Aeroxon Insect Control GmbH · Postfach 1471 · D-71332 Waiblingen

EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL
Single Market for goods
Prevention of Technical Barriers

Aeroxon Insect Control GmbH
Bahnhofstraße 35
D-71332 Waiblingen
thomas.updike@aeroxon.de
www.aeroxon.de

Telefon +49(0)7151 1715-142
Fax +49(0)7151 1715-76

Waiblingen, 26.04.2021

Subject: Comments and contribution on Germany's notified "*Verordnung zur Neuordnung nationaler untergesetzlicher Vorschriften für Biozid-Produkte*"
Your ref.: TRIS Notification No. 2021/42/D

In accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ("**Directive (EU) 2015/1535**"),[1] Germany notified on 27 January 2021 its "O*rdinance on the reorganisation of secondary national legislation on biocidal*" ("**Draft German Ordinance**")[2] to the European Commission ("**Commission**"). The end of the standstill period is 28.04.2021. Until this date comments can be submitted to the Commission by interested parties and Member States in connection with that Draft German Ordinance. Within the framework of this ongoing consultation, Aeroxon Insect Control GmbH ("**AEROXON**") hereby provides you with its comments on the Draft German Ordinance.

AEROXON is a company active in making available biocidal products in the European Union ("**EU**") and strongly believes that the Draft German Ordinance should not be adopted. As explained below, it constitutes a serious breach of EU law.

Therefore, AEROXON urges the Commission to take action against Germany and to prevent the entry into effect of the Draft Germany Ordinance, starting with issuing a detailed opinion on the Draft German Ordinance pursuant to Article 5(1) of Directive 2015/1535, to protect the integrity of the European Union ("**EU**") internal market, the free movement of goods and the good functioning (*effet utile*) of the EU Biocidal Products Regulation 528/2012 ("**BPR**").[3]

---

1 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1–15, as amended.

2 "*Verordnung zur Neuordnung nationaler untergesetzlicher Vorschriften für Biozid-Produkte* ", see Notification Number: 2021/42/D to the European Commission, available at, https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2021&num=42.

3 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123, as amended.

I. SCOPE AND CONTENT OF THE DRAFT GERMAN ORDINANCE

1. The objective of the Draft German Ordinance is to improve the practical application of the BPR in Germany, by ensuring the implementation of (or compliance with) the conditions of use contained in biocidal product authorisations.[4] Germany argues that the Draft German Ordinance "*take this objective into account by providing information to the purchaser with a view to improving compliance with use-related requirements.*"[5]

2. In sum, the Draft German Ordinance introduces **a ban on the self-service of certain biocidal products intended for use by consumers** (§ 10) and it imposes that making available of those biocidal products to consumers is subject to a **compulsory 'talk**' with that customer (§ 11).

3. This ban on making available of biocidal products via self-service is set forth in § 10(1) of the German Draft Ordinance (emphasis added):

> "*The following biocidal products may only be **offered and supplied** in a form in which the purchaser does **not have free access** to the biocidal product: […]*
> 1. *Biocidal products, where one or more uses of these products are not authorised to the general public according to the labelling specified by the authorisation.*
> 2. *Biocidal products that do not fall under subparagraph 1, and that are classified under the following product types in Annex V to Regulation (EU) No 528/2012:*
> a) *Product type 14 'Rodenticides' (products used for the control of mice, rats or other rodents, by means other than repulsion or attraction),*
> b) *Product type 18 'Insecticides, acaricides and products to control other arthropods' (products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction), and*
> c) *Product type 21 'Antifouling products' (products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water)."*

4. It follows that this prohibition with regard to self-service supply applies only to biocidal products falling in the category of **product types 14, 18, 21** (see § 10(1)(2) under a, b, c), provided they do not fall within the category of biocidal products for which use by consumers is not allowed pursuant according to the biocidal product authorisation (and corresponding labelling) concerned (see § 10(1)(1)).

5. The compulsory 'consumer talk' is set forth in §11 *("Requirements for the person responsible for the handover, supply meeting").* Essentially, this implies a mandatory talk with the customer upon the making available of a biocidal product (supply) by expert-personnel, in which *(i)* it must be established that the customer is a 'consumer' and not 'professional user' and *(ii)* that consumer must be informed about, notably, the intended use, methods for alternative treatment and the necessary precautionary measures and *(iii)* that this consumer intends to correctly use the product in question. § 11 provides (emphasis added):

---

[4] In addition, the existing provisions of the Ordinance on notification of biocidal products [*Biozid-Meldeverordnung*] and the Biocidal product authorisation ordinance [*Biozid-Zulassungsverordnung*] are also adapted.

[5] Draft German Ordinance, Section A. Problem and Objective on page 1.

> *"(1) Biocidal products under §10(1) **may only be supplied by a person that is employed by the company** and who fulfils the **qualification requirements** pursuant to §13.*
> *(2) Biocidal products under §10(1) may **only be supplied if***
> *1. the **person responsible for the handover** is aware, or has obtained confirmation from the purchaser, or been provided with evidence through the submission of the appropriate documentation, that the purchaser belongs to the category of users specified in the authorisation and intends to use the biocidal products in an appropriate and proper manner,*
> *2. in the case of biocidal products under §10(1)(2), the **person responsible for the handover** has informed the purchaser during the supply meeting about*
> *a. possible preventive measures to control harmful organisms and possible alternative low-risk measures,*
> *b. the intended and appropriate use of the biocidal product in accordance with the instructions for use, in particular concerning prohibitions and restrictions,*
> *c. the risks associated with the use of the biocidal product and possible measures to mitigate the risks,*
> *d. the precautionary measures required when the substance or mixture is used as intended and in the event of unforeseen spillage or release, as well as proper storage and proper disposal."*

6. This obligation to organise compulsory 'consumer talks' also applies to online and mail order sales in an adapted form (§ 12, emphasis added):

> "*If the supply takes place in online trade or otherwise by mail order, § 10(2) and § 11 shall apply with the stipulation that technical or organisational measures shall be taken to ensure that, before the conclusion of the contract of sale of the biocidal product*
> *1. compliance with the requirements of § 11(2)(1) has been verified by a qualified person in accordance with § 13, and*
> *2. **a telephone conversation** or a **conversation via video** transmission in accordance with § 11(2)(2) has been demonstrably conducted by a qualified person in accordance with § 13.*"

7. With regard to the expertise of the personnel handing over the biocidal products in question to the consumer (referred to in § 13), Germany claims that no new rules are created. Instead, Germany argues that the already existing rules regarding qualification requirements for supplying chemical substances are declared applicable to selling these biocidal products too.[6]

8. AEROXON considers that by restricting the "*making available*" (supply) of approved biocidal products in this way, the Draft German Ordinance amounts to a ***de facto* ban of affected products**. The typical places where consumers purchase the biocidal products covered, *e.g.* hypermarkets and supermarkets, do not have the qualified staff and organisational structures in place to ensure the – timely and continuous - compliance with the required 'consumer-talk' and prohibition of free access to the products in question in this magnitude. And in the case of online and mail order sales it appears at first sight basically impossible to comply with this 'consumer talk'-requirement purely from a practical point of view already.

---

[6] See Main Content of the Notification Message, available at https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2021&num=42&mLang=EN.

9. As explained below, the Draft German Ordinance breaches the BPR and infringes free movement rules of the TFEU.

II. INFRINGEMENT OF THE EU BIOCIDAL PRODUCTS REGULATION 528/2012 ("BPR")

10. The BPR regulates the *making available* and *use* of biocidal products and thus all forms of the sale, *i.e.* whether direct or indirect.[7] To achieve this, the BPR brings a two-level risk regulation and management system: all *biocidal products* are subject to a risk assessment procedure and require, by way of risk management, an authorisation (at national level or at Union-level) before they can be placed on the market and used. Moreover, the *active substances* contained in such biocidal products must, in combination with the relevant product type, also be approved beforehand under a risk assessment and management (approval) procedure at EU-level (albeit subject to transitional rules provided for in Article 89 BPR).

