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BPR improvement options

Results of a broad inventory

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1. About this report

- *Options for improvement*

This report describes options to improve the Biocidal Product Regulation (BPR; EU 528/2012). They have been collected in conversations with 20 different parties and individuals that are – or were – involved and that have – or had – a stake in the way the BPR is functioning. The list of consulted persons and parties is included in annex A to this report.

- *Main goal: food for thought and discussion*

The main goal of presenting these options, is to allow all parties involved in the evaluation and the REFIT (or possible revision) of the BPR – in particular the Dutch Ministry of Infrastructure and Water Management, that commissioned the drafting of this report – to take a wide range of possible, and perhaps sometimes unconventional, measures into account for changing the BPR and for changing the roles and tasks of institutions involved. As such, all of these options must expressly be seen as thought and conversation starters. Most of them have not been thought through in terms of their exact design, legal implementation or detailed consequences.

- *No consistency and no ownership*

Conversation partners were asked to share general and, if they wanted, radical ideas. Thus, and by definition, the complete collection of ideas does not present a consistent proposal. The presented options sometimes contradict one another. What may seem an improvement of the BPR to one, may look like an imminent disaster to someone else. Yet, these options are presented here side by side, for the reader to make its own appreciation.

Given the way in which we have collected and written them down, and given our intention in doing so, it is not important who exactly submitted which proposal. The options are therefore presented without reference to specific conversation parters. They bear no responsibility for the collection of ideas that is presented here, nor for how they are formulated. The author of this report is solely responsible for the latter. For the rest, it is up to the reader to decide.

- *Reading this report*

The report is divided into sections that deal with broad, general themes: substance approval, product authorisation, innovation, et cetera. The last section addresses an overarching topic that can be supported by changes in and around the BPR but that may also requires changes in attitudes: trust and cooperation.
Occasionally, options presented in different sections are interrelated.

All options are presented against the backdrop of current experiences and problems with the BPR. These problems are briefly outlined at the beginning of each chapter, without, however, claiming to provide a thorough or balanced evaluation.

The presented options are accompanied by a brief description of the given arguments behind the option, and of the way in which they are expected to contribute to an improved

functioning of the BPR. Once again, it is up to the reader to judge whether the presented arguments and effects are complete, convincing and conclusive.

2. Substance approval

2.1 Current problems

Procedures for substance approval are slow, expensive and demanding and outcomes are often uncertain for applicants. The Review programme takes excessive time, deadlines have been postponed several times and the present deadline is again not likely to be met. Moreover, dossier requirements change during the process, making it even more time-consuming and uncertain. There are questions – in both directions – about the strictness and the degrees of protection that are achieved. Also, there can be tension with other EU legal frameworks.

Consequences of these bottlenecks are: little or no business case for innovation and small markets, high market barriers for SMEs, harmful substances that are still on the market and entering the environment, limited or even inadequate means for fighting pests (and efficient means disappearing from the market), lack of means for 'small' applications, illegal and improper use.

2.2 Rely (more) on REACH and CLP

Several options are mentioned for speeding up the approval process and to avoid interference and double work in the process. Some of these are based on the 'One Substance One Assessment' (OSOA) principles that the European Commission is currently implementing.

1. Align the assessment of hazards of active substances with (slightly amended) REACH and CLP procedures and allow for the legal acceptance of the outcomes of these assessments in both REACH/CLP and the BPR

Hazards are intrinsic characteristics of substances. If they have already been assessed within REACH and/or classified in CLP, there should be no reason to repeat this work for BPR purposes (or for any other framework). The same holds true the other way around: BPR hazard assessments should be accepted within REACH/CLP. Provided, of course, that data requirements and information flows are aligned between all legal frameworks (through OSOA), and that possible issues with data ownership are solved. There is (at least) one critical provision to this option: data requirements in REACH depend on tonnages of the substance, whereas for the BPR full dossiers are also required for low tonnage substances. For this option to be viable, an amendment of REACH is therefore needed ('in case of use as active substance, more data are required'). A further proposed amendment is to integrate R4BP (3), the central hub through which all biocides' applications are submitted to ECHA and national authorities, in REACH.

Relying on, and referring to REACH/CLP for hazards assessment and classification, could lead to the implication that the BPR only needs to regulate risk and efficacy assessments for substance approval. A more radical variant (option 2) also relies on REACH for risk assessment, including risk management measures and communication in the supply chain.

2. Rely on REACH/CLP for hazard assessment, risk assessment (based on exposure scenarios, DNEL/DMEL and RCR), risk management measures (RMM) and communication in the supply chain

In this option, the BPR only needs to regulate the efficacy assessment. Of course, all provisions described for option 1 also apply here.

2.3 Abandon (elements of) substance approval

In the current substance approval process, both hazards (of the substance) and risks and efficacy (of a reference product) are assessed. Several options are proposed to make the process of allowing substances and products on the market more lean and efficient by abandoning elements of the approval process, or by abandoning approval as a whole.

3. Abandon the risk and efficacy assessment of a reference product, as this basically doubles the work that is done for product authorisation and does not add to efficiency

The underlying idea of assessing risk and efficacy of a reference product during substance approval, is to ascertain beforehand the possibility of safe use and efficacy of a product based on the substance (that is designed to be lethal to certain organisms) and to increase efficiency of product authorisation. Both these presumed advantages are contested. Safe use (and efficacy to a lesser extent) are highly application and context dependent characteristics (efficacy also depending on co-formulants in the product). Therefore the argument is put forward that they can be better (and are indeed) addressed during product authorisation – the latter implying that there are hardly efficiency gains from the assessment of the reference product.

4. Abandon efficacy assessment for the most part or altogether, and leave this (more) to the market, since efficacy is an – expensively paid for – quality aspect of a product

According to some, current efficacy testing is problematic. The availability, quality and reliability of efficacy tests is substandard. Only few experts are available to develop and improve these tests. Sometimes tests are lacking or lead to false negative outcomes. (Also, products are sometimes specifically designed to just meet test standards). (Largely) abandoning this assessment (or relying more on format-free proof by industry) diminishes the burden of these tests without loss of quality of the products (as the market would sanction this immediately).

