National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

On an exceptional basis

A methodology for decision-making on biocides for public interests

RIVM letter report 2021-0174

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DOI 10.21945/RIVM-2021-0174

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This research was carried out on behalf of the Ministry of Infrastructure and Water Management, as part of the project Policy advice and methodology for plant protection products and biocides.

Published by:
National Institute for Public Health and the Environment, RIVM
P.O. Box 1 | 3720 BA Bilthoven
The Netherlands
www.rivm.nl/en

Synopsis

On an exceptional basis
A methodology for decision-making on the use of biocides in the public interest

Organisms can harm our living environment. Think of viruses, bacteria and fungi, or of mosquitoes, ants and rats. Biocides are products to control these organisms. However, biocides may be harmful for human, animal and environmental health. They are therefore only allowed after extensive testing to ensure that they are safe and work properly.

In practice, it may be that a new organism threatens people's health and there is no time to wait for this whole procedure. Think of the high demand for disinfectants in the outbreak of the coronavirus SARS-CoV-2. It is also possible that no biocide for a certain use, such as the control of rats, can meet the strict requirements. Exceptions are sometimes possible for reasons of public health or the environment. RIVM has devised a methodology to make well-founded considerations for this.

The methodology ensures that the public interest, the risks of the biocide, and available alternatives are properly weighed. For example, it must be carefully examined whether the threat to health or the living environment is so great that the government has to intervene. It must also be ensured that the organisms cannot be tackled in any other way. In addition, careful consideration should be given to whether any risks of the biocide offset the benefits of using it on an exceptional basis.

Keywords: societal interest, public interest, biocides, pesticides, methodology, exemption

Publiekssamenvatting

Bij wijze van uitzondering
Een systematiek voor de besluitvorming over het gebruik van biociden bij een publiek belang

Organismen kunnen ervoor zorgen dat leefomgeving niet meer veilig en gezond is. Denk aan virussen, bacteriën en schimmels, of aan muggen, mieren en ratten. Biociden zijn middelen om deze organismen te bestrijden. Alleen kunnen biociden schadelijk zijn voor de gezondheid van mens, dier en milieu. Ze worden daarom pas toegestaan nadat uitgebreid is getoetst of ze veilig zijn en goed werken.

In de praktijk kan het zijn dat een nieuw organisme de gezondheid van mensen bedreigt en er geen tijd is om deze hele procedure af te wachten. Denk aan de grote vraag naar desinfecterende middelen bij de uitbraak van het coronavirus SARS-CoV-2. Het kan ook zijn dat geen enkel biocide voor een bepaald gebruik, zoals de bestrijding van ratten, aan de strenge eisen voldoet. Vanwege de volksgezondheid of het milieu zijn soms uitzonderingen mogelijk en mogen ze toch worden gebruikt. Het RIVM heeft een methode bedacht om hier goed onderbouwde afwegingen voor te maken.

De methode zorgt ervoor dat het publieke belang, het risico van het middel, en beschikbare alternatieven goed worden afgewogen. Zo moet goed worden gekeken of de dreiging voor de gezondheid of leefomgeving zo groot is dat de overheid moet ingrijpen. Ook moet zeker zijn dat het organisme niet op een andere manier kan worden aangepakt. Verder moet goed worden nagedacht of risico’s van het middel opwegen tegen de voordelen om het bij uitzondering te mogen gebruiken.

Kernwoorden: maatschappelijk belang, publiek belang, biociden, bestrijdingsmiddelen, systematiek, vrijstelling

Contents

Summary

A safe and healthy living environment can be harmed by organisms. Think of viruses, bacteria and fungi, or of mosquitoes, ants and rats. Biocides are products to control these organisms. However, biocides may be harmful for human, animal and environmental health. They are therefore only allowed after extensive testing to ensure that they are safe and work properly.

In practice, it may be that a new organism threatens people's health and there is no time to wait for this whole procedure. Think of the high demand for disinfectants in the outbreak of the coronavirus SARS-CoV-2. It is also possible that no biocide for a certain use, such as the control of rats, can meet the strict requirements. Exceptions are sometimes possible for reasons of public health or the environment. RIVM has devised a methodology to make well-founded considerations for this.

The methodology ensures that the public interest, the risks of the biocide, and available alternatives are properly weighed. For example, it must be carefully examined whether the threat to health or the living environment is so great that the government has to intervene. It must also be ensured that the organisms cannot be tackled in any other way. In addition, careful consideration should be given to whether any risks of the biocide offset the benefits of using it on an exceptional basis.

This report provides a methodology for making this assessment carefully. The methodology structures in a number of steps what needs to be done in order to arrive at a well-considered decision. The step-by-step plan below has been taken as a basis for this.

Phase		Step / Question
I	Exploration	1. Provide a brief description of the case. What questions does the case raise?
II	Explication	2. What is the central (moral) question?
		3. Which options for action are open (at first sight)?
		4. What factual information is currently missing?
III	Analyse	5. Who is involved in the case, and what is the perspective of each of those involved?
		6. Which arguments are relevant to answer the central question?
IV	Assessment	7. What is the weight of these arguments in this case? Make an inventory of the rights, duties and responsibilities of those involved. Does this shift the picture with regard to the assessment of the options for action?
		8. Which course of action is preferable on the basis of these considerations? (conclusion + argumentation)
V	Approach	9. What concrete steps follow from this?

These steps have been further elaborated for biocides into a system for specific situations, in which exceptions may be made according to European regulations.

The system has been drawn up from an ethical perspective. This can help the competent authority to substantiate the granting or refusal of an exception within the legal boundaries. An ethical perspective is characterized by being clear about which values must be protected. This must concern fundamental goals worth pursuing in itself (like health an well-being). The interests and views of all parties involved must be taken into consideration, with the aim of doing justice to all perspectives as much as possible. The standards that are set must also apply equally to everyone.

The methodology has two points of departure. First, there must be a 'public interest' at stake, which applies to society as a whole. This concerns societal interests that can only be adequately protected with government intervention. Secondly, the weighing of interests, risks and alternatives is inextricably linked.

In practice, complex considerations will have to be made. Among other things, these will revolve around an assessment of the extent to which the biocidal product for which an exception is requested contributes to an important public interest (e.g. public health); and if so, whether this indeed outweighs the risks of the biocide for human, animal and environmental health. But the extent to which alternatives score better or worse is also relevant for the assessment.

The answer to the question of whether an exception should be made does not automatically follow from the methodology, but always requires a substantiation in words. The application of the methodology will have different accents in each case and will require different considerations. As more assessments are completed, new insights will improve working agreements and the methodology.

1 Introduction: exceptions to the authorization procedure in specific situations

1.1 Authorization of effective and safe biocides

The national government strives for a clean, safe and healthy living environment, which is also experienced as such[1]. Human and animal health, the environment, and natural and manufactured materials can be harmed by organisms. This damage can be prevented or reduced by combating or repelling the organisms with biocides. This use poses other risks to health and the environment. The Netherlands has the ambition to achieve a socially responsible use of biocides. The main goals of the Biocides Policy Program[2] are:

- Exclusive use of authorized biocides, in accordance with the instructions for use;
- Only use biocides when absolutely necessary[3,4];
- Availability of an adequate repository of products;
- Improving communication between involved companies and governmental organizations.

The Biocidal Products Regulation (BPR), Regulation 528/2012, (hereinafter: the BPR or the Regulation) regulates the placing on the market and use of substances, treated articles and products (biocides) that are intended to destroy, deter, render harmless, or exert a controlling effect on harmful organisms. The first recital of the BPR reads: "Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns."

The BPR regulates that biocides are prohibited, unless authorized. With the authorization system, the BPR aims to harmonize the European market while offering a high level of protection for humans, animals and the environment (BPR recital 3; Article 1). The BPR is an important instrument for realizing an adequate repository of products. The correct use of authorized biocides – when it is really necessary – can subsequently contribute to the health of humans, animals and the environment, and to the sustainability of materials.

1.2 Exceptions to the authorization procedure in specific situations

With the authorization system, the BPR aims to harmonize the European market while offering a high level of protection for humans, animals and the environment. Notably, the BPR considers that active substances with

[1] Letter to the House of Representatives 32861 nr 42 of 21 December 2018.
[2] Letter to the House of Representatives 27858 nr 92 of 5 October 2010.
[3] in the Biocides Policy Program, which was presented to the House of Representatives in 2007 (TK, 2006–2007, 27 858, no. 59), the concept of prevention was introduced. The concept of sustainable use of (authorized) biocides was introduced in Directive 2009/128/EC, and is mentioned in Article 18 of the BPR.
[4] Chapter 3 addresses the question of when an application is deemed necessary.

"*the worst hazard profiles*" should not to be approved, "*except in specific situations*" (BPR recital 12).

There are nine articles of law that provide for these 'specific situations'. These articles are discussed in more detail in Chapter 2:

- European substance assessment: Articles 4.1, 5.2.b and 5.2.c
- National and Union authorizations: Articles 19.5 and 55.3
- Mutual Recognition: Articles 37.1 and 39.1
- Exemptions and derogations: Articles 2.8 and 55.1.

This report examines the decision-making in these specific situations. The BPR envisages an assessment of public interests, risks and/or alternatives, but does not offer a blueprint for actually making the assessments. This report presents a methodology as a guidance for the competent authority how to balance public interests in the specific situations referred to: how to make an exception[5].

This methodology is intended for the national competent authority and for the parties involved. In the case of substance assessments, exemptions and derogations, the competent authority is the Ministry of Infrastructure and Water Management (Ministry of IenW), and in the case of authorizations and mutual recognitions, it is the Board for the Authorization of Plant Protection Products and Biocides (Ctgb).

Input for the methodology was collected in a series of workshops with representatives of the Ministry of IenW, the Ctgb, and the National Institute for Public Health and the Environment (RIVM). Discussing case histories has provided insight into challenges to make exceptions in certain specific situations. This also provided insight into the need for tools that can further support decision-making.

In addition to criteria for the substantive assessment of whether or not to make an exception for certain specific situations, the methodology also contains elements of a decision tree where possible. With the step-by-step plan, the process of reflection – whether or not to make an exception for a biocide that falls under a specific situation – can be organized and documented. By always making explicit how a judgment is reached and what considerations are made, the step-by-step plan helps to build up the argumentation for the final decision.

The methodology is not worked out in detail for each specific situation. It concerns an overarching methodology, which can be used as a basis in any specific situation. By using the methodology more often, experience can be gained as to which working arrangements are necessary and in which respects the methodology could be tailored to each specific situation.

5 Strictly speaking this could be seen as an exception to an exception. The authorization would then be exception the general ban. The possibility to approve exclusion-substances, or to allow or exempt products, based on a specific situation, is the exception to this exception. In this report we always denote the approval or authorization or exemption in one of the specific situations by 'exception'.

Reading Guide
The methodology is presented in a layered manner in this report. In its most concise form, the methodology consists of a clear step-by-step plan (1 A3), in which all relevant elements are given a place. In that sense, the A3 can serve as a format for reporting and substantiating the decision. This A3 is included as a separate figure after the reading guide.

Chapters 2 to 7 contain all elements of the methodology, which are explained in detail in those chapters.

In Chapter 2 we discuss the wordings of the articles in the BPR that provide for making exceptions for 'specific situations'.

In Chapter 3 we identify elements of a systematic methodology: an ethical perspective, requirements for content, and requirements for the decision-making process.