11. Under the BPR, Member States do not have the margin of discretion to introduce the type of supply restrictions/bans with regard to making available of biocidal products in the way set forth in the Draft German Ordinance. Suffice it to highlight in this respect that Germany seeks to justify the measures at stake by reference to the aim of guaranteeing a general high level of protection of human and animal health as well as of the environment against the effects of biocidal products. That is the same purpose as pursued already, in a harmonised way, with the BPR.[8] Reference is made to the objective and purpose section of the Draft German Ordinance, which reads (emphasis added):

> "*With regard to the use of biocidal products, it only contains general principles, and no specific provisions. Biocidal products are intended to kill or otherwise control harmful organisms. Due to this intended effect,* ***biocidal products pose a high potential risk to human health, to non-target organisms and to the environment****, which in principle also applies to products for which authorisation has been granted.* ***The anticipated adverse effects based on this potential risk must be countered by ensuring the implementation of (or compliance with) the conditions of use contained in the authorisation***"[9]

12. AEROXON submits that the EU Member States should refrain from adopting more restrictive measures in their national legislations than already defined in the BPR. The BPR provides for a fully harmonised framework for regulation of the making available and use of biocides across the EU in light of the risks that they may pose to humans or the environment. The measure proposed and the aim pursued by the Draft German Ordinance are already exclusively and exhaustively covered by and regulated under the BPR. In this respect AEROXON draws attention to the following.

---

[7] Article 3(1)(i) BPR defines the term 'making available on the market' as "*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*" The Commission Note for discussion with Competent Authorities for Biocidal Products 'Concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012' CA-Sept15-Doc.7.6 – Final (SANTE 2015-10467) establishes that *"The BPR applies to all forms of supply, including distance selling and selling through electronic means. Hence, regardless of the selling technique products within the scope of the BPR and intended to be made available on the Union market must be in conformity with the BPR*." (p. 2)

[8] Article 1(1) BPR: "*The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment.*"

[9] See Objective of the Draft German Ordinance, p. 1.

A. BPR harmonised framework for "making available" and "use" of biocidal products

a. Scope and legal basis of the BPR

13. The BPR concerns the placing on the market and use of biocidal products and aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. Article 1(1) confirms (emphasis added):

> *"The purpose of this Regulation is to improve **the functioning of the internal market** through the **harmonisation** of the rules on the making available on the market and the use of biocidal products, whilst ensuring a **high level of protection** of both human and animal health and the environment. The provisions of this Regulation are underpinned by the **precautionary principle**, the aim of which is to **safeguard the health of humans, the health of animals and the environment**. Particular attention shall be paid to **the protection of vulnerable groups**"*

14. Moreover, Article 1(2) BPR provides (emphasis added):

> "*This Regulation lays down rules for:*
> *[…]*
> *(c) the **mutual recognition of authorisations within the Union**;*
> *(d) **the making available on the market and the use of biocidal products** within one or more Member States or the Union; […]*"

15. The legal basis of an act indicates its purpose and therefore helps with its interpretation, in particular with respect to how much room (if any) is allowed for national diverging rules. Similar to Regulation (EC) No 1907/2006 ("**REACH**"), Article 114 of the Treaty on the Functioning of the European Union ("**TFEU**") is the *sole* legal basis of the BPR.

16. Accordingly, the BPR is a harmonisation measure which aims at approximation of laws of the EU Member States that affect the establishment or functioning of the internal market with respect to biocidal products. It is straight forward from the reading of Article 1(1) BPR that *"the rules on the making available on the market and the use of biocidal products"* – and specifically the restrictions to such making available and use because of "*direct or indirect risks they pose for human health or the environment*" - are thus harmonised at EU level.

17. This understanding is confirmed by Articles 19(4) and 19(5) of the BPR, which lay down the conditions according to which biocidal products can be "*made available to the general public*" or for when biocidal products have *to be restricted to professional users* in light of the risks that such product may pose for the human health or the environment (developed further below).

18. Clearly, the BPR has establishes a full harmonization of the conditions for biocidal products to be made available to consumers (and professional users) in the EU.

19. Consequently, the EU Member States cannot regulate the making available and use of biocidal products (*i.e.* including the sale and commercial practices / advertising) beyond the requirements set

forth in the BPR. This would be a breach of the BPR and infringement of the free movement of goods and good functioning of the internal market as provided under the BPR and ultimately the TFEU.

20. This understanding is also emphasized by the *type of the legal act itself*: the BPR a 'regulation' and not a 'directive'. The EU legislator's choice of the legal act in question adds to the conclusion that EU Member States are not supposed to deviate from the provisions set forth in the BPR when making the BPR operational in their national legal order. A different reading of the Member States' competences regarding making available of biocidal products to customers (consumers or professional users) would undermine the harmonisation sought and provided for under the BPR.[10]

b. <u>The concept of "making available" of biocidal products pursuant to the BPR</u>

21. There is no doubt that the activities regulated by the Draft German Ordinance fall within the scope of the concept of "making available" given that these activities qualify as "supply" within the meaning of the BPR.

22. The text of Draft German Ordinance itself confirms this already with the various references to 'supply' and 'handling over'. See *§10(1) which reads that the "following biocidal products may only be **offered and supplied** in a form in which the purchaser does **not have free access** to the biocidal product …"* and *§11(2) which confirms that "Biocidal products under §10(1) may **only be supplied if** …".*

23. And also in the justification provided in Section 9 of the TRIS notification No 2021/42/D Germany explicitly admits that it is a measure aimed at regulating the making available, *i.e.* the "*manner of supply*" or the "*process of supply*":

> *"The regulations on **the manner of supply** of biocidal products contribute to improving the enforcement of the requirements contained in authorisation decisions under Regulation (EU) No 528/2012. Since the biocidal product authorisation only formally binds the authorisation holder, national regulations are required that also cover **the process of supply** from the distributor to the consumer. This will ensure that a biocidal product **may only be supplied** to persons within the authorised user group."*

24. For the avoidance of doubt, AEROXON repeats that the regulated activity of "*making available*" is defined as follows in the BPR (emphasis added):[11]

> *"making available on the market means **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"*

---

[10] The BPR is a regulation within the meaning of the TFEU. Article 288 TFEU provides that a regulation shall be binding in its entirety and directly applicable in all Member States. This obviously means that it has legal effect in the EU Member States independent from any national law. It is standard case law from the ECJ in this regard that: "[b]*y virtue of the obligations arising from the Treaty and assumed on ratification, Member States are under **a duty not to obstruct the direct applicability inherent in Regulations** and other rules of Community law*"[10], adding importantly that "[s]*trict compliance with this obligation is an indispensable condition of **simultaneous and uniform application of Community Regulations throughout the Community***" (emphasis added), see: ECJ Case 34/73, *Variola v Amministrazione delle Finanze*, EU:C:1973:101, para. 10.

[11] Article 3(1)(i) BPR.

25. This definition confirms that the supply of biocidal products to a customer (whether a consumer (general public) or a professional users) is indeed covered by the scope of the BPR already. Consequently, the EU Member States cannot have in place own rules that deviate from the BPR provisions on making available (supplying) of biocidal products.

26. This understanding is confirmed by the Commission's own **Note for Discussion with Competent Authorities for Biocidal Products of September 2015**.[12] That guidance document seeks *"to clarify the concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012 (the BPR) and to address frequently asked questions in relation to these concepts"*. Concerning the definition of "*making available*", it refers to the Commission's **Blue Guide on the implementation of the EU product rules** to explain that the term 'supply' in the BPR is to be understood broadly and that supply is an activity that falls within the realm of the broad concept of "*making available*" as defined in the BPR.[13]

27. The Draft German Ordinance aims to bring restrictions on the supply, *i.e.* making available, of certain biocidal products by prohibiting the self-service sale and by imposing a compulsory 'customer talk'. Failing to have in place the possibility of having the intended 'compulsory talk' at the moment of handing over a biocidal product to the consumer, implies that the "making available" (*i.e.* supply to the customer) of that biocidal product is **entirely banned**.