5. Completely abandon substance approval – as this unnecessarily reduces the contents of the formulators' toolbox – and rely on product authorisation only
   (5 (a): Only reject substances in the highest hazard categories)

The suggestion to abandon substance approval altogether rests on two pillars. One is that hazards (and risks) are already assessed within REACH (see options 1 and 2). The other is that within the product authorisation process risks and/or efficacy are still – and better – assessed for specific applications and uses. Abandoning substance approval radically speeds up the process, saves costs and work and prevents the disappearance from the

market (e.g. for reasons of high costs) of active substances that may be highly effective and can be used safely in specific circumstances, thus promoting innovation.
The variant to only reject substances in the highest hazard categories is a small modification to the option – but it does of course blur the principle of 'no substance approval'.

2.4 Other ways to speed up substance approval

6. Ensure that approval criteria do not change during the process. This can be done by fixating requirements and guidance documents at a certain point in time, for example at the moment of a pre-submission done by an applicant one year (or one month) before actually filing the application

As was mentioned in the introduction to this section (2.1), dossier requirements that change during substance approval make the process even more time-consuming and uncertain for applicants and authorities. To prevent this from happening, a legal provision is required that ensures that the criteria remain the same during the process ('guidance freeze'), even in case of delays. New criteria will only apply in a next renewal process. Pre-submissions are also helpful for ECHA and national authorities to make the process more predictable and allow for improved time and resource planning.

Such a provision may also need to be so strong as to be defensible against legal claims that all information, including the most recent information, must be taken into account in an assessment. (Although some assume that such claims will be rare in the biocides field – as opposed to similar claims in the field of plant protection products).

7. Limit/target assessments to endpoints on which they may possibly lead to a restriction or rejection

Substance approval can be sped up by not by default always doing a full assessment on all endpoints. Targeted assessments can be carried out, that only include endpoints on which a restriction or rejection may possibly be expected.

8. In case of new information: carry out a quick scan to judge its potential effects on the PNEC or DNEL. If there are none to be expected, there is no need for a reassessment

New information on hazards or risks may give rise to a new assessment or even a complete renewal. It is proposed to first carry out a quick scan on the expected impact of this new information, so as to prevent that much work is done to no real effect.

9. Semi-continuous updates of dossiers

Semi-continuous inclusion of new data and studies in dossiers during the approval or authorisation period,[1] instead of only at the moment of renewal, reduces the amount of work and the time needed once the renewal is taking place, thus reducing lead times.

[1] Reportedly, this procedure is applied in Canada.

10. Abandon periodical renewals and replace them by a (more stringent) obligation for the applicant to share new information with the authorities (which in turn may lead to a re-assessment)
    (10a: prolong renewal periods to 20 years for low risk active substances and to 10 year for active substances of concern)

Periodical renewal of substance approvals – currently every 5, 7 or 10 years – is costly and time and capacity consuming. It puts continuous pressure on the system and creates a recurring workload for the assessment authorities, which is also set to grow significantly, as only half of the substances have been through the review programme so far.

Its purpose, to ensure that all relevant (new) information on hazards and risks is included in the assessment, may be better achieved by only starting a renewal process in case new (concern-raising and impactful; see options 7 and 8) information is available. This can create more certainty, more predictable business cases and reduced costs for applicants, and can also reduce ECHA workload. So, it is proposed to abandon periodical renewals completely, in combination with a more stringent obligation for applicants to share all new information immediately with the authorities.

An alternative to this option is not to completely abandon periodical renewals, but to prolong the renewal period to 20 years for low risk substances and to 10 years for substances of concern (again, in combination with a more stringent obligation for applicants to share new information). This too would diminish the burden of periodical renewals, It is noted that the real effect of this amendment on actual renewal periods would not even be that great, as the present deadlines of 5, 7 and 10 years are often not met and therefore prolonged.

11. Fewer and more predictable renewals i.e. reapprovals may be realised by options like:
– No reassessment of efficacy, except in cases of evident resistance
– Reassessment of hazard characteristics after a certain period (see above) only focuses on selected new endpoints (or when new impactful information arises in the field of any endpoint)

Other options to reduce the burden and workload of renewals are to limit the reassessment of intrinsic characteristics of the active substance. So, efficacy of an active substance only needs to be reassessed in case there are clear signs of developing resistance. Reassessment of hazard characteristics is only required for new endpoints where insights and test methods are relatively new and are still developing. (For other endpoints, new information still must be shared and taken into account).

12. Abandon specification of substance approvals to Product Types (PTs). These specifications are only required for product authorisation

Particularly if the risk and efficacy assessment of a reference product is abandoned, there is no need to carry out PT-specific assessments. This means that multiple approvals for the same active substance for different PTs – sometimes with years of delay between them – are no longer required; one approval suffices.

13. Introduce a regulation that provides for automatic adoption of the BPC opinion in case the European Commission does not take a decision on substance approval within a certain, set period of time

One final option to speed up the approval process is to put a deadline on the time that the European Commission (EC) can take for a risk management decision based on the BPC opinion (which reflect its risk assessment). At the moment of the deadline, the BPC opinion is considered to be the EC's decision.

2.5 Other ways to improve substance approval

Next to ideas for speeding up the process, ideas were also put forward for improving substance approval in other aspects.

14. More room for risk management (next to risk assessment): invoke the precautionary principle when dealing with new generations of pesticides

New generations of active substances are effective in very low doses, add to the already existing and problematic cumulative interaction of biocides in the environment, and together disturb the environment in complex and fundamental ways that can hardly be comprehended. Therefore, the precautionary principle must be invoked, which should mean that biocides may not be applied for preventive reasons, that the application of integrated pest management (IPM) principles is mandatory and that curative use of biocides may only take place under highly restricted conditions. See further the options for Pest Management Regulation (chapter 6).

