in Article 5(2) of the BPR are satisfied.

- Better understand the technical and economic feasibility of potential alternatives;
- Determine if the alternatives are suitable and available in order to enable the substitution;
- Identify potential areas for development of alternatives.

The stakeholder involvement might also help identifying what actions and timescale would be required to make potential alternatives suitable and available.

During this process, it should be kept in mind that competition law and issues related to confidential business information remain applicable and that not all information may be shared between the involved parties.

Stakeholder involvement should take place within and outside the applicant's supply chain and involve<sup>40</sup>:

- In-house consultation
- Downstream users of the biocidal active substance for which an alternative is sought and suppliers of alternatives
- Suppliers of alternatives
- Trade/sector organisations
- Key process/technology developers/producers not within the substance supply chain
- Leading academic and research institutions in the field
- Trade/labour unions, NGOs
- Etc.

### **Tips for reporting the stakeholder engagement undertaken during the preparation of the analysis of alternatives**

- When third parties are involved, include company names and contact details but do not provide names of persons.
- Provide as much details as possible about companies that provide alternative substances, technologies, or services to meet the function of the active biocidal substance for which an alternative is sought;
- As relevant, provide details of how you have involved (parts of) the supply chain(s), in particular the applicant's customers and/or downstream users and any other organisations contacted;
- Provide information about any surveys you have done with the customers and other actors regarding the availability of alternatives;
- Describe how you assessed the users' acceptance of alternatives that you have been

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<sup>40</sup> If no analysis of alternatives has been received from the applicant and that a MSCA conducts such an AoA, the consultation referred to in Art.10(3) of the BPR can serve as a replacement of the stakeholder involvement if none has been organised during the preparation of the AoA. The MSCA can always conduct additional targeted consultations when preparing its analysis of alternatives (recommended approach).

investigating (e.g., by running customers' surveys, performing market analysis, or indicating the relevant sectoral technical standards, pre-agreed performance criteria, etc.).

- Provide details of other organisations such as trade associations, consumer interest groups etc. that you have contacted.
- Report the information collected in the relevant sections of the analysis of alternatives.

### 3.3.1.2 Research and development

High-level non-confidential information on past, current and/or planned R&D activities undertaken to identify potential alternatives should be considered appropriate to include, to the extent feasible, in the analysis of alternatives.

These activities can be undertaken by the applicant, suppliers of biocidal substances or products, suppliers of alternatives, downstream users, regulators, universities, research institutes and others by using in-house information, publicly available information and/or by communicating within and outside the supply chain.

This information aims at providing a general picture on the possible developments which could lead to a progressive substitution of the CfS. It would increase the understanding of the regulators regarding the reasons for present alternatives being non-suitable for certain uses and prospects for future availability of suitable alternatives.

### 3.3.1.3 Data searches

Data searches from several sources of information can lead to valuable insight on the availability of alternatives.

Such information can come from:

- Scientific literature, academic/trade journals
- Journals and conferences for the respective user groups (e.g. pest controllers)
- Publicly available tools and databases
- EU and non-EU programmes on chemical safety
- Patents databases
- Other sources

**Box 6: Examples of source of information on biocides and their alternatives**

- The list of active substances included into the Union list or Annex I, or under examination (under the review programme set up in Article 89 of the BPR or outside the review programme applied for a new active substance) for the same product type, and similar uses (pattern of use, target organism, etc.) – see [ECHA biocides database](#);
- The list of biocidal products authorised in R4BP for the same product-type, and similar uses (pattern of use, target organism, etc.) – see [ECHA biocides database](#);
- Any information available to Member States Competent Authorities, including on biocidal products still placed on the market under the transitional period set up under Article 89 of the BPR (only available to Member States Competent Authorities);
- Outcome of consultations of interested third parties in accordance with Article 10(3) of the BPR (if available);
- German [Blue Angel products database](#): gathering more than 20 000 products and services labelled as environmentally friendly
- [ECHA's substitution pages](#): contains links to several databases, tools and methodologies relevant for the different steps of an analysis of alternatives and substitution projects
- [SCOTTY](#) platform: information on biocides and their alternatives
- [SUBSPORTplus](#): substitution portal with lists of assessed alternatives, tools and guidance for substance evaluation and substitution management
- [ChemSec Marketplace](#): online platform with alternatives to substances of concern, enabling buyers and sellers of alternatives to hazardous chemicals to interact
- [CORDIS database](#) of projects under the EU Research and Innovation funding programmes: information on all EU-supported R&D activities, including programmes (H2020, Horizon Europe, FP7 and older), projects, results, and publications
- [OECD substitution toolbox](#): a compilation of resources relevant to chemical substitution and alternatives assessments

This section should be used to list the information sources consulted and summarise the outcome. The more detailed findings and argumentation about the technical and economic feasibility, availability, reduction of overall risk or other information can be described in the relevant sections of the "Suitability and availability of potential alternatives" heading.

### 3.3.2 Identification of alternatives

#### 3.3.2.1 Screened alternatives and selection for further assessment

The list of all alternative substances and non-chemical alternatives that have been identified for the different intended uses of the CfS should be provided here. If there are differences in the alternatives identified and selected for the different intended uses, this should be mentioned.