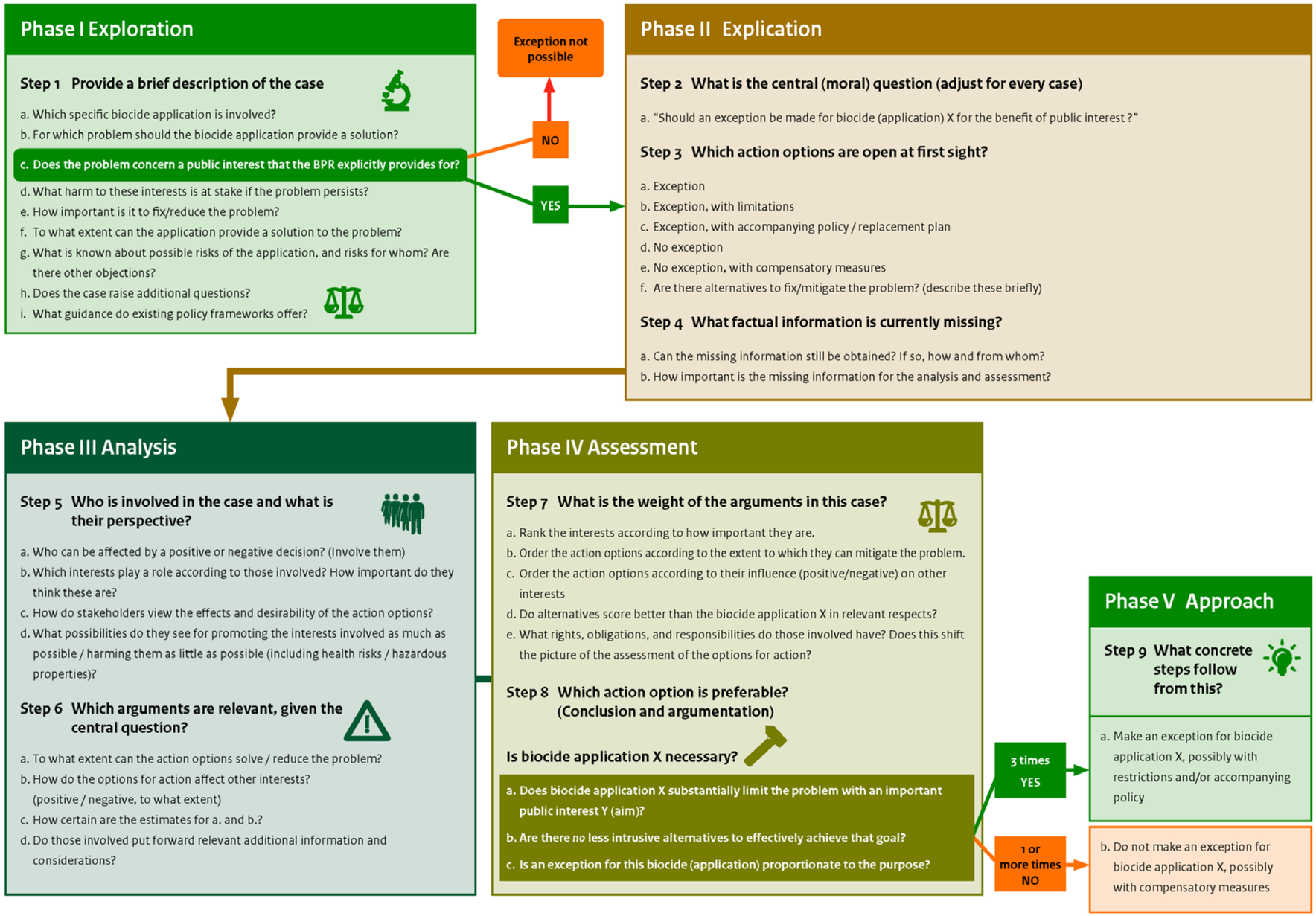
In Chapters 4, 5, and 6, we look in more detail at what is at stake when it comes to public interests, the trade-off against risks, and the availability of alternatives.

In Chapter 7 we outline how decision-making can take into account the differences in policy context of all procedures.

Chapter 8 is, as it were, an intermediate form: it presents the same steps as the A3, and elaborates them further, with examples that the user could consider when applying the methodology. It is conceivable that when using the methodology it will initially still be necessary to occasionally refer back to Chapters 2 to 7, and that the more often the methodology has been applied, the elaboration in Chapter 8 and eventually the A3, will suffice.

Chapter 9 provides an outlook to the practical application of the methodology.

The methodology at a glance



2 Specific situations in the Regulation

2.1 Specific situations

By means of the authorization system, the BPR aims to harmonize the European market while offering a high level of protection for humans, animals and the environment. Active substances with "*the worst hazard profiles*" should not to be approved, "*except in specific situations*". The BPR deals with the so-called 'specific situations' in 9 articles. These relate to:

- European substance approval: Articles 4.1, 5.2.b and 5.2.c
- National and Union authorizations: Articles 19.5 and 55.3
- Mutual Recognition: Articles 37.1 and 39.1
- Exemptions and derogations: Articles 2.8 and 55.1.

The comparative assessment of biocides (Article 23.3) is part of some of these procedures. See Figure 1.

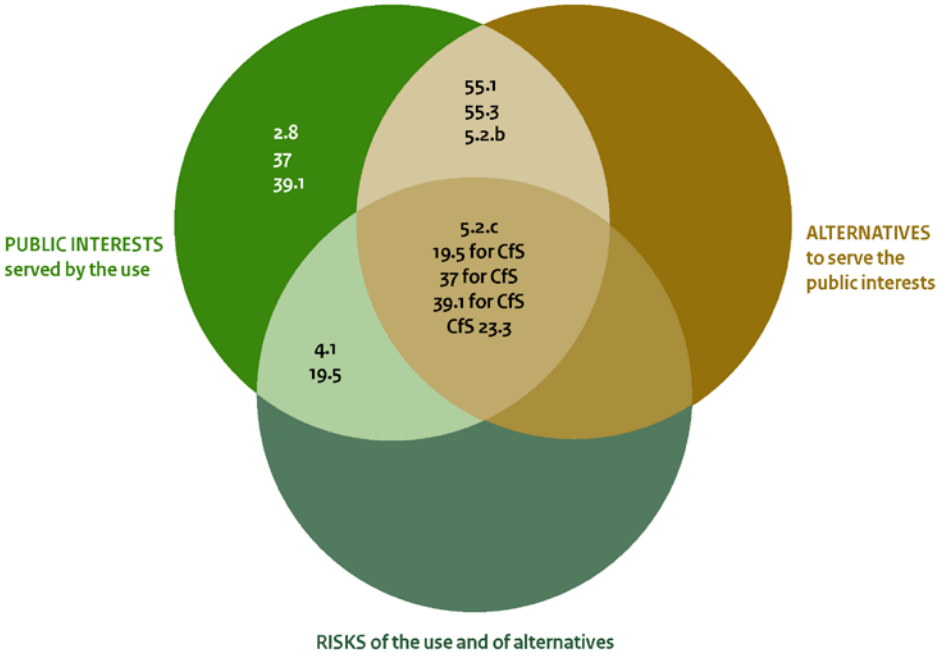


Figure 1 The various articles of law for specific situations to make an exception. In all cases, it is a matter of weighing public interest against risks and alternatives. CfS stands for 'candidate for substitution', biocides containing these substances are eligible for a comparative assessment in accordance with Article 23.3.

The relevant articles in the BPR are cited and discussed below.

2.2 European substance assessment

The BPR regulates that active substances in biocides or treated articles must be approved at the EU level. The use of an active substance in at least one biocide must meet the criteria for acceptable effects on

humans, animals and the environment. In addition, some 'exclusion criteria' have been set for (properties of) the active substance, which exclude approval if the substance meets one of those exclusion criteria.

If either (or both) of the conditions are not met, the substance cannot be approved. However, in this case the BPR also arranges that, if a number of special conditions are met, the substance can still be approved. In this report we speak of making an exception. When it comes to European substance evaluation, the BPR Articles 4.1, 5.2 and 19.5 outline what should be included in the decision to make an exception.

First of all, Article 4.1 provides: "*An active substance shall be approved ….. if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5)*." We see here that active substances are assessed at EU level against the same risk criteria as products at Member State level, including Article 19.5. Article 19.5 provides (in the case of authorizations of biocides) that the public interest can be weighed against the (unacceptable) risks. If it is established during substance assessment that there is an application with an unacceptable risk, this opens the possibility to investigate whether an exception (still approve the substance) is nevertheless necessary. In the next section on national product authorizations, we will discuss Article 19.5 in more detail.

In addition, Article 5 regulates active substances that meet certain exclusion criteria. These substances may not be approved (Article 5.1) except for two specific situations in which the interest of the use is weighed:

- Article 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*";
- Article 5.2.c: [it is shown that] "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".

The BPR imposes the following condition on this decision: Article 5.2, second paragraph:
"When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration."

2.3 National product authorizations

Article 19 regulates the authorization of products, the biocides. These must be admitted if they meet the conditions of Article 19.1. If the biocide does not comply, it may not be authorized, but Article 19.5 subsequently regulates:
"Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the

market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.
The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met."

Article 19.5 therefore provides that the use of a product that poses an unacceptable risk to humans, animals or the environment can nevertheless be authorized if there is an important public interest. The article also attaches conditions to the use of the product for which an exception is made. The exception should not be granted without appropriate risk mitigation measures to ensure minimal exposure. These measures do not have to remove the risk completely, but they should do so as much as possible (via minimal exposure).

Article 19.5 does not provide that alternatives must be compared. However, this comparison is mandatory for biocides with substances that must undergo a comparative assessment (see section 2.6).

The articles on mutual recognition also provide for exception exceptions, in Articles 37.1 and 39.1. With these articles, the competent authority has two procedures at its disposal to make authorized biocides available relatively quickly to meet public interests.

Article 37.1 provides that an authorization and its conditions, at mutual recognition, can be adjusted if there are good reasons for doing so in view of public interests (either absence or presence) and risk. For these reasons, this adjustment can be a limitation, but also an extension of the conditions.
Article 37.1: "*By way of derogation from Article 32(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:*

a. *the protection of the environment;*
b. *public policy or public security;*
c. *the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;*
d. *the protection of national treasures possessing artistic, historic or archaeological value; or*
e. *the target organisms not being present in harmful quantities.*

Any of the Member States concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or Article 10(1) applies."

Article 37.1 therefore gives the competent authority the option of refusing, restricting or extending an authorization. A restriction or a refusal can be based on reasons a) to e); while an extension on the grounds of controlling (avoiding or combating) damage to the interests a) to d) may be appropriate.

Article 39.1 provides that a biocide authorized in another Member State may also be applied for by official bodies:
Article 39.1: "Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or the protection of public health may apply, under the mutual recognition procedure provided for in Article 33 and with the consent of the authorisation holder in that other Member State, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that Member State.
The applicant shall demonstrate that the use of such a biocidal product is of general interest for that Member State.

Since in this article *official or scientific bodies* take on the role of applicant and thus interfere in the free market, we understand that there must be a public interest, for which the government can (and must) act (see also chapter 4).

The specific situations above concern biocidal products with approved active substances[6]. There is also a derogation for biocidal products for which the active substance has not been approved. Article 55.3 provides that the Commission may "… *allow a Member State to authorise a biocidal product containing an non-approved active substance, provided that it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available*". [7] If this derogation is granted, a national product authorization will follow.

Articles 37.1 and 39.1 do not explicitly mention the consideration of risks or alternatives. However, the BPR provides for a comparative assessment (see also section 2.6) for the authorization of biocidal products containing certain active substances. This includes substances that meet the exclusion criteria of Article 5.1, as well as (Article 10.1.e) substances that (partly in view of the application) give rise to concern. A comparative assessment will be legally required for some biocides, but not for others. This depends on the properties of the active ingredient.

2.4 National exemptions and derogations

In addition to the national product authorizations, the BPR has two procedures for exempting biocides from authorization.

Article 55.1 provides that a competent authority may "*permit … the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent*

6 Transitional measures apply to active substances that have not yet been harmonized.
7 See for example Commission Implementing Decision (EU) 2020/1049

authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means."

