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Position and recommendations relating to the Commission's draft regulation concerning the placing on the market and use of biocidal products

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PAN Germany's key positions and recommendations are summarised in what follows. Key demands for the review of the Biocides Directive 98/8/EC and recommendations in greater detail on the individual thematic priorities can be downloaded as a pdf document at http://www.pan-germany.org/deu/~stellungnahmen.html.

Purpose of the Regulation

Environment and human health / precautionary principle

The protection of the environment and human health against potential adverse effects resulting from the use of biocidal products should be the main purpose of the proposed regulation. In ensuring this, the precautionary principle should be applied. However, the one-sided focus on the promotion of the marketing of biocides, led to the draft contradicting this fundamental principle of European chemical and pesticide legislation (cf. Recital 3 and Article 1 of the biocide regulation draft). The necessity of relevant amendments to several sections of the draft is crucial.

We therefore urge you:
Amend Article 1: The purpose and content of the regulation draft should be adapted according to the above mentioned issues (protection of environment and health, applying the precautionary principle).
Amend Article 3: Missing criteria for the protection of the environment have to be added. Objectives must contain concrete provisions to protect vulnerable groups of the society like unborn life, children or pregnant women.
Specific risks should be taken into consideration. For example: combination effects or risks resulting from nanotechnology (see below).

Scope for the use of biocidal products

The intended scope for the use of biocidal products is too vague. While pesticides are applied against pests in plant protection, and the use of pesticides has to be carried out according to the "threshold of damage" principle, biocides, as stated in the draft, can continue to be used in order to combat unwanted organisms which do not cause any harm (Article 3 (g)). At the same time the term "unwanted" is not further clarified.

We therefore urge you:
Amend Article 3: The definition of pests should be adapted to the approach in the Regulation on Plant Protection Products. The term "unwanted (organism)" should be deleted and the paragraphs in the draft on the use of biocidal products should be put in concrete terms (see "Controlling the use of biocidal products").

Coherence to other EU legislation and policies

EU legislation has to be compatible with other political and/or thematic strategies of the European Union and has to be developed in accord with the objectives of other relevant legislative bodies. The draft gives the overall impression that this adjustment was only half successful. Protection targets are not adjusted to European environmental legislation. There are, for example, no explicit references to the Water Framework Directive, to the revised Groundwater

Directive, to the Habitats Directive, to the Action Programme on Environment and Health or to the EU Biodiversity Action Plan for the Conservation of National Resources.

We therefore urge you to:
Amend Article 1, 16 and 39: Review and complete the draft to guarantee coherences with other political, legislative objectives within the EU. In particular, targets and provisions of the proposed regulation have to be made compatible with other European chemical and environmental legislation/policies, for example, with the environmental quality targets of the Water Framework Directive 2000/60/EC and with the EU Biodiversity Action Plan for the Conservation of National Resources. Article 1, 16 and 39 should point out relevant provisions or policies.

Exclusion of certain biocides with hazardous active substances

The exclusion (cut-off) of certain biocides with hazardous active substances with effects such as being carcinogenic, toxic to reproduction, mutagenic or endocrine disruptive is a step in the right direction (Art. 5). However, this requirement remains insufficient as long as other relevant potential hazards are not taken into consideration. For instance, substances with adverse environmental effects are not addressed -i.e. biocides with properties like:

- PBT (persistent, bioaccumulative and toxic),
- very persistent (vP) and very bioaccumulative (vB) or
- properties similar to those of persistent organic pollutants (POP).

Furthermore, the proposed provision would continue to allow for the marketing of substances with developmental neurotoxic or immunotoxic effects.

Besides, the draft regulation fails to establish a consistent and effective cut-off scheme as it introduces several, imprecise exemptions (Article 5(1)(a),(b),(c)). Art. 5(1) (a) includes unclear notions (e.g. “negligible” or “disproportionate”) so that it is likely to authorise highly hazardous substances. The exemption 5 (1) (c) foresees that highly hazardous substances may be included in Annex I if “disproportionate negative impacts” arose from their non-inclusion. Thus, we are concerned that the proposed text might even result in a roll-back of standards established by current biocide legislation.