As mentioned in section 2.3, the range of potential alternatives should be considered widely and from a user perspective, prior to any potential narrowing of the list of alternatives considered for a deeper assessment.

A list of the criteria that served for this first selection of potential alternatives should be presented.

Following the compilation of a first list of potential alternatives, the key criteria used to select a sub-set for a more in-depth analysis should be described and justified.

When setting up these key criteria it is important to keep in mind that non-chemical alternatives in a broad sense could be suitable alternatives for the intended uses. Therefore, the selection criteria should properly take into account this viewpoint and not be substance-centric but function-centric instead.

Based on the initial list of potential alternatives and the key selection criteria described above, a shortlist of potential alternatives selected for a more in-depth analysis should be developed.

The reasons why the alternatives from the initial list of potential alternatives have been selected or rejected should be clearly stated. The results can be presented in tables, such as the ones below.

It should be noted that an active substance meeting the substitution criteria is not excluded *a priori* from being a potential alternative to another active substance meeting the substitution criteria, as it may present a better profile on certain aspect(s) compared to the active substance subject to examination for its approval/renewal of approval.

**Table 1: Initial list of chemical and non-chemical alternatives and outcome of the selection for further assessment**

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment

**Table 2: Shortlisted chemical and non-chemical alternatives for further assessment**

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of alternative

### 3.4 Suitability and availability of potential alternatives

Alternatives have to be assessed for their suitability with regard to the intended uses. Each alternative which has been shortlisted in the previous step should be assessed in more details regarding the different criteria listed below:

- Reduction of overall risk to human health, animal health and the environment compared to the use of the CfS
- Technical feasibility (including efficacy and resistance of target organisms)
- Economic feasibility
- Availability
- Other information (if relevant)

It is recommended to report this assessment **by intended use and potential alternative** (see AoA template). The sections below describe the desired information content for each suitability criterion. However, it should be noted that each criterion does not necessarily need to be assessed in the same level of details, e.g. if a potential alternative clearly fails some suitability criteria for the intended uses (e.g. technical or economic feasibility), the other criteria do not need to be assessed in great details. The sections below describe in general terms how the different components of the suitability of alternatives can be assessed. Several more detailed guidance documents and tools exist to conduct such assessments and can be used to complement<sup>41</sup>.

#### 3.4.1 Description of the alternative: substance identity and properties (chemical alternative) or description of the non-chemical alternative

If the alternative is a substance, a description of it in a similar manner as done for the active

<sup>41</sup> See e.g. list of methodologies and tools referred in [ECHA's webpages on substitution](#) and the [OECD substitution toolbox](#).

substance meeting the substitution criteria should be provided (see section 3.2.1<sup>42</sup>), as well as a general description of the way it is used. More detailed technical information on the use conditions can be provided in the technical feasibility section.

For non-chemical alternatives, a description of the means of control or of the prevention method should be provided. The description should be sufficiently detailed to allow the reader to understand what the main components of the method are, what it does precisely and under which conditions. More detailed technical information on the use conditions can be provided in the technical feasibility section.

### 3.4.2 Reduction of overall risk

The use of a suitable alternative in a given product should result in a reduction of the overall risk to human health, animal health and the environment compared to the use of the CfS.

#### 3.4.2.1 Assessing and comparing with the risks of potential chemical alternatives

For chemical alternatives, a detailed comparative risk assessment can be a complex task. For this reason, a targeted approach can be adopted, focusing on the hazards and, where feasible, adding information on potential exposure. In terms of hazard endpoints, the ones related to the exclusion/substitution criteria, such as described in point 6.2.2.1.1 of the Technical Guidance Note (TGN) for the Tier I-B comparative assessment of biocidal products (EC, 2015) should be addressed:

- (a) Concerning human or animal health:
  - CMR properties (exclusion criterion),
  - ED properties (exclusion criterion),
  - Respiratory sensitiser (substitution criterion).
- (b) Concerning the environment<sup>43</sup>:
  - PBT properties (exclusion criterion),
  - Two out of the three P/B/T properties (substitution criterion).
- (c) Concerning the identity of the substance:
  - Significant proportion of non-active isomers or impurities (substitution criterion).

However, if the active substance has been identified as CfS on the basis of Art 10(c)<sup>44</sup> or 10(e)<sup>45</sup>

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<sup>42</sup> If the alternative is a micro-organism, report the micro-organism identification and biological properties as most appropriate.

<sup>43</sup> Even though not listed under the TGN, ED properties for non-target organisms could also be added if information is available.

<sup>44</sup> The acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario.

<sup>45</sup> There are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures.

of the BPR, these endpoints should be considered as well<sup>46</sup>.

At a minimum, information on the identification (e.g. endocrine disruptor), classification or on the values for these hazard endpoints should be mentioned. In certain cases, other priority endpoints than the ones listed above might be relevant to consider to better compare the hazard profiles of the alternative and the CfS (e.g. acute aquatic toxicity, flammability, neurotoxicity).