15. More room for risk management (next to risk assessment): also include societal interests including the interests of effective pest control (as well a possible lack of such interests).

Even though 'societal interests' allow for approval of so-called 'exclusion substances', there still is a fundamental flaw in the BPR: hazards and risks of biocides largely determine their approval (and authorisation), without properly considering the hazards and risks that these biocides aim to prevent or combat. There should be more room for risk management decisions based on the careful weighing of these interests.

Conversely, lack of societal interest of a certain biocide should be ground for refusal of an authorisation (an option that admittedly is more at home in the next chapter on product authorisation than in this chapter on substance assessment). (See also options 25 and 36).

16. Improve methods for efficacy assessment so that the required dose can also be assessed (and overdosing can be prevented)

This options mirrors the one described before (option 4). The same underlying argument – current efficacy tests are substandard – here leads to the suggestion to improve these tests. The main shortcoming that should be overcome, according to this suggestion, is the current

impossibility to assess the required dose and therewith, to prevent (reference) product formulations from containing unnecessarily high doses of the active substance.

17. Require industry to also submit measurement protocols with its assessment dossiers; all substances must be demonstrably and affordably detectable in the environment

The argument for this option is that active substances are increasingly effective at lower concentrations – and therefore often more toxic. This makes them more difficult to detect. New substances are often only detected in measurement programmes once environmental standards have already been exceeded. The number of residues that are harmful but cannot be detected is increasing. Therefore this additional principle is advocated.[2] It is assumed to hardly or not bring along extra work for industry, as it needs measurement protocols anyway for its own synthesis processes. If necessary, alternative options are to add a measurable proxy to the product, or to prescribe and enable effect-based tests.

18. Include derivation of an MRL (Maximum Residue Limit) in dossier requirements

Currently the available MRLs for food products are based on exposure by the use of plant protection products (PPP) and/or veterinary medicinal products (VMP), which sometimes contain the same active substances as biocides. These MRLs are based on concentrations in raw agricultural commodities. There is no procedure to include biocidal exposure when deriving these MRLs or to derive MRLs for active substances in biocides that are not used in PPP or VMP. Also a procedure to derive MRLs for processed, mixed and composite foods is lacking, while biocides are used when producing this type of foods.

19. Grouping, analogies and New Approach Methodologies (NAMs): allow for and engage in other and new test and assessment methods

The idea has been put forward that, by making more use of the possibility of grouping (e.g. by mode of operation),[3] the approval process can become more efficient and intelligent (also allowing for comparative assessments, for opening new avenues of innovation and preventing regrettable substitution). The potential and possible pitfalls of this option require further exploration. For example, as 'groups of substances' may not always have one or more clearly identifiable owners, group assessment may require public money.

The application of methods for quantitative risk assessment, of methods based on analogies and of newly developed test methods (NAMs) that may reduce or replace animal testing, should get more room. In general, the idea is that a learning process is needed to obtain experience and to let acceptance grow. For some, these methods may also help to lower the initial barrier to entrance on the market for innovative products (only requiring more extensive testing in a later marketing phase; see chapter 4). For others, these methods could help authorities (as a first tier) to remove groups of substances of concern – e.g. based on a similar mode of operation – more efficiently from the market. If industry feels that for a

[2] Reference article is: Vijver MG, de Snoo GR, Visser MD. Low-cost environmental traceability of pesticides is essential for safety. *Integr Environ Assess Manag*. 2025 Sep 23:vjaf132. doi: 10.1093/inteam/vjaf132. Epub ahead of print. PMID: 40985662. See: https://pubmed.ncbi.nlm.nih.gov/40985662/

[3] There is a clear connection here with working with 'risk envelopes'. Also note references to 'biocides families' elsewhere in this report.

specific substance this rejection is unjust, it may proof so by means of more extensive testing.

3. Product authorisation

3.1 Current problems

Product authorisation faces largely the same problems as substance approval: slow, expensive, demanding and uncertain. Lack of capacity is an important issue here as well. This all adds to the bottlenecks for, amongst other things, business cases, innovation and getting harmful substances off the market that were described in the previous chapter.

Several of the options that were suggested for improvement of the substance approval process, are also expected to have a positive impact on product authorisation. These include: stronger reliance on REACH/CLP (options 1 and 2), abandoning efficacy assessment (4), ensuring that criteria do not change during the process (6), improvement of efficacy tests (16), requiring measurement protocols from industry (17), derivation of an MRL (18).

In this chapter, additional options for improvement of product authorisation are described.

3.2 Options for improvement of product authorisation

Although in all conversations there was room to come up with radical options, none of the interviewees advocated the abandonment of product authorisations. All of them agreed that at least for reasons of risk management and control, an authorisation system is needed.

20. Provide for only one type of authorisation: Union authorisations

The most far-reaching suggestion for improving product authorisation, is to only have one type of authorisation: the Union authorisation. Limitation to just this one type of authorisation centralises and streamlines the authorisation process, also to the effect that the authorisation immediately allows applicants to enter the entire common market with their authorised products (one of the *raisons d'être* of the EU, and a boost for the business cases of many products and for larger investors). It is suggested to change some of the procedures of the current Union harmonisation process – notably the high level of involvement and even veto-powers of all separate EU Member States. Higher costs of Union authorisations can be a barrier for smaller applicants and products with smaller or more regional markets; an issue that also needs to be addressed.

Of course, it is yet to be established if all relevant national or regional conditions can be integrated as restrictions into the SPC's (e.g. not for use close to waters or in certain climate regions).[4] The impression is that conditions for industrial application of biocides vary less throughout the EU than may be the case for other professional and consumer use. The current exemptions for certain PTs and exclusion substances from Union authorisations should also be reviewed. If necessary, some use conditions can be regulated in e.g. national permits for users.

[4] Compare the authorisation of Plant Protection Products in which 'zones' are distinguished.

