DRAFT THOUGHT STARTER FOR A BIOCIDES CA NOTE ON

HARMONISED IMPLEMENTATION OF ARTICLE 55(1) OF THE BPR

**Subject: Note on the harmonised implementation of Article 55(1) of the BPR**

# Background and purpose of the document

1. The Covid-19 pandemic created an urgent need for disinfecting biocidal products, particularly hand[[1]](#footnote-2) and surface[[2]](#footnote-3) disinfectants to prevent further spreading of the disease. This resulted in an unprecedented reliance by Member States[[3]](#footnote-4) on the Article 55(1) BPR emergency derogations in order to ensure prompt and sufficient availability of disinfectants on their territory.
2. There have been significant differences between the national approaches taken by Member States to implement the Article 55(1) derogations, which might have impacted the speed at which the products covered by the derogations could be legally made available.
3. The experience gained from the use of Article 55(1) derogations shows that this provision can be used effectively and provide flexibility in light of emergency situations. It is recognised that some of the most efficient practices developed with Article 55(1) during the Covid-19 crisis managed to strike a balance between ensuring prompt market access for needed biocidal products, relying on time-limited derogations and flexibility (e.g. as regards changes to products requirements such as packaging sizes, production sites, language requirements or enforcement), and ensure safety of the biocidal products made available on that basis.
4. The objective of this document is to agree on principles for the harmonised implementation of Article 55(1) of the BPR, in anticipation of potential future needs to rely on this legal provision and to facilitate its implementation at that stage in order to efficiently ensure “*a high level of protection of both human and animal health and the environment*”[[4]](#footnote-5).

# RELEVANT PROVISIONS OF THE BPR

1. The placing on the market[[5]](#footnote-6) and use[[6]](#footnote-7) of biocidal products has to be authorized under the BPR[[7]](#footnote-8), unless a derogation applies[[8]](#footnote-9). Article 55(1) of the BPR on derogations from the requirements covers emergency situations.
2. As per Recital (48) of the BPR:

*“In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to permit, for a limited period of time, the making available on the market of biocidal products which do not comply with the requirements of this Regulation.*” (emphasis added)

1. Article 55(1) of the BPR provides:

*“1.   By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.*

*The competent authority referred to in the first subparagraph shall, without delay, inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall, without delay, inform the other competent authorities and the Commission of the revocation of such action.*

*On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).”* (emphasis added).

# PRINCIPLES FOR THE HARMONISED APPLICATION OF ARTICLE 55(1) OF THE BPR

1. [Note : We suggest a discussion of and ideally agreement on, amongst others, the following items related to the implementation of Article 55(1) by Member States, the Commission and ECHA:]
2. ***Scope of the Article 55(1) derogations (biocidal products):***
3. By formula or product group (e.g. WHO formula), or
4. By individual biocidal product on a case-by-case basis
5. ***Scope of the Article 55(1) derogations******(active substances):***
6. Cover active substances approved for relevant PTs
7. ***Procedural requirements****:*
8. Notification versus evaluation?
9. Fast-track procedure (see paragraphs (9) to (14))
10. Data required for Article 55(1) application

Applicants to use an EU template for new biocidal products (see Appendix 1).

1. ***Communication and coordination:***
2. Emergency procedures/ guidance by Member States to be easily available and available in English on top of local language(s)
3. Centralised point where all guidance, national emergency procedures and contact points are being collected by ECHA/the Commission
4. “European Emergency Helpdesk” by ECHA/Commission (e.g., via HelpNet)
5. Creation of a “crisis unit” (with representatives from the Commission, all Member States, ECHA and Stakeholder organisations) to be activated by the Commission at the beginning of each crisis.
6. Considerations for fast-track procedure (item c) (ii)):
* *For authorisation and for changes under BPR:*
1. The BPR prescribes the following timelines:
* For national product authorisation[[9]](#footnote-10) can take from +- 460 days to 760 days.
* A mutual recognition[[10]](#footnote-11) in parallel adds another +- 150 days to the above at minimum.
* In case of a Union authorisation[[11]](#footnote-12), can take from +- 670 days (incl. Commission decision) to 940 days.

In practice, we see that longer timelines might even apply, especially in case of Union authorisation. Furthermore, the same timelines as above apply to biocidal products families (BPF), while authorisation timelines are much longer.