28. This is unlawful, because the BPR does not foresee in residual rights for Member States in this respect.

c. Authorisation of biocidal products

29. The BPR imposes that "making available" and "use" of biocidal products is conditional on their authorisation:

---

12 CA-Sept15-Doc.7.6 – Final (SANTE 2015-10467).

13 O.J. 2016 C 272 26.07.2016. The aforementioned Note for Discussion from the Commission (see Footnote 18) cites this Blue Guide as follows (see page 2):
"***Supply*** *includes any* ***offer for*** *distribution or* ***use*** *on the Union market which could result in* ***actual supply*** *(e.g.* ***an invitation to purchase, advertising campaigns****).*
The ***concept*** *of making available* ***refers to each individual product, not to a type of product****, and whether it was manufactured as an individual unit or in series.*
The ***making available*** *of a product* ***supposes an offer or an agreement*** *(written or verbal) between two or more legal or natural persons for the* ***transfer of ownership****,* ***possession*** *or* ***any other right*** *concerning the product in question after the stage of manufacture has taken place.* ***The transfer does not necessarily require the physical handover of the product****.*
This transfer can be for payment or free of charge, and it can be based on any type of legal instrument. Thus, ***a transfer of a product is considered to have taken place, for instance, in the circumstances of sale****, loan, hire, leasing and gift. Transfer of ownership implies that the product is intended to be* ***placed at the disposal of another legal or natural person****.*
Supplying *a product is only considered as making available on the Union market,* ***when the product is intended for end-use*** *on the Union market.*
The supply of products for further distribution, for incorporation into a final product, for further processing or refinement with the aim to export the final product outside the Union market is not considered as making available.
Commercial activity *is understood as* ***providing goods in a business related context****. Non-profit organisations may be considered as carrying out commercial activities if they operate in such a context. This can only be appreciated on a case-by-case basis taking into account the regularity of the supplies, the characteristics of the product, the intentions of the supplier etc. In principle, occasional supplies by charities or hobbyists should not be considered as taking place in a business related context."*

"*Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.*" [14]

30. Furthermore, Article 17(5) BPR explicitly confirms:

"*[b]iocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.*"

31. Accordingly, any restrictions regarding making available and use of a biocidal product considered necessary are to be determined by / in a specific authorisation.

32. In Article 22 BPR, it is foreseen that such an authorisation must stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product and include a summary of the biocidal product characteristics, such as, among other things, product-type and an exact description of the authorised use, application doses as well as, crucially, categories of users and the instructions for use, hazard and precautionary statements, particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment, instructions for safe disposal of the product and its packaging, conditions of storage and shelf-life of the biocidal product under normal conditions of storage and where relevant, other information about the biocidal product.[15]

33. Article 69 prescribes in addition that the authorisation holder is required to classify, package and label a biocidal product "*in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008*".[16]

34. It follows that BPR foresees in an all-encompassing mechanism of requirements for authorisation holders and notably suppliers of biocidal products to inform the users about any risks or dangers and to limit the category of users (general public or professional users) if deemed necessary.

35. AEROXON observes that the Draft German Ordinance does not introduce new information to be conveyed to the user than the mandatory information already established through labelling pursuant to Article 69 BPR.

---

14 Article 17(1) BPR « *Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.*"

15 Article 22(1) BPR and Article 22(2) BPR. See also Article 69 BPR for applicable labelling requirements and rules on avoiding misleading advertisement for biocidal products.

16 See Article 69 BPR. At the moment of adoption of the BPR (2012) and until 1 June 2015, mixtures were still classified and labelled in accordance with the old EU Dangerous Preparations Directive 1999/45/EC. See Article 61(1) second sentence of the CLP Regulation on transitional provisions: "*Until 1 June 2015, mixtures shall be classified, labelled and packaged in accordance with Directive 1999/45/EC.*" This explains the reference in the BPR to this old directive alongside the CLP Regulation. Accordingly, at present the classification of biocidal mixtures is to be defined in accordance with the rules of the CLP Regulation.

(i) As indicated above, the compulsory 'consumer talk' is only supposed to address topics such as 'is the consumer a consumer and not a professional user' or *vice versa*. See § 11(2)(2) cited above, where it is foreseen that the person responsible for the handover of a biocidal product to a consumer must verify that "*the purchaser belongs to the category of users specified in the authorization"* and that this particular user (the customer wanting to purchase the biocidal product) *"intends to use the biocidal products in an appropriate and proper manner".*

(ii) The 'consumer talk' is further supposed to cover information about *"possible preventive measures to control harmful organisms and possible alternative low-risk measures", "the intended and appropriate use of the biocidal product in accordance with the instructions for use, in particular concerning prohibitions and restrictions, "the risks associated with the use of the biocidal product and possible measures to mitigate the risks", "the precautionary measures required when the substance or mixture is used as intended and in the event of unforeseen spillage or release, as well as proper storage and proper disposal."* (see above). Essentially, this information to be provided mimics the information already to be provided pursuant to the mechanism of the BPR (notably via the authorization requirements and labelling/use instructions).

36. Consequently, the Draft German Ordinance breaches the harmonised rules to the extent that they provide for further restrictions on the making available of biocidal products to consumers than the ones already foreseen by the BPR to ensure that users (customers) obtain the necessary information on the risks from an authorisation holder/supplier of a biocidal product.

37. Even more, it remains unclear why the proposed restrictions in the Draft German Ordinance are necessary in the first place, *i.e.* in addition to the already applicable and severe BPR requirements (authorisation requirements and, notably, labelling/use instructions). No justification or evidence is given by Germany for the need to introduce the additional restrictive measures of a ban on self-service by and a compulsory 'consumer talk'.

38. AEROXON reiterates that the BPR sets out stringent efficacy and safety conditions for authorisation of biocidal products and contains a set of dossier requirements for applicants and also foresees in a stringent risk assessment procedure.[17] More specifically, the BPR explicitly regulates when a biocidal product should not be authorised "*for making available on the market for use by the general public*" by mere reference to its inherent chemical characteristics (hazards):

> *"A biocidal product shall not be authorised for making available on the market for use by the general public where:*
> *(a) it meets the criteria according to Directive 1999/45/EC for classification as:*
> *— toxic or very toxic,*
> *— a category 1 or 2 carcinogen,*
> *— a category 1 or 2 mutagen, or*
> *— toxic for reproduction category 1 or 2;*
> *(b) it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:*

[17] *See e.g.* Article 19 and Article 20 BPR.

— acute oral toxicity category 1, 2 or 3,
— acute dermal toxicity category 1, 2 or 3,
— acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,
— acute inhalation toxicity (vapours) category 1 or 2,
— specific target organ toxicity by single or repeated exposure category 1,
— a category 1A or 1B carcinogen,
— a category 1A or 1B mutagen, or
— toxic for reproduction category 1A or 1B;
(c) it consists of, contains or generates, a substance that meets the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;
(d) it has endocrine-disrupting properties; or (e) it has developmental neurotoxic or immunotoxic effects."[18]

39. Article 19(5) BPR also establishes that a biocidal product may under certain circumstances still be authorised for making available on the market for use by the general public even if it meets the hazard-based criteria listed above.

40. It follows that there is no competence left for Member States to adopt even more stringent rules on making available biocidal products to members of the general public (consumers). The BPR does not create such competence for the Member States. The BPR entails complete harmonisation of the rules for making available biocidal products to consumers. If there is a need to regulate such supply, for the alleged reasons underpinning the Draft German Ordinance, this is to be addressed in the context of the authorisation procedure foreseen by the BPR already albeit within the harmonised limits defined by the BPR in that respect.

d. Enforcement of the BPR

41. The foregoing is also confirmed by Article 87 BPR, which defines the parameters for the enforcement of the BPR:

> *"Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 September 2013 and shall notify the Commission without delay of any subsequent amendment affecting them."*

42. Enforcement of requirements included in the biocidal product authorisations, and use instructions and restrictions (on labels) of biocidal products by consumers, can be established by the Member States in form of *penalties*, including any measure necessary to ensure that "*they*" – meaning the penalties – are implemented.