Article 2.8 provides that "*Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence"*.

In these specific situations of exemptions and derogations, a consideration of risks or alternatives is not explicitly mentioned. It does not concern product authorization, so a comparative evaluation according to Article 23.3 is not in play. The competent authority will have to consider risks (because "*for limited and controlled use, under the supervision of the competent authority*") and alternatives (because "*which cannot be contained by other means"*).

Article 55.3 provides that a biocide with a non-approved active substance may be authorized in a Member State. This procedure is therefore discussed under national product authorizations (section 2.3).

2.5 Union-authorizations

Article 41 of the BPR provides that the Commission can grant Union authorizations to biocides, under the same conditions as national authorizations. This means that these biocidal products must contain approved active substances, and that an exception can also be made under Article 19.5 for Union authorizations if there is a public interest. According to Article 42.1, however, a Union authorization is not possible for biocidal products with active substances that have been approved under Article 5.2. The BPR does not provide for derogations like in article 55.1, nor for authorization of a product with an unapproved active substance, like in Article 55.3, at European level.

2.6 Comparative assessment at authorization

The BPR provides for a comparative assessment for biocides with certain active substances: the 'Candidates for Substitution' (hereinafter: CfS). This involves a comparison of the risks between the application of a biocide with a CfS and alternatives. Article 10.1 provides for the following:
Article 10.1: "*An active substance shall be considered a candidate for substitution if any of the following conditions are met:*

- *(a) it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);*
- *(b) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;*
- *(c) its 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;*
- *(d) it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006;*
- *(e) 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;

(f) it contains a significant proportion of non-active isomers or impurities.

The BPR regulates via Article 10.1, for the specific situations of Articles 5.2.b and 5.2.c, that a consideration of risks, resistance and alternatives is always involved in the product assessment (also in the case of renewals). What has been arranged for this in Article 23.3 is relevant when applying the methodology.
Article 23.3: "*The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI ('comparative assessment') demonstrates that both of the following criteria are met:*

(a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;

(b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism."

In chapter 6 on alternatives, we discuss Article 23.3 in more detail.

3 Requirements to the methodology

3.1 Principles for making assessments

The market for biocides is restrictively regulated, as detailed in the previous chapter. This underlines that important public interests are at stake, including human, animal and environmental health. It places high demands on the interests that could justify an exception, for example if on balance the result is safer or healthier for people, animals and the environment, or if the development towards a better quality of the living environment becomes possible. The BPR does not offer a systematic approach for actually making the assessments.

This report is guided by two basic principles :

1. A public interest is at stake, for example because the market or (standard) regulations may fail to (timely) provide measures to protect that interest,
2. The consideration of interests, risks and alternatives is inextricably linked.

The first principle is that important public interests (i.e. the protection of human, animal and environmental health) are at stake to restrict the market for biocides in the BPR. Public interests always refer to social interests, but not every social interest is a public interest. For example, there is (only) a question of public interest if the protection or promotion of the public interest requires intervention by the government. In the context of the BPR, this means, for example, that government action can be legitimized if the market or society cannot adequately solve a social problem itself.[8] This may justify the competent authority making an exception and actually intervening in the free market.

If we look at all these 'specific situations', this always requires weighing up public interests, risks and alternatives. Our second principle is that these are always inextricably linked. We will come back to that in section 3.3.

This report examines the question of how the competent authority can weigh a public interest in the specific situations referred to. To this end, we supplement the legal framework of the BPR with an ethical perspective. The methodology will provide a generic interpretation of which aspects must be weighed (content), and in which order which considerations must be made (process).

3.2 An ethical perspective

Four characteristics

In order to make an exception, the public interest must be weighed. For this it is helpful to take an ethical perspective. To this end, this section first briefly describes the characteristics of an ethical perspective.[9] There are four.

8 Chapter 4 discusses how to determine whether there is a public interest.
9 Bolt LLE, Verweij MF, Van Delden JJM (2007). Ethics in practice [In Dutch: Ethiek in praktijk]. 6th imprint. Assen: Royal Van Gorcum BV.

An ethical perspective is first and foremost "normative". That is, we evaluate a choice or action using values and standards. In the case of biocides, for example, the decision to make an exception (or not) in the specific situation. Which values should be promoted or protected? And which standards can help with that?

A second characteristic of an ethical perspective builds on the first. The values and standards with which we evaluate choices and actions must be aimed at *fundamental goals worth pursuing in themselves*. Examples are health, well-being, happiness. We strive not only for health, well-being and happiness to achieve other goals, but also because we want to be healthy, because we think well-being is important, because we want to be happy. In that sense, these values are fundamental. For an ethical answer to the question of whether or not an exception can be made for a biocide in the specific situation, it is therefore important to specify the values and standards that relate to objectives that are worth pursuing in themselves.

A third characteristic of an ethical perspective entails that the interests and views of all parties involved (must) be included in the assessment, with the aim of doing justice to all perspectives as much as possible.[10] A relevant question is how this can be organized in BPR procedures.

The fourth characteristic of an ethical perspective is called "universalizability". It means that the values and standards with which we evaluate a choice or action (see first characteristic) could in principle be universally valid. That, in principle, standards apply equally to everyone, and that you (as the competent authority) do not make exceptions to the rules for yourself. In the context of the BPR, for example, it means that standards on the basis of which an exception is made or not in the specific situation can in principle apply equally to everyone.

Taking an ethical perspective can help the competent authority to substantiate whether or not to grant an exception within the legal boundaries of the BPR. A decision does not automatically follow from a few facts and principles. Decision-making, and the 'weighing' of information and uncertainty, is a process of interpretation, analysis and testing of arguments. The assessment leads to judgement. It requires argumentation:

- (in the case of exception) which gain in public interests is at least proportional to the risks associated with the use, or
- (in the case of non-exception) which loss of public interests is smaller compared to the avoided risks;

and to account for the interests and perspectives of all concerned. Perfect justification is often not possible when principles, interests and/or values conflict. What is possible, however, is to substantiate choices in such a way that we can have *sufficient* confidence that those choices are justified. We strive for balanced decision-making by

10 In Dutch this is called "alpartijdigheid".

substantiating choices on the basis of values, facts, moral principles and concrete moral judgments that mutually support each other.[11]

Generally accepted criteria for assessments
When making concrete assessments, the competent authority can – within the legal boundaries of the BPR – rely on a number of generally accepted ethical and legal considerations:

- **Effectivity/Expediency**: does an application contribute effectively to the intended goal?

Based on the foregoing (second characteristic), the question is: what *is* the goal? And is that goal worth pursuing in itself? This includes the overarching goals of the BPR, including protecting the safety of humans, animals and the environment. Is a biocide (application) necessary to effectively protect human, animal and/or environmental health? But it also revolves around (other) social interests on the basis of which the BPR makes it possible to make exceptions. These are discussed in Chapter 4.

Finally, it is relevant what the policy goals and ambitions are of national policy with regard to the protection of human, animal and environmental health. This partly determines how high the bar is set for any exception. It is recommended that these policy goals and ambitions be made explicit in a concrete case before the final assessment is made. The policy goals and ambitions can thus serve as benchmarks. This provides guidance and prevents policy goals and/or ambitions from being unintentionally adjusted during the assessment. If during the assessment process there appears to be a need to deviate from these principles (for example due to new insights), this can also be clearly justified.

It also matters how much the exception will contribute to its intended purpose. In terms of effectiveness, it is reasonable to require that an application contribute *substantially* to its intended purpose in order to legitimize an exception. The rule of thumb could be that the contribution should be greater the more the biocide (application) can have a negative effect on other relevant values and interests.

- **Subsidiarity**: are there less intrusive alternatives available to effectively achieve the intended goal?

This again revolves around the overarching goals of the BPR and the public interests on the basis of which the BPR allows exceptions in specific situations. But there is also something to add: it is not just a question of whether and to what extent a biocide (application) can make a positive contribution to these goals and social interests. It also concerns the question of whether and to what extent a biocide (application) can adversely affect other relevant values and interests. If there are alternatives to the biocide application that can effectively achieve the intended goal, and that can have less adverse effects on

11 In ethics this is known as the search for a 'reflective equilibrium'.

other relevant values and interests, then those alternatives are morally preferable. After all, they protect the relevant values and interests best.

Complex situations can arise if an alternative is slightly less effective than a biocide (application), but can also be less detrimental to other relevant values and interests. Then the competent authority is faced with the question: how effective is effective enough? Although it does not automatically provide a conclusive answer, one can go back to a point already mentioned above, namely that the contribution that a biocidal product (application) can make to the intended purpose must first of all be substantial, in order justify an exception.

If there is a less intrusive alternative with which the intended goal can be effectively achieved / with which the intended problem can be effectively limited, there is in principle no longer any moral reason to make an exception for a biocide (application).

If less intrusive alternatives are not available at the time of a decision, then subsidiarity could be used as a design principle, making (temporarily) an exception for a biocidal product, while actively working towards the availability of less intrusive alternatives .

- **Proportionality**: is the means in reasonable proportion to the end?

Suppose a biocide is the least invasive option to achieve the intended goal / to mitigate the intended problem. This does not automatically mean that making an exception is also in reasonable proportion to the intended purpose. The disadvantages of this option may be considered too great, and the expected benefits may not outweigh them. Whether making an exception for a biocide (application) is proportionate, therefore, requires a separate assessment.

To do this, we first need to determine how important the goals we started with are. For example, the interests on the basis of which the BPR allows exceptions must be made as concrete and tangible as possible. Which concrete problem arises if no exception is made for a biocide (application)? And how important is it to fix that problem?[12] Only if this can be made concrete and tangible is it possible to determine whether a means (and the effects that the means can have) are in reasonable proportion to that goal.

A judgment must also be made about how important the possible negative effects, of the choice whether or not to make an exception for a biocide (application), are. Negative effects that would go hand in hand with violation of rights naturally carry a lot of weight. Text box 1 illustrates this on the basis of the right to health.

12 We note that article 37.1.e provides for refusing a mutual recognition, or adjust the terms and conditions of the authorisation, for reasons of " the target organisms not being present in harmful quantities".

Text box 1 The right to health places high demands on making exceptions.

To illustrate: the right to health

The right to health is a fundamental human right. Ethically and legally, this cannot simply be weighed against other values. It's not out of the question, but it means the bar is set high. First of all, this requires a strong justification (high requirements for substantiation) for making an exception. From an ethical perspective, in principle, only values of the same order can be weighed against each other. With regard to the latter: from an ethical perspective, the right to health is of a completely different order than, for example, economic value(s). Health is a goal and interest worth pursuing in itself, economic value is not. This means that, in principle, there are ethical reasons for setting limits to allowing additional health risks for economic development. Or more broadly, to the idea that additional health risks could be acceptable as long as there is sufficient compensation in other areas. These considerations place limits (or at least high demands) on making exceptions.

In assessing proportionality, it is also helpful to look at how the benefits and burdens are distributed as a result of a choice. Which groups benefit? And are there groups that are disproportionately confronted with (possible) disadvantages? For example, if vulnerable groups are disproportionately confronted with the disadvantages of a choice, then a means is less likely to be in reasonable proportion to the goal (because the benefits and burdens are distributed unjustly).

The duration of possible negative effects, whether they are reversible, and whether those involved can be realistically and adequately protected against them (by their own actions or through the efforts of third parties), also influence the question whether an exception for a biocide (application) stands in reasonable proportion to the purpose. If the disadvantages are less severe, last shorter, are reversible and, moreover, those involved can be realistically and adequately protected against them, making an exception for a biocide (application) will be more reasonably proportionate to the purpose. And vice-versa.