We therefore urge you:
Amend Article 5: The list of cut-off criteria should be extended and rendered more precisely according to the above mentioned criteria, for example, by establishing a deadline for the development of standardised procedures to classify substances with endocrine, developmental neurotoxic/- immunotoxic properties. The new Pesticide Regulation[1] already provided such a procedure for endocrine properties.
Delete Article 5 (1) (a) – (c): The exemption clauses proposed in Article 5 (1) (a) – (c) should be deleted because they significantly contradict the purpose of Article 5, and as they are not necessary due to other provisions in the draft (see Article 45).

[1] REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Amend Article 45: In the case of a necessary authorisation of such a substance or product pursuant to Article 45 (in the sense of a provision in case of an imminent danger) this should be exceptionally, only regulated on a national level and restricted to the specific regions and periods (no mutual recognition). Such a limited authorisation must be combined with binding phase-out schemes (promotion of alternatives).

Applying the substitution principle

If active substances of concern identified according to defined criteria are approved for inclusion in Annex I, they are to be marked as candidates for substitution. Under certain circumstances authorisation has to be reviewed more frequently than in the case of "normal" biocides, for which the regulation draft foresees a review every 10 years (Article 9 (4)). On the product level the substitution will be carried out by means of a comparative assessment. In this procedure the relevant biocide will be compared with other products of low concern or with non-chemical alternatives. The authorisation period of products which include candidates of substitution is limited to five years. Basically, we welcome the principle of substitution that is already embedded in the current Directive 98/8/EC. However, the Commission´s proposal is insufficient and signifies a setback to existing legislation. Problematic active substances, for example, can, if necessary, be authorised again for ten years, while they would not be accepted under the effective directive or be taken from the list of active substances (Annex I) after four years at the latest. Thus, the draft should be amended.

We therefore urge you:

Amend Article 21: The authorisation of a product with active substances to be substituted should be carried out on a national level (no mutual recognition of authorisations) since the comparative assessment has to consider regional conditions like the availability of alternative techniques. Furthermore, an authorisation should be regarded as a transitional phase. Thus, a member state should develop a binding phase-out scheme for a product which at the same time would stimulate innovation towards alternatives on the part of producers.

Amend Article 9: The criteria for identifying substitution candidates should be rendered more precisely and supplemented to ensure a clear delimitation of the procedures between cut-off criteria on the one hand and "normal" active substances on the other. For example environment related criteria must be added. Active substances or metabolites frequently detected in the environment and standing in the way of the achievement of objectives established in the environmental legislation (e.g. the objectives of the Water Framework Directive) should be substituted.

Amend Article 9 and 21: The authorisation for such active substances or relevant products should be granted only once: For active substances to be substituted this should only apply for a maximum period of 5 years (amend Article 9), and for products containing these substances for a maximum period of 3 years (amend Article 21). New products which include candidates for substitution shall no longer be placed on the market (supplement Article 21).

Applying the comparative assessment

We very much welcome that the draft considers non-chemical alternatives for the comparative assessment. This amendment makes it possible to give precedence to alternative techniques over risky chemical approaches. However, when other passages of the draft are also considered, the comparative assessment would be significantly restricted so that current standards would be weakened: The existing directive requires that the assessment criteria be applied to all active substances and not only to candidates for substitution. This implies a concept of dynamic minimisation of risk in the use phase or one of the substitution of biocidal products. This necessary concept should be preserved. Besides, the current directive has already established the substitution principle on the substance level and not on the product level.

We therefore urge you:
Amend Article 9 and 21: The comparative assessment should be applied to both levels, the product and the substance levels. Member states shall still also be able to carry out such an assessment for products which do not correspond to the substitution criteria. At least, the relevant passage from the newly adopted Regulation on Plant Protection Products (compare Article 50 (2)) could be considered to amend the regulation draft (amend Article 21 accordingly).

Low-risk biocidal products

The draft proposes an authorisation at Community level low-risk biocidal products. It should be ensured that this approach really promotes safe products. However, this is one thing which the draft does not guarantee. The criteria catalogue for identifying such low-risk products is insufficient, being too vague. Relevant active substances are not intended to be included in Annex I and consequently are not subject to further assessment. On the other hand, the proposal allows the inclusion of highly hazardous substances in this category if the potential for exposure to a specific product can be regarded as negligibly low for its whole life cycle. It has to be questioned for which biocide applications this can be effectively ensured, for example, great quantities of disinfectants could be discharged from "closed" cooling systems into water bodies during the cleaning of systems or a breakdown, even if there is a downstream wastewater treatment plant.