A quantitative comparative exposure assessment would be needed to determine if the substitution to the alternative would result in an overall reduction of the risk. However, this is only possible if the use patterns are well understood, which is most likely not the case at active substance approval/renewal stage<sup>47</sup>. Conducting an exposure assessment can therefore be limited to the cases where the exposure patterns for the intended uses are known and where there is a clear added value in making such an assessment at the active substance level for determining the overall risk reduction of the alternatives. At product authorisation level, detailed comparative risk assessments between products can be performed. However, if more generic information on potential exposure to the alternatives (compared to the CfS) and on the potential resulting risk is available, this can be provided as it could provide useful insight.

The OECD guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative (OECD, 2021) describes different approaches to select endpoints of relevance, making and presenting the comparative risk assessment and ways to address identified trade-offs, supported by an example.

### **Qualitative comparative exposure assessment**

*The purpose of a qualitative comparative exposure assessment is to determine the differences in the intrinsic exposure potential of alternatives relative to a priority chemical for humans and ecosystems, regardless of external exposure controls in place (such as gloves), over the life cycle of the substance and its potential alternatives. This component of the assessment will help answer the question: Is the alternative preferable, equivalent to, or potentially worse than the priority chemical given the potential for exposure?*

*Conducting a comparative exposure assessment may not be necessary if the alternatives have similar forms, use patterns, and physical-chemical properties. In the more likely case, where alternatives' physical-chemical properties vary, it is important to know whether these properties will impact a determination about which alternative is safer. A qualitative exposure assessment can help determine whether properties of the substance or its use characteristics can increase or decrease specific hazards. Chemicals and their alternatives can then be compared across hazards using the potential for exposure.*

*Exposure assessments that are conducted as part of an alternatives assessment are comparative and consider the potential for exposure based on inherent or intrinsic chemical and physical properties as well as expected use scenarios and do not, necessarily, attempt to quantify those exposures, except where necessary to understand potential exposure trade-offs. A quantitative assessment is typically used in conducting risk assessments. The U.S. National Research*

<sup>46</sup> See also CA-Nov14-Doc.4.4 – Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR available here: <https://circabc.europa.eu/w/browse/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c>

<sup>47</sup> If available, the CARs and PARs can be useful sources of information.

*Council's (NRC) alternatives assessment framework established the use of the term intrinsic potential for exposure because it focuses on the use of physical-chemical properties and qualitative exposure considerations such as use conditions and plausible routes of exposure (National Research Council 2014). This guidance lays out the steps by which a qualitative exposure assessment should be carried out by identifying exposure pathways and comparing exposure potential.*

*The main components for a qualitative exposure assessment are:*

*A. Identifying exposure pathways and reasonably foreseeable exposure scenarios throughout the lifecycle; and*

*B. Comparing exposure potential*

*[...]*

Source: OECD (2021): Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative

If a risk assessment is performed, the comparison can focus on elements from a qualitative to a more quantitative nature. As mentioned in the TGN, 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 (adapted from EC, 2015):

- The risk assessments of the alternatives might have been based on previous guidance documents, exposure models, etc.
- 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.
- The exposure patterns of the alternatives 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...).

The aim is to assess the effects of the substitution to the alternative in reducing the risk (compared to the CfS) while not causing other risks that cannot be controlled.

For example, in relation to alternative substances, the work involved may include (adapted from ECHA, 2021):

- collecting data on the properties of alternative substances from manufacturers and importers or other sources (e.g. from ECHA's database or other sources<sup>48</sup>);
- examining the hazard profiles of the alternative substances and comparing them to the hazard profile of the CfS to assess whether it is possible to determine with sufficient certainty that the alternative would result in a lower level of risk;
- examining the exposure levels of the alternative substance, e.g.,

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<sup>48</sup> See e.g. ECHA's substitution webpages which includes several links to hazard databases: <https://echa.europa.eu/search-for-alternatives-for-substitution>

- examining information on emissions to the environment and/or environmental concentrations of the alternatives and data on current levels of exposure of workers or consumers from publicly available sources or impacts associated with alternative options;
- using exposure modelling
- where necessary, combining the hazard and exposure data for alternatives to determine whether they would result in a lower level of risk
- if appropriate, quantifying and valuing the change in risk following the approach taken for the evaluation of the CfS.

It is not required to generate new hazard data for each of the alternatives. The risks associated with alternative substances or non-chemical alternatives do not necessarily need to be assessed in the same detail as the risk assessment made for the CfS in the AS approval/renewal or BP authorisation processes. The level of effort that needs to be put into this assessment will be a matter of judgement for the author of the analysis of the alternatives, based on the case and the information which is available. For example, the comparison of hazard profiles may indicate that the alternatives clearly present a lower level of risk. In these cases, no additional assessment may be necessary. When a comparison of hazard profiles or a lack of data raises concern regarding the overall reduction of the risk by using the alternative, then there may be a need for more detailed assessment of any changes in risk following as appropriate the approaches described in the ECHA BPR guidance on human health and the environment, if this is possible to do at the active substance approval/renewal stage.