43. The Draft German Ordinance does not constitute a measure ensuring implementation of a penalty.

44. It is clear, therefore, that the Draft German Ordinance seeks to regulate something that is already harmonised under the BPR. And it cannot be justified under Article 87 BPR.

---

[18] Article 19(4) BPR.

45. This makes the Draft German Ordinance unlawful. There is no room for separate restrictions or bans on the supply (making available), justified by a Member State with vague and fully unsubstantiated references to risks for humans, animals or the environment. This can also be clarified by pointing out the following.

e. Public drinking water supply and defence exceptions

46. Article 2(7)-(8) BPR provide that EU Member States may restrict or ban the use of biocidal products "*in the public supply of drinking water*" and also "*where necessary in the interests of defence*". The Draft German Ordinance does not fall within these categories of exceptions.

f. 'Safeguard Clause'

47. Accordingly, the only other possibility for Germany to derogate from the provision on the making available and use of biocidal products for the reasons referred to by the government, would be to have recourse to the *safeguard clause* set forth in Article 88 BPR or Article 114(5) TFEU. However, the Draft German Ordinance is not based on these provisions. It cannot be qualified as a measure under the applicable safeguard clauses provided in EU law.

48. By way of background:

49. Article 88 of the BPR sets out the possibility for Member State to adopt appropriate provisional measures, based on '*new evidence*', for reasons of immediate or long-term risk to the health of humans, or animals, or to the environment:

> "*Where, on the basis of **new evidence**, a Member State has justifiable grounds to consider that a biocidal product, **although authorised in accordance with this Regulation**, constitutes a **serious immediate or long-term risk** to the health of humans, particularly of vulnerable groups, or animals, or to the environment, it **may take appropriate provisional measures**. The Member State shall, without delay, inform the Commission and the other Member States accordingly and give reasons for its decision based on the new evidence."* (emphasis added)

50. Similarly, Article 114(5) TFEU establishes the prerogative of a Member State to introduce national measures based on 'new scientific evidence' relating to the environment, or on a ground specific to that Member State:

> *"Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on **new scientific evidence** relating to the **protection of the environment** or the working environment on grounds of a **problem specific to that Member State** arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them."*

51. EU Member States may therefore deviate from the BPR if **(1)** well-grounded and **(2)** new evidence indicates that **(3)** a qualified ("*serious*") degree of risk or a problem "specific" for that Member State

is associated with the use of a particular biocidal product. In such a case, the EU Member State may take **(4)** appropriate **(5)** provisional measure and **(6)** notify both the Commission and other EU Member States. And even then, it is clear that it is not for the Member State concerned to decide on the measure to adopt: it is **the Commission's competence and prerogative** to ultimately take the necessary measures when a Member State invokes the safeguard clause. All a Member State can do is take a temporary, provisional, measure in the interest of protecting the environment, humans or animals.

52. Germany itself admitted already that the Draft German Ordinance is indeed not a safeguard clause within the meaning of Article 88 BPR or 114(5) TFEU. *See explicitly Section 11 of the TRIS Notification No 2021/42/D.*

53. As indicated above, the German Draft Ordinance is explicitly justified for reasons of controlling risks for humans and the environment and to ensure compliance, in general, so not specifically for a given biocidal product, with the requirements set forth in the product authorisation and labelling (use instructions) in that respect: "*The anticipated adverse effects based on this potential risk must be countered by ensuring the implementation of (or compliance with) the conditions of use contained in the authorisation.*"[19] Germany also wrote the following in Section 9 of the TRIS notification No 2021/42/D (emphasis added):

> *"The regulations on **the manner of supply** of biocidal products **contribute to improving the enforcement of the requirements contained in authorisation decisions** under Regulation (EU) No 528/2012. Since the biocidal product authorisation only formally binds the authorisation holder, national regulations are required that also cover **the process of supply from the distributor to the consumer**. This will **ensure that a biocidal product may only be supplied to persons within the authorised user group.**"*

54. Clearly, Germany ignores the scope of the concept of "placing on the market". As explained above, this covers all forms of supply ("*any supply*"). There is no reason to think that this would not cover "*the process of supply from the distributor to the customer*". The justification provided by Germany even contains a contradiction in terms, given that 'supply' is explicitly within the scope of 'making available' and thus covered by the BPR already (see above). Moreover, AEROXON considers that Germany's view that the "*biocidal product authorisation only formally binds the authorisation holder*" is irrelevant in this context and even wrong, given that no 'making available', and 'use', of a given biocidal product is allowed without such authorisation, *i.e.* irrespective as to who is the authorisation holder and irrespective as to who makes the biocidal product available to the customer. If there is no authorisation, the latter step in the supply chain cannot take place. This also applies to the supply by a distributor to a customer. So AEROXON fails to understand why a distributor or person responsible for supplying a product to a consumer would not be concerned by the existence and requirements set forth in the relevant biocidal product authorisations and corresponding labelling requirements (and user instructions) on the products.

---

19 *See* Objective of the Draft German Ordinance, page 1.

55. AEROXON, also highlights here that the requirement in §11(2) to verify whether a consumer is a consumer makes no logical sense. Because biocidal products not intended for the general public should not be offered for sale to such consumers in the first place already anyhow pursuant to the BPR. Moreover, AEROXON wonders how a consumer must prove its intention to correctly use a given biocidal product and how this can be verified by the selling person at all. AEROXON considers that these vague obligations and illogical requirements feed the perception that the Draft German Ordinance is deliberately designed to factually ban supply of biocidal products to consumers (this will be addressed further below in more detail too).

56. For completeness' sake, AEROXON first still adds the following.

g. <u>The ECJ's case law regarding residuary competences in</u>

57. As indicated, under the BPR the Member States have no residuary competences to regulate the making available of biocidal products to consumers (apart from the said 'safeguard clause' and 'enforcement' by means of imposing penalties, and the exceptions regarding 'defense' and 'supply of drinking water').

58. This does not mean that EU Member States have no right to determine the level of health protection desired for their citizens or the environment in the absence of EU harmonisation measures. The Court of Justice of the EU ("**ECJ**") confirmed this for example as follows in the context of REACH: [20]

> *"To that end, the REACH Regulation introduces **an integrated system** for monitoring chemical substances, including registration, evaluation and authorisation, together with possible restrictions on their use. The cardinal principles governing those factors were presented by the European Commission in the introduction to its Proposal for a Regulation COM(2003) 644 final of 29 October 2003. That proposal describes 'the REACH system' as comprising, first of all, registration, which requires 'industry to obtain relevant information on their substances and to use that data to manage them safely', next, '[e]valuation[, which] provides confidence that industry is meeting its obligations' and authorisation for substances of very high concern whose '[r]isks associated with uses are adequately controlled, if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies'. Lastly, '[t]he restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system'"*[21]

> *"[…], free movement in the internal market is ensured by the fact that, pursuant to Article 128(1) of the REACH Regulation**, the Member States are under an obligation not to prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance on its own, in a mixture or in an article which complies with the regulation and, where appropriate, with Community acts adopted in implementation thereof.** Nonetheless, under Article 128(2) of the REACH Regulation, **nothing therein is to prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where that regulation does not harmonise the requirements on manufacture, placing on the market or use**."*[22] *(emphasis added)*

---

20 ECJ Case C-472/14, *Canadian Oil*, EU:C:2016:171, par. 25 and 26. Similarly, *see also*, ECJ, Case 97/83, *Criminal Proceedings against Melkunie*, EU:C:1984:212, par. 18.