We therefore urge you:
*Amend Article 17: We recommend that the criteria catalogue be amended and clarified. For instance, low-risk products should not contain persistent **or** bioaccumulative **or** toxic substances. The principle shall be preserved that only those active substances can be included in biocidal products which are listed in Annex I of the regulation, and which are consequently assessed and reviewed frequently.*
*Amend Article 3: This Article shall be amended with a definition of low-risk biocidal products: Such a product should have a low hazard **and** low exposure potential throughout its entire life cycle, and should not contain any other problematic (additive) substances.*

Products treated with biocides

The draft will extend the scope of the biocide legislation as it intends to regulate articles and materials treated with biocides. Products like paints, textiles, carpets or leather goods are treated with biocides. A plethora of biocide-treated products are imported from third countries into the EU. Consequently, the draft will close a significant gap in the current Directive. Only those products with a biocidal treatment authorized in at least one Member State of the EU will be allowed to be placed on the internal market. It is irrelevant whether the product is produced in a third country or within the EU or whether it includes a biocide with an "external" function (e.g. chemically treated textiles protecting people against mosquitoes) or whether the active substance shall protect the product itself (e.g. biocides to protect carpets from moth damage). The new provision will not only protect consumers from hazardous biocides applied in treated products, but it can also be expected that this amendment will promote occupational safety in third countries. To control the compliance (e.g. at customs), it is necessary to introduce a labelling obligation for the treated products (labelling, compare Article 47). This improved obligation to inform can also strengthen the protection of consumers because a label can provide explicit product information and, if needs be, safety instructions. For this reason, we very much welcome the draft but recommend the addition of three further aspects.

We therefore urge you:
Amend Article 47: To ensure transparency the label should prominently indicate that the product is treated with biocides (such information should be stated before the name of the active substance). When authorising a biocidal product for a certain use (e.g. applied for the treatment of carpets) data should be gathered in order to clarify if non-treated products unintentionally come into contact with relevant treated products (e.g. during transport or storage) and as a result, possibly contain residues. To guarantee legal certainty in the case of inspections, producers have to ensure that un-treated articles do not contain residues, e.g. by means of quality assurance.
Amend Article 81: The deadline to register relevant biocides for authorisation (biocides used for the treatment of products) should be advanced from January 1, 2017 to the first anniversary after the effective date of the regulation (probably end of 2013).

Biocides with nanotechnology

The regulation has to take biocides with nanomaterials into account and consider its specific characteristics. The behaviour, persistence, effect or decomposition of chemical substances or elements, such as silver, are changed when nanotechnology is used. But this technology useful for producers can have adverse effects on the environment or human health which have not been adequately investigated or are currently not foreseeable. Against this background, the German Federal Environment Agency (UBA) recently issued a critical statement on the use of nanomaterials.[2] UBA recommends: "Any use of products that contain or might release nanomaterials should be avoided if at all possible as long as their effect on mankind and the environ-

[2] Umweltbundesamt (2009): Nanotechnik für Mensch und Umwelt - Chancen fördern und Risiken mindern. PDF-Download der Studie und Presseinformation unter: http://www.umweltbundesamt.de/uba-info-medien/mysql_medien.php?anfrage=Kennummer&Suchwort=3765

ment is largely unknown.".
Therefore, it is important to align the test procedures relating to active substance approval and product authorisation accordingly, i.e. that those "nanomaterials/-products" have to be examined in a separate, specifically adjusted test and assessment procedure. The draft does not give any explanation on that matter.

We therefore urge you:
Amend Article 2: A section should be added to the regulation text explaining that nano active substances and nanoproducts are subject to a separate and, if needs be, specifically adjusted test procedure. A time limit should be set on the development of specific test procedures and assessment criteria on environmental and health risks.
Amend Article 58: Furthermore, biocidal products containing nanomaterials should be subject to an obligation to label.

Controlling the use of biocidal products

The Regulation, compared to the directive, should be complemented with an important point. Thus, the Regulation not only should regulate the placing of biocidal products on the market but also the use phase of these products. Up to now harmonised regulations and standards have been absent at EU level. Every Member State decides, for example, on the form of its training and expert knowledge certification for professional users, what is understood by "expert use" or "necessary minimum" of use, how risky applications, such as the use of airborne biocides, are dealt with, and what technological requirements apply for application. There is no common understanding of the aforementioned central terms or what is meant by integrated pest management. This significant deficit in biocide legislation is one of the main reasons why, at the moment, one has to be sceptical about Community authorisation or greatly extended mutual recognition. It is not just variable regional factors such as climate which are relevant for applications in an open environment. If products are handled differently, then those variables have to be considered in risk assessment, particularly in exposure assessment.