#### *Lifecycle assessment*

Ideally the assessment should address all potential risks throughout the entire lifecycle of the substances including all relevant compartments and populations. The reason for this is that, while an alternative may reduce the specific identified risks of the CfS, it may pose other risks at different points in its lifecycle or may shift the risks to other compartments/populations when it replaces the CfS. In other cases, the use of alternatives may have secondary adverse effects that may not be immediately recognisable, for example, an increase in the production of hazardous waste at the end of the lifecycle or increased energy consumption.

In practice, since this type of information is not expected to be readily available for the CfS and the alternatives and to avoid a too cumbersome assessment, the author of the analysis of alternatives should identify if a lifecycle assessment would be meaningful and feasible. If this is the case, the most relevant life cycle stages, environmental compartments, living organisms and human populations to assess the risk of the alternative should be identified and assessed. A description of the rationale for the choices made, the outcome of the assessment and the identified trade-offs should be reported.

#### 3.4.2.2 Assessing and comparing with the risks of potential non-chemical alternatives

The comparison with non-chemical alternatives can normally not be fully quantitative (i.e. with directly comparable numeric values) as the risks will not be expressed in similar terms, but will in most cases be qualitative or semi-quantitative. Nevertheless, a clear and transparent description should provide a good basis to conclude whether overall risks are reduced when

using the alternative.

For alternative technologies consideration should for example be given to environmental controls, working practices and legislation controlling other risks (e.g., fire and explosion, confined spaces and extreme temperature and pressure). Care should be taken to assess other potential secondary effects of the alternative, such as potential increases in the production of hazardous waste or increased energy consumption (see also box 4 "Sustainability aspects, beyond chemical safety" under section 3.1).

Physical hazards to human health or other living organisms can arise from the use of non-chemical alternatives such as potential exposure to high temperatures, raised levels of pressure, noise, ultrasounds, vibrations, radiations or increased risk of fire and explosion.

Where hazards have threshold effects, no-effect 'safe' levels could be determined and compared with the estimated exposure. Member State Competent Authorities for the protection of worker health will often have information available on the assessment and control of non-toxic hazards. It is recommended that such guidance is consulted to determine the relevant risks (and control measures) from alternative techniques.

#### *Conclusion on the reduction of overall risk of using the alternative*

The comparative assessment of the overall risk of the alternative and the CfS should result in a conclusion – to the extent feasible - whether using the alternative is likely to present a significant lower overall risk for (1) human health, (2) animal health and (3) for the environment or not (the three components should be concluded on separately). This means if the 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 corresponding use of the CfS.

Due to the probable lack of detailed information available to determine the overall reduction of risk of using the alternative, it is possible that no clear-cut conclusions can be drawn. However, the author of the analysis can highlight the main findings related to this issue.

The biological significance of the effects are understood in a similar way as defined in the TGN (adapted from EC, 2015):

- "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 use of the CfS and the use of the alternatives are not marginal but relevant in terms of biological significance for the safety to humans, animals or the environment.
- "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 use of the CfS and the use of the CfS alternatives are only marginal and not relevant in terms of biological significance for the safety to humans, animals or the environment.
- 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.

### 3.4.3 Technical feasibility

For the purpose of this guidance the term “technical feasibility” comprises the feasibility of the implementation of the alternative substance in products or alternative methods from the following perspectives:

1. technical and practical point of view;
2. efficacy towards the target organisms<sup>49</sup>;
3. resistance of target organisms.

Technical feasibility of an alternative is based on the alternative fulfilling or replacing the function of the CfS. It is therefore closely linked to the function that this substance performs, i.e. the specific task that the substance performs and under what conditions the function must be performed. Therefore, as described in section 3.2.2, the function of the substance in the intended uses must be clearly defined before considering the technical performance and feasibility of the alternatives.

Based on the outcome of the stakeholder involvement, literature searches, data collected and the technical requirements specified (section 3.3.1) a transparent assessment of the technical feasibility of the alternative should be presented. It should be shown how the criteria for equivalent function were applied to the potential alternative to determine its technical feasibility and how the information gathered in the consultation was integrated in the assessment. The methodology, data sources (preferably obtained from trusted, independent sources), assumptions made, uncertainties and their effects on the conclusions on the technical feasibility of the potential alternative should be presented and justified.

The possible process or method changes required for a substitution to the alternative substance or non-chemical alternative and how these affect the technical feasibility of the alternative should be described. Based on the definition of practical disadvantage mentioned in the Technical Guidance Note on comparative assessment of biocidal products (EC, 2015), the following changes (positive, negative or neutral) affecting the technical feasibility of substitution should be identified in the present assessment<sup>50</sup>:

- (a) Any adaptations or changes in the technology, process, procedure or device, modification of end-product or other solutions necessary to replace the relevant product<sup>51</sup> (e.g. the requirement for new/additional equipment, risk mitigation measures, energy, personnel changes and training needs, raw materials, waste, etc.).

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<sup>49</sup> Recognising that details on efficacy might not be known at active substance level.

