Main elements of the EU Biocide Regulatory system

MARISTELLA RUBBIANI

ISTITUTO SUPERIORE DI SANITÀ

ROMA

ITALIA

Biocides

- The term ‘Biocide’ is derived from *bios*, the Greek word meaning ‘life’ and the Latin *caedere* meaning to kill, so literally something that is capable of ‘killing life’.
- The term is used to describe a diverse range of chemicals that are used to control harmful organisms (typically, but not exclusively, microorganisms).
- Biocides include products like disinfectants, preservatives and chemicals used to control microbial growth on surfaces, plus other products such as insecticides, repellents and rodenticides.

22 Product types

MAIN GROUP 1: Disinfectants

- These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar product
- *Product-type 1: Human hygiene*
- Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary pur of disinfecting the skin or scalp.
- *Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals*
- Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.
- Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.
- Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.
- Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.
- Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
- *Product-type 3: Veterinary hygiene*
- Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.
- Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.
- *Product-type 4: Food and feed area*
- Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.
- Products used to impregnate materials which may enter into contact with food.
- *Product-type 5: Drinking water*
- Products used for the disinfection of drinking water for both humans and animals.

Main group 1: Disinfectants These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.		
PT 1	Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
PT 2	Disinfectants and algaecides not intended for direct application to humans or animals	Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities. Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
PT 3	Veterinary hygiene	Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function. Used to disinfect the materials and surfaces associated with the housing or transportation of animals.
PT 4	Food and feed area	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Used to impregnate materials which may enter into contact with food.
PT 5	Drinking water	Used for the disinfection of drinking water for both humans and animals.

Main group 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

PT 6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Used as preservatives for the storage or use of rodenticide, insecticide or other baits.
PT 7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
PT 8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products.
PT 9	Fibre, leather, rubber and polymerised materials preservatives	Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
PT 10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack.
PT 11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
PT 12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
PT 13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

Main group 3: Pest control		
PT 14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
PT 15	Avicides	Used for the control of birds, by means other than repulsion or attraction.
PT 16	Molluscicides, vermicides and products to control other invertebrates	Used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.
PT 17	Piscicides	Used for the control of fish, by means other than repulsion or attraction.
PT 18	Insecticides, acaricides and products to control other arthropods	Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
PT 19	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
PT 20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction.

Number	Product-type	Description
Main group 4: Other biocidal products		
PT 21	Antifouling 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.
PT 22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof.

A short history

- Historically the regulation of biocidal products and the active substances that they contain has varied considerably across Member States within the EU, with some products being regulated and others not.
- This was considered a barrier to free trade within the EU and resulted in the implementation of the Biocidal Products Directive (BPD), a common EU policy, in 1998.
- The objectives were to harmonise the regulation of biocidal products throughout the EU; to provide a high level of protection for humans, animals and the environment; and to ensure that products are sufficiently effective against target species.

The Biocidal Products Directive 98/8/EC (BPD)

- The Biocidal Products Directive 98/8/EC (BPD) was an important step towards tackling the risks of biocides through the systematic identification of biocides marketed in the EU and the establishment of a harmonised framework for authorisation.
- However, several shortcomings and delays have resulted in a failure so far to protect human health and the environment.
- The introduction of an EU biocide policy was necessary as most countries within the EU did not have specific provisions for the authorisation (of all kinds) of biocides (particularly Austria, France, Germany and Luxembourg).