There are only a few sections of the draft that contain reference to the use-phase, for example, in relation to biocide-treated products, or state that carcinogenic, immunotoxic or mutagenous products should not be used by non-professional users. Throughout the document, there is a general lack of explanations, definitions and references regarding these points. Objectives, such as that of sustainable, risk-reduced application, are also similarly neglected. Member States are also not obliged to take responsibility. Thus, the draft does not correspond at all to the political orientation manifested in the Thematic Strategy on the sustainable use of pesticides and in the related new Pesticide Framework Directive. Although the Regulation itself could be amended with relevant rules and annexes, this would not be worthwhile seeing as flexibility on the part of individual states relating application regulations is desirable. This hardly can be implemented through the legal instrument of an EU regulation.

We urge you to:
Amend Article 15 (5): Include a clause. The draft should at least have a concrete time frame for the implementation of a legislation for the use-phase (cf. e.g. also art. 55 of the new Plant Protection Products Regulation). It would be necessary to develop an adequate provision parallel to the implementation of the regulation.

In many aspects the Pesticide Framework Directive and its daughter regulations on the maintaining of statistical records of use, and quality and control of application devices can be applied to the biocide sector.
An idea would be an expandable "miniature" framework directive which includes already established and approved provisions for the pesticide sector or refers to these, for example, with regard to standards in Integrated Pest Management, further education and expert knowledge of professional users, provisions concerning airborne application or measures for the development of National Action Plans.
In addition, product- and risk-related levies should be introduced to provide further incentives to minimise the risks related to the use of biocidal products as well as to promote innovations in favour of safer products. For this purpose, art. 70 (2) should be modified accordingly

Reporting and provision of information

Reporting and generating information of the use of biocides is, in various aspects, an important area of regulation. It shows the state of implementation, as well as being the prerequisite for the transparent regulation of the use phase of biocidal products. It can also be used to assess risk management measures. The biocide sector currently stands out for the gaps in knowledge and totally insufficient data available in many areas: from information about marketing quantities to the cases of poisoning. This, amongst other things, is very impressively substantiated by the COWI report published in 2009.[3] The draft proposes a few improvements which would be very welcome, for example, a Community register for biocidal products, the obligatory establishment of poison information centres in the Member States, and documentation requirements for producers, importers and commercial users. However, these measures are neither here nor there because although data has to be gathered, it does not have to be published in a binding systematic fashion or only has to be published at intervals significantly far apart from one another. For example, the first Commission report on the implementation of the regulation was supposed to be published in 2023, with national reports being made at 3-year intervals. A record keepingg, e.g. for marketing and use data, is a good thing, but nevertheless, it is not the same as mandatory reporting or means that the authorities responsible have to publish annual reports on biocidal product sales (for example, annual registration and reporting requirements for pesticide sales, section 19 Plant Protection Act).

We urge you to:
Amend Article 54: Ensure transparency. Yearly national reporting during which data is generated and published on: authorisation, sales volume, intensity of application, monitoring of advertisement, product labelling, trade, and on the part of users, the regulations of what constitutes informed best practice in the application of biocides, cases of poisoning as well as environmental and health impairments. A registration requirement for sales volume according to product type (domestic, export) should be made mandatory (adapted to section 19 Plant Protection Act). The first Commission report should be published after five years at the latest.
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[3] European Commission, Environment Directorate-General: Assessment of different options to address risks from the use phase of biocides. Final report, March 2009. Compiled by COWI A/S. PDF-Download: http://ec.europa.eu/environment/biocides/pdf/report_use.pdf

Amend Article 15 and 54, respectively: In addition, as embodied in the German constitution, competent authorities within the EU should be obliged to "provide information on physical, biological, chemical and other measures as an alternative or to minimise the use of biocidal products to the public" (Biocide Act Art. 22(5)).