21 ECJ Case C-106/14, *FCD and FMB,* EU:C:2015:576, par. 32.

22 ECJ Case C-358/11, *Lapin luonnonsuojelupiiri,* EU:C:2013:142, par. 32.

59. The ECJ has also ruled already on the compatibility of national legislation regulating areas that are controlled under REACH. In case of *restrictions* and *authorisations* of a chemical substance, the adoption of conditions other than those set out in REACH was found to be incompatible with the objectives of that regulation.[23] However, for *registration* of substances, the ECJ followed another line of logic *(emphasis added)*:

> *"[…] the REACH Regulation must be interpreted as not precluding national legislation which requires an importer of chemical products to register those products with the competent national authority when that importer is already under an obligation under that regulation to register those same products with ECHA,* ***provided that that registration with the competent national authority does not constitute a pre-condition to the placing of those products on the market****, it concerns* ***information different from that required*** *by that regulation and* ***contributes to the achievement of the objectives pursued by that regulation****, in particular those of ensuring a high level of protection of human health and the environment and the free movement of such substances in the internal market, in particular, by the implementation of a system of controls of the safe management of such products in the Member State concerned and the evaluation of that management, which it is for the referring court to ascertain."*[24]

60. Conversely, it follows from this case law that <u>if a given subject matter is harmonised</u>, the EU Member States may act (within that subject matter) only if **(i)** allowed (or required, as the case may be) by the applicable harmonisation measure through the so-called safeguard measures or **(ii)** provided the conditions established by case-law are met, meaning ***(a)*** the national measure does not constitute a pre-condition to market access and ***(b)*** the requirements concern different aspects than the ones as harmonised.

61. As concluded above:

(i) the Draft German Ordinance has <u>not</u> been adopted using the safeguard procedure established by the BPR and is <u>not</u> a measure to implement penalties for enforcement purposes. So it is not allowed (or required, as the case may be) by the applicable harmonisation measure (BPR);

(ii) the Draft German Ordinance represents a clear pre-condition to the making available of certain biocidal products, because it entails an outright ban or restriction of certain forms of making available (*supply*) of certain already authorised biocidal products to consumers (see §10(1) "[…] *biocidal products may only be offered and supplied in a form in which the purchaser does not have free access to the biocidal product*"). And the requirement of the compulsory 'consumer talk' represents a pre-condition of lawful making available of the biocidal products that are subject to the self-service ban. It was also explained already that the ban of self-service and compulsory 'customer talk' do not contain aspects that are not yet harmonised (under the BPR).

62. Accordingly, the ECJ's case law confirms AEROXON's view that the Draft German Ordinance infringes the BPR

---

23 Opinion of Advocate General Sharpston in Case C-472/14, 10 December 2015, par. 38.

24 ECJ Case C-472/14, *Canadian Oil*, EU:C:2016:171, par. 41.

III. IN THE ALTERNATIVE: INFRINGEMENT OF ARTICLE 34 TFEU

A. Measures having equivalent effect to quantitative restrictions ("MEQR")

63. Even if it were to be considered that the BPR does not fully harmonize the conditions for making available of authorised biocidal products to the general public (*quod non*), then AEROXON observes, in the alternative, that the Draft German Ordinance would still be illegal as it would amount to a measure that has an equivalent effect to a quantitative restriction ("**MEQR**") that is prohibited under Article 34 TFEU.

64. Article 34 TFEU provides that "*quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*". The ECJ has clarified in the landmark cases *Dassonville* and *Keck* that MEQR are the following:

> "*5. … all trading rules, enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra Community trade"*[25]

65. According to AEROXON it is beyond doubt that the Draft German Ordinance is a MEQR within the meaning of *Dassonville.* For the avoidance of doubt, the Draft German Ordinance is <u>not</u> a 'selling arrangement' as developed in *Keck (emphasis added)*:

> *"16. By contrast, contrary to what has previously been decided, the application to products from other Member States of national provisions restricting or prohibiting certain **selling arrangements** is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the Dassonville judgment, so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States.*
> *17. Provided that those conditions are fulfilled, the application of such rules to the sale of products from another Member State meeting the requirements laid down by that State is not by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products. Such rules therefore fall outside the scope of Article 30 of the Treaty".*[26]

B. De facto ban on "making available" certain biocidal products in Germany

66. The Draft German Ordinance clearly affects the sales modalities as it seeks to regulate the economic activity of "*making available*" (*i.e.* supply) of certain biocidal products. However, the contested requirements are prompted solely by reference to the <u>product specific characteristics</u> (biocidal products).

67. As indicated above, Germany admitted already itself in the objective and purpose section of the Draft German Ordinance that the measure is based on alleged *health and safety risk concerns* in connection with the biocidal products falling under its scope (see above).

---

25 ECJ, Case 8/74, *Procureur du Roi v Dassonville,* EU:C:1974:82*,* par. 5

26 ECJ, Joined Cases C-267 and C-268/91 *Keck and Mithouard*, EU:C:1993:905, par. 16 and 17.

68. In the "Brief Statement of Grounds" under Section 9 of the TRIS Notification 2021/42/D, Germany further claims explicitly that for that reason the provisions in de Draft German Ordinance are aimed "*to improving the enforcement of the requirements contained in authorisation decisions*" and "*the possibility of verifying whether the purchaser belongs to the authorised user group at the point of sale*".

69. This confirms that the Draft German Ordinance is not a selling arrangement of any kind: it is aimed to ensure compliance with the biocidal product authorisation requirements (user instructions and other) that apply pursuant to the BPR and to impose further restrictions to regulate presumed risks in connection with the use of the products concerned despite the conclusions already adopted in that respect pursuant to the BPR (in the product authorization and labelling requirements). This makes it a MEQR.

70. It is sufficient for the qualification as an MEQR that there is a mere presumption that a given measure could affect the making available of biocidal product from other Member States more heavily than the making available of domestic products.[27] When reading §§10-12 of the Draft German Ordinance it would appear that they apply indistinctly to imports and domestic biocidal products. However, when examining the measures more closely it becomes clear that the requirements in question are likely to affect imported products far more than domestic products. The German Draft Ordinance will *de facto* prevent foreign suppliers to enter the German market.

- *Costs are borne by the manufacturer and/or supplier of biocidal products*

71. As explained further below, the costs associated with the implementation of the Draft German Ordinance are significant (excessive) in light of the turnover of the sector. AEROXON expects these costs to be indirectly borne by the manufacturer and/or supplier of the affected biocidal products, in order to maintain market access in Germany (it was already indicated above that the typical places where consumers buy biocidal products, hypermarkets, supermarkets, do not have the personnel and systems in place today to ensure compliance with the requirements).

72. As a result, domestic suppliers with potential bigger market presence will have a bigger incentive to invest/compensate business partners, in order to ensure continued supply to consumers, for the necessary trainings of personnel and organizing the point of sale in such a way to warrant that self-service (free access by customers) is not possible anymore. AEROXON believes that notably for small and medium sized enterprises ("**SMEs**") who are manufacturing and supplying biocides from outside Germany, and having a smaller market presence in Germany, such additional financial burden will simply not be economically viable.

73. Therefore, it must be concluded that instead of contributing to the free movement of authorised biocidal products, the Draft German Ordinance will hinder and hamper the market access in Germany and favor the already present economic operators in Germany.

---

[27] ECJ, Case C-34-36/95, *De Agostini*, EU:C:1997:344, par. 42 and Case C-405/98, *Gourmet*, EU:C:2001:135, par. 25.

- *Import basically impossible (de facto ban): especially for internet sales*

74. And what is more, the restrictions of the Draft German Ordinance, if applied to the same categories of biocidal products, would *de facto* make it impossible for imported products to enter the German market via online sales. Hence, the Draft German Ordinance discriminates against imported products.

75. As indicated, the Draft Ordinance prescribes that "*If the supply takes place in online trade or otherwise by mail order, § 10(2) and § 11 shall apply with the stipulation that* ***technical or organisational measures shall be taken*** *to ensure that, before the conclusion of the contract of sale of the biocidal product: 1. compliance with the requirements of § 11(2)(1) has been verified by a qualified person in accordance with § 13, and 2.* ***a telephone conversation*** *or a* ***conversation via video*** *transmission in accordance with § 11(2)(2) has been demonstrably conducted by a qualified person in accordance with § 13*" (emphasis added).