<sup>50</sup> The TGN refers to “practical and economic disadvantages”, however, in the present document, the assessment of the technical and economic feasibility refers to “changes” rather than “disadvantages” since the alternative can also perform better than the CfS for certain criteria. The conclusion of the feasibility of the alternatives can refer to disadvantages in case the alternative is considered not suitable.

<sup>51</sup> In the context of this guidance, replacing the CfS active substance is the target.

- (b) Any other changes in terms of compliance with legislation on worker safety, relation with community, etc.
- (c) Any change in time for effect or higher amounts of alternative active substance or BPs needed to achieve the control of the target organism<sup>52</sup>.

In addition, to the extent possible, information and discussion on the potential effect of the substitution on the resistance of the target organisms should be included.

The assessment of the technical feasibility of an alternative is case by case and it is not possible to derive a precise list of criteria or data to be assessed in this guidance document. It is for the author of the analysis of alternatives to determine which are the most relevant criteria to include and how to assess the results. If available and relevant, existing guidance should be used, e.g. ECHA's guidance on efficacy<sup>53</sup>.

Comparing the technical feasibility of chemical substances and non-chemical alternatives can be challenging, especially in terms of efficacy. Specific guidance or previous analysis of alternatives might exist for certain active substances, biocidal products, product types or uses, which can help in determining the most appropriate criteria and assessment methods to use<sup>54</sup>. The assessment should indicate if there is information available whether the non-chemical alternative is likely to be sufficiently effective, i.e. if it would provide similar or acceptable levels of protection, control or other intended effects to those of the products using the CfS.

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 described.

The technical feasibility assessment of an alternative should include the qualification of the changes whether these constitute significant disadvantages or not. Following the same approach as the TGN (EC, 2015), a significant disadvantage of an alternative from a technical point of view can be defined as 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<sup>55</sup>

#### *Conclusion on the technical feasibility of the alternative*

Based on the above, a conclusion on the technical feasibility of the alternatives for the intended uses should be drawn, to the extent feasible.

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<sup>52</sup> cases where the alternative takes a longer (or shorter) time to have an effect in eliminating/controlling the target organism or if higher (or lower) amounts of the active substance or biocidal product are needed to achieve the same result.

<sup>53</sup> Available at <https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

<sup>54</sup> E.g. Guidance for the Evaluation of Rodent Traps, which is relevant for assessing traps as non-chemical alternatives to rodenticides (UBA, 2021), available at <https://www.umweltbundesamt.de/en/publikationen/nochero-guidance-for-the-evaluation-of-rodent-traps>; Analysis of alternatives on antifouling paints performed for the Washington State: Washington State Antifouling Boat Paint Alternatives Assessment Final Report (WA-S, 2017), available at <https://www.northwestgreenchemistry.org/news/release-of-the-washington-state-antifouling-boat-paint-alternatives-assessment-report>

<sup>55</sup> The « disproportionate costs » element in the TGN relates in the present guidance to the economic feasibility criterion.

It should be clarified if the alternative can be considered technically feasible for sub-sets of the intended use or specific markets but not for others.

Due to the probable lack of detailed information available to determine the technical feasibility of the alternative, it is possible that no clear-cut conclusions can be drawn. However, the author of the analysis can highlight the main findings related to this issue.

If it is concluded that the alternative is not technically feasible for the intended use or a sub-set of the intended use, possible actions (including R&D, production trials, etc.) from the applicant or other actors and timeframe within which technical feasibility could be achieved should be described if known, including obstacles or difficulties expected.

### 3.4.4 Economic feasibility

The economic feasibility of an alternative is focused on the economic viability of the use of the alternative for the intended use at the user level. However, if the use of alternatives is expected to lead to significant economic impacts to other stakeholders than the users, these can be reported as well at a general level<sup>56</sup>.

The basis of determining the economic feasibility of alternatives is a cost analysis. This identifies the costs associated with using the biocidal product or treated article/end-product based on the CfS and compares this with the costs of using the potential alternatives. It is important to also consider the savings (i.e. negative costs) that the use of the alternative could provide compared to the CfS (e.g. savings in biocidal product/end-product use and disposal, protection measures, clean-up). In the context of this guidance, a basic economic feasibility assessment is proposed, aiming at determining if the transition to the alternative(s) would lead to costs which are considered disproportionate or, to the contrary, acceptable. In this case, a qualitative assessment of the economic feasibility may be sufficient.

The economic feasibility assessment should reflect the situation at the time of writing the analysis of alternatives but since the price of using the alternatives is likely to evolve over time<sup>57</sup>, the trend of costs evolution and related timeframe should be described where possible (to also be put in perspective with the market trends described in section 3.2.3).

#### Qualitative assessment

An option for a qualitative assessment of the economic feasibility is a tiered approach in which initially the relative/qualitative costs are provided on a 5-points scale (e.g. "significantly lower", "lower", "comparable/identical", "higher (but not disproportionate)" and "significantly/disproportionally higher") based for instance on stakeholder's questionnaire results or expert statements (including evidence/justification). The main types of costs and savings should be described (e.g. price per litre of the biocidal product for similar quantities to be used, need to purchase new equipment to be able to use the

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<sup>56</sup> Impacts to other stakeholders than the users should rather be part of a separate socio-economic analysis.