The shift to Union authorisations-only also brings along opportunities for improving the quality and efficiency of the authorisation process and for solving capacity issues. The full advantage of this adjustment lies in its combination with the next one.

21. Let there be only one authorisation authority: ECHA

A centralised authorisation procedure would require one central authority. ECHA is the designated agency for this role. In the most radical option, national authorisation bodies will do their work on Union authorisations following the standards and procedures of ECHA, and under the authority of ECHA. This way all capacities and forces are joined to efficiently respond to the market's need for authorisations (without the distraction of costly and time and data-consuming national authorisations and mutual recognitions).

Several less radical options for co-operation between ECHA and the Member States are discussed in the final chapter of this report, that deals with trust and cooperation (chapter 7).

22. Only translate SPC to MS-languages after full approval of English SPC

In EU decision making on authorisations, Member States (MSs) make use of Summaries of Product Characteristics (SPCs) that are translated into their own separate languages. When modifications of SPCs are required, the translation process is repeated. It is far more efficient to make use of an SPC in English in the decision making process, and to only translate the SPC to the different MS-languages after full approval.

23. Improve functioning of 'biocidal product families' within authorisations

'Biocidal product families' have been introduced to gain efficiency in the authorisation process, by allowing a group of biocidal products that are used for similar purposes and that contain active substances with the same specifications, to be covered by one authorisation under the BPR. Thus, several biocidal products can be grouped under a single authorisation, provided that the difference in the composition among the "members" of the family remains within a specified range. In several conversations it was mentioned that improvements are required to make this work. First of all, a family cannot be too big and dispersed. The number of uses and applications must be limited. Secondly, the costs for authorisation of a biocidal product family need to be kept in check. Currently, ECHA and many Member States can raise fees for the (maintenance of) the authorisation. And lastly, attempts to alter and clarify the functioning of 'families' have resulted in an insufficiently transparent guideline, that needs reworking.

24. Include labels in dossiers, or enable authorities to issue prescriptions for labels

Authorisation holders must ensure that biocidal products are classified, packaged and labelled in accordance with the approved SPC of the biocidal product. It is found, however, that the label of the product sometimes contains confusing or misleading information. A solution for this could be to include the design of the label in the dossier (making it mandatory to only use this label) and/or to enable authorities to issue prescriptions for the label.

25. Enable authorities to refuse product authorisation in case of lack of societal interest

This option was already mentioned for substance approval (option 15). Currently, lack of societal interest cannot be a reason for refusing a product authorisation (or mutual recognition). Nevertheless, authorisations are regularly requested for products – particularly consumer products – that are intended to combat organisms that cause little or no harm or nuisance, or that are used for disinfection where this is unnecessary or even harmful. For these instances a legal option to refuse authorisation is welcomed. (See also options 36).

26. Enable authorities to issue prescriptions for maximum doses

Although the efficacy of a product with a certain dose of the active substance has been tested, authorities currently have no mandate to prescribe maximum doses for the product. (The current tests do not enable them to do so either; see option 16). It is suggested to offer authorities a legal basis for intervention in case a product is marketed with an unnecessarily high dose of the active substance – as is sometimes the case.

27. Create fatal deadlines for authorisations

Putting extra pressure on attaining deadlines can help in the prioritisation of actions and therewith speed up the process.[5] This adds to the predictability of the process for applicants and reduce their uncertainty, including some sort of satisfaction in case deadlines are not met. Possible redresses are a return of fees or a temporary or even a full authorisation. Fatal deadlines can have their starting point after completeness check of the dossier and may of course vary depending on the complexity of the application.

28. Provide for proper protection of health and environment and a European level playing field during transition law period

With the delay of the Review programme, the repeated postponement of the deadline and the widely held expectation that the new deadline will also be unachievable for the completion of the Review programme, there is a suggestion to better safeguard the protection of health and the environment and the European level playing field during the ongoing transitional period. Current differences between MSs of authorisation/notification-procedures of products with active substances that have not yet been part of the working programme, lead to lower levels of protection of health and the environment in some MSs, and to more stringent legal requirements in other MSs. This has been going on and will still go on for too long to be acceptable.

[5] It must be ensured that assessment authorities do not respond to this by limiting the number of accepted applications.

4. Promoting innovation

4.1 Current problems

Innovation is slow, if happening at all in the field of biocides. There are too few incentives for industry to invest in the development of new biocides, new modes of operation or alternative techniques. For a large part this has to do with a lack of business cases, due to the high costs, long lead times and uncertain outcomes of current approval and authorisation procedures, particularly in the light of relatively small markets and turnovers and long return on investment periods for biocides in general. Moreover, there are hardly or no positive stimuli within the BPR or brought about by public authorities to promote targeted innovation in this field (only 'negative' stimuli like bans or designations as substitution or exclusion substance).

Consequences are hazardous active substances (substitution or exclusion substances) remaining on the market; declining varieties of active substances and biocides; lack of alternatives; limited or even inadequate means for fighting pests; lack of means for 'small' applications.

4.2 Options for the promotion of innovation

The first improvement option that is mentioned in conversations on innovation of biocides, is public funding for innovation and public procurement of innovative products. However, these options fall outside of the scope of BPR improvements. Several other options do fall within this scope.

29. Give highest priority to the approval of new, innovative active substances

There is still a long queue of substances waiting for approval in the review programme. When applications for approval of new, innovative active substances have to join the back of this queue, this can lead to long processing times and increased uncertainty (also because of interim changes). However, giving them priority treatment strengthens the business case for these innovations and brings alternatives to outdated and more harmful active substances sooner to the market.