Basically, to be able to make an exception, you need:

- that the biocide (application) serves a purpose linked to public interests on the basis of which the BPR allows exceptions (see chapter 4);
- that the biocide (application) makes a substantial contribution to limiting a problem affecting those public interests (effectivity);
- that there is no less intrusive alternative that can effectively limit the problem (subsidiarity); and
- that making an exception is in reasonable proportion to the purpose (proportionality).

Consulting all those who may be affected by a decision, provides input on all aspects, including the extent to which there is support for making an exception.

Text box 2 illustrates that comparable considerations form the basis for making considerations in the context of the Dutch Environment and Planning Act.

Text box 2 Considerations for justifying deviations from limit values in the context of the Environment Act.

Motivating deviations from limit values (Environment Act)
Deviation from the basic level of protection in the zoning plan is only possible after thorough substantial assessment and with good justification. The competent authority therefore addresses in the decision at least the following questions:

- Is the purpose justified? The goals of the Environment and Planning Act and the balanced allocation of functions to locations play an important role in this regard.
- Is the deviation suitable for achieving the goal?
- Is the deviation in reasonable proportion to the purpose?
- Is the deviation from the limit values necessary? In other words, can it be done differently and is compensation or monitoring necessary?
- Is there enough public support for the deviation from the limit values?

Attention must be paid to the relationship of the intended deviation to the policy included in the environmental visions and programs of the relevant authorities. In this way, the competent authority can take a well-considered decision. It must also be possible for interested parties to have an idea of the consequences of the decision to deviate from the limit value. Their legal position remains thus clear.
In the case of a temporary deviation from the limit value, there will sooner be a sufficiently compelling social interest to justify a deviation, than in the case of a permanent deviation.

Source: Information Point Environment (in Dutch)

We note that in most procedures the BPR mentions the balancing of interests, risks, and alternatives, but in a few only talks about the interests, or about interests and risks (but not about alternatives), or about interests and alternatives (but not about risks). The starting point for the methodology is that all three aspects are inextricably linked from a moral point of view. If it is the case that from a legal point of view an aspect may and should not be considered, then in the specific case it will have to be discussed separately what this means for the assessment.

Guided by the methodology the competent authority can assess a request for an exception. We then have a framework to discuss: what is needed for the parties involved to perform the desired role, and what exactly needs to be supplied, by whom, in terms of information in this process?

3.3 Content of the methodology

The methodology will focus on 3 core components:

1. interests,
2. alternatives, and
3. risks.

We briefly explain these three core components:

1. Interests. Given the nature of the specific situation, we assume that the competent authority will make a decision in the specific situations with a view to the interest for society: the public interest. The BPR provides some guidance on what should be considered as a public interest. [13]
   The judgment may be that public interests are not at stake, or are not important enough, because
   - there is no threat, or it is not serious enough; or
   - the contribution of the product to controlling harmful organisms is too small, or not clear enough.

   This may be sufficient to reach a decision (not make an exception) because here no (sufficient) interest can be established. The judgment may also be that those interests do exist, which raises the following question: that of weighing the risks or alternatives.
2. How should alternatives be taken into account? Which alternatives can be considered? How do their risks and benefits weigh in relation to the risks and benefits of the biocide application for which the exception is sought? More on that in Chapter 6.
3. Which risks must be weighed? The interests served by using the product may be different from the associated risks and/or affect other groups in society. More about this in chapter 5. From an ethical perspective, this touches on the question of a fair distribution of benefits and costs.

The methodology starts with considering the interests and underlying values: this is the reason to consider an exception. It then depends on the type of procedure (authorization, exemption) whether it is more efficient to consider the risks first, or the alternatives first. For example, it could be thought that if there are no risks associated with the use of the product, then alternatives need not be considered. After all, the primary purpose of the BPR – protecting the safety of humans, animals or the environment – is then not at stake. One reason to always look at alternatives may be that the authorization of substances with undesirable properties can be avoided. Even if there are alternatives, there may still be reasons to look at the risks of a biocide. It is expected that there will always be a discussion about the extent to which alternatives score better in relevant respects.

It is conceivable that in a concrete case the risk or the alternatives need not be weighed up, if the assessment of values and interests already offers sufficient guidance. For example, if there is no public interest at stake on the basis of which the BPR may offer leeway for exceptions.

Burden of proof
As the risk of a biocidal product for human, animal and environmental health increases, stricter requirements can be imposed on the justification of a plea to make an exception. The burden of proof lies with the party claiming the exception. If it can be made plausible that

13 N.B. the BPR does not use the term "public interest" explicitly, but speaks more generally about general interest, or the interest of society. That the BPR is actually pointing at public interests can be deduced a) from the generally accepted premise that government intervention can only be legitimized by the presence of a public interest (see chapter 4), and b) from the fact that making an exception is a government intervention.

alternatives score worse in relevant respects than the biocide (application), then this contributes to the strength of the reasons for making an exception.

However, a broader policy can also provide a framework to look at all active substances in a product group in its entirety in order to avoid that in the end, for example for administrative reasons, the worst alternative remains last, or that all respective applicants in all respective procedures (for example substance evaluations within one product group (Product Type PT)) must always provide the same information about possible alternatives. This could place part of the burden of proof on the competent authority, or the competent authority could request relevant facts from interested parties.

3.4 Process of decision-making

In the process leading from a request for approval, authorisation or exemption, to the final decision-making, several parties play a role and there is undoubtedly a need for mutual exchange of information, whereby the relationships between the department (the State of the Netherlands) and the Ctgb (an Independent Administrative Body) are observed. Table 1 provides an overview of who is the competent authority for the various specific situations.

Table 1 Overview of procedures for specific situations and the competent authority.

Procedures	**Articles specific situations**	**Competent authority**
Substance approval	5.2.b 5.2.c	European Commission / Ministry
Authorization	19.5 37.1 and 39.1	Ctgb
Authorization	55.3	European Commission / Ctgb
Union-authorization	19.5	European Commission
Exemption Derogation	2.8 55.1	Ministry

The methodology specifically aims to support the balancing of interests. In order to arrive at a sufficiently justified decision in all reasonableness, some general principles can be provided. [14] For example, it must be possible to go through the procedure impartially, without bias, regardless of who the applicant is. The methodology must also support the competent authority in weighing the relevant interests, collecting the relevant facts, and seeking advice or organizing public participation.

The BPR provides the legal basis that the applicant must provide the necessary information if he wants an authorization for a biocide that falls under a 'specific situation'. However, the BPR does not regulate which information the applicant must provide for the assessment. In doing so, we must bear in mind that the General Administrative Law Act (Article

14 The system does not describe the precise workflow that the competent authority must follow for the handling of all procedures.

3.2) provides that, when preparing a decision, the competent authority gathers the necessary knowledge about the relevant facts and the interests to be weighed. It concerns finding material truth – so broader than an assessment of what the parties themselves have put forward – while at the same time it is clear that one hundred percent certainty cannot be obtained. It is therefore desirable to be clear about which facts must, or do not need to, be proven; who must prove which facts; how these must be proven; and how to deal with uncertainties. This is desirable in order to distribute the burden of proof fairly, to provide legal certainty and equality about what is expected, and to ensure that decisions can be taken in a timely manner. All this is also necessary to be able to account for the decision.

When describing, assessing and comparing the interests, alternatives and risks and uncertainties involved, it is inevitable that the parties involved make their own assessments based on divergent social values and interests. This can be done justice by involving insights from multiple angles for each issue.[15,16] This ties in with two important policy principles[17]: "Ensure a transparent decision-making process and make the responsibilities of government, business and citizens explicit in those decisions".

15 Van Zijverden M, Maas RJM, Mennen MG, Montforts MHMM (2017) A scan of the safety and quality of our environment (In Dutch: Een scan van de veiligheid en kwaliteit van onze leefomgeving). RIVM letter report 2017-0030.
16 Van Eeten M, Noordegraaf-Eelens L, Ferket J, Februari M (2012) In Dutch:Waarom burgers risico's accepteren en waarom bestuurders dat niet zien. Ministerie van BZK.
17 Ministerie van Infrastructuur en Milieu (2014) In Dutch: Beleidsnota bewust omgaan met veiligheid: rode draden.

4 Public interests and values are the core

The first principle in this report is that important public interests and values (namely: the protection of human, animal and environmental health) are the reason to strictly regulate the market for biocides in the BPR. The BPR provides rules to make exceptions (in 'specific situations'), because, for example, the market or regulations can fail to deliver biocides or other solutions in a timely manner to protect the same, or equivalent, interests.

The public interest is distinguished from private (business, commercial or personal) interests: it is an interest that applies to the whole of society, i.e. an interest that is regarded by the entire society as a general interest, even if it affects only certain groups of people or certain areas of a country. These interests are linked to shared values in the fields of health, safety, social equality and employment, culture and traditions, human rights, nature and economic development. And public interests concern social interests that can only be adequately protected or promoted through government intervention.

The first step in any 'specific situation' is to determine whether there is a public interest that could justify the use of the substance or biocidal product, and thus the decision to make an exception.[18] Text box 3 briefly indicates how it can be determined whether there is a public interest.

If it has been determined that there is a public interest, for example because there is a market failure[19], it does not automatically follow that an exception must be made. For the specific situations listed in the BPR, the question is still relevant whether the interest a) is explicitly mentioned in the relevant article of the BPR as a possible exception, or whether it b) can reasonably fall within the scope of the article.

In summary, the following questions are relevant for the specific situations: what is the problem that *the application* needs to solve? Which public values and/or interests, and what damage thereto, are at stake if the problem continues? Is the interest explicitly mentioned in the BPR as a possible ground for an exception, or can it reasonably fall within the scope of the article? See Table 2 below.

If there is *no* question of a public interest, then there is no legitimacy for government intervention, and no grounds for making an exception. Is there really a public interest, and is this interest explicitly mentioned in the BPR as a possible ground for an exception? Then the next question is what the relationship is between this interest and the use of the substance or product for which the procedure is followed. What

18 See also section 3.2, when discussing the criterion of 'effectiveness'.
19 In the background are complex questions about what government tasks are and what can be left to the market. The view on the boundary between government and the market changes over time (see (in Dutch) kcwj.nl). In this report it is left open whether there must always be at least a market failure (reason 4 in Textbox 3), in order to speak of a public interest, or whether the first three reasons are sufficient.

contribution does the application make to the protection or safeguarding of these values and/or interests?

Text box 3 How to determine whether there is a public interest?

Public interest

One may use the following questions to determine whether there is a public interest.

1. **Is there a task for the national government?**
   Check whether the government intervention fits within the tasks of the central government: ensuring security, safeguarding the rule of law, protecting classical and social fundamental rights, ensuring equal treatment of citizens, protecting human rights and protecting the weak in the society.
2. **Is the redistribution of wealth necessary?**
   A skewed distribution of wealth or of citizens' starting positions can be a reason for government intervention.
3. **Is there a reason to correct behavior?**
   The advantages or disadvantages of using certain goods are known, but in the eyes of the government this does not lead to the right choices. This may be a reason for the government to intervene. For example, the government discourages smokers, while it is generally known that smoking is unhealthy. […].
4. **Is there a market failure?**
   If the functioning of the market does not contribute, or contributes too little, to social welfare, public interests may be at stake. Then there is a market failure and this can manifest in different ways:
   - External effects that the market cannot (sufficiently) correct. These are effects that involve costs for which there is no market (for example environmental pollution). As a result, the price of goods or services is too low without intervention.
   - Public (collective) goods. In the case of public goods, production via the market is excluded, because the proceeds benefit everyone and the use by one does not exclude the use by the other (for example dikes, or defence).
   - Information skew between buyer and supplier – this leads to opportunistic behavior or sub-optimal choice behavior, which prevents the market from functioning properly.
   - Unfair competitive relationships (monopoly formation).
   - This is a situation where one provider gains so much power that the price mechanism of the market no longer functions properly.
   - Transaction costs that are too high. If the transaction costs are too high, there will be no market.