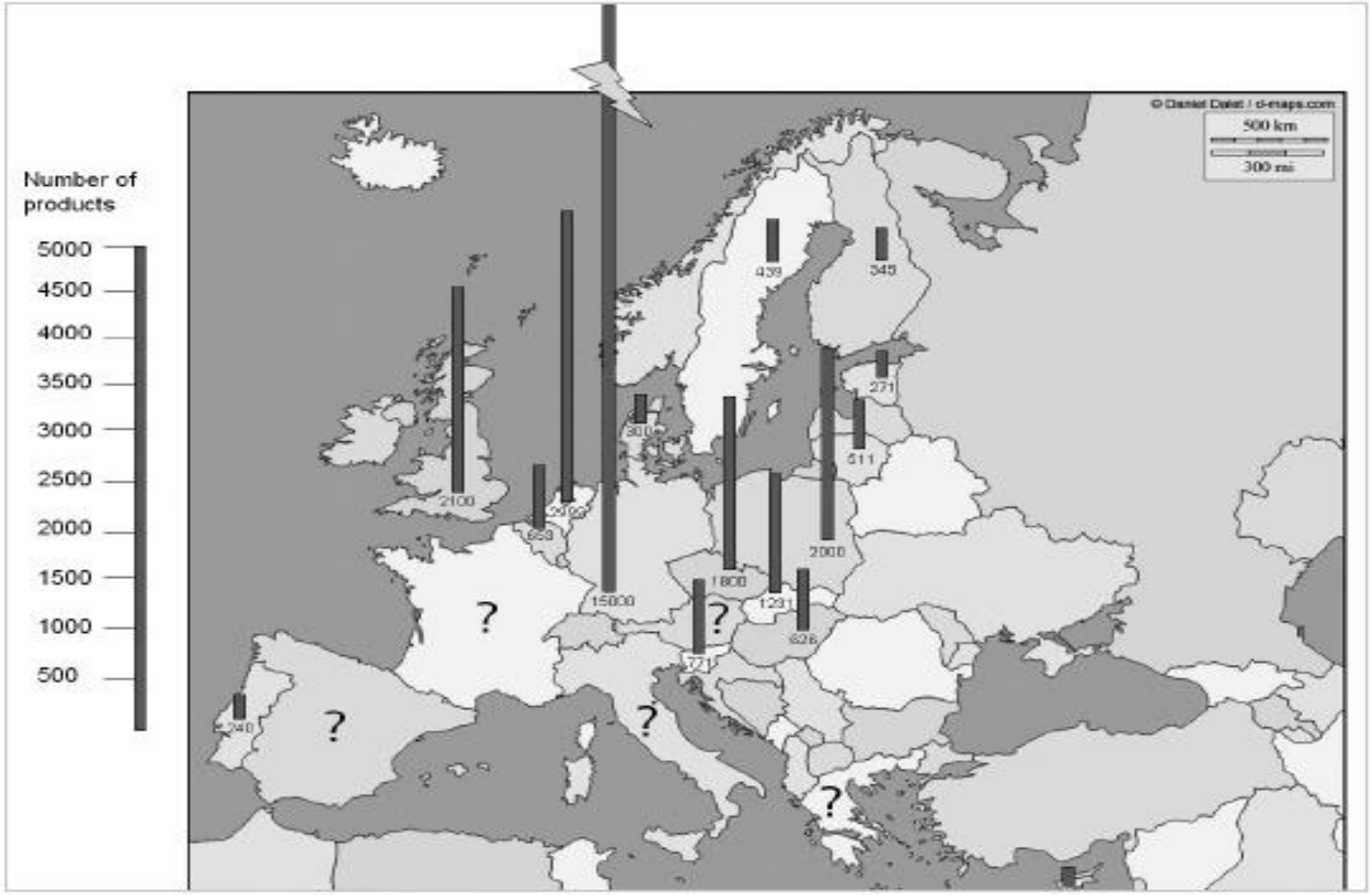
The Biocidal Products Directive 98/8/EC (BPD)

In order to achieve this, the BPD required a harmonised mechanism for the authorisation of biocides:

- Before a newly developed active substance be sold in the EU (e.g. in a biocidal product) it must be approved for inclusion into a Community list.
- In this framework the competent authorities evaluate the relevant ingredient based on a specific risk assessment scheme. Besides, requirements have been established so as to harmonise national product authorisation and inspection systems. To check old active substances which were already on sale before May 2000 a programme has been introduced which systematically registers and reviews those biocides (through a ten-year review programme).
- Subordinated regulations and guidelines have been adopted for clarifying and adapting this programme.
- Furthermore, the BPD introduced the substitution principle (the replacement of hazardous substances with less problematic ones), the promotion of low-risk substances (establishment of a positive list) and provisions for reducing animal testing and tackling poisonings.
- In addition, the requirements for accurate advertising and labelling biocidal products can be regarded as a further positive outcome as well as the binding establishing and publishing of implementation report

(Figure 3) Number of biocidal products authorised in the EU member states

Data source: European Commission 2006[45], Design: Sarah Kullmann



The Directive and the Regulation

- The Biocidal Products Directive was repealed and replaced by the Biocidal Products Regulation (BPR) which has applied since 01 September 2013.
- The move to the BPR has resulted in major changes to the biocide market within Europe, introducing, for example, new administrative processes, exclusion and substitution criteria for active substances and the regulation of articles treated with biocidal products.
- A Directive needs time and mode of implementation, a regulation apply same way same time to all member states in EU

Timelines

- The BPR does, however, retain the two stage evaluation process originally introduced by the BPD. The first phase of the evaluation involves the hazard and risk assessment of active substances with the intention of declaring EU wide approval of substances for their specified use(s).
- The assessment of all active substances notified into the process was originally expected to be completed over a 10 year period finishing in 2010.
- However, the scale and complexity of the process required an extension, initially to 2014, but subsequently to the end of 2024, in part to recognise the additional impact of the BPR on the process timing.