30. Create opportunities to place new products on the market after a light assessment, up to a certain tonnage and for a certain period of time

Temporarily lowering the barriers to market entry – for example by less extensive data requirements or by the acceptance of quantitative risk assessments for a first approval and/or authorisation (see option 19) – allows for instance start-ups and innovative SMEs to test-market their products and to immediately start earning first returns on investments. This enables them to cover the costs of the oncoming application for full approval and/or authorisation for which all data requirements will have to be met (and thus helps to overcome the 'death valley' issue of having no earnings until all R&D, approval and authorisation procedures are finalised). This option is largely comparable to the tonnage-dependency of data requirements in REACH – although the 'tonnage'-criterium cannot be fully applied in case

of biocides (hence the proposed additional limitation to 'a certain period of time'). (One way to create such opportunities, could be to develop so-called 'regulatory sandboxes').

31. Include generic criteria for (more or less) automatic inclusion of evident low-risk substances in Annex I

Having more low-risk substances in Annex I enlarges the toolkit for biocide developers to work on low-risk alternatives that can be developed and authorised at relatively low costs. An obvious way to enlarge this toolkit, is by turning to substances that have already been tried and tested as low-risk actives under other legal frameworks and that can therefore be (more or less) automatically added to Annex I. Think of substances that are permitted in food, or that are on the list of low-risk substances for crop protection (several other criteria can be considered as well, such as basic substances). This also contributes to the explainability (e.g. by enforcement officers) of which biocidal products are and are not permitted.

32. Ease the efficacy requirements for low-risk/bio-control biocides

By imposing the same efficacy requirements on biocidal products based on higher and lower risk active substances, low-risk and bio-control products may not be approved even though their efficacy is acceptable for less serious pests (with sometimes a narrower spectrum) and their use could lead to an actual reduction in risks. This can be resolved by creating the possibility to adhere less strictly to these efficacy requirements.

33. Allow low-risk products to contain classified substances, provided that they are not present in or above concentrations that trigger labelling requirements

A strict ban on classified substances (as added ingredients or co-formulants) in low-risk products complicates their effective formulation. By allowing for concentrations of these substances in low-risk products below the level that triggers labelling requirements, the room for formulation and innovation is enlarged without significant additional risks to health or the environment.

34. Authorities should comply with the requirements of the amended Annex I for the assessment of low-risk biocidal products and stop requiring a complete dossier

Even though the amended Annex I of the BPR clearly describes less stringent assessment procedures for low-risk biocidal products, in practice authorities often still require full dossiers. This impedes the development and marketing of these products. There is no need for adaptation of the BPR in this respect; the authorities only need to comply in a trustworthy way with implementing regulation 88/2014 that establishes a procedure for the amendment of Annex I (see also chapter 7).

35. Regulate the assessment of effectiveness of non-chemical agents (and of non-biocidal chemical agents)

The innovation of non-chemical pest control must also be stimulated. One way to do this is to develop effective procedures for the assessment of non-chemical agents, for example for

inclusion in a specific annex.[6] On the one hand this stimulates innovation of and competition between non-chemical agents (also vis-à-vis chemical agents). On the other hand, this helps to broaden the horizon for regulators to include non-chemical agents as alternatives in a comparative assessment (see also chapter 6).

In broadening the assessment scope, also non-biocidal chemical agents can be addressed, which have been a blank spot until now.

36. Stricter criteria for (demonstrating) (lack of) public interest/essential use

Less hazardous biocides (that are sometimes more expensive, particularly when still produced in small quantities) have a hard time competing with mature biocides based on (often cheaper) substitution or exclusion substances. Mechanisms to get the latter substances off the market are more or less ineffective, mostly because it proves quite difficult to refute claims that these substances are of crucial public importance (in accordance with art. 5.2 BPR). This can be improved by stricter criteria for the applicant to demonstrate that there are no alternatives to an exclusion substance, as well as stricter criteria for public importance (art. 5.2 BPR), and to include in the comparative assessment procedure that the applicant must demonstrate superior efficacy with less risks than identified (non) chemical alternatives (art. 23 BPR). By pointing at possible alternatives or by peer-reviewing applicants' claims, substitution centres (yet to be established) may play a critical quality-enhancing role in this regard.

A provision may be introduced that also allows authorities to (re)assess the availability of alternatives in between renewals (which is particularly of importance when renewal periods are extended or abandoned), e.g. based on substitution plans.

In order to prevent effective non-chemical means and practices (e.g. hand washing or surface cleaning) from being replaced by unnecessary and sometimes harmful (resistance development) use of biocides, an "essential use" requirement should be included in the BPR.

37. Ensure that there are no free riders on the Article 95 list who are not actually (participating in) conducting studies

The purpose of BPR Article 95 is to expressly prevent free riding and thereby promote fair competition. As a result of the regulation, it is no longer deemed possible to market a biocide after 1 September 2015 without having invested in a substance dossier. Without proper supervision and enforcement, however, there still is the possibility for companies to register for the Article 95 list without investing in studies, thus obtaining huge and unfair competitive advantages over companies that do invest.

38. Use grouping for the evaluation of active substances to prevent the introduction of look-alikes (regrettable substitution) and thus to stimulate real innovation

[6] An example is the Non-Chemical Alternatives for Rodent Control (NoCheRo), a guidance on the assessment of efficacy and animal welfare impact of traps that was developed by a working party and that is published on the website of the German Umwelt Bundesamt (https://www.umweltbundesamt.de/en/topics/chemicals/biocides/non-chemical-alternatives-for-rodent-control).

A ban of a substance with a particularly harmful mode of operation not seldomly leads to a shift towards the use of a similar substance with the same mode of operation ('a lookalike'). The use of grouping can prevent this 'regrettable substitution' and prompt 'real' innovation.

39. Allow profiling (on labels, in advertisements) of green claims under clear conditions (in line with the Green Claims Directive)

Currently, all advertisement and green claims with biocides are forbidden. As a stimulant for the development of low-risk alternatives, an exception may be made for green claims that meet the criteria of the Green Claims Directive.

40. Do not punish organic farmers who may be occasionally forced by circumstances to use curative biocides, by stripping them of their 'organic' label for several years

Organic farmers are well-intentioned towards the avoidance of chemical control. They may, however, occasionally be forced by circumstances to use curative biocides. By immediately stripping them of their 'organic' label for several years following this use, they are punished disproportionately as compared to non-organic farmers who are often free to use biocides for prevention and cure.