<sup>57</sup> E.g. the price of suitable alternatives is likely to decrease over time due to its likely increased sales volumes. Also, the initial investments costs to switch to the alternative (one-off costs) could be recovered over time thanks to lower annual costs of using the alternative.

alternative, maintenance hours per year needed, savings in risk management, etc.)

In cases where the economic feasibility of an alternative is uncertain and requires a more in-depth analysis, quantitative data should be provided. In case of significant regional differences, these should be mentioned.

### Quantitative assessment

If a quantitative assessment is performed, the direct and/or indirect costs associated with the transitioning to the alternatives for the intended use should be identified.

Data should preferably be presented on a unit basis that allows a comparison of the different alternatives and with the CfS (e.g. cost per square meter of treated surface and per year). 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 described.

The quantitative cost assessment may also include:

- The investment and recurrent costs for using the product with the alternative substance or non-chemical alternative, including how they may change over time.
- Other costs of substitution to the alternative – including equipment, training, energy use, regulatory costs, potential downtime and handling to the extent these are not covered under recurrent costs.

The process of a (quantitative) cost assessment can be summarised as:

- Categorising and determining the costs that are incurred by using the product with the CfS and the alternative(s).
- Perform a comparative cost analysis of the current use of the products with CfS versus the alternatives.

In the same way as for the technical feasibility assessment, the economic feasibility assessment of an alternative aims at qualifying the changes whether these constitute significant disadvantages or not. Following the same approach as the TGN (EC, 2015), a significant disadvantage of an alternative from an economic point of view can be defined as 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 disproportionate costs<sup>58</sup>

This means in practice that some higher but proportionate costs should, in principle, not be considered as a significant disadvantage. No specific value for judging on the economic feasibility of an alternative is provided since this is case-specific<sup>59</sup>. However, a customer's survey indicating

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<sup>58</sup> The « very high efforts » element in the TGN relates here to the technical feasibility criterion addressed separately.

<sup>59</sup> E.g. in a very competitive market for treated articles/end-products where the profit margins are small, a small increase of the price of the biocidal products to be used in high quantities might lead to a significant loss of markets compared to competition (the alternative could then be considered as non economically feasible). In contrast, for other types of

their acceptance to pay a higher price for an alternative can be a good basis for judging on the economic feasibility of this alternative.

#### *Conclusion on the economic feasibility of the alternative*

Based on the above, a conclusion on the economic feasibility of the alternatives should be drawn, to the extent feasible.

It should be clarified if the alternative can be considered economically feasible for sub-sets of the intended use or specific markets but not for others.

Due to the probable lack of detailed information available to determine the economic feasibility of the alternative, it is possible that no clear-cut conclusions can be drawn. However, the author of the analysis can highlight the main findings related to this issue.

To the extent possible, if it is concluded that using the alternative is technically feasible but not economically feasible, possible actions from the applicant or other actors and timeframe within which economical feasibility could be achieved should be described, including obstacles or difficulties expected.

### **3.4.5 Availability**

Alternative substances can be regarded as available when they are reasonably accessible to the operator in the required quantity. To be considered available, both chemical and non-chemical alternatives have to fulfil the relevant legal requirements (e.g. an active substance need to be approved under the BPR or included in the review programme for the intended uses; or the use of an alternative technique or process may require authorisation under other pieces of legislation).

An important issue in identifying the availability of alternatives is also timing: alternative substances may not be available immediately or they may not be available in the required tonnage but could become available in the market at some point in the future. For chemical alternatives, a description of the approval status under the BPR and prospects about its availability on the market should be described. If the availability of the alternative is highly dependent on the approval/non-approval status of the CfS, this should be described. In other words, in case the CfS would not be approved any longer, would the production capacity of the alternative active substance and related biocidal products be able to meet the market demand or are there particular constraints impeding this?

For non-chemical alternatives the same basic consideration applies: is the necessary equipment or technology already available (or able to become available without undue delay) in the market in sufficient quantities? The time needed to invest, install and make alternative techniques operational should be considered. Here as well, fulfilling specific legal requirements may require time.

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treated articles/end-products where the overall cost of using a biocidal product is marginal compared to the overall cost of the article or profit margins, a significant increase of the cost of the biocidal product would still be acceptable by the customer (the alternative could then be considered as economically feasible).

#### *Conclusion on the availability of the alternative*

It should be concluded in a clear and transparent manner whether the alternative is available (in the required quantity), to the extent feasible.

Due to the probable lack of detailed information available to determine the availability of the alternative, it is possible that no clear-cut conclusions can be drawn. However, the author of the analysis can highlight the main findings related to this issue.

In the event it is concluded that the alternative is not currently available, it should be described which actions would be necessary to make this alternative available and the expected timeline. Obstacles or difficulties identified or expected should be reported<sup>60</sup>.

### **3.4.6 Other relevant information**

Other information which is considered relevant and important for the assessment of the alternatives and which has not been reported in the other sections of the report can be described here (e.g. broader sustainability aspects or impacts to society).