76. AEROXON understood that the idea would be that industry has to organize its making available of biocidal products to consumers via online sales along the following steps:

- *a buyer who searches an offer on a website first has to click on a "purchase" button;*
- *a video screen pops up presenting a live person;*
- *the live person should perform the 'customer talk' (in the language of the buyer or only in German even presumably);*
- *after the 'customer talk', the buyer must receive a code;*
- *the buyer enters the code on the website and the purchase is finalized.*

77. This way of operating in case of online supply of consumer goods is simply impossible to implement.

78. At the outset, AEROXON wishes to express that the from the German government as set forth in the Draft German Ordinance essentially brings us all back to the 'stone age' and thus unveils the true aim of the measures in question: it is nothing but a requirement that installs a factual ban (non-supply) of the biocidal products to consumers. The demand for a personal video/phone consultation at each purchase in by nature fast moving sales via the internet is unprecedented. AEROXON submits that the mandatory personal consultation with a buyer at each separate online transaction via, for example, telephone or video, is simply an excessive requirement. It is unrealistic to expect this to work in practice.

79. For example, already at the start it cannot be assumed that all online buyers have video and microphones. Moreover, the requirements in question trigger serious concerns with regard to (personal) data protection rules. For example: there is, albeit theoretically, a possibility to organize the 'consumer talk' by phone, but if the supplier's qualified person has to call the buyer to prevent phone charges, this would lead to data protection issues.

80. Moreover, it is unlikely that websites like Amazon will invest into Software and Technology to enable the service required to ensure compliance with the Draft German Ordinance. And they will for sure

not invest in people and necessary training to ensure an appropriate 'consumer talk' by video or phone at each online transaction. Instead, suppliers of biocidal products will have to organize and finance this by themselves. This requires a huge amount of people to serve the buyers, notably on Saturdays and Sundays evenings which are the known peak-times for internet sales by consumers.

81. AEROXON made a rough estimate and considers that for its online sales via one main known leading online sales platform alone, already 72 persons would be needed to handle the amount of purchases during such peak times. In total Aeroxon and/or Amazon only would need to have available an amount of 180 people to perform the 'consumer talk' tasks in the case of online sales of AEROXON's products (taking into account 3 shifts, holiday, etc.). By way of reference: AEROXON *and* its mother company (Fr. Kaiser GmbH) together currently employ 160 people in total!

82. This shows already the absurd and entirely disproportionate nature of the measure in question. To put it constructively: Germany has not provided convincing arguments which could possibly justify that AEROXON may reasonably be expected to double its personnel to ensure compliance with the legislation in only 1 Member State (and this only to have individual 'consumer talks' at every only transaction, regarding, moreover, already fully risk assessed and authorized products) and which would still allow AEROXON to remain economically viable.

83. It is of note in this respect that the Advocate General in the *German Parkinson* case explained the following in its Opinion:

> *"Surely, it is not internet pharmacies that should be compared but pharmacies in general. And then a different picture emerges, for the simple reason that, as DPV correctly points out, German and non-German pharmacies rely on the internet to varying degrees. A pharmacy already present in Germany will, typically, if at all, resort to the internet in a limited capacity only, whereas a pharmacy based outside Germany does not have any means other than the internet to serve patients based in Germany. In other words, while for a German pharmacy, delivery by way of mail order constitutes but an additional channel of distribution, for a non-German one it is the only channel of distribution."*[28]

84. Accordingly, the Advocate General concluded that:

> "*In a situation where the effect of a measure is to block or at least reduce market access for internet pharmacies, which are typically foreign, so as to maintain a viable structure of physical pharmacies, I deem it impossible to speak of an indistinctly applicable selling arrangement.*"[29]

85. The ECJ indeed confirmed thereafter that a prohibition on mail-order delivery of pharmaceutical products was "*more of an obstacle to pharmacies outside Germany than to those within it*".[30]

---

[28] ECJ, Opinion of AG Szpunar delivered on 2 June 2016 in Case C-148/15, *Deutsche Parkinson Vereinigung eV v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, EU:C:2016:394, par. 34.

[29] ECJ, Opinion of AG Spunar delivered on 2 June 2016 in Case C-148/15, *Deutsche Parkinson Vereinigung eV v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, EU:C:2016:394, par. 37.

[30] ECJ, Case C-322/01, *Deutscher Apothekerverband*, EU:C:2003:664, par. 74.

86. This confirms the aforementioned point made by AEROXON that imports, and notably via online sales/mail orders, are likely to be more severely affected by the German Draft Ordinance, leading to the inevitable conclusion that it is an unlawful MEQR.

87. Unlike confirmed selling arrangements such as, for example, a prohibition to sell products at a loss or provisions regulating opening hours of shops,[31] the restrictive measures in the German Draft Ordinance on the "*making available*" of biocidal products directly affect the competitive advantage of an economic operator *and are far more severe* than the known selling arrangements from the perspective of free movement rules. And especially for online (import) businesses, the imposed measures are of a nature to constitute a *de facto* ban or at least will significantly reduce (eliminate) realistic market access chances.

88. AEROXON expects that a majority of companies involved in biocides supply to consumers via import or online sales simply does not have the business model or capabilities (resources) to ensure the technical set-up and necessary trainings of personnel and to warrant the possibility to sell products only after a talk with the consumer (before concluding the supply agreement or actual handing over the product they desire). Moreover, additional trade barriers are to be expected for companies not necessarily based in Germany, as they will have to organize counselling/advice sessions with customers – and training of their personnel - in the German language. The training of salespersons and the 'consumer-talk requirement' pose an enormous obstacle. This is also demonstrated by the following.

- *Disproportionate requirements and costs for regulatory compliance in Germany*

89. The obligations set forth in the Draft German Ordinance impose an unreasonable additional cost on the sale of biocidal products to the intended users (consumers) and they are thus likely to inhibit or indeed diminish that sale and therefore also the import. This further confirms the nature of being an illegal MEQR and not a selling arrangement.[32]

90. The Draft German Ordinance is nothing more than an unjustified regulatory inhibition of economic activity and thus also infringing rights of market operators, such as AEROXON, to enjoy the full opportunity of ownership rights, the right to have the opportunity (actually also protected by the BPR) to recover with the sale of biocidal products the investments made to obtain the necessary regulatory authorisations/approvals, etc. This point cannot be underestimated: economic operators initiate investments in such authorisations/approvals with the understanding that their making available is regulated as foreseen in the BPR. It is excessive to expect them to organize themselves, and to incur the additional costs required, to ensure compliance with additional measures such as set forth in the Draft German Ordinance.

---

31 ECJ, Opinion of Szpunar delivered on 2 June 2016 in Case C-148/15, *Deutsche Parkinson Vereinigung eV v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, EU:C:2016:394, par. 25.

32 ECJ, Joined Cases C-158/04 and C-159/04*, Alfa Vita v. Elliniko Dimosio and Nomarchiaki Aftodioikisi Ioanninon* [2006] ECR I-8135, par. 16, 18-19. See also Commission Notice Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU), p. 48-49, OJ C 100, 23.3.2021, p. 38–89.

91. The Draft German Ordinance is further in breach of EU law simply because it goes beyond labelling requirements set forth by the BPR in order to ensure protection of the user of biocidal products (consumers) and the environment. This makes the measure disproportionate. Indeed, following the same line of reasoning as set forth in the Draft German Ordinance: the German Government might also want to consider banning the direct-sale (self-service) and imposing compulsory 'consumer talks' for a variety of other intrinsically dangerous products, such as beer, cigarettes, cars, or any other product that can be considered risky for humans, animals or the environment. The Draft German Ordinance is in this respect also potentially discriminatory, given that biocidal products – being already amongst the most heavily regulated products in the world for reasons of health and safety concerns – are now made subject to sales (making available) restrictions and other, far less risky products, can be purchased by consumers via self-service still.

92. In the same vein, the choice of Product Types covered by the Draft German Ordinance (PTs 14, 18, 21) appear totally arbitrary. There are many more biocidal products, falling in other Product Types as defined by the BPR, which are approved for use by consumers (general public) and which are made available via self-service, online sales etc. Typically, one can think of the abundant number of disinfectant products for household use (PTs 2, 3, 4). The German Draft Ordinance gives no clear and convincing justification for the restriction of said PTs 14, 18, 21, which creates inequality (discrimination). This adds on to the unlawful nature of the Draft German Ordinance of course.