Procedures

Revision of decisions

Decisions on substance evaluation and product authorisation always have to be made according the latest scientific findings This includes having taken note of all current peer-reviewed studies and other information from the competent authority, which, if necessary, could result in the revision of a decision. This business-as-usual for substances and products requiring approval cannot and should not replace the revision in specified intervals. Such a revision is done actively. There are defined responsibilities and the drawing up of reports, their presentation in committees and their publication ensure a transparent course of the revision. However, the draft provides that active substances included in Annex I are only assessed once after a set interval and then never again. This proposal limits transparency in and control of decision-making in substance assessment drastically. On account of precaution and rapid scientific progress, intervals between the renewal of decisions should be chosen adequately.

We therefore urge you to:
Amend Article 10 (3): A biocide active substance should be included in Annex I for ten years at the most and then be subject to renewal.
Amend Article 9 (4): An active substance classified as a candidate for substitution should be included in Annex I for a limited period of time and just once for five years. A biocidal product should be authorised for a maximum of ten years (in accordance with the draft).
Amend Article 21 (6): Products containing active substances to be substituted should be authorised for a maximum of three years.

Mutual recognition and Community authorization

The draft proposes amendments to the area of responsibility for product authorisation procedures. On the one hand, the mutual recognition of authorisation is extended with there now being the possibility of mutual recognitions happening as early as during the first authorisation in a reference state, i.e. parallel to the reference state. In addition, products with new active substances and products with low-risk active substances should be granted Community authorisation. The assessment is incumbent on the national authority chosen by the applicant, which is being validated by ECHA and the decision is enacted pursuant to the regulatory procedure with scrutiny (approval from Council and Parliament). Community authorisation should accelerate the procedure for the applicant. Moreover, Community authorisation of biocidal products should be, if needs be, extended in the future.
The draft lacks comprehensible reasons why new products, in contrast to old products, should be granted Community authorisation. It is not differentiated whether such products actually have to be used within all EU countries or if it related to products which remain unaffected in their application and exposure by regional conditions including climate, soil conditions (e.g. for those which are applied in industrial closed systems) or technical standards for use and disposal.

However, those important factors which significantly influence behaviour and persistence of residues, and therefore, possibly also the applied methods of exposure assessment have to be taken into consideration. The draft even permits the authorisation at EU level of new problematic products, active substances for substitution or even those with cut-off properties. In contrast, when it comes to Community authorisation, low-risk products, as long as the criteria are clarified and tightened as mentioned above, are preferable over problematic products. Before Community authorisation it should be clarified or examined with the introduction of an adequate provision in Art. 33 if the product should effectively be marketed and used within all EU countries. If this is not the case no Community authorisation should be granted for the product or the Member States can reject authorisation in their area.

We urge you to:
Amend Article 33: Comprehensible reasons for Community authorisation have to be put forward, for example, that it these products are worth it to be promoted, have a low hazardous potential and a low exposure potential, their exposure potential is not negatively changed by region-specific conditions, and that their use is beneficial all over the EU and is supported by all Member State authorities. Considering the existing gaps in plausibility, Community authorisation of new or other products is to be rejected.

Room for manoeuvre of the Member States

In the points relating to cut-off and substitution criteria, it has already been demonstrated that decision-making powers have to be given to those Member States which have to perform a comparative assessment for their region and develop phase-out plans.
This means that for both mutual recognition and Community authorisation power of veto should be granted to the Member States, but this is not possible according to the draft. At best, a temporary rejection is possible which can, however, be ignored by the Commission. Certainly the Council decides in the regulatory procedure in the end, but a qualified majority (> 50%) is necessary for a decision.
This procedure is not only problematic in relation to the continued sovereignty of the Member States and the subsidiarity principle, but it is also not in accordance with the closely related pesticide legislation which, despite the new zone authorisation for pesticides, grants individual Member States the freedom of making the final decision themselves (cf. article 50 of the new Pesticide Authorisation Regulation). The draft allows this possibility of national rejection concerning the mutual recognition of authorisation, however, it limits this possibility to the product types 15, 17 and 23. A rejection can be explained, for example, by stating health concerns for people, animals and plants. It is incomprehensible why this provision is or should be limited to these product types.

We urge you to:
Amend Article 15: No product authorisation according to the rules of mutual recognition or the rules of Community authorisation for products containing active substances subject to the cut-off or substitution scheme. General entitlement of Member States, according to the principle of deterioration prohibition for national protection standards, to the right to be able to reject authorisations based on scientific findings or to restrict the use of products.