Transitional period

- It is important to note that, while active substances remain under evaluation, the existing national rules for regulating biocidal products remain in force in each Member State with only certain aspects of the BPR having effect.
- The second phase of the evaluation requires biocidal products containing EU approved active substances to be authorised in Member States where those products are placed on the market.
- Application for authorisation must be submitted for all existing biocidal products by the official Approval date for the active substance which is set in the substance Approval Regulation.
- For products that are based on more than one active substance, it is the Approval date for the last active substance in the product to be approved that triggers the deadline for the application for authorisation.

Suppliers

- Biocidal products on the EU market should only contain approved active substances, or active substances being supported for approval through the EU review process.
- It is also a requirement of the BPR that, after 01 September 2015, only biocidal products consisting of, containing, or generating a relevant substance, can be made available on the EU market if the substance supplier or product supplier is included in the approved supplier list (Article 95 list) for the product type to which the product belongs.
- This list is regularly updated by the European Chemical Agency (ECHA) and is publicly available on the ECHA website.

Product categories

- We are now at the stage where many of the active substances that are used in consumer products are completing their evaluation and obtaining EU approval.
- This is triggering the process for authorising commonly used products such as antibacterial trigger sprays, household disinfectants, household insecticides and bleach based toilet care products but also rodenticides.
- Also many of the preservatives used in household products are now being approved and since the BPR regulates treated articles, only articles treated with biocidal products containing approved preservatives (or those remaining under evaluation) can be placed on the EU market and specific labelling requirements introduced by the BPR must be followed.

EU Regulation for biocidal products

The Biocidal Products Regulation (EU) 528/2012 came into force on 1 September 2013, replacing the Biocidal Directive (98/8/EC).

The Biocidal Products Regulation (EU) 528/2012 (BPR) applies directly to all Member States of the European Union.

However the Regulation does provides room for Member States to take into account the specific situation in their own country.

- It is important to keep a number of important dates in mind which have been set down in the Biocidal Products Regulation

Deadlines

1 January 2017

- From this date, Union authorisations can be requested for biocidal products with uses within Product Types 2, 6 and 13.

1 September 2017

- Article 93 Biocidal Products Regulation (EU) 528/2012: from this date, biocidal products not covered by the scope of Directive 98/8, but that fall within the scope of the Biocidal Products Regulation, can no longer be placed on the market if no application for authorisation has been submitted before 1 September 2016.

1 January 2020

- From this date, Union authorisations can be requested for biocidal products with uses within Product Types 7, 8, 9, 10, 11, 12, 16 and 22.

Amendments to Biocidal Products Regulation (EU) 528/2012

- On 11 March 2014, Regulation 334/2014 was officially published. This includes the amendments to Biocidal Products Regulation (EU) 528/2012. The amendments are primarily clarifications, but a number of amendments are more substantive.
- The Biocidal Products Regulation results in some major changes.

These are changes that affect multiple parties: not only companies that are responsible for placing biocidal products on the market, but also companies that trade in articles treated with biocides (treated articles),CAs (enforcement), as well as the activity of the European Chemical Agency (ECHA) in Helsinki.

Amendments to Biocidal Products Regulation (EU) 528/2012

- A temptative of harmonisation of fees and charges at the EU level:
- Under the Regulation, applications for a derived authorisation will require a Letter of Access to the complete dossier of the original authorisation. After the derived authorisation is issued, there will no longer be a link with the original authorisation, and the derived authorisation can be amended as desired;
- As part of the authorisation process, it will become possible to request multiple product names under a single authorisation number;
- Important role for ECHA in Helsinki as organiser and quality guardian of European authorisations and assessments;
- More important role for the R4BP (EU database for biocidal product applications and authorisations).

