

For our environment

**PARTNER EVENT OF THE EU GREEN WEEK:**

**THE BENEFITS OF INCLUDING BIOCIDES IN SUSTAINABLE USE DIRECTIVE 2009/128/EC**

# Proposal for a way forward

Dr. Stefanie Wieck  
Unit IV 1.2 „Biocides“  
German Environment Agency

## Conclusions

- Inclusion of biocides in the **Directive on Sustainable Use** or a similar separate legislation is needed.
- Measures under the Directive need to be **adapted** to biocides.
- **Benefits:**
  - Reduced environmental pollution and less effects on biodiversity
  - Foster innovation in chemicals and non-chemicals sector
  - Harmonisation of current national legislation on aspects of sustainable use between member states
- Several member states have already developed **national legislation** on single aspects that would be covered in legislation on sustainable use of biocides. Examples given in the next slides were mainly derived from the Technical Regulation Information System (TRIS) database of DG Growth.

## National Action Plans

- **National Action Plans** (NAP, article 4 of SUD) could be developed for biocides as well. Some member states include some biocidal uses in their NAPs already. Stakeholders needed to be involved in the development are very different to plant protection products.
- These NAP would be a valuable tool to provide **concrete support** for users to make informed sustainable choices.



# Training

- Comparable **training** (article 5 of SUD) requirements for professional users and distributors are necessary for biocides. Training subjects as specified in Annex I of SUD would need to be adapted to biocidal products types.

**Regeling gewasbeschermingsmiddelen en biociden**

**Annex VI**

**A. Final attainment levels for training relating to the certificate of professional competence for the control of vermin and wood-destroying organisms**

After successfully completing the theory and practical examinations for this function the candidate can:

- a. recognise and name the most relevant vermin and wood-destroying organisms, occurring in and around buildings, and knows their most important biological characteristics;
- b. read the provisions and guidelines on the label of a biocide, interpret the symbols and systematically look up matters about biocides in reference books, furthermore the candidate must know the workings of most applied toxicology groups;
- c. demonstrate adequate knowledge of the required equipment and appliances and use them to carry out optimal pest control in the correct manner;
- d. indicate the most important repelling and containing methods for each rodent or wood-destroying organism as well as the methods for restricting the use and the emission of biocides;

**Ordinance on the reorganisation of secondary national legislation on biocidal products**  
§ 13

**Qualifications for supply**

(1) A qualified person in accordance with § 11 for the supply of biocidal products refers to a person who fulfils the requirements under:

- § 11(1)(1) and (2), also in conjunction with paragraph 3 of the Chemical Prohibition Ordinance of 20 January 2017 (BGBl. I p. 94), as last amended by Article 300 of the Ordinance of 19 June 2020 (BGBl. I S. 1328), in the currently applicable version, provided that the qualifications also covers the supply of biocidal products, or
- § 9(1)(4) of the Plant Protection Act [Pflanzenschutzgesetz] of 2 February 2012 (BGBl. I p. 148, 1281), last amended by Article 278 of the Ordinance of 19 June 2020 (BGBl. I p. 1328), in conjunction with the Ordinance [Ordinance on the Supply of Specialist Qualifications in Plant Protection [Pflanzenschutz-Sachkundeverordnung] of 19 June 2013 (BGBl. I p. 1953), as last amended by Article 376 of the Ordinance of 19 August 2015 (BGBl. I p. 1474), in the currently applicable version, provided that it can be demonstrated that a training course pursuant to paragraph (1)(2) of the Chemical Prohibition Ordinance, that imparts knowledge of biocidal products, has been attended for the first time or repeated and that the course was attended for a period of more than the period specified in § 11(1)(2) of the Chemical Prohibition Ordinance.
- § 15b(1) in conjunction with Annex I(1) of the Hazardous Substances Ordinance [Gefahrstoffverordnung] of 26 November 2010 (BGBl. I pp. 1643, 1644), as last amended by Article 2 of the Ordinance of [insert: date of issue and reference to the Ordinance amending the Biological Substances Ordinance and other Ordinances on Occupational Health and Safety [Arbeitsschutzänderungsverordnung – ArbSchÄndV], provided that the qualifications relate to the product type to which the biocidal product supplied is to be assigned.

(2) Evidence of the professional qualifications or acquired competence issued in other Member States of the European Union or other contracting parties of the Agreement on the European Economic Area shall meet the requirements set out in paragraph 1 insofar as the authority responsible for recognising equivalence has established this equivalence.