Choice of the responsible administration

In the authorisation procedure for active substances, applicants for active substances may decide which Member State evaluates their application (article 7.1.). It is not comprehensible why

this decision is not made by ECHA or the Commission. Only in this way can a balanced allocation of tasks between the Member States be ensured and possible application accumulations for individual Member States be avoided.

We urge you to:
Amend Article 7: The ECHA or the Commission should decide on the allocation of applications between the Member States. With this, it should be taken into consideration whether Member States have prior experience in the examination of closely related substances or if the active substance was already tested earlier in the review programme. Therefore, Member States should be able to express their interest in the examination of individual substances.

Frame formulations

Frame formulations play an important economic role in the marketing of products. The draft significantly extends the definition for frame formulations compared to the current definition of the directive (cf. article 3(p) in conjunction with art. 20 (3) c).). Thus, all non-active ingredients can be replaced in a frame formulation. According to the guideline this was restricted to pigments, dyes, and perfumes. Frame formulations are to be authorised together with the reference product. However, no further requirements are made for this reference product. Therefore, products with candidates for substitution or other problematic substances can be a reference product. The result is a definition of the term and procedure which is vague and strongly watered down.

This unrestricted or insufficiently proven variation opportunities of constituents can cause problems as constituents can change the behaviour, persistence and effect of a product, and combination effects among those constituents or with the active substance are possible. Certainly, such changes to product properties should continue to remain excluded from frame formulations. But the draft has no answer for how this can be controlled since it is explicitly stated that there should be no comprehensive tests on specific products in the context of frame formulations.
One recent example from the pesticide sector illustrates the problem. The non-selective herbicide Roundup is marketed with different formulations. A few product variations contain the surfactant Tallowamin, while others have different surfactant. Over the last few years increasingly more scientific studies have pointed out that Tallowamin on its own has a toxic potential, and in synergy with the pesticide active substance Glyphosate significantly increases the toxicity of the product. Suspicions in relation to this combination effect have consolidated to such an extent that the authorities responsible are currently examining the authorisation of these Roundup variations with Tallowamin. Furthermore, if we consider that up to now there has been no experience with the authorisation of frame formulations in the biocidal sector, we recommend the preservation of the regulation based on the current definition instead of giving a carte blanche to a risky and, in addition, totally incalculable flood of formulations.

We urge you to:
Amend Article 3: Add the term “reference product” to article 3 with reference product only comprising low-risk products. This appears to be necessary due to numerous insecurities and lack of experience in authorising frame formulations. In addition, before extending the current effective definition for frame formulations it should be checked if and to what extent an extension of replaceable substances is useful and necessary, and how this process can be made transparent. As a matter of principle, it is essential that frame formulations have to be subject to the same high test standards as other products.

Parallel trade of biocide products

Concerning the regulations for parallel trade, the conditions governing products identical to the reference product are to be corrected. Article 44(3) permits through its wording that each product can be marketed in parallel trade, even if the active substances or the total formulation differ from one another.

We urge you to:
Section (a), (b) and (c) of article 44(3) are not to be separated and should be linked with "AND". Besides, a transparent statistical record should be ensured in order to demonstrate the quantity of sales of imports via parallel trade.

Data requirements / Test procedure

„Waiving" of data requirements

Annex II and Annex III describe the data requirements for the testing of active substances and products. Annex IV contains general conditions for deviations from these data requirements, which are put in concrete terms in article 6(2) on the approval of active substances and article 19(1) on product authorisation. The applicant can propose deviation from data requirements ("waiving"). This, however, requires that the performance of a test be not scientifically necessary, or not technically possible or by means of an exposure assessment, has been proven not to be necessary. The understanding of the European Commission on this exposure-related "waiving" is illustrated in the following quote: "It will become possible to waive requirements [...] if it is not relevant (there is no need for marine toxicity studies, for example, if a product is reserved for use on dry land)".[4] This concept of exposure assessment is baffling from a scientific standpoint. Exposure assessments have to consider the possible environmental input and the fate of a biocide. With biocides used in an open environment, there is, for example, the risk of rainwater discharge into water bodies. It is known, for example, that biocides from treated house facades can be washed out at concentrations of a few hundred microgrammes per litre, resulting in the risk of discharge into water bodies even though buildings are usually erected on "dry land".[5] Exposure assessments are often linked with significant uncertainties, and particularly in terms of the diverse application types of biocides there is a need for further development and harmonisation within the EU when it comes to methods and models. The proposed exposure-related "waiving" approach bears too many risks and uncertainties for both, environmental and health protection, and for that reason should be resoundingly rejected. There exists the risk of undermining the accepted principle according to which substance and product evaluations in authorisation procedures have to be carried out based on the latest scientific findings. It is