41. Introduce an obligation for articles treated with biocides based on substitution or exclusion substances, to carry a label that mentions the hazard characteristics of these substances

An obligation to provide public information on hazard characteristics of substitution or exclusion substances in treated articles may create an extra impulse to substitute or phase out these substances. Such an obligation is comparable to the provisions for articles containing SVHCs in REACH articles 7.2 and 33.2.

42. (Even) higher fees for biocides involving exclusion or substitution substances

As was stated before, innovative less hazardous biocides are sometimes more expensive, particularly when still produced in small quantities. To draw this competition more even, the costs for keeping biocides with exclusion or substitution substances on the market may be increased by raising (ECHA) fees for biocides involving these substances.

5. Enforcement

5.1 Current problems

Two major problems hamper enforcement of the BPR (apart from possible capacity issues). One is the rather poor information position of the inspectorate, with little or no insight into the volumes of active substances, biocides and treated articles that are on the market. Ditto where use of illegal biocides and illegal use are concerned. The other problem concerns competence issues with regards to international and internet trade in biocides. As enforcement is a national competence, the inspection is dependent on the cooperation of their international counterparts when it comes to dealing with illegal cross-border (internet) trade.[7]

Consequently, the inspectorate operates with too little information and is partly dependent on the goodwill of its international counterparts.

5.2 Redefining roles and improving the provision of information

In most conversations the importance of having adequate enforcement was stressed, as well as of having sufficient capacity for adequate enforcement. Since enforcement is, however, a national competence (as was already mentioned above), options with respect to enforcement capacity fall outside the scope of this report.

43. More binding and less non-committal cooperation between enforcement authorities in different Member States

To reduce dependence on goodwill of national enforcement authorities (NEA's) and improve enforcement in the field of illegal cross-border (internet) trade, several provisions can be made. They include minimum provisions/agreements for cooperation or follow-up on requests from other Member States (including follow-up on ICSMS)[8]; (more or less) mandatory participation of NEAs in EU-wide BPR enforcement projects (and optional participation in pilots); the development of a European enforcement approach to internet trade.

44. Improvement of enforceability of internet trade by Economic Operator at Member State level

Enforceability of internet trade improves by requiring internet traders to have an Economic Operator (EO) physically present in the Member States in which they are not resident and to which they direct their trade. Of course, this also requires clear definitions of and obligations for the EO.

[7] For example: cross-border sales to consumers of products that are only authorised for professional use. It may be expected that there will be less (opportunity for) illegal cross-border (internet) trade once the period of transitional law is over, and even less so when all new authorisations will be Union authorisations. However, illegal cross-border trade will always exist, both within the EU and beyond, because of ignorance or ill will.

[8] ICSMS (Information and Communication System for Market Surveillance) is the comprehensive communication platform for market surveillance on non-food products and for mutual recognition for goods. This platform enables market surveillance and custom authorities to exchange information and coordinate their activities.

45. Make the entire product chain responsible and liable for (eliminating) the consequences of diffuse pollution or accidents, which are currently borne by the taxpayer

When major environmental problems related to biocides – like Dutch problems with water quality – gradually become apparent, it often shows that many parties are involved: producers, suppliers, various types of users. Usually it is possible to trace which parties are involved, but not which party is responsible. As a consequence, it is ultimately the government – and thus the taxpayer – who pays the bill for cleaning up the mess. It should be possible to say: you are all jointly responsible, so you are all accountable. Currently, the system is too focused on "caught in the act". For parties dealing with biocides it is almost lucrative to keep their involvement vague for as long as possible. But if the entire chain has made the use possible and actually applied it, then that entire chain is also responsible.

46. Digital Product Passport (DPP) for categories of Treated Articles

Treated articles (TA's) are hard to trace. TA labelling obligations (art. 58 BPR) are hard to enforce. An improvement opportunity arises with the introduction of EU digital product passport (DPP) obligations for certain relevant product categories (e.g. textile). It is imperative that BPR requirements are aligned with these DPP obligations. Moreover, it is desirable that certain other product categories that are relevant as TAs under the BPR (e.g. preserved wood) are also brought under DPP obligations.

47. Regulate registration of sales figures and monitoring of effects of biocide use in BPR

NEA's information position improves greatly when biocides sales figures are registered in a harmonised way in all EU MS's (including in those MS's that currently lack such registration systems, like the Netherlands). The obligation for the holders of approvals and authorisations can be integrated in the BPR.

Advantages of registration that are mentioned include an improved identification of societal risks; a realistic picture of how much biocides are used and of how much can end up in the environment.

An additional way to identify risks is to regulate impact-oriented monitoring of the use of biocides (for example, by monitoring the concentrations of active substances at specific hotspots to gain insight into the extent to which the use of biocides poses risks to water quality).

5.3 Refining and clarification

48. Clarify definitions in the BPR and align them with national legislation and SPCs:
- Clarify definition of 'biocides'
- Align definitions of user types in BPR, national legislation and SPCs
- Clarify definition of 'use'

Clarify what is to be understood as 'biocides', including borderline cases such as enzymes and biofilms.

Use one and the same definition for user types. Currently and confusingly, wordings include 'general public', 'non-professional user', 'industrial user', 'professional user', 'educated professional user', 'trained professional user' (where also it is generally unclear which education or licence is required).
In the definition of 'use', distinguish between 'having in stock' and 'applying' (e.g. conditions for keeping a biocide safely in stock, can be part of use according to the SPC).

49. Prohibit marketing of biocides for none-authorised uses (and promoting unauthorized biocides)

Currently, the BPR only prohibits *use* of biocides in breach of SPC prescriptions, not the *marketing* in breach of SPC prescriptions. Thus, the latter is not enforceable. The same holds true for promoting unauthorized biocides and promoting unauthorised use as biocide, this too is not prohibited and therefore not enforceable.