93. Also, AEROXON considers that **the costs required to ensure compliance** with the requirements of the Draft German Ordinance are excessive in comparison to the actual risks presumed with regard to the biocidal products covered by it. And even more so in comparison to the benefit that such biocidal products actual provide (there is a need for such products, they serve a purpose, there is a demand. That is why they are being developed and made available, in accordance with the stringent requirements of the BPR, by companies like AEROXON).

94. The following is also to be considered.

95. To obtain market access in the first place, significant investments have to be made already up front by industry operators like AEROXON to obtain approvals under the BPR for the biocidal products in question and, first, the active substances contained therein. And 'participants' in the review program and 'applicants' for product authorisations under the BPR are supposed to recover those investments by means of the making available of the biocidal products of course. By blocking that possibility or making it excessively difficult, *i.e.* with a ban on self-service supply to customers and with a compulsory 'consumer talk', the German government seriously harms the rights and legitimate interests of economic operators concerned. AEROXON finds it disappointing how little understanding the German Government shows for the efforts made by economic operators, and notably SMEs like AEROXON, to generate and submit data needed for the appropriate risk assessments of biocidal active substances and products, sustain the long procedures, pay all the costs and fees required in this respect, make the efforts of bringing biocidal products to the market in the first place, and so forth. The light arguments put forward by way of justification of the market access restrictions in the Draft German Ordinance do not seem to take the legitimate interests of economic operators into account at all.

- *Costs erroneously presented by the German government*

96. Suffice it in this respect to point out that the German government has made a totally unrealistic estimate of the costs required for compliance with the measures in the Draft German Ordinance. It is evidently wrong.

97. AEROXON refers to the information on the expected costs for organizing (training) and performing (time, availability of trained persons) that has been investigated and collected in an aggregated way (for reasons of competition law) by the German trade association (IVA). Their research shows that **these costs alone already significantly outrun the market turnover**.[33] **The cost/benefit ratio is 67**. Indeed, the yearly cost of 161,9m Euro outruns the yearly benefits of 2,4m Euro by a factor 67. If AEROXON saw it correctly, even the (incorrect) calculation of the German Government would be a 9/1 cost benefit ratio.[34]

98. These costs need to be incurred while these products are all already entirely risk assessed, and approved for supply, under intense procedures and based on scientific evidence pursuant to the BPR. If authorised, they should be considered fit for sale and use without further burdens relating to minimizing those presumed risks in connection with the modalities for the making available. The Draft German Ordinance is undoubtedly unfit and disproportionate (excessive) in order to achieve the purpose *allegedly* pursued with it.

99. Indeed, as indicated, due to the excessive additional costs it is to be expected, according to AEROXON, that many companies in the business of supplying consumer-use biocidal products will not be able to sustain the additional costs required to comply with the measures defied in the Draft German Ordinance.

- *Price increases are unavoidable*

100. In this respect it is also of note that as a direct consequence of having to incur the said additional costs for implementation (*i.e.* a yearly additional expenditure of 161,9m Euro compared to a market turnover (end consumer price) of 66.2m Euro) is likely to **trigger a daunting price increase (potentially by 200-300%)** of the consumer products in question.[35] Moreover, this is expected to stimulate an unwanted "grey" market on non-German online websites making it potentially very attractive to purchase biocidal products that way to circumvent the hazzle of a mandatory 'consumer talk' etc. The measures of the Draft German Ordinance could also raise competition law concerns as the price of the same biocidal product, authorised across the EU pursuant to the same harmonised legal framework (BPR), would potentially be double or even triple in Germany compared to the prices in other Member States, simply because of the excessive additional requirements for the making available of the products to consumers in Germany.[36]

---

33 IVA Position paper, attached hereto as Annex.

34 Draft German Ordinance, Section 4 of the Explanatory Memorandum, p. 15-20.

35 IVA Position paper, attached hereto as Annex.

36 See also the IVA Position paper in this respect, attached hereto as Annex.

- *Final comment*

101. AEROXON trusted as 'participant' in the review program for active substances under the BPR and as 'applicant' for biocidal product authorisations in EU lawmaking and implementation thereof at national level. This is why AEROXON invested in costly and time-consuming procedures and market-access requirements. Now with the German Draft Ordinance, the question will be how AEROXON could ever recoup the investments made to secure continued market access by means of BPR-compliance. The possibilities to recover those costs via sales in Germany will essentially be made impossible if the Draft German Ordinance would enter into effect.

102. **In view of the above, Article 11 of the Draft German Ordinance is a MEQR that is prohibited under Article 34 TFEU**.

103. The question whether such measures can be justified on the grounds provided in Article 36 TFEU, and *inter alia* on the ground of the protection of health and life of humans must also be rejected. The burden of proof for showing that the measure would be justified under Article 36 TFEU rests on the German Government. AEROXON reiterates though, that if a biocidal product raises such concerns, it should either not be approved for supply and use to/by consumers in the first place in accordance with the BPR provisions and, alternatively, it should be made subject to the aforementioned safeguard procedure under the BPR. This is all evidently not the case, as the Draft German Ordinance still allows the supply (making available) of biocidal products to customers albeit under severe and unjustified restrictions.

IV. BREACH OF DIRECTIVE (EU) 2015/1535

104. In addition to the arguments regarding breach of the BPR and infringement of the treaty requirements on free movement of goods, AEROXON also observes that Directive (EU) 2015/1535 provides the following (emphasis added):

> *"Where, in particular, the draft technical regulation* ***seeks to limit the marketing or use of a chemical substance,*** *preparation or product* ***on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance****, preparation or product concerned and to known and available substitutes, where such information may be available, and* ***communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out*** *as appropriate in accordance with the principles provided for in the relevant part of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council."*[37]

105. To the best of AEROXON's knowledge, the German Government did not forward any supportive documentation for its choice of limiting the making available on the market of biocidal products listed in § 11(1)(2) of the Draft German Ordinance or an analysis of the presumed risks carried out as appropriate, as explicitly required by Directive 2015/1535. As indicated above, the biocidal products concerned are approved under the rules of the BPR upon an intensive, costly and time-consuming

[37] Article 5(1) para. 4 Directive (EU) 2015/1535.

procedure for risk assessment and risk management. And there are harmonized procedures in place in case of (new) concerns (safeguard clauses in applicable EU legislation). Accordingly, a high standard of proof is incumbent on Germany to show that there are any risks with regard to the biocidal products concerned that justify the measures set forth in the Draft German Ordinance and, also, that this is not yet fully regulated under existing EU law (BPR or other). AEROXON submits that Germany fails to provide the evidence and justifications required in this respect.

106. For this reason alone, the Draft German Ordinance should be considered already unlawful. Because in the absence of such evidence and justifications, it must be concluded that the measures are arbitrary and potentially constitute an abuse of power and are vitiated by manifest errors of assessment as to the impact, practical feasibility, enforceability and regulatory necessity in the first place. Indeed, on the face of it the Draft German Ordinance seems designed to ensure that "making available" of biocidal products for consumer-use (as opposed to professional use) will no longer be economically viable for economic operators, and notably SMEs, such as AEROXON. Considering the rights provided to economic operators by the BPR, the Commission should not endorse such harming of the biocides industry (making supply of approved biocidal products virtually impossible) by a Member State.

***

For the reasons stated above, AEROXON submits that the Draft German Ordinance should not be adopted and enter into force, as it constitutes a serious breach of EU law. AEROXON requests the Commission to issue a reasoned opinion as per Article 5(1) of Directive 2015/1535, and prevent Germany from adopting the contested measures, to protect the integrity of EU internal market, the free movement of goods and the good functioning (*effet utile*) of the BPR.

With kind regards,

Thomas Updike
CEO

Annexes (1):

- IVA position paper

ANNEX 1

Industrieverband Agrar

Biozidrecht

Referentenentwurf

Verordnung zur Neuordnung nationaler untergesetzlicher Vorschriften für Biozid-Produkte (Stand: 25. Januar 2021)

Anhang zur Position des Industrieverbands Agrar e. V.