### **3.4.7 Conclusion on the suitability and availability of the alternative**

Based on the previous conclusions on reduction of overall risk, technical and economic feasibility, and availability, a general conclusion on the suitability and availability of the alternative for the intended use should be made. In the cases where the alternative is not suitable and/or available, to the extent possible, the main actions of the applicant or other actors and timelines for making it suitable and available should be presented.

## **3.5 Conclusion and summary table: overall comparison of alternatives for the intended use**

From the assessment performed in the previous sections for a given intended use, an overall comparison of all shortlisted alternatives (chemical and non-chemical) with regard to their overall risk reduction, technical and economic feasibility, and availability should be made. These conclusions can be presented in a table for an easier comparison, with a ranking of the alternatives for each criterion.

## **3.6 Efforts taken by the applicant(s) to develop suitable alternatives**

When the author of the analysis of alternatives to the use of a CfS is a manufacturer of this CfS,

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<sup>60</sup> Knowing that a safer alternative is technically and economically feasible, currently not available but which could become available under certain conditions is an important piece of information for longer-term actions by policy makers.

it is requested to describe - to the extent feasible<sup>61</sup>- the efforts taken by itself or at industry sector level to develop suitable alternatives and/or the identified needs for making it happen.

The information can comprise:

- What research and development activities are needed and/or planned to develop an alternative substance(s) or non-chemical alternative, or to develop equipment or processes enabling the use of alternative(s); and
- What testing must be done and what criteria need to be satisfied before an alternative can be used for a particular function, including the timing for such product testing and research.

This information can help stakeholders in having a better understanding of the status of the development of suitable alternatives and of future prospects.

### **3.7 Overall conclusion**

An overall conclusion of the report, covering all assessed intended uses, should be made. This comprises:

- A brief description of the steps taken to identify potential alternatives (including R&D efforts) and alternative providers.
- The main conclusions of the analysis regarding the identification of potential alternatives and the suitability and availability of these alternatives for the identified uses should be reported (preferably in the format of a table).
- If there are no or insufficient suitable and available alternatives, a summary of the actions needed or underway to make potential alternatives suitable and available and the timescale for these actions.

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<sup>61</sup> i.e. to the extent known and without breaching competition law or other applicable legislation.

## 4. References

CA, 2018: Towards the substitution of active substances of high concern in biocidal products and innovation in areas where a need for alternatives is identified; Note agreed by Member States' Competent Authorities for biocidal products - CA-Sept18-Doc7.4-rev1. Available at: <https://circabc.europa.eu/w/browse/f9b8ea84-28b5-4db1-80b3-c16509b71c08>

EC, 2015: European Commission, 2015: Technical Guidance Note on comparative assessment of biocidal products; CA-May15-Doc.4.3.a – Final. Available at: <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>

ECHA, 2021: Guidance on the preparation of an application for authorisation. Available at [https://echa.europa.eu/documents/10162/13643/authorisation\\_application\\_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7](https://echa.europa.eu/documents/10162/13643/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7)

Tickner Joel A. et al., 2015: Advancing Safer Alternatives Through Functional Substitution. Environ. Sci. Technol. 2015, 49, 742–749. Available at <https://doi.org/10.1021/es503328m>

IC2, 2017 : Interstate Chemicals Clearinghouse Alternatives Assessment Guide Version 1.1. Available at: [http://www.theic2.org/article/download-pdf/file\\_name/IC2\\_AA\\_Guide\\_Version\\_1.1.pdf](http://www.theic2.org/article/download-pdf/file_name/IC2_AA_Guide_Version_1.1.pdf)

OECD (2021): Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative, OECD Series on Risk Management, No. 60, Environment, Health and Safety, Environment Directorate, OECD. Available at: <https://www.oecd.org/chemicalsafety/risk-management/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemical-alternatives.pdf>

UBA, 2021: German Environment Agency - NoCheRo-Guidance for the Evaluation of Rodent Traps - Part A Break back/Snap traps; available at <https://www.umweltbundesamt.de/en/publikationen/nochero-guidance-for-the-evaluation-of-rodent-traps>

WA-S, 2017: Washington State Antifouling Boat Paint Alternatives Assessment Final Report, available at <https://www.northwestgreenchemistry.org/news/release-of-the-washington-state-antifouling-boat-paint-alternatives-assessment-report>

## Annex 1. Confidentiality claims

### Public and confidential versions of the analysis of alternatives

With the consent of the author of the analysis of alternatives (AoA), ECHA will publish on its website the “public version” as a part of the information provided for the third parties’ consultation made according to Article 10(3) of the BPR. It is important that the public version of the analysis of alternatives has minimum redacted (blacked out)<sup>62</sup> confidential information, if any. Confidential information can instead be reported in a slightly more generic, non-confidential manner e.g. by using non-confidential ranges for figures<sup>63</sup>.