50. Make the label part of the dossier; regulate language and trade name on SPC; introduce an enforceability assessment for SPC's of products with Union authorisation

Facilitate the enforcement of correct labelling by making the label part of the dossier on which the authorisation of the biocidal product is based (see also option 24).
Include in art. 69 BPR the obligation to mention the trade name on the label and to have the label in the official language(s) of the MS in which they are placed on the market.
Introduce an enforceability assessment for SPC's of products with Union authorisation, as current SPC's of those products prove to be hard to enforce.

51. Mandatory notification of all experiments with biocides

Currently the BPR (art. 56) only requires notification of experiments with non-authorised biocides when they are or can be released into the environment. It is preferable that all experiments with non-authorised biocides are notified.

52. Clarify whether unauthorised biocides may or may not be exported

It is not clear why actions taken with a view to exporting a biocidal product are exempt from the definition of 'use'. Does this imply that operations with non-authorised biocides destined for export outside of the EU may take place in the Netherlands?

53. Make ECHA the point of contact for questions about compliance and enforceability, particularly in relation to Union authorizations

National inspectorates need a point of contact for clarification of the exact obligations following from approvals and authorisations. Particularly where Union authorisations are concerned, a point of contact with ECHA is required.

6. General Pest Management Regulation

6.1 Current problems

The BPR is an inadequate means for the goal that it aims for: enabling effective pest management (other than crop protection) while ensuring a high level of protection of human health, nature and the environment. After all, this goal is best served by following the principles of *Integrated Pest management* (IPM). These principles include the setting of action thresholds, the monitoring and identification of pests, the prevention of pests, and finally the control of pests through the application of respectively: non-chemical measures: physical, mechanical, biological; low-risk agents; agents with acceptable risk; and as a (temporary) last resort biocides with risk or undesirable substances (with mandatory registration). Only these last steps are regulated by the BPR. Therefore, the BPR is no real driver to achieve the goals that it aims for. In fact, it mainly enables the use of chemical products (biocides) for pest management.

Moreover, it is suggested in some of the conversations that new generations of active substances are effective in very low doses, add to the already existing and problematic cumulative interaction of (older) biocides in the environment, and together disturb the environment in complex and fundamental ways that can hardly be comprehended. Therefore, the precautionary principle must be invoked, which should mean that biocides may not be applied for preventive reasons, that the application of IPM principles is mandatory and that curative use of biocides may only take place under highly restricted conditions. For this mandatory application of IPM principles, the BPR alone is insufficient for the reasons stated above.

6.2 Options for a General Pest Management Regulation

An option is to introduce a General Pest Management Regulation, that regulates all disinfection, preservation, pest control and antifouling activities, and that refers to the BPR for the regulation of biocides for these purposes.

54. Introduce a General Pest Management Regulation (GPMR)
   - Include IPM (particularly for professional pest management) for all disinfection, preservation, pest control and antifouling activities, as a specific provision of the general duty of care, and elaborate on what this entails (if possible, for all different PTs/applications)
   - Also include the assessment of the effectiveness of chemical (with reference to the BPR) and non-chemical agents

To be clear: this option is essentially outside or above the BPR.[9]
It can be said that IPM is already an obligation following from the general duty of care irrespective of the existence of a GPMR. However, the GPMR specifies what IPM entails, if possible, for specific PTs/applications, thus providing everyone, and particularly professionals in disinfection, preservation, pest control and antifouling activities, with clear guidelines.

[9] Another option is to include biocides in the Sustainable Use Directive (SUD) (including relevant further proposals of this chapter). In that case the registration of biocides sales figures (proposal 47) can also be regulated in the SUD.

Rules for the assessment of effectiveness of all chemical and non-chemical pest management measures are to be an integral part of the GPMR.[10] Amongst others, this enables comparative assessments of chemical and non-chemical measures. For the assessment of biocidal measures, the GPMR refers to the BPR.

55. Include in the GPMR a requirement for specific IPM steps to be listed on the label of consumer products

It is not feasible to oblige consumers to apply IPM. However, it is worthwhile to inform consumers about alternatives and the advantages of IPM (and the efficacy of other than biocidal measures). This can be done by including a labelling obligation in the GPMR for biocides for consumer use, making it mandatory to list alternatives and relevant IPM steps on the label (e.g.: first remove food scraps to prevent rodents from causing nuisance).

56. Enable the assessing authorities to relate risks, activity levels, and required doses of biocides to previous IPM steps

The efficacy of specific doses of biocides and the risks of the uses of these doses, for a large part depend on the extent in which previous IPM steps have been taken and on their quality. For example, using disinfectants in a contaminated environment strongly reduces their effectiveness. In the GPMR, risks, activity levels, and required doses of biocides can be related to previous IPM steps including requirements for the way in which these steps have been carried out (possibly varying under different conditions).

57. Where necessary/desirable, enable a link in the GPMR to a national licensing system
– For professional users of specific substances (or groups of substances), specific applications or above certain limits (e.g. volumes)
– For suppliers (for prescription-only/regulated distribution)

On top of generic rules, it may be necessary to set specific requirements, in correspondence to national conditions, sensibilities or problems. For example, it may be necessary to enforce IPM by only allowing the use of biocides with risk or undesirable substances by licensed applicators, on prescription, by controlled distribution or by following a mandatory, self-drafted IPM Plan.

[10] This would be another way of implementing proposal 35.

7. Last but not least (or even first): trust and cooperation

7.1 Introduction

In addition to suggestions for formal changes to the BPR, in various conversations also suggestions for made for addressing the underlying mechanisms that hinder the effective implementation of the BPR. The BPR is a highly complex regulation that demands a great deal from all parties involved in terms of capacity, effort, and competence. Communication, cooperation, learning, and trust are cited as important factors in making the BPR work. According to several discussion partners, these elements should not be overlooked. Perhaps they should even be at the top of the list.