Amendments to Biocidal Products Regulation (EU) 528/2012

- Possibility for applying for a European authorisation for biocidal products instead of national authorisations. Beginning on 1 September 2013, EU authorisations can be requested for biocidal products with uses within Product Types 1, 3, 4, 5, 18 and 19. For the other PTs (with the exception of PTs 14, 15, 17, 20 and 21), this possibility will follow several years later;
- Simplified European authorisation for biocidal products based on active substances included in Appendix I of the Regulation;
- Specification of the assessment and authorisation of systems that generate active substances in situ;
- Clarity concerning the actual biocidal product that requires authorisation in these cases;
- Improved specification of the frame formulation concept in product families;
- A scheme for treated articles (articles that have been treated with biocides, such as socks impregnated with silver, products containing preservatives and toilet seats with antimicrobial characteristics). These articles are allowed to contain only active substances that have been included in the work programme of Directive 98/8/EC or have been included in Annex I for the specified use of the treated article.

In addition, treated articles with a primary biocidal claim will be assessed as a biocidal product.

- The PT23 has become the new PT20; in addition, changes will be made to the details of other PT groups.

Amendments to Biocidal Products Regulation (EU) 528/2012

Biocidal product families

- Amendments to the biocidal product families involve changes to Article 3 (1) (s) and Article 19 (6).
- The definition of a biocidal product family has been clarified and simplified.
- In addition, the assessment method for a biocidal product family is described more clearly.

Amendments to Biocidal Products Regulation (EU) 528/2012

Amendment of Article 89 (transitional law / National law of the Member States)

Article 89 concerns transitional measures. Among other provisions, the Article states that a Member State is permitted to apply its national legislation to biocidal products that contain only active substances which have been, or are being, evaluated in the work programme for existing active substances (review programme) for the corresponding Product Types.

A new provision is that a Member State may now apply its national legislation to biocidal products that are a combination of approved active substances and existing active substances that have not yet been approved but which are included in the review programme for the relevant PT.

Additionally, the term for renewal (re-registration), which is specified in Article 89, has been extended: re-registration of biocidal products based on this active substance must be completed within 3 years.

This extension takes account of the time-consuming steps in the process of re-registration, especially when Member States disagree about the mutual recognition and the decision is referred to the Commission.

Amendments to Biocidal Products Regulation (EU) 528/2012

- **Amendment of Article 93 (transitional measures for biocidal products that are not subject to the Biocidal Products Directive)**
- Article 93 concerns transitional measures for biocidal products that did not fall within the scope of Directive 98/8/EC. Article 93 has been clarified and now contains the following provisions: Member States are permitted to apply their national regime to biocidal products that did not fall within the scope of Directive 98/8 and for which the active substance was marketed or used in biocidal products on 1 September 2013;
- This applies up to 3 years after approval of the last active substance or up to 12 months after non-approval, provided that the request for approval of all active substances for the relevant Product Type is submitted no later than 1 September 2016.
- If a request for approval has not been submitted before this date, such biocidal products may be marketed or used only until 1 September 2017.

Amendments to Biocidal Products Regulation (EU) 528/2012

Amendment of Article 94 (treated articles)

Article 94 concerns transitional measures for treated articles.
A new provision is that Article 94 not only applies to treated articles that were placed on the market before 1 September 2013, but also to new treated articles.

Article 94 also specifies more clearly which active substance/Product Type combinations are permitted for treating the articles (active substances included in the work programme as of 1 September 2016, new active substances for which approval is requested no later than 1 September 2016, active substances that have been included in Annex I, or each combination thereof).

If a decision is made after 1 September 2016 to not approve the active substances (for the corresponding use in a treated article), the treated article can be still being marketed for 180 days following this decision.

The amended Article 94 also specifies a deadline for treated articles that contain active substances for which no application for approval is submitted before 1 September 2016: these articles can be on the market no later than 1 March 2017.

Amendments to Biocidal Products Regulation (EU) 528/2012

Amendment Article 95 (anti-free-riders provision)

- Article 95 concerns transitional measures about access to the substance dossiers. Article 95 has been amended and can be summarised as follows:
  the Agency maintains a list with all active substances and precursors for which a complete substance dossier has been submitted. The amended article clearly states that this concerns a dossier which has been submitted under the provisions of the Biocidal Products Directive;
- this list includes the names of all persons who have submitted a substance dossier for a specific substance/Product Type combination. A new aspect is that the list now includes persons who have access to these dossiers (by means of a Letter of Access). In addition, the right to refer to data has been expanded to include all studies that are required (all toxicological and eco-toxicological studies, as well as studies about the environmental fate and behaviour, including studies for which no tests on vertebrates are involved);
- a person who is included on the list must reside in the EU and produce or import the active substance (substance supplier) or produce or market a biocidal product containing that active substance (product supplier);
- from 1 September 2015, a biocidal product with an active substance appearing on the list can only be marketed by persons who are also on the list.