Source (in Dutch): Knowledge Center Legislation and Legal Affairs.

Table 2 Overview of public interests named in the articles of the BPR in which specific situations are regulated.

Article BPR	**Public interests**	
2.8		Defence
5.2.b	Essential to prevent or control serious danger	Human health
		Animal health
		Environment
5.2.c 19.5	Disproportionate negative	Impact on society
37	Protection	Environment
		Health and life of humans, particularly of vulnerable groups
		Health and life of animals or plants
		National treasures possessing artistic, historic or archaeological value
Art 37		Public policy or public security
Art 39.1		Pest control activities or the protection of public health
Art 55.1	Danger	Public health
		Animal health
		Environment
Art 55.3	Protection	Cultural heritage

The contribution that the use of the biocide for which exception is sought, makes to the protection or safeguarding of these values and/or interests also affects the assessment of the contribution that *alternatives* could offer.

The BPR identifies a number of interests in the various procedures: see Table 2 and Figure 2. Making these interests concrete is an important step in each case. The meaning of adjectives such as 'danger' also deserves attention. The degree of protection, danger, importance or consequences that should be at stake will differ per case, although everyone will agree more quickly on the extremes (protection of life, control of an epidemic). This consideration is given attention in the methodology.

The challenge mainly lies in how these interests – especially if they are contradictory – can be weighed. A relevant question is: are all public values equal? And are they equivalent to the (to be avoided) risks: health of humans, animals and the environment? This will have to be worked out on a case-by-case basis.

The fact that biocides that do not meet the admission requirements are in principle not authorized, and that the BPR specifies which interests can weigh so heavily that an exception can be made (Table 2 and Figure 2), makes it plausible to take the list of interests mentioned in the

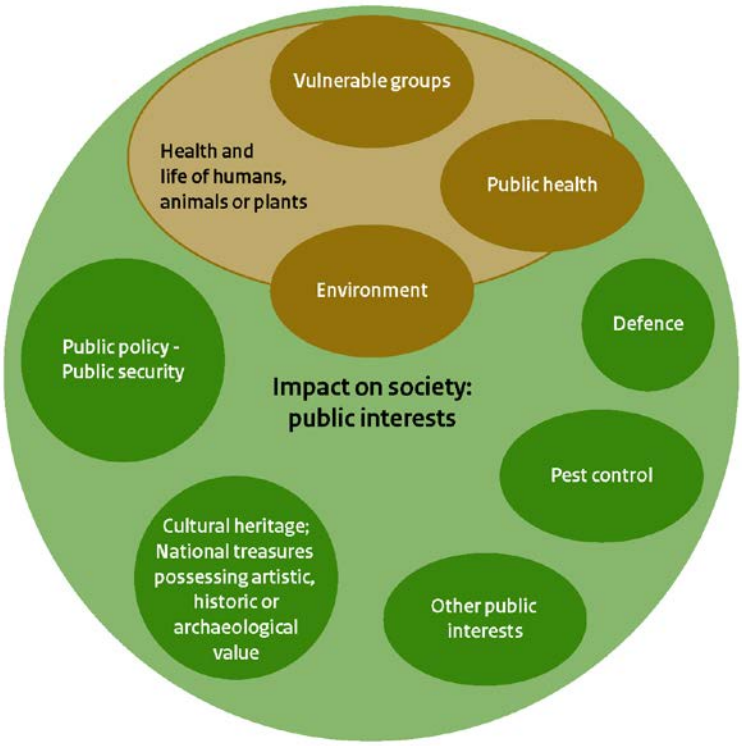


Figure 1 Exceptions can be made to protect public interests, when amongst others there is a disproportionate negative impact on society. Some articles articulate specific interests.

articles in the BPR, in principle as exhaustive. After all, if other interests could also be grounds for an exception, it is not immediately clear why it was decided to explicitly mention only certain interests. At the same time, considering the list of interests as exhaustive raises broader questions. Such as how to deal with concrete interests that may play a role in specific situations, but which are not explicitly mentioned in the BPR as a possible ground for an exception. For example: in the case of an Article 55.1 derogation, danger to public health, animal health, or the environment are mentioned. Should other, not mentioned interests such as public order or public security (as mentioned in Article 37) be completely disregarded, even if they are there? This is an example of a broader, political question, which is beyond the scope of this report.[20]

Finally, it is relevant that two articles do not specify which *concrete* interests must be involved in order to be allowed to make an exception. Article 5.2.c and Article 19.5 refer more generally to 'disproportionate negative impact on society' of not authorizing a biocide (see Table 2). That raises several questions. First, how that relates to the proposition that the list of interests should be understood as exhaustive. Is that compatible? We think so. The challenge in article 5.2.c. and Article 19.5 is mainly that if we regard the list of interests as exhaustive, this gives

20 It is not to be said, however, that other interests may not play a role at all if the list of interests is regarded as exhaustive. One perspective would be to think that interests other than those explicitly mentioned may be taken into account, but cannot in themselves constitute decisive legitimacy for an exception. Even then, the list of interests that can legitimize an exception is in crucial respect, exhaustive.

little direction for Article 5.2.c. and 19.5, because no concrete interests are mentioned. That does not make it any less useful (or impossible) to regard the list of interests that are mentioned as exhaustive.

A second question is of a more fundamental nature. Namely whether the relative openness of the conditions of article 5.2.c. and Article 19.5 nullifies the limitation obtained by an exhaustive list of interests. Can interests that are excluded by the other articles be decisive according to article 5.2.c. and Article 19.5?

We cannot deal with this question exhaustively here. However, there are reasons to think that the effect will be limited. We note that the effect would not play out in all proceedings in any case. Article 5.2.c only relates to substance approval; Article 19.5 only on admission and Union admission (see Table 1) Furthermore, also in Article 5.2.c. and 19.5 there should be a public interest to legitimize a government intervention. Is any disproportionate harm to society automatically a public interest? The relative openness of Article 5.2.c. and Article 19.5 could, for example, raise the question whether an interest such as prosperity could legitimize an exception (in the specific situations covered by Articles 5.2.c. and 19.5). We have already seen (Text box 3) that there may be a public interest if the redistribution of wealth is necessary. This imposes a first requirement on how prosperity could play a role, namely that there must be a skewed distribution of prosperity (or starting position) between citizens that must be straightened out. Prosperity growth or economic development as such seems out of the question. The content of Textbox 1 is also relevant here, namely that from an ethical perspective the right to health is of a completely different order than, for example, economic value(s). Health is a goal and interest worth pursuing in itself, economic value(s) are not. This means that, in principle, there are ethical reasons for setting limits to allowing additional health risks.

5 Balancing interests against risks

The previous chapter discussed how public Interests and values are at the heart of the consideration of whether an exception should be made. The BPR also regulates that this interest must be weighed against the risks of using the biocide in question.

The BPR regulates in articles 4.1 (referring to 19.1 and 19.5); 5.2, 19.5, 37 and 39.1 that the risk to human, animal or environmental health must be weighed against the public interest, when

- the application of the biocide results in unacceptable effects on human, animal or environmental health (Article 19.1.b).
- the active substance has certain hazardous properties (Article 5.1).

The articles do not provide any further information about which risks are referred to. We assume that this refers to the risk criteria of Annex VI of the BPR, since Article 23.3 refers to Annex VI for the comparative assessment, and given how Annex VI links the term 'unacceptable effects' of Article 19.1.b and the 'characterization of the risk'. Annex VI also makes a distinction between the 'determination of the hazards' and the 'characterization of the risk'. The *hazardous properties* of the active substance lead via in Article 5.1 and 5.2 to this assessment of the public interest against *risks*, but are themselves no longer involved in this assessment.

In addition to specifying the risks, it is important how the risks are weighed against the interests, and how the risks are mutually weighed between the (dissimilar) alternatives. There will always be a balancing of dissimilar values. In addition, there will usually also be uncertainty about the probability or magnitude of negative or positive effects, due to a lack of information. The methodology provides for this by naming this, but cannot frame this completely in advance. What exactly needs to be discussed will differ per case, depending on the application(s) and the products for which exception is requested, and the procedure. However, some rules of thumb can be formulated. For instance:

- The more uncertainty there is about the probability and magnitude of positive effects of a biocide application, the weaker the justification for making an exception. As mentioned, a biocide must (be able to) make a substantial contribution to mitigating an important problem in order to legitimize an exception;
- More uncertainty about the probability and magnitude of negative effects of a biocide application does not automatically make the justification for making an exception for the application stronger. It is possible that it weakens the basis. Whether it does depends on how severe the potential negative effects are. The next question is whether the odds of those effects occurring, are considered acceptable. This room for consideration is only available if there is sufficient certainty about the expected positive effects of the biocide application;
- If the possible negative consequences of the biocide application are equal to those of an alternative, this reinforces the case for

the option for which it is least certain that these adverse effects will actually occur (provided that a substantial positive effect is sufficiently certain);
- In case of equal uncertainty about the expected effects (positive and negative) of a biocide application in comparison with an alternative, the alternative is preferred (after all, it is not necessary to make an exception in that case); and
- If the potential contribution of the biocide application to mitigating an important problem is equal to that of an alternative, this strengthens the case for the option for which it is most certain that those effects will actually be realized.

Although this list of rules of thumb is not exhaustive, it makes it clear that uncertainty does not have to paralyze judgment, but can be made manageable with the help of such rules of thumb. For example, by assigning pluses and minuses to a biocide application and possible alternatives using such rules of thumb.

It is also important how judgments are formed with regard to the *risk management* aspect.
- The BPR imposes a condition on the use of biocides that are permitted under Article 19.5: this "*shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised*." The BPR imposes the same condition on the active substance in Article 5.2.
- Article 55.1 provides for exemptions that it concerns "*a limited and controlled use under the supervision of the competent authority*".

The BPR therefore states that it is the government's task to limit the use of these biocides, to control them, with appropriate risk-mitigating measures, or place the use under supervision. The BPR does not regulate what is necessary to guarantee this and to make it demonstrable, for example with prescription, with user certification, supervised application, or with reporting obligations. This must be organized by the competent authority itself.

What place does the option to take risk-mitigating measures have, when considering whether or not to make an exception? It is always important that making an exception requires argumentation that makes it clear that an exception is necessary. The fact that any risks and/or exposure can be limited is not in itself an argument in favor of the need for an exception. It weakens certain arguments that could be advanced against making an exception: namely arguments that refer to exposure and risks. However, this does not alter the fact that, in order to be able to make an exception, it must be argued that and why making an exception is necessary.

As soon as exposure, supervision of use, etc., no longer constitute an argument for not granting the exception, consideration must also be given to who in the use chain is responsible for this, and who is responsible for supervising compliance with it. What requirements does that condition impose on whom (Competent authority? User?), and what

responsibilities does that entail? What can the competent authority expect from the user (Can the user comply in all reasonableness? Who is liable if something goes wrong?)? How does that weigh in the decision-making process, and what does that mean for the participation of users in the decision-making process?

6 Availability of alternatives

In the previous chapter, it was discussed that public interests must be weighed up against the risks of the application of the substance in question. In addition, there is the question of whether alternatives can sufficiently provide for the public interest that the biocide (application) could also provide.

The availability of alternatives plays a major role in the BPR.

- Article 5.2 states: "*When deciding whether an active substance may be approved …, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration*."
- the articles for derogation (article 55.1) and authorization of a product with an unapproved active substance (article 55.3) formulate as follows how alternatives should be involved in the decision-making:
  - Article 55.1: "… *if such a measure is necessary because of a danger … which cannot be contained by other means*."
  - Article 55.3: "… *and that no appropriate alternatives are available*."
- The other procedures must take into account alternatives due to the link with Article 23.3 (the comparative assessment for the CfS).