7.2 Trust as an issue

58. Walk the talk: all Member Sates must contribute to implementation

The highly demanding BPR can only function if all 27 EU Member States jointly commit to it. This is currently not sufficiently the case. Not all Member States contribute proportionally, with one of the consequences being that the Review programme is constantly being delayed. In not contributing proportionally, MSs are undermining the effectiveness of their own regulations and also their own trustworthiness.

59. Invest in mutual understanding and partnership in implementation

The challenge of implementing the BPR means that all parties involved – the EC, ECHA, Member States and industry – have too much on their plate. The first thing to fall by the wayside because of that, is talking and listening to each other. People no longer take the time to do so, even though they are struggling with the same challenge. This in turn causes new problems and ambiguities that ultimately cost even more time than if people had sat down together earlier in the process. Investment in mutual understanding and partnership is therefore paramount.

60. Avoid unnecessary scapegoating of industry

In some conversations the impression comes to the fore that the authorities base their approach, their dealings and their external communications too much (and wrongly) on the image that industry is unreliable and has dubious motives. This is evident, for example, in actions and communications around the failure to meet deadlines and around the expiry of data protection. It is emphasised that it is true that mistakes are also made on the part of the industry and that there are sometimes black sheep (e.g. exploiting the complexity of the regulations). However, the overall picture is unnecessarily negative (consider, for example, the fact that companies do often meet their deadlines). Blaming others does not contribute to good cooperation and public confidence.

At the same time, mention is made in the conversations of a systematic bias in the assessment of studies by industry, through which industry serves its self-interest. This undermines trust in industry data.[11]

61. Improve efficiency by building on increased mutual trust between Member States

Targeted BPR adjustments can help to simplify and speed up the process and to prevent double and superfluous work by building on trust between MS's. These include explicit mention in the BPR that a qualitative assessment is sufficient; majority decision-making in expert working groups and coordination group (instead of requiring consensus); only taking on board comments of other MSs in case they change the outcome of the assessment; putting ECHA in the role of assessor instead of secretariat; limiting the number of peer reviewers (e.g. max. 2). (To be clear: it is not suggested to abandon peer review, as this is essential to both scientific rigour and legal certainty).

62. Build on scientists' improved self-confidence so that they do not play it safe unnecessarily

Fear of making mistakes, of being called out in public discussions in scientific committees, and uncertainty about the judgement of scientific colleagues can prompt assessors to "play it safe". This can result, for example, in them conducting (or redoing) full assessments when a quick scan or partial assessment would have sufficed. By working on increasing self-confidence of assessors (without compromising scientific rigour), assessment work, discussion and decision-making can focus better (and more efficiently) on key issues. It is also suggested that, prior to decisions being made, scientists should explain the scientific background to an assessment to regulators in a more informal setting.

7.3 Cooperation

63. Establish new forms of cooperation between ECHA and Member States to make optimal use of available capacity, expertise and procedures.

As capacity, expertise and time are critically scarce resources, new forms of cooperation between assessors can contribute to speed and quality of the process. One example was already presented in option 21, where it was proposed that national authorisation bodies will do their work on Union authorisations following the standards and procedures of ECHA, and under the authority of ECHA. This would in fact turn all national assessment boards into branches of ECHA.

[11] Reference is made to the article: van Zwanenberg, P., Millstone, E. & Ortolani, A.L. Asymmetric evaluations of scientific evidence indicating harm compared to evidence indicating an absence of harm in regulatory appraisals. *Environ Sci Eur* **37**, 138 (2025). See: https://link.springer.com/article/10.1186/s12302-025-01176-9. In the same article it is concluded that asymmetric regulatory appraisals reinforce this bias. Several hypotheses are put forward to explain this asymmetry, including the hypothesis of mutual trust between regulators and industry.

Several other, less far-reaching options have been mentioned as well. These include:

- For each dossier, assemble a pool of national and ECHA experts, who will then work together (partly online) on the dossier. In fact, two groups are needed: one for the dossier and one for critical evaluation.
- Create 'Centres of expertise' within the EU that focus on and specialise in specific aspects of assessments. Member States can contribute to one or more of these Centres. Balance is required; it shouldn't be the case that one Member State or a handful of experts monopolise a domain of expertise or assessment.
- Establish a stronger and clearer division of tasks between ECHA and the national evaluation authorities. For example: ECHA evaluates active substances, Member States grant authorisations.
- Let ECHA assist Member States that are temporarily unable to make progress due to a lack of expertise or staff.
- Adopt similar procedures for assessment by ECHA and by national authorities, following ECHA's lead (as ECHA procedures are clear and stringent).
- Give ECHA a stronger coordinating and procedural role, including enforcing deadlines.

64. Learn from procedures and experiences in problem-solving in other areas

Processing and evaluating dossiers, assessing hazards, risks and efficacy, approving substances and authorising products are not unique for implementing and executing the BPR within the EU (with ECHA as agency). Similar processes and activities take place in other legal frameworks (with other agencies, in slightly different roles) and also in countries outside the EU (even including, for example, the UK, that still regulates biocides in a similar way as the EU). It is more than worthwhile to learn from how things are handled within those other frameworks, together with those other agencies, and in those other countries, and from how all those involved solve the problems that the EU, Member States, ECHA, industry and other parties involved are currently facing with the BPR.

Annex A: List of consulted parties and persons

Interviews have been held with in total 20 persons, from the following organizations and positions:

- Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
- Employee of European chemical sector association
- Former chairman/head of unit at ECHA
- Former director of branch association in the formulating industry
- Former employee at various companies in the chemical and pharmaceutical industry and former independent consultant
- Former regulatory affairs officer and consultant in the formulating industry
- Lawyer in BPR-cases
- Human Environment and Transport Inspectorate (ILT)
- Ministry of Infrastructure and Water Management
- Netherlands Food and Consumer Product Safety Authority (NVWA)
- Scientific Director and Professor of Ecotoxicology