Frankfurt am Main, März 2021

Anhang

IVA-interne Schätzung zum Erfüllungsaufwand gemäß BMU-Referentenentwurf

Vorgehensweise:

- Betrachtet wurde nur der Aufwand bezogen auf Produkte der **PA 18** (Insektizide).
- Rechenweg wie BMU
- Eckdaten:
  - Anzahl Mitarbeiter pro Filiale: 3
  - Lohnkosten pro Stunde 28,00 EUR
- Apotheken bei Anzahl Filialen in Berechnung IVA nicht enthalten

Ergebnisse (Kosten / Aufwand in EUR):

		jährlich		einmalig	
		BMU	**IVA**	**BMU**	**IVA**
Anzahl Filialen		34.000	41.407	34.000	41.407
Absatzzahl Biozide/Jahr (Filialen)		1.217.000	34.007.239	1.217.000	34.007.239
Absatzzahl Biozide/Jahr (Online)		121.700	3.400.700	121.700	3.400.700
Kosten Verkaufsschrank		33	66	500	1.000
Vorgabe	Kostenart				
§ 6 Abs.1	Aktualisierung Meldung	25.025	25.025	-	-
§ 6 Abs. 2	Bestätigung Meldung	19.892	19.892	-	-
§ 10 Abs. 1+2	Selbstbedienungsverbot	1.122.000	2.760.467	17.000.000	41.407.000
§ 11	Abgabe-/Beratungsgespräch	18.390.000	142.973.410	76.825.280	123.426.000
§ 12	Abgaberegelungen Online	579.870	15.869.000	121.770	121.000
§ 16	Erstmeldung Biozidprodukte	303.333	303.333	-	-
Erfüllungsaufwand (gesamt)*		20.440.120	**161.951.127**	93.947.050	**164.954.000**
Nutzen**:		2.400.000	**2.400.000**		
zum Vergleich: Lieferkettengesetz[1]:			*43.500.000*		*109.000.000*

* Berechnung IVA nur für PA 18

****** Berechnung BMU für alle zu regulierenden Produktarten

[1] Referentenentwurf Bundesministerium für Arbeit und Soziales v. 15.02.2021, S.2 E2

Anhang 1
Kosten-Nutzenverhältnis BMU-Referentenentwurf

Im BMU-Referentenentwurf stehen der erzielbare Nutzen und die anfallenden Kosten der Erfüllung in keinem verhältnismäßigen Zusammenhang.

	Gegenüberstellung Kosten- und Nutzenberechnung BMU - Real					
			jährliche Kosten		einmalige Kosten	
			BMU	Real	BMU	Real
		Anzahl Filialen	34.000	41.407	34.000	41.407
		Absatzzahl Biozide/Jahr (Filialen)	1.217.000	34.007.239	1.217.000	34.007.239
		Absatzzahl Biozide/Jahr (Online)	121.700	3.400.700	121.700	3.400.700
		Kosten Verkaufschrank	500	1.000	500	1.000
	Quelle	Kostenart				
1	§6 Abs.1	Aktualisierung Meldung	25.025	25.025	0	0
2	§6, Abs 1	Bestätigung Meldung	19.892	19.892	0	0
3	§10 Abs 1+2	Selbstbedienungsverbot	1.122.000	2.760.467	17.000.000	41.407.000
4	§11	Abgabe-/Beratungsgespräch	18.390.000	142.973.410	76.825.280	123.426.000
5	§12	Online-Abgaberegeln	579.870	15.869.000	121.770	121.000
6	§16	Erstmeldung Biozidprodukte	303.333	303.333	0	0
		Kosten:	20.440.120	161.951.127	93.947.050	164.954.000
		Nutzen:	2.400.000	2.400.000		

Für einen jährlichen Nutzen von 2,4 Mio € (BMU-Entwurf) fallen jährliche Kosten (BMU-Entwurfsberechnung mit belegbaren Absatzzahlen*) von mind. 161 Mio. € an.

Dazu kommen Einmalkosten von mind. 164 Mio. € (BMU-Entwurfsberechnung mit realen Zahlen).

Zum Vergleich:

Lieferkettengesetz: **Kosten (Erfüllungsaufwand): jährlich 43,5 Mio €, einmalig: 109 Mio € (D)****

REACH: **Kosten (Erfüllungsaufwand): jährlich 0,5 Mrd €, Nutzen: jährlich 2,0 Mrd. € (EU)*****

Pro Mitgliedsland anteilig: jährlich 20 Mio €, Nutzen: jährlich 80 Mio €

*Nielsen, GfK für Biozide PT 18 (z. B. Mottenpapier, Insektensprays, Ameisen- und Silberfischchen-Köderdosen, Fliegenköder, Mückenstecker usw.) im LEH, DM, Baumärkten und Gartencentern in Deutschland 2020

**Referentenentwurf Bundesministerium für Arbeit und Soziales v. 15.02.2021, S.2 E2

***ECHA/NR/21/09

Anhang 2
Kosten-Nutzenverhältnis BMU-Referentenentwurf

Kommentare zu den realen Zahlen aus der Gegenüberstellung der Kosten „BMU-Real“ und dem Nutzen aus dem BMU-Referentenentwurf. Eine tiefergehenden Untersuchung der im BMU-Referentenentwurf eingesetzten Werte wird zu einer weiteren Erhöhung der Kosten (Erfüllungsaufwand jährlich und einmalig) und zu einer Verringerung des jährlichen Nutzens führen. Die Forderungen des Referentenentwurfs sind unmöglich umzusetzen und führen faktisch zu einem Verkaufsverbot!

Kosten:

Anzahl Filialen:
Zusätzlich zum BMU-Entwurf sind Baumärkte und Gartencenter berücksichtigt. Nicht in der Aufstellung enthalten sind Apotheken.

Absatzzahlen - Biozide / Jahr (Filialen und Online):
Die Absatzzahlen der **Filialen** sind auch nach dem Einbezug der Nielsen- und GfK-Daten noch zu niedrig:

BMU-Entwurf:	PT 7,8,10,14,18,21 (ohne Beleg, Herleitung S.20, Pflanzenschutzmittel 2006)
Realistische Zahlen:	Belege für PT18 - ohne Absätze in Apotheken und dem Onlinehandel. Bei Überprüfung der Zahlen aus den übrigen Bereichen für PT 18 und den anderen Produktgruppen PT 7,8,10,14,21 ist eine weitere deutliche Erhöhung der Fallzahlen (ähnlich PT 18) zu erwarten.

Die **Online-Absatzzahlen** sind im gleichen Verhältnis wie die Filialabsätze angepasst. Zu niedrig?

Selbstbedienungsverbot (Sachkosten)
Sind 1000,- € ausreichend für Kauf und Installation eines abschließbaren Schrankes? Wie hoch sind die Online-Sachkosten (Hardware, Software)?

Abgabe- Beratungsgespräch (Schulung):
Stationär: Ist die Anzahl der zu schulenden Mitarbeiter (BMU: 3 MA pro Filiale) mit Einbezug aller Abgabestätten und unter Berücksichtigung eines saisonal unterschiedlichen Absatzverlaufes ausreichend?
Online: Eine Einzelberatung pro Kauf über Video ist für Haushalt-Verbrauchsgüter weltweit einmalig und technisch und administrativ nicht umsetzbar.
Sind die Schulungskosten (o. Gebühren und Nebenkosten) zu niedrig angesetzt?

Material- und Gesundheitsschäden:
Die Kosten von verdorbenen Lebensmitteln oder zerstörten Kleidungsstücken sowie entstehende Kosten durch Gesundheitsschäden sind nicht berücksichtigt.

Nutzen:

Die Nutzenrechnung basiert auf der Fallzahl für Pestizide und Repellentien (PiMont-Studie 2019). Nur ein Teil davon fällt auf Biozide zurück. Der Nutzen im BMU-Entwurf ist zu hoch angesetzt.