Below we discuss various criteria, which have been established in the procedures, about what may qualify as an alternative. What is meant by 'other means', 'appropriate', 'availability', 'suitable'' and 'sufficient' is important for decision-making. This is explained below.

The text of Article 23.3 (see section 2.5) elaborates on the characteristics of alternatives that are eligible for the comparative assessment. In the case of the comparative assessment of biocides (which must be followed when authorizing biocides with Article 5.2 substances), (only) *authorized* biocides are included, as well as *existing* non-chemical alternatives (control or prevention). Biocides that are exempted or derogated, are by definition not *authorized*, and are therefore not regarded as possible alternatives. Treated articles do contain an active substance, but do not require authorization (in that event they would be regarded as biocidal products). It remains to be seen how treated articles, which may be on the market via import, can be included in the comparative assessment. A European guideline is available for the comparative assessment of Article 23.3. [21]

Procedures that are separate from Article 23.3, such as the derogations, are not limited in the alternatives that may be involved:

21 Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a-Final)

- Substances[22], non-chemical control methods, prevention methods and technologies that *are available* or *exist*.
    - Approved substances or non-approved substances[23] (including in situ generation) in
        - Authorized biocides
        - Unauthorized biocides
        - Derogated Biocides;
    - Treated articles;
    - Technologies including
        - non-chemical control methods
        - prevention methods.
- How to appreciate 'existence', in light of the relevant period for which the product authorization or substance approval, or temporary derogation, applies?
    - Being available at the time of approval? (the requirement for biocides in Article 23.3),
    - Remaining available (foreseeable or long enough) during the relevant period, and/or
    - Becoming available (on time) during the period?
- The alternatives are sufficient:
    - The supply on the market must be able to meet the demand (scarcity), and
    - The alternatives (jointly) cover the necessary functionalities of use for which an exemption is requested;
    - The chemical diversity of the (approved) active substances is sufficient to minimize the risk of resistance developing in the harmful target organism.
- The alternatives are also suitable:
    - They must be sufficiently effective;
    - For Article 55.3 they must be 'appropriate';
    - Economic disadvantages must be assessed in Article 23.3;
    - Practical disadvantages must be assessed in Article 23.3. This is about practicality in practice. For example, they must be usable for the materials to be treated.

With regard to the availability of alternatives, three situations are conceivable:

- There are sufficient effective alternatives with fewer risks than the application of the biocide;
- There are alternatives, but they have similar risks to the biocide (application), are expected to be less effective, or entail other objections,
- There are no alternatives available.

The first situation is relatively simple from a moral point of view: if there are effective alternatives that entail fewer risks, then it is not necessary to make an exception. In fact, making an exception can then hardly be justified from a moral point of view. After all, it does not meet the criterion of subsidiarity. Although subsidiarity is also a generally accepted principle from a legal point of view, the BPR seems to offer

22 In the context of the BPR article 5.2, where it concerns the assessment of active substances, we understand by (alternative) 'substances': (other) active substances for use in biocides or treated articles.
23 Substances that have not yet been assessed in the European work program also count – these are subject to national regulations.

slightly more leeway from a legal point of view. Article 5.2 stipulates that “availability of suitable and sufficient alternative substances or technologies shall be a key consideration”. In administrative law, a ‘consideration’ means that the competent authority may deviate from these provisions, if justified. In these situations, the competent authority can therefore decide to grant the exception (for example, limited) even if suitable alternatives are available. Or not to grant the exception, even if alternatives perform less well or are not available. This decision should be justified.

If there are alternatives, but they do not score better than the biocide (application) in all respects, a complex assessment is required. In chapter 3, guidelines for dealing with this are given (see, for example, the discussion of 'subsidiarity', the criterion that the least intrusive effective means is in principle preferable from a moral point of view).

Finally, if there are no alternatives, they cannot of course be taken into account. Subsidiarity could then be used as a design principle, whereby (possibly temporarily) an exception is made for a biocide (application). At the same time, active efforts could be made to ensure the availability of less intrusive alternatives.

7 The context influences the decision making

In the previous chapter it was discussed that public interests must be weighed up against the risks of the application of the substance in question, and whether alternatives could sufficiently provide for this public interest. The trade-off between interests, risks and alternatives is inextricably linked.

Decision-making in these situations has multiple contexts, which we discuss below. The first context is that of policy. It is relevant that the BPR is not the only policy instrument to manage health, a secure living environment and sustainable use of materials. Making an exception is a decision that could fit within a broader policy framework, aimed at a safe living environment. The procedures for European substance approval and national authorization and derogation, each form a specific context for decision-making.

Policy framework for biocides and a secure living environment
The national government strives for a clean, secure and healthy living environment, which is also appreciated as such. The authorization of biocides is one of the policy instruments in this regard, which in turn is accompanied by a policy on sustainable use and correct use, for example by stimulating information and knowledge exchange, by certifying users, or by requirements in procurement criteria. This broader perspective is also relevant for decision-making when a threat to or from the living environment presents itself, whereby the exceptional authorization or derogation can facilitate a transition. One can think of stimulating prevention, of innovation of materials or systems or technologies, or of services. The BPR does not require such innovation, but it does not exclude it either. In this respect, national policy can therefore offer an important additional guiding framework, in addition to the BPR.

For example, the BPR regulates a harmonized market for biocides, taking into account a transition situation until all existing active substances have been assessed. These existing biocides and treated articles do meet a certain societal need, and existing customers will be familiar with the application of these products. It is conceivable that the European substance assessment shows that applications do not meet the criteria. It is possible that the market is too small to recoup the investment in the product (including the costs of the authorization procedure), or in an alternative. The product then disappears from the market and/or alternatives are not (timely) developed, so that no or insufficient alternatives remain. It may also be that the very availability of these biocides up to the time of assessment discouraged the innovation of new products or techniques. These are developments that are easily foreseeable and that can be responded to (supported by policy), for example in the form of a replacement plan.
A broader policy can provide a framework to look at all active substances in a product group in an integrated way to prevent that ultimately, for administrative reasons (for example because of the order in a work program), the worst alternative remains last. Or that each

applicant, in turn, must again provide all the information about all possible alternatives. Chapter 3.2 also pointed out that this touches on the question of who bears the burden of proof (for all alternatives).

Table 3 The context for decision-making per procedure.

Context / Procedure	**European**	**National (framed by the BPR)**
Substance assessment	Article 4.1 Article 5.2.b Article 5.2.c Member States have a say	Product Authorization
Treated article		No control except for import restrictions via REACH
Union Authorization biocides	Article 19.5 Member States have a say	No control
Authorization biocide		Article 19.5 Article 23.3 Article 37.1 Article 39.1
Authorization biocide for cultural heritage article 55.3	Commission decides	Member state consults with Commission. Ctgb authorizes after positive decision Commission
Derogation biocide article 55.1	Commission decides on extension	Member State grants derogation
Exemption biocide or treated article for defence article 2.8		Member state grants exemption

Authorization of active substances and biocides
It matters whether a substance is approved at European level or whether a biocidal product is authorized at national level, as this has different consequences for the actors in the Member State. This can affect decision-making. See also Table 3.

When it concerns a specific national situation (an authorization or an exemption or a derogation), the competent authority has the task of weighing up the public interest for the Member State.

When a substance is approved at European level under Article 5(2), this offers different contexts for the Member State:

a) The Member State then has the option of nationally authorizing biocidal products containing this substance or of not authorizing them, or not mutually recognizing them. The fact that some Member States see a public interest does not force other Member States to make the same decision at national level. This could be a rationale that it suffices if the applicant demonstrates the public interest in at least 1 Member State ('one essential use').

b) When a substance in a treated article is approved, the Member State no longer has the means within the BPR to stop these articles from entering the market. This could be a rationale that the applicant substantiates the public interest for all Member States, or for the EU as a whole, or that the Member States themselves substantiate that this interest is or is not there.
c) In the case of Union authorizations, the Member State will have similar considerations as for treated articles. This could be a rationale that the applicant substantiates the public interest for all Member States, or for the EU as a whole, or that the Member States substantiate that this interest does not exist. Biocidal products with active substances that have been approved under Article 5.2 are not eligible for Union authorization (BPR Article 42.1).
d) The BPR does not regulate or exclude whether a substance approval can be restrictive. It seems a justifiable choice to limit the approval of the active substance to those specific situations where it has been established that an important public interest is served that outweighs the risks of product authorization or placing treated articles on the market.

8 The methodology in more detail

In the previous chapters, a number of aspects were discussed that are relevant when making an exception. The BPR provides a legal framework with procedures for specific situations. The application of that legal framework requires a normative assessment. Should the competent authority in a specific situation deviate from the standard: only authorize if the authorization procedure is completed and a high degree of protection of human, animal and environmental health is met? Is there a justification for still approving a substance or authorizing or derogating a biocide, based on the weighing of risks against public interests, taking into account alternatives?

This chapter briefly describes a methodology for weighing the public interest. The methodology ought to support this complex assessment for each case by providing criteria and guidelines so that the competent authority can make a reasonable decision. It was decided not to work out a method in detail for each specific situation, but to outline an approach. This methodology should be general enough to be used for each specific situation, and – at least that is the aim – concrete enough to allow for concrete considerations in more detail.

A generic model that is often used in practice for choices and considerations with an important ethical component[9] was used to design the methodology. Table 4 provides a brief overview of that generic model. It consists of 9 practical steps, divided into 5 phases. The model has a logical sequence in which the problem is first explored, unraveled step by step (make explicit, analyze), in order to finally be able to make an assessment and determine the concrete approach.

This model is briefly elaborated below for application in the context of the BPR. For convenience, the discussion of each phase concludes with a picture of how it is represented in the A3 version of the methodology (see the front of this report).

Phase I: Exploration

Step 1. Brief description of the case

A request for an exception will arise in the work program for substance evaluation, or in the authorization of biocides, or be prompted by an unforeseen development (derogations). The case as it is presented will usually address a problem, but will not automatically contain all aspects necessary to make a decision. In Step 1 it is therefore important to provide a sufficiently rich description of the case in order to ultimately be able to arrive at a balancing of interests. The following questions are relevant:

- Which specific biocide application is involved?
- For which problem should the biocide application provide a solution?

Table 4: A commonly used model for making ethical choices

	Phase	Step / Question
I	Exploration	1. Provide a brief description of the case. What questions does the case raise?
II	Explication	2. What is the central (moral) question?
		3. Which options for action are open (at first sight)?
		4. What factual information is currently missing?
III	Analysis	5. Who is involved in the case, and what is the perspective of each of those involved?
		6. Which arguments are relevant to answer the central question?
IV	Assessment	7. What is the weight of these arguments in this case? Make an inventory of the rights, duties and responsibilities of those involved. Does this shift the picture with regard to the assessment of the options for action?
		8. Which course of action is preferable on the basis of these considerations? (conclusion + argumentation)
V	Approach	9. What concrete steps follow from this?

- Does the problem concern a public interest that is explicitly mentioned in the BPR? [24]
- What harm to these interests is at stake if the problem persists?
- How important is it to fix/reduce the problem?
- To what extent can the application provide a solution to the problem?
- What is known about possible risks of the application, and risks for whom? Are there other objections?
- Does the case raise additional questions?
- What guidance do other relevant policy frameworks offer?

All things considered, the key question is how important it is to solve the problem in question (see above). That question cannot be answered at once. It is important to get a first picture of it in Step 1. This can be done, for example, by intuitively expressing it in a number from 1-10. On the basis of later steps, this picture can be further refined, if more information has been obtained, and it is also clear what the perspectives of other parties are.

What guidance do existing frameworks offer?
Making an assessment is made easier by formulating a number of (more or less) benchmarks as early as possible. This provides guidance and helps prevent moving away from important beacons when making the assessment.