# Requirements for sales

- **Requirements for sales** (article 6 of SUD) including online sales are needed for biocides as well to
  - i. ensure that only persons allowed to use the products can buy them
  - ii. provide information to non-professional users of certain product types.

Training of distributors of those products is therefore necessary as well.



## Ordinance on the reorganisation of secondary national legislation on biocidal products

§ 10

### Self-service ban

(1) The following biocidal products may only be of the purchaser does not have free access to the biocidal products:

1. Biocidal products, where one or more uses of these general public according to the labelling specified
2. Biocidal products that do not fall under subparagraph 1. the following product types in Annex V to Regulation (EU) No 528/2012:
  - a) Product type 14 'Rodenticides' (products used for rodents, by means other than repulsion or attraction)
  - b) Product type 18 'Insecticides, acaricides and other arthropodicides' (products used for the control of harmful arthropods, crustaceans), by means other than repulsion or attraction
  - c) Product type 21 'Antifouling products' (products for the settlement of fouling organisms (microbes and species) on vessels, aquaculture equipment, etc.)

(2) Biocidal products that do not fall under paragraph 1. the following product types in Annex V to Regulation (EU) No 528/2012 and supplied if it is ensured by organisational measures in the sales contract by a person who fulfils the requirements of paragraph 1.

§ 11

### Requirements for the person responsible for the handover, supply meeting

(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

the person responsible for the handover is aware, or has obtained confirmation from the purchaser, or has 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 safe manner.

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

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,

§ 12

### Requirements for supply in online and mail order trade

If the supply takes place in online trade or otherwise by mail order, § 10(2) and § 11



## Order on control agents<sup>1)</sup>

### Chapter 5

### Special provisions for rodenticides

**§ 26. Rodenticides approved for professional use under the Biocides Regulation or the Plant Protection Products Regulation may only be supplied to and held by an authorised person. If the person in question only has an R2 authorisation however, the person may only receive and possess control agents expressly approved for the use of persons with R2 authorisation.**



## Decree banning the unrestricted sale of certain categories of biocidal products to non-professional users

### Article 1

In Book V, Title II, Chapter II, Section 5 of the Environmental Code (regulatory part), after Article R522-16-2, an Article R522-16-3 is inserted worded as follows:

'Article R522-16-3. - Subject to the terms of the authorisations issued for various biocidal products in line with the aforementioned Regulation (EU) No 528/2012 of the European parliament and of the Council of 22 May 2012, the categories of biocidal products mentioned in Article L522-5-2 which may not be sold directly over the counter to non-professional users are as follows:

'- products for which the development of resistance may be established or suspected from the data;

'- products for which cases of unintentional poisoning have been reported;

'- products not eligible for the simplified authorisation procedure mentioned in III of Article R522-16-2, for which the data establishes that they are frequently used in breach of the regulations intended to preserve human health and the environment, appearing on the marketing authorisation of the products or on the extended leaflet created by the manufacturer thereof.

'An Order of the Minister for the Environment, issued after consulting with the National Agency for Food, Environment and Occupational Health and Safety, shall specify the biocidal products, potentially defined as all products containing the same active substance, or types of biocidal products, that shall fall under each of these categories. This Order shall determine the time the distributors have to implement the ban mentioned in the first paragraph on the over-the-counter sale of these products.'

### Article 2

A paragraph worded as follows shall be inserted before the final paragraph of I of Article R522-25 of the Environmental Code:

'9. Selling one of the products mentioned in the last paragraph of Article R522-16-3 over the counter to non-professional users.'



### Closed circuit

Biocidal products with a high risk to health belong to the closed circuit. They can be toxic, carcinogenic or harmful to reproduction. This is why, under the Royal Decree of 4 April 2019, these biocides are mainly reserved for professional users. This is why, under the [Royal Decree of 4 April 2019 \(NL/FR\)](#), these biocides are mainly reserved for professional users.

Do you want to buy or sell a closed circuit biocide? Then register online and observe the safety regulations. This is mandatory.

## Information and awareness raising

- **Information and awareness-raising** (article 7 of SUD) is already regulated in Article 17(5) of the BPR, however, SUD article also includes gathering information on pesticide acute poisoning incidents, as well as chronic poisoning developments.