Any confidentiality claim should be duly justified. In case the author of the document wishes to provide confidential information to the eCA and BPC, then they must prepare two versions of the same AoA document: one containing confidential business information (clearly marked as such) and another “public version” which should blank out (redact) confidential business information. Please be aware that the confidential version of the AoA is still subject to access to documents requests under different pieces of legislation (see legal note below).

Always include justifications for each item that you have claimed as confidential in the “public version” of the AoA<sup>64</sup>. Give a clear numbered reference to each piece of information claimed confidential. Redacted items should be limited to a minimum and cover only that information for which disclosure presents a direct threat to commercial interests. The size of redacted text/figure should correspond to the actual size of the text/figure which has been redacted (e.g., if an entire page has been redacted, it should be visible in the “public version” that an entire page has been blanked out).

If the redacted text concerns qualitative information, make sure that the public version still contains enough information to constitute a meaningful non-confidential summary. Use non-confidential ranges to replace exact confidential figures. If the text left visible after redaction would not be understandable to the reader without the confidential information, include a non-confidential description/summary of what has been redacted next to the redacted area [in square brackets].

The confidential AoA should be made available to the eCA as an unprotected Word (or rtf) file. As regards the public version, ensure that the redacted parts cannot be removed or the underlying text revealed by technical means<sup>65</sup>.

The two versions of the format need to be identical apart from the parts containing confidential business information that are redacted in the public version. In the confidential version, confidential information should be readable and marked in red or highlighted in yellow. In the public version each redacted part should be clearly referenced with a number and this reference should be made visible. This is to allow an unambiguous link with the justifications for why the

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<sup>62</sup> The term “blacked out” is used as a synonym of the term “redacted” which is often used in that context. Please ensure that it is not possible to copy text that has been blackened or otherwise obliterated. The eCA or ECHA does not take any responsibility for unobliterated information that is marked as public.

<sup>63</sup> Informative ranges would protect the applicant’s business information whilst still providing an order-of-magnitude estimate of the actual figures, e.g., an annual tonnage of 536 kg should be described by a range no wider than 100-1 000 kg, preferable would be a range of e.g. 200-800 kg. Similar ranges should be applied to other relevant information such as profit figures, price margins, etc. if relevant.

<sup>64</sup> The justification will help ECHA when processing Access to Documents Requests under Regulation (EC) 1049/2001.

<sup>65</sup> Please enable the search function as well as printing and copying of text for the confidential version and at least printing for the public version.

information should not be made publicly available. These justifications need to be provided in an annex to the confidential version of the AoA<sup>66</sup>. Further instructions on the redaction and justifications for confidentiality are provided in the Legal Note and in the AoA template. The same approach should be taken for all documents provided as annexes (except for the annex with the justifications for confidentiality).

## Legal Note

With the consent of the author of the analysis of alternatives (AoA), ECHA will publish on its website the public version as a part of the information provided for the third parties' consultation made according to Article 10(3) of the BPR. It is the applicants' responsibility to ensure that no confidential business information is present in this document. ECHA does not assume any liability for damages resulting from the publishing of confidential information that you may have included in the public version.

Please note that the confidential version of the analysis of alternatives is subject to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents and Regulation (EC) No 1367/2006 regarding the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making, and Access to Justice in Environmental Matters to Community institutions and bodies.

The justifications and motivations for not disclosing specific information in the public version will play a crucial role in ECHA's assessment of what information should be disclosed following an access to documents request under the aforementioned Regulations. This holds without prejudice to ECHA's final decision on the disclosure of the requested document in accordance with the aforementioned regulations.

## Instructions for how to provide a justification for confidentiality

Any information submitted to ECHA is subject to Regulation 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information and to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. Therefore, applicants or MSCAs submitting analysis of alternatives are asked to provide a justification for confidentiality for each comment or attachment submitted to ECHA and Member State Competent Authorities. If the submitter's justification is sufficient and falls under one of the exceptions envisaged in Regulation 1049/2001, there will in principle be no need to request further clarification from the submitter why a request for access to part or all information marked confidential in the submission should be denied. The submitter's justification for confidentiality should contain the following three elements:

- **Demonstration of Commercial Interest**

Description of the nature of the third-party commercial interest and demonstration that this commercial interest is worthy of protection by the non-disclosure of information.  
Demonstration of any specific measures the submitter has taken to keep the information claimed confidential secret to date.

- **Demonstration of Potential Harm**

Explanation of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. A causal link between disclosure and such harmful effects should be clearly explained.

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<sup>66</sup> Justifications for confidentiality claims will not be made publicly available as part of the BPR Art.10(3) consultation.

- **Limitation to Validity of Claim**

The period of time for which the claim will be valid: until a certain date, until the occurrence of a particular event (which should be clearly specified), or indefinitely.

See also the ECHA Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR):  
[https://echa.europa.eu/documents/10162/992289/guidelines\\_assess\\_bpr\\_conf\\_claims\\_en.pdf/3c579364-5a0b-b098-06bf-3323f5b8a496?t=1632295766830](https://echa.europa.eu/documents/10162/992289/guidelines_assess_bpr_conf_claims_en.pdf/3c579364-5a0b-b098-06bf-3323f5b8a496?t=1632295766830)

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