24 See Table 2 in Chapter 4 for an overview of public interests on the basis of which the BPR allows exceptions under certain conditions.

Although the BPR itself already offers important tools, supplementing parts could be helpful. For example, the BPR aims to offer a high level of protection for the health of humans, animals and the environment. But how high is high? Moreover, it is conceivable that when considering whether to make an exception for a biocide (application) to protect human, animal and environmental health, the interests of humans, animals and the environment are at odds with each other, and fight for priority. It is then helpful to have an idea beforehand whether there is generally a certain hierarchy in the interests of humans, animals and the environment. If in general a certain hierarchy is considered defensible (as part of standing policy), this can also provide guidance in concrete cases.[25]

By making explicit in Step 1 what the ambition is for the case for protecting the health of humans, animals and the environment, it becomes clear how high the bar is for whether or not to make an exception. Other policy frameworks (than the BPR) may offer additional guidance on this point. Policy frameworks, goals and ambitions that may be relevant to cases can be laid down in, among other things:

- Positions taken in (previous) substance approvals
- Environmental Safety and Risk Policy
- Biocides Policy Program
- Chemicals Strategy / Substances of Very High Concern Policy
- Policy on Invasive Species
- Infection Prevention and Vector Control Policy
- Circular economy policy.

Making explicit the policy ambitions that are relevant to the exception, together with the level of ambition with regard to the protection of humans, animals and the environment, contributes to consistent policy, while also leaving room for customization within the cases.

Is there a clear (no) public interest?
In this phase also determine whether there is a public interest that could justify the use of the substance or product, and thus the decision to make an exception. Whether there is a public interest can be determined on the basis of the following questions:

- Is there a task for the national government?
- Is the redistribution of wealth necessary?
- Is there a reason to correct behavior?
- Is there a market failure?[26]

This step (1) already contains an important element of **the decision tree**:

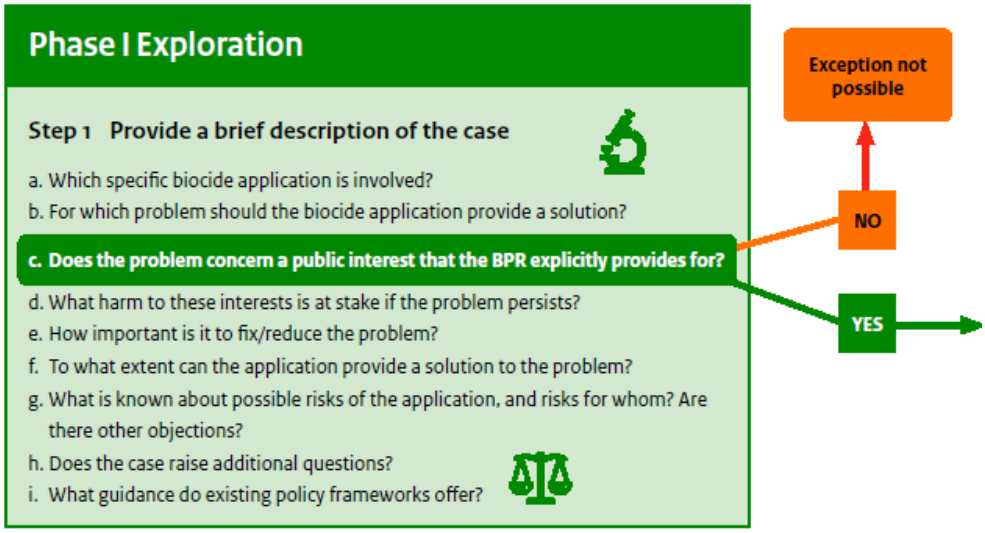
- If there is no question of a public interest that is explicitly provided for in the BPR, then it stops (no exception possible).[27]

Explanation: there is only legitimacy for government action if there is a public interest, but there is only a public interest if certain conditions are

25 In this respect, for example, shifts in social views on the position of animals and the environment are also relevant.
26 See Text Box 3 in Chapter 4.
27 This also includes what Article 5.2.c. and Article 19.5 stipulate for making an exception, namely that there must be disproportionately negative impact on society.

met (see Text box 3 in chapter 4). One of the reasons why there may be a public interest is that the market and/or society cannot adequately solve the problem. If the market and/or society can adequately solve the problem, there may be no justification for government intervention.[28] Therefore, as part of this step, try to determine, among other things, whether the market and/or society can adequately solve the problem. It is also conceivable that, in order to definitively answer this question, other parties will have to be consulted first, and that the methodology will then have to be run through again.[29]

In the A3 version of the methodology, Phase I is shown as follows:



Has all the information already available about the case been collected, and is there a public interest that is explicitly provided for in the BPR, or can it reasonably fall under the heading of 'disproportionate negative impact on society'? Then you can proceed to phase II, that of explication.

Phase II: Explication

The explication phase consists of 3 steps: formulating the central question in the case, formulating action options, and mapping out which factual information is missing, which is necessary to be able to make a judgment about which of the action options has preference.

Central question (Step 2)

Part of the central question in the context of the BPR has always been at the table: whether or not to make an exception for a biocide (application). From a moral point of view, different variants are in principle conceivable:

1) *may* I make an exception under certain conditions, and
2) *should* I make an exception under certain conditions?

28 As mentioned (see footnote 19), this report leaves open whether there must always at least be a market failure in order to be a matter of public interest.

29 Consultation is discussed in Step 5. If it is only possible to determine definitively in Step 5 whether the market and/or society can adequately solve the problem, then it may be necessary to return to Step 1 from Step 5, and start over.

Based on the verbatim text of the relevant articles from the BPR, the first option seems to apply in principle. For example, article 5.2 states: "may be approved", and article 19.5 says: "may be authorized". From a legal point of view, it is allowed and it is not mandatory.

At the same time, there are reasons to think that the question that arises from the BPR, is whether an exception *should* be made. We explain this in more detail. To begin with, an exception may only be made if compelling public interests are at stake (from the exhaustive list in the BPR, Table 2). This may concern the health of humans, animals and/or the environment, but also other interests (e.g. defence). An exception may be made if the interests in question outweigh the (possible) risks to human, animal and environmental health that a biocide (application) entails. But *if* the judgment is that those interests do indeed prevail, and that all additional conditions are also met, then it is difficult to see what the argumentation could be for not making the exception. After all, the conclusion that all conditions have been met comes down to the conclusion that a biocide (application) is necessary. And if a biocide (application) is indeed necessary, then it is obvious that an exception must be made. Conversely, if those public interests do not prevail, and all additional conditions are not met, then no exception should be made. In that case, it is basically not allowed, because making an exception is then *not* necessary.

The central question in the assessment therefore always has the following general form:

Should an exception be made for biocide (application) X, for the benefit of public interest Y?
This question can be further elaborated on per case: which biocide (application) is involved, and for the benefit of which public interests should an exception possibly be made?

Options for action (Step 3)
At first glance, there are always two options for action, namely whether or not to make an exception. At the same time, combinations are conceivable for each of these action options. For example: a temporary exception is made for a biocide, but at the same time specific innovation is stimulated with accompanying policy to make the exception superfluous within a reasonable period.[30] In general, the action options are:

1. Exception;
2. Exception, with restrictions;
3. Exceptions with accompanying policy / replacement plan;
4. No exception;
5. No exception, with compensatory measures.

30 This is not a strict requirement from the BPR. However, it could be a policy ambition.

Always include risks and alternatives
Section 3.2 explains why risks and alternatives should always be included in a consideration in the specific situations of the BPR, even if the BPR does not explicitly require this.

If the possible risks of biocides are relevant for the motivation to use a process of substance approval and authorization, then they are also relevant for the consideration of whether or not to make an exception. Those are two sides of the same coin.

If there are good alternatives, it automatically affects how strong the reasons are for making an exception. The better alternatives score in relevant respects compared to the product for which an exception is requested, the less strong the reasons for making an exception are.[31] A description of action options therefore always includes an inventory of possible alternatives.

Missing factual information (Step 4)
When going through the step-by-step plan, it is conceivable that new information will emerge that is relevant to previous steps. It may also become clear that important information is still missing in order to be able to take the next steps, and to ultimately reach a decision. In the latter case, try to collect this information before continuing. Can the missing information still be obtained? If so, how and from whom? In the first case: check whether the new information has consequences for the previous steps. How important is the missing information for the analysis and consideration?

The following points can provide guidance and direction in this step:

- The *burden of proof* lies with the party wishing to claim an exception. In principle it is up to this party to supply the information needed to substantiate a decision. Ultimately, if essential information necessary for a positive decision is missing, this could provide a basis for not making an exception. The party making the trade-off could theoretically choose to assume some of the responsibility for obtaining essential missing information. However, this need not be an automatism and it cannot reasonably be expected of the evaluating party.
- *Consulting* all parties who are (or may be) affected by a decision – whether or not to make an exception – offers the opportunity to gather information in addition to the perspective of those involved on the problem and possible solutions. In line with the previous point, consultation could also be used to gather information that is essential to possibly reach a positive decision, if the evaluating party decides to assume some of the responsibility for gathering this information.

31 See further at Steps 7 and 8.

In the A3 version of the methodology, Phase II is shown as follows:

Phase II Explication

Step 2 What is the central (moral) question (adjust for every case)

a. "Should an exception be made for biocide (application) X for the benefit of public interest ?"

Step 3 Which action options are open at first sight?

a. Exception
b. Exception, with limitations
c. Exception, with accompanying policy / replacement plan
d. No exception
e. No exception, with compensatory measures
f. Are there alternatives to fix/mitigate the problem? (describe these briefly)

Step 4 What factual information is currently missing?

a. Can the missing information still be obtained? If so, how and from whom?
b. How important is the missing information for the analysis and assessment?

The next phase (Analysis) consists of two steps: mapping out the perspective of the parties involved (Step 5) and mapping out which arguments are relevant for answering the central question (Step 6).

Phase III: Analysis
Which parties are involved and what is their perspective? (Step 5)
It has already been stated in chapter 3 that adopting a moral perspective means, among other things, that the perspective and interests of all parties involved are taken into account. This concerns all parties that may be affected by the decision whether or not to make an exception.

These include (some overlap is possible):

- The relevant value chain. Solutions are preferably found in the value chain (chain responsibility).
- Governments (central government, Ctgb, provinces, municipalities, water boards). In the case of a substance approval or of derogation of a product, the Ministry of Infrastructure and Water Management is the competent authority in the Netherlands. Ctgb is the competent authority in the case of an authorization. It is obvious that a position on an exception to substance approval (Ministry decision) can have consequences for existing or new authorizations, which the Ctgb must then decide on. Within the national government, the Minister of Infrastructure and Water Management is responsible for policy, but the decision may have consequences for other ministries (for example those responsible for defence, health, worker safety,

science, or nature), for implementing parties (for example inspectorates or water boards) or for other authorities.
- Stakeholders in the current situation, who may suffer negative consequences from the decision to make an exception for a biocide (application). Or vice versa, stakeholders, who could potentially experience positive consequences from the exception. It is important to involve them, also whether they see alternatives.
- Independent experts, who have no interest in the decision, but who do have knowledge of the potential utility, the market, and the value of a biocide (application) and alternatives for users.

How broad or narrow involving stakeholders is organized may depend on several factors, including:
- Time: timelines can be so tight that only a limited inventory can be made of the perspective of all parties involved.
- How easy or difficult parties are to reach. Non-organized parties may be (but are not necessarily) less easily accessible. Independent experts may also be able to articulate the perspective of hard-to-reach non-organized stakeholders.

It is recommended to always make explicit on the basis of which considerations which parties are involved or not.

A point of attention when involving interested parties is to put what is important *to them* central; what their perspective is on the problem, on possible solutions, and their desirability.