### Bundesrecht konsolidiert: Gesamte Rechtsvorschrift für Giftinformations-Verordnung 1999, Fassung vom 02.06.2021

#### Mitteilungspflicht bei Vergiftungen

**§ 7.** (1) Die verantwortlichen Leiter von Abteilungen und sonstigen Organisationseinheiten in Krankenanstalten, in denen die Diagnose und Behandlung oder die Beurteilung der Folgen einer Erkrankung erfolgt, bei der zumindest der begründete Verdacht besteht, daß sie durch einen Stoff oder eine Zubereitung verursacht worden ist, haben diese Vergiftungsfälle dem Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft mitzuteilen. Dies gilt auch für Arbeitsmediziner und ärztliche Leiter von arbeitsmedizinischen Zentren.

(2) Die Mitteilung hat hinsichtlich der Person des Patienten in anonymisierter Form unter Verwendung eines Formblattes nach dem Muster der **Anlage 3** zu erfolgen.

(3) Sie hat

1. bei akuten Erkrankungen nach erfolgter Therapie bzw. bei Entlassung aus stationärer Behandlung,
2. bei chronischen Erkrankungen nach Stellung der Diagnose,
3. sofern im Falle einer Erkrankung mit Todesfolge eine Obduktion durchgeführt wird, nach deren Abschluß

unverzüglich zu erfolgen.

### Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz - ChemG)

#### § 16e Mitteilungen für die gesundheitliche Notversorgung und für vorbeugende Maßnahmen

(1) Das Bundesinstitut für Risikobewertung nimmt als benannte Stelle nach Artikel 45 Absatz 1 der Verordnung (EG) Nr. 1272/2008, auch in Verbindung mit Artikel 73 der Verordnung (EU) Nr. 528/2012, die Aufgaben nach Artikel 45 Absatz 1 in Verbindung mit Anhang VIII der Verordnung (EG) Nr. 1272/2008 wahr.


(2) Wer als Arzt zur Behandlung oder zur Beurteilung der Folgen einer Erkrankung hinzugezogen wird, bei der zumindest der Verdacht besteht, dass sie auf Einwirkungen gefährlicher Stoffe, gefährlicher Gemische, von Erzeugnissen, die gefährliche Stoffe oder Gemische freisetzen oder enthalten, oder von **Biozid-Produkten** zurückgeht, hat dem Bundesinstitut für Risikobewertung den Stoff oder das Gemisch, Alter und Geschlecht des Patienten, den Expositionsweg, die aufgenommene Menge und die festgestellten Symptome mitzuteilen. Die Mitteilung hat hinsichtlich der Person des Patienten in anonymisierter Form zu erfolgen. § 8 Absatz 1 Nummer 1 zweiter Halbsatz des Infektionsschutzgesetzes vom 20. Juli 2000 (BGBl. I S. 1045) gilt entsprechend. Satz 1 gilt nicht, soweit diese Angaben einem Träger der gesetzlichen Unfallversicherung zu übermitteln sind; dieser hat die Angaben nach Satz 1 an das Bundesinstitut für Risikobewertung weiterzuleiten.

(3) Das Bundesinstitut für Risikobewertung übermittelt die in den Mitteilungen nach Anhang VIII der Verordnung



## Equipment for the application of biocides

- Inclusion of equipment for the application of biocides in **Directive 2006/42/EC on machinery** as already foreseen in the 3<sup>rd</sup> recital of *Directive 2009/127/EC amending Directive 2006/42/EC with regard to machinery for pesticide application* is needed to provide general requirements for the machinery.
- **Inspection of equipment in use** (article 8 of SUD) would be important for the application equipment of biocides as well.
- Regulation for machinery closely related or equal to equipment for the application of plant protection products can be **easily transferred** from existing regulation.
- Regulation should also include basic requirements (incl. efficacy) for **non-chemical alternatives** for the control of harmful organisms to establish a level playing field at comparative assessment under the BPR and for support IPM/Best Practice Codes.

 Order issued pursuant to Article R. 522-16 of the Environmental Code and relating to the conditions for using certain categories of biocidal products

### Article 7 (rodenticides authorised for professional use)

I. - The baiting posts in which the rodenticides are used [presented in the form of bait] and intended to be used by people holding the certificate of competence provided for in the aforementioned Order of 9 October 2013, as amended, shall be designed in such a way that children and non-target animals are prevented from gaining access to the bait through direct contact.



Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)  
§ 18 Behördlich angeordnete Maßnahmen zur Desinfektion und zur Bekämpfung von Gesundheitsschädlingen, Krätzmilben und Kopfläusen; Verordnungsermächtigungen

(1) Zum Schutz des Menschen vor übertragbaren Krankheiten dürfen bei behördlich angeordneten Maßnahmen zur

1. Desinfektion und
2. Bekämpfung von Gesundheitsschädlingen, Krätzmilben oder Kopfläusen

nur Mittel und Verfahren verwendet werden, die von der zuständigen Bundesoberbehörde anerkannt worden sind. Bei Maßnahmen nach Satz 1 Nummer 2 kann die anordnende Behörde mit Zustimmung der zuständigen Bundesoberbehörde zulassen, dass andere Mittel oder Verfahren als die behördlich anerkannten verwendet werden.  
(2) Die Mittel und Verfahren werden von der zuständigen

**NoCheRo-Guidance for the Evaluation of Rodent Traps**

Part A Break back/Snap traps



SCOTT

## Aerial spraying / Spray drift

- Some biocides (insecticides) are applied via **aerial spraying** (article 9 of SUD) as well. The provisions from the SUD for plant protection products can be transferred.
- **Information of persons exposed to spray drift** (article 10 of SUD) might be relevant for example for large-scale insecticides applications.



## Specific measures

- **Specific measures to protect the biodiversity and drinking water** (articles 11 and 12 of SUD) could also be applied to biocidal products used in the direct vicinity of or in vulnerable areas. The provisions would have to be adapted to the specific setting biocidal products are used in (e.g. nature protection sites).



Bekendtgørelse om begrænsning af import, salg og anvendelse af  
biocidholdig bundmaling<sup>1)</sup>

It is not permitted to import, sell or use anti-fouling paint

- containing irgarol (cybutryne, CAS-No. 28159-98-0), on ships shorter than 25 metres;
- on pleasure boats which sail mainly in fresh water; or
- on pleasure boats of less than 200 kilos and which sail mainly in salt water (The ban does not cover wooden boats and pleasure boats that have permanent mooring space in harbours designated as A and B harbours by the insurance sector harbour survey); and
- on pleasure boats of 200 kilos and more and which sail mainly in salt water and on which the release of copper to the aquatic environment exceeds 200 µg Cu/cm<sup>2</sup> after the first 14 days and 350 µg Cu/cm<sup>2</sup> after the first 30 days (calculated from the time of application).



### Gesetz des Landes Baden-Württemberg zum Schutz der Natur und zur Pflege der Landschaft (Naturschutzgesetz - NatSchG) Vom 23. Juni 2015<sup>1 2</sup>

#### § 34 Verbot von Pestiziden

Die Anwendung von Pestiziden (Pflanzenschutzmittel und Biozide) gemäß Artikel 3 Nummer 10 der Richtlinie 2009/128/EG des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über einen Aktionsrahmen der Gemeinschaft für die nachhaltige Verwendung von Pestiziden (ABl. L 309 vom 24.11.2009, S. 71, ber. ABl. L 161 vom 29.6.2010, S. 11), die zuletzt durch Verordnung (EU) 2019/1243 (ABl. L 198 vom 25.7.2019, S. 241) geändert worden ist, in der jeweils geltenden Fassung ist

1. in Naturschutzgebieten außerhalb von intensiv genutzten land- und fischereiwirtschaftlichen Flächen, ab dem 1. Januar 2022 auf der gesamten Fläche und
2. in Kern- und Pflegezonen von Biosphärengebieten, gesetzlich geschützten Biotopen und bei Naturdenkmälern außerhalb von intensiv genutzten land- und fischereiwirtschaftlichen Flächen

verboten.

In Landschaftsschutzgebieten und Natura 2000-Gebieten sowie auf intensiv genutzten land- und fischereiwirtschaftlichen Flächen in Kern- und Pflegezonen von Biosphärengebieten, in gesetzlich geschützten Biotopen und bei Naturdenkmälern erfolgt eine Anwendung von Pflanzenschutzmitteln nach den Grundsätzen des Landes zum Integrierten Pflanzenschutz gemäß § 17c LLG. Satz 2 gilt in Naturschutzgebieten bis zum 31. Dezember 2021 entsprechend.

(2) Das für die Landwirtschaft zuständige Ministerium kann im Einvernehmen mit dem für den Naturschutz zuständigen Ministerium für das ganze Land oder Teile des Landes befristete Ausnahmen vom Verbot des Absatzes 1 Satz 1 zulassen, wenn und soweit dies zur Bekämpfung von Schadorganismen im Sinne des § 6 Absatz 4 des Pflanzenschutzgesetzes, die erhebliche Schäden verursachen, erforderlich ist.