Companies that sell active substances or biocidal products on the common market

From 1 September 2015, a biocidal product can be sold on the EU market only if the manufacturer or supplier of the relevant substance in the biocidal product, or the manufacturer or supplier of the biocidal product for the applicable product type, is included on the Article 95 list of the Biocidal Products Regulation.

Check whether the manufacturer or supplier of your biocidal product or of the relevant substance in your biocidal product is included on this list

Article 95 list

ECHA compiles and updates the Article 95 list that contains three aspects:

1. the active substances ('relevant substances'), which can be traded as active substance or as part of a biocidal product only by

2. the EU-based suppliers on the list for

3. the listed product types. The list includes only suppliers (or their representatives within the EU) who demonstrably possess or have access to a complete EU substance dossier or equivalent.

The aim of this scheme is to counter 'free riding' and thereby to promote fair competition.

As a result, after 1 September 2015 it will no longer be possible to sell a biocidal product without having invested in a substance dossier.

Inclusion in the Article 95 list is an extra requirement, which applies in addition to the regular authorisation requirements.

You can download the Article 95 list on the ECHA website.

Additional information about the procedure for being included on the Article 95 is available on ECHA website

Obligations for authorisation holders

From 1 September 2015, a biocidal product can be placed on the market only if – in the chain from producer to substance applicant - at least one party is included on the Article 95 list. From 1 September 2015, each authorisation holder must demonstrate compliance with Article 95 for all biocidal products for which he or she holds the authorisation;

This must be done at the following times:

- During an inspection by/at the request of the Inspectorate
- During an application for authorisation, re-registration of the authorisation, renewal of the authorisation, applications for major changes of the authorisation and when changing the supplier of the active substance.
- The proof of compliance with Article 95 should be kept in the applicant's authorisation dossier. From 1 September 2015, if compliance with Article 95 cannot be demonstrated in an application, then this application will not be processed

Demonstrating compliance with Article 95

- The authorisation holder must provide that has complied with Article 95.
- This can be done with a written and signed statement.
- The European commission has developed a format for such a statement.
- This format can be used to demonstrate compliance with Article 95 for a specific biocidal product.
- More information on compliance with and enforcement of article 95 can be found in the document issued by the European Commission at the Competent Authority Meeting of May 2015..

Relevant substances

- Relevant substances are all active substances for which an EU substance dossier has been submitted.
- These substances are on the Article 95 list.
- A derogation applies to products and active substances that did not fall under the authorisation requirement of Directive 98/8 (the Biocidal Products Directive), but are now subject to the Biocidal Products Regulation. This derogation is described in Article 93 of the Regulation.
- For active substances and biocidal products that fall under Article 93 of the Regulation, a substance dossier does not have submitted immediately. Such dossiers have been given derogation until 1 September 2016.
- Therefore, the requirement for inclusion of these substances and products on the Article 95 list has also been postponed until that date.
- For substances that have been included in Annex I in categories 1-5 or 7 of Biocidal Products Regulation 528/2012, inclusion on the Article 95 list is not required.
- This concerns substances that have been acknowledged as low-risk substances EU-wide.

Request for inclusion on the Article 95 list

- Parties who have submitted substance dossiers for the review programme are obligated to cooperate with the inclusion of substance or product suppliers on the article 95 list by providing a Letter of Access (LoA) to all toxicological, ecotoxicological, fate and behaviour studies;
- A reasonable fee can be charged for providing this access.
- The contact details of these parties can be requested from ECHA.
- If the negotiations between suppliers and customers about a LoA fail, then ECHA sets the fee.
- The ECHA website has a suggested templates suggested template for submitting an Article 95 notification

Status active substances

- The active substances in your product have all been included on the list of approved active substances of the Biocidal Products Regulation for the correct product type: in that case, applications must comply with the requirements of the Biocidal Products Regulation.

1)The active substances have been included on the list of approved active substances, but not for the correct product type (PT).

- Example: if the active substance has been included for use as a wood preservative (PT8) and you want to obtain an authorisation for an anti-fouling agent (PT21) with the same active