1. The timelines to obtain an authorisation for changes to an existing authorisations vary[[12]](#footnote-13):
* For an administrative changes, the timelines in the Change Regulation correspond to either immediately (ex-post notification) or 30 days unless rejected (ex-ante notification).
* For a minor change (no changes in risk and efficacy profile, e.g. change in packaging size and material or certain changes in labelling and classification), the procedure can range from +- 195 days to 315 days.
* For a major change (such as addition of target organism or extension to non-professional use), the procedure can range from +- 330 days to 450 days.
* In case there is doubt for the qualification of the change, ECHA can deliver its opinion within 45 days of receiving a request. That adds another 45 days to the above timelines.
1. The scenarios set out above for full authorisation or changes in accordance with BPR are too long in times of crisis.
2. There is today no harmonised fast-track procedure provided for in the BPR in case of a national or EU-wide or global emergency situation. The only option is foreseen in Article 55(1), which allows each Member State to take its own actions and the Commission to prolong those individual Member State actions.
* *Working with existing BPR Article 55:*
1. **Step 1: Member State procedures**
* Member States will aim to install swift procedures under Article 55(1).
* Preference is given to notification procedures only.
* In case a registration is required, the following guidance is provided:
* A fast-track lane should be applied for in a distinct manner from general authorisation applications.
* A validation phase, including eligibility check for fast track procedure, should be completed within 7 days and the evaluation within 21 days after the validation is completed.
* the CA will authorise the BP and inform the applicant and the other CAs.
1. **Step 2**
* The Commission can prolong all existing national emergency authorisations via one Commission implementing decision[[13]](#footnote-14).
* In accordance with Art 55(1), the Commission shall decide on extensions without delays.
* Commission could only do so in case there is still an emergency situation in force in a Member State or EU wide or globally.
* Bearing in mind the efficiencies gained by combining multiple product extensions under one Commission Implementing act, the Commission will track all MS 180-day derogations and co-ordinate with MSs, with a view to assisting in the receipt of reasoned opinions and the swift inclusion of those products in the Commission implementing act.
* In order to be included in the emergency authorisation Commission implementing decision, Member States are required to notify products allowed to market under Article 55(1), so that the Commission can easily prolong the authorisation.
* A database or notification portal is set up by the Commission or ECHA for that purpose.
1. No amendment of the BPR is needed for the implementation of the above.

**Appendix 1: EU template for Article 55(1) applications**

**To be used for new (i.e. not existing) biocidal products**

**1. Information required for notification:**

* Company placing the biocidal product on the market
* Company name, address, contact person, email
* Active substance information:
* CAS no.
* Supplier (SDS) (source of active substance)
* PT
* Compliance Criteria for active substances:

Minimum concentration of active substance to guarantee the efficacy

[Note: authorities to prepare at the beginning of the crisis (or ideally before) a public list of active substances efficacy limits?]

* Biocidal Product information:
* Composition 100% (including minimum content for efficacy of the respective active)
* SDS of the Co-Formulants (information on Substance(s) of Concern (SoCs))
* SDS of the Biocidal Product
* Label
* Compliance criteria for Co-Formulants:

Simple formulations with non-hazardous, classified as low hazardous co-Formulant, no unacceptable risk to human animals and environment

**2. Information required for notification prolongation (in case of continued pandemic):**

- Information on stability

- Information on Efficacy testing

1. PT1 - Human hygiene [↑](#footnote-ref-2)
2. PT2 - Disinfectants and algaecides not intended for direct application to humans or animals. [↑](#footnote-ref-3)
3. Article 55(1) notifications by Member States, available at: <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/47c6e2b3-27a1-4137-83e4-9605a64e2de7?p=1&n=10&sort=modified_DESC> [↑](#footnote-ref-4)
4. Article 1 of the BPR. [↑](#footnote-ref-5)
5. i.e. *“any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge”* (Article 3(1)(i) of the BPR) [↑](#footnote-ref-6)
6. i.e. “*all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;*” (Article 3(1)(k) of the BPR) [↑](#footnote-ref-7)
7. Article 17(1) of the BPR [↑](#footnote-ref-8)
8. Articles 55 and 56 of the BPR [↑](#footnote-ref-9)
9. In particular Articles 29 and 30 of the BPR [↑](#footnote-ref-10)
10. In particular Articles 34 and 35 of the BPR [↑](#footnote-ref-11)
11. In particular Articles 43 and 44 of the BPR [↑](#footnote-ref-12)
12. Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised, OJ L 109, 19.4.2013, p. 4 [↑](#footnote-ref-13)
13. Article 82(3) of the BPR [↑](#footnote-ref-14)