(3) Die Anwendung von Pestiziden kann als befristete Ausnahme von dem Verbot des Absatzes 1 Satz 1 zugelassen werden, soweit dies zur Gewährleistung der Verkehrssicherheit von Schienenwegen oder zur Vermeidung von Beeinträchtigungen der menschlichen Gesundheit oder des menschlichen Wohlbefindens erforderlich ist.

(4) Auf Antrag kann die Verwendung bestimmter Mittel für land- und fischereiwirtschaftliche Betriebe zugelassen

## Handling operations

- Measures to avoid dangerous **handling operations** (article 13 of SUD), for example by limiting sizes of containers or packaging, can be relevant for biocides as well.



Decree establishing the list of products for which sale in bulk is prohibited for public health reasons

### Article 1

Before Chapter 1 of Title II of Book 1 of the Consumer Code, a Chapter 1 A shall be inserted as follows:

‘Chapter I A

Encouraged business practices

Sole Section

Sale of products without packaging

Article D120-1.- In accordance with the third paragraph of Article L120-1, the products which cannot be sold in bulk for public health reasons are as follows:

...

8. Rodenticides in accordance with the provisions of Article 5 of the Order of 20 April 2017 adopted in accordance with Article R522-16 of the Environmental Code and relating to the conditions for using certain categories of biocidal products;

9. Biocidal products, as defined in Article 3 of 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, where sale in bulk is not provided for in the marketing authorisation;

## Integrated Pest Management

- The goal of **Integrated Pest Management (IPM)** specified in article 14 of SUD is a complement to the “minimum necessary” specified in article 17 (5) of BPR.
- However, IPM is elaborated in **much more detail** in annex III of the SUD and *Regulation 1107/2009 concerning the placing of plant protection products on the market* refers to these details in the requirements relating to the placing on the market and use of the plant protection product in its article 31.
- Similar detailed **Best Practice Codes** are needed for biocidal products as well. Product authorisation has shown that those Codes are very much needed and are an important support for users in daily-life to facilitate a proper use according to article 17(5) of BPR.
  - Proper use of plant protection products (article 55 of Regulation 1107/2009) <> General principles of integrated pest management (Annex III of SUD)
  - Proper use of biocides (article 17(5) of BPR) <> Best Practice Codes (missing)
- Putting more emphasis on adherence to proper use might **foster innovation** towards more sustainable substitutes.



## Data / Exchange between member states

- Inclusion of biocides in **Regulation 1185/2009 concerning statistics on pesticides** is an important basis for data collection, extension to biocides is already foreseen in its 5<sup>th</sup> recital.
- **Harmonised risk indicators** (article 15 of SUD) for biocides across the EU would be important to make data comparable.



**Ordinance on the reorganisation of secondary national legislation on biocidal products**

§ 16

**Notification of biocidal products made available on the market**

(1) Someone who, as manufacturer, importer or user using his or her own trade name, makes a biocidal product available on the market for the first time within the scope of this Ordinance, or exports a biocidal product manufactured within the scope of this Ordinance, shall report the following to the Federal Office for chemicals annually by the end of the day on 31 March for the preceding calendar year:

1. the nature and quantity of the biocidal products which he or she has supplied to recipients that reside or are domiciled in the country, or products which he or she has exported, and
2. the active substances contained in the biocidal products supplied or exported.

(2) The notification shall be made separately for each biocidal product and shall

**Subject to approval by Federal Council, End of June 2021**

- **Exchange of information and best practice** is crucial, also for biocides. The variety of uses is already very complex, synergies between member states should be used.

## Next steps

We call for the Commission to **start the process** towards EU-wide legislation on a sustainable use of biocides – either by including it in the Directive 2009/128/EC on a Sustainable Use of Pesticides or by a similar separate legislation.

Member States are invited to provide **experience** with national legislation and existing Best Practice Codes supporting a sustainable use of biocides, we are willing to start a request via the CA meeting.

# Thank you for your attention!

**Dr. Stefanie Wieck**

Stefanie.Wieck@uba.de

[https://www.umweltbundesamt.de/en/topics/chemicals/  
biocides/sustainable-control-of-harmful-organisms-in-the](https://www.umweltbundesamt.de/en/topics/chemicals/biocides/sustainable-control-of-harmful-organisms-in-the)

[www.biozid.info](http://www.biozid.info)