[4] European Commission (2009) Questions and answers on the new biocides regulation,MEMO/09/275,Brussels, 12 June 2009: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/275&format=HTML&aged=0&language=EN&guiLanguage=en

[5] Burkhardt, M., Junghans, M., Zuleeg, S., Schoknecht, U., Lamani, X., Bester, K., Vonbank, R., Simmler, H., Boller, M. (2009): Biozide in Gebäudefassaden – Ökotoxikologische Effekte und Belastungsrisiko. UWSF 2009, published online.

common practice that the relevant authorities approach data requirements in a somewhat flexible way. Sound information from, for example, in-vitro methods or quantitative structure-effect relationships for a group of substances under suspicion can be used for evaluation, as well as meaning a reduction in animal experiments. These decisions, however, are made according to the specific case and at the discretion of the authority. On principle, all existing peer-reviewed surveys should be used in the assessment of the active substance or product. Annex IV changes this procedure fundamentally. Now, authorities have to explain to the applicants why they possibly do not want to waive data requirements. Moreover, the Commission itself wants to establish the criteria for the regulatory procedure with scrutiny if exposure-related data waiving is indicated (article 6(4), article 19(3)). The problem lies within the fact that not necessarily experts for environmental and health protection from the competent expert authorities of the Member States or from ECHA are consulted. Experts should be consulted to make the decision-making process for Council and Parliament in the regulatory procedure with scrutiny easier since complex scientific topics are dealt with (e.g. prognostic modelling on exposure).

In addition, the competent authorities have to support the applicant actively in the proposals and justifications (article 6(3), article 19(2)). It is foreseeable that this won´t result in a relief but rather in a significant burden for the authorities. Moreover, it is not clear whether the applicant, if needs be, could bring an action on the basis of these provisions if data waiving is denied by the authority. This would also not lead to a reduction in bureaucracy. In summary, the proposed procedure is neither compatible with the procedures of the closely related area of pesticide authorisation nor with the precautionary principle. In contrast, mandatory information sharing (article 51) to avoid animal testing is very much welcomed.

We urge you to:

Delete Annex IV and the paragraphs mentioned above of article 6 and 19.

Two-phase test procedure for active substances

It is comprehensible that a gradual test concept reduces costs, capacities and animal experiments; however, it should still be in accordance with the precautionary principle. One positive example worth mentioning is the implementation of cut-off schemes based on hazardous substance properties. A gradual test concept under the application of the precautionary principle can only be accepted if the test cascade stops as soon as there is enough evidence that a substance should **not** be included in Annex I or for the non-authorisation of products. The two-phase test procedure for active substances (Annex II) proposed in the draft, however, implies the opposite approach. Basic information (Level I) is used to decide whether further information is required at the next inspection level (Level II). According to the concept, this becomes particularly necessary when risks to health and the environment have already been found at Level I. The frequently used argument of the saving potential of a gradual test procedure does not apply here. On the other hand, there is the risk that active substances will be approved after inspection level I because adverse affects which would only have become perceptible in inspection level II have been overlooked. This risk is accepted and justified with saving potentials. Much information pertinent to any decision is only inquired after inspection level II, this includes e.g. carcinogenicity, damage to progeny, long-term toxicity among invertebrates and human exposure to the active substance. Therefore, it can be seen that the gradual test concept subject to current requirements for risk evaluation cannot adequately demonstrate the risks to people and the environment, and should be reviewed. Moreover, no attention is paid to the adjustment

to relevant data requirements, including those of the EU Groundwater Directive 2006/118/EC. This directive bears the groundwater ecosystem in mind and defines values for permissible groundwater concentration of biocidal products containing active substances and its metabolites which, if necessary, have to be set more strictly or, depending on monitoring results, result in further measures for waters protection and protected areas.

We urge you to:

Revise Annex II, renunciate the inflexible "two-tiered concept" in decision-making. More importance should be attached at regulation level to the definition of the standards of evaluation and decision criteria according to which data requirements have to be oriented comparable with the common assessment principles for biocidal products in Annex VI.

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