Relevant questions are:
- Who can be affected by a positive or negative decision? (involve them)
- Which interests play a role according to those involved? How important do they think this is?[32]
- How do those involved view the effects and desirability of the action options?
- What possibilities do they see for promoting the interests involved as much as possible/ harming them as little as possible (including health risks/dangerous properties)?[33]

Which arguments are relevant for answering the central question? (Step 6)
In terms of content, there is a lot of overlap between Step 6, in which relevant arguments are collected, and Step 7, in which the final assessment must be made. The difference is that in Step 6 no judgment has to be made about how convincing an argument is, or about which course of action is preferable. In Step 7, however, a judgment has to be made about this.

Relevant arguments to list in Step 6 include (in outline):
- To what extent can the action options solve/reduce the problem?

32 By combining this with our own assessment made in Step 1, a more complete picture can be obtained of how important the problem is that making an exception should solve.
33 This can provide additional information about whether there are promising alternatives to the biocide (application).

- How do the options for action affect other interests? (positive/negative; to what extent)?
- How certain are these estimates?

It is conceivable that the interested parties involved themselves will put forward relevant additional arguments. As part of the consultation, it may be considered to ask an open question about this.

In the A3 version of the methodology, Phase III is shown as follows:

Phase III Analysis

Step 5 Who is involved in the case and what is their perspective?

a. Who can be affected by a positive or negative decision? (Involve them)
b. Which interests play a role according to those involved? How important do they think these are?
c. How do stakeholders view the effects and desirability of the action options?
d. What possibilities do they see for promoting the interests involved as much as possible / harming them as little as possible (including health risks / hazardous properties)?

Step 6 Which arguments are relevant, given the central question?

a. To what extent can the action options solve / reduce the problem?
b. How do the options for action affect other interests? (positive / negative, to what extent)
c. How certain are the estimates for a. and b.?
d. Do those involved put forward relevant additional information and considerations?

The next phase (Assessment) consists of two steps: determining the weight of the arguments that have been mapped (Step 7) and determining which action option is preferable (Step 8).

Phase IV: Assessment
What is the weight of these arguments in this case? (Step 7)
An exception may only be made if public interests are at stake, which outweigh the protection of human, animal and environmental health. Insofar as those public interests relate to the health of humans, animals and the environment itself, it is required that the positive effect on those interests is substantially greater than the risks that the biocide (application) may entail.

The answer to the question of whether an exception should be made does not automatically follow from the methodology, but always requires a substantiation in words.

In practice, complex considerations and decisions will have to be made, which will largely revolve around an assessment of:

a) The extent to which the product for which the exception is sought contributes to the important (public) interest;
b) Whether this important (public) interest indeed outweighs the interest of protecting human, animal and environmental health (whether the benefits for human, animal and environmental health substantially outweigh the risks);
c) The extent to which the biocide (application) poses risks to human, animal and environmental health;
d) The extent to which alternatives score better or worse in relevant respects (see a and b) than the biocide (application);
e) The extent to which relevant information was available, and the extent to which the data and assumptions are surrounded by uncertainty;
f) The extent to which the decision enables the competent authority to maintain control (EU approval *vs.* national approval); and
g) The extent to which in the end an improvement is possible, and in what period of time (with regard to supporting measures to solve the problem otherwise).

Using the points above:

- the interests involved can be ranked according to how important they are;
- the action options can be ranked in terms of the extent to which they can help mitigate the problem;
- the options for action can be ranked in terms of their influence (positive and/or negative) on other relevant interests; and
- it can be determined whether possible alternatives score better in relevant respects than the biocide (application).

It is recommended to visualize these rankings, for example in the form of a table or a graph.

Before it can be determined which course of action is preferred, it is important to determine whether the parties involved have specific rights, obligations and responsibilities, on the basis of which the assessment of the course of action could turn out differently. For example (this list is not exhaustive):

- That the burden of proof lies with those who wish to claim an exception. This could be relevant if not all information that is considered relevant for a positive decision has ultimately become available;
- Specific responsibilities of the government, for example to in particular protect vulnerable groups;
- The right to equal treatment, which could be more at stake if the advantages and disadvantages of a decision are more skewed;
- The right to health, an interest that is a fundamental human right, which should only be weighed up against comparable interests, and only if there really is no other option.

Which course of action is preferable on the basis of this consideration? (conclusion + argumentation) (Step 8)
Briefly describe which course of action on the basis of which arguments is preferable.

In essence, this comes down to answering the question of whether it is **necessary** to make an exception for the biocide (application) concerned.

All the input collected in the previous steps can be brought together for this purpose using the following questions[34]:

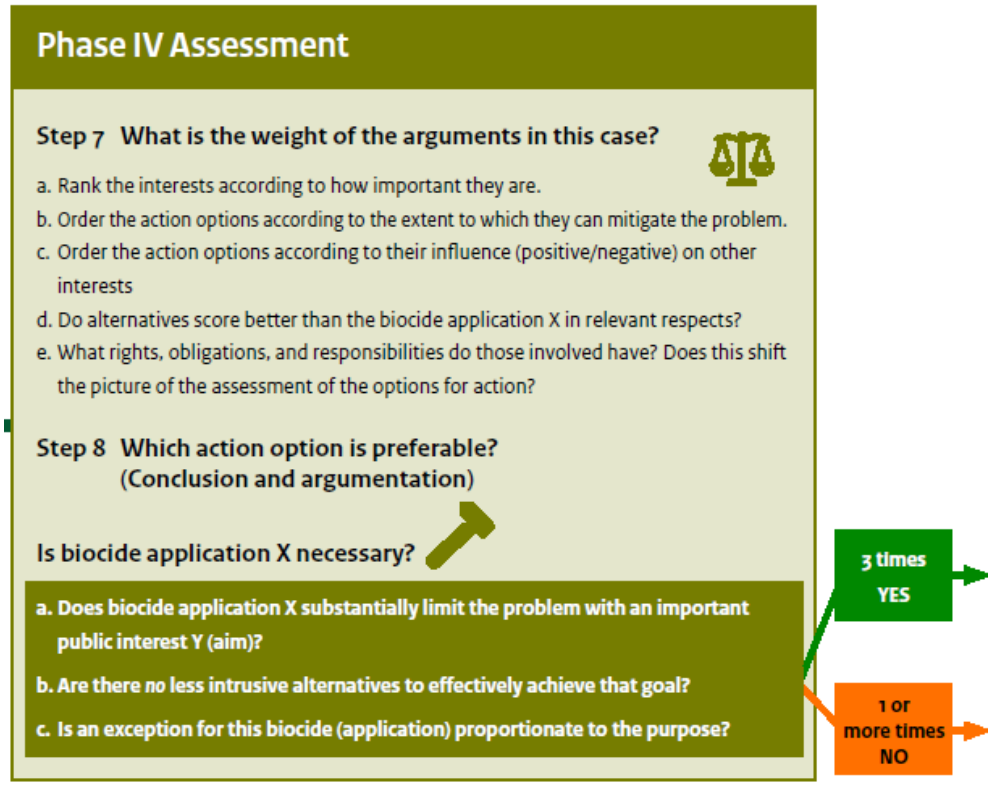
- Does the biocide (application) substantially limit the problem with an important public interest?
- Are there *no* less intrusive alternatives to effectively achieve that goal?
- Is an exception for this biocide (application) reasonably proportionate to the goal?

If the application does not contribute substantially to combating a problem of major public interest, then there is no need to make an exception. There must be a major public interest at stake. And the application must make a substantial contribution to protecting that interest.
If so, the next question is whether there are less intrusive alternatives to effectively achieve that goal. If those alternatives exist, then there is no need to make an exception. If those alternatives are not available, the final question is whether making an exception, amongst others in view of the possible risks and hazards, is reasonably proportionate to the goal: protecting an important public interest.
As soon as one of the questions has to be answered in the negative, it is apparently not necessary to make an exception.

It also follows from the above that if the three questions have to be answered in the affirmative, the conclusion is that the biocide (application) is necessary, and that an exception must be made for the biocide (application).

34 These are the widely recognized ethical and legal criteria of effectiveness, subsidiarity and proportionality respectively. See section 3.1.

In the A3 version of the methodology, Phase IV is shown as follows:



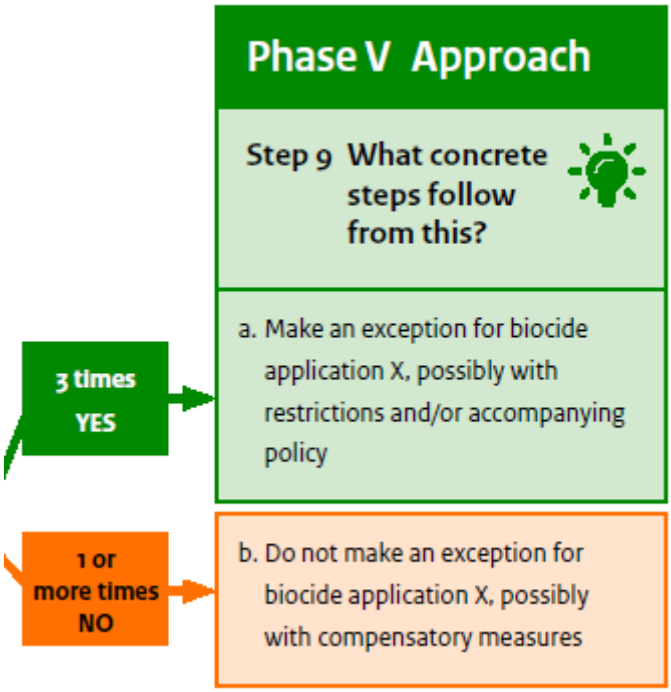
Phase V: Approach
Briefly describe which concrete steps result from the above. Who will/may/must do what specifically? (Step 9)

It goes without saying that the competent authority takes a decision. It may be that in addition to the decision, the necessary arrangements must be made.

The BPR states that it is the government's task to limit the use of these biocides, to control them with appropriate risk-mitigating measures, or to supervise them, but it does not regulate what is necessary to guarantee this and to make it demonstrable, for example by dispensing on prescription, with certifications of users, under the supervision of an inspector, or with reporting obligations. This will require the involvement of, for example, executive bodies (in supervision) and others.
It is also logical that agreements are made about managing the underlying problem, so that the exceptions are no longer necessary in the foreseen term (after all, authorizations and derogations are temporary).

Often, even after drawing a conclusion, there are still open questions. It is recommended that these are briefly noted, as well as any lessons learned from the application of the methodology, which can be included in the assessment of a subsequent biocide (application).

In the A3 version of the methodology, Phase V is shown as follows:



9 Practical application

The methodology provides a basis for the considerations in the various procedures for making a biocide available on an exceptional basis. Ultimately, the competent authority will have to substantiate the outcome of those considerations, the decision, in words.

The methodology structures in a number of steps what needs to be done in order to arrive at a well-considered decision. The case discussions with the Ministry of Infrastructure and Water Management and Ctgb have shown that the steps of the general model can be easily applied. Specific questions were formulated on the basis of the case discussions, aimed at making the exceptions covered by this report. How the methodology is applied in the practice of assessment is still open. Every procedure is different when it comes to urgency and context. The competent authority will have to fill this in on a case-by-case basis. A recommendation is to make working agreements to efficiently run through the methodology for each type of procedure. After all, the methodology requires the organization of information and the exchange of knowledge. Those involved must know timely what is expected of them.

The methodology also supports the structuring of decision-making, which requires cooperation between authorities. For example, the Ministry of Infrastructure and Water Management and the Ctgb are both competent authorities to make decisions in the various procedures, while the inspectorates can, for example, be tasked to supervise the controlled use.

The application of the methodology will have different accents in each case and will require different considerations. As more case studies are completed, new insights will give rise to further improvement of working arrangements and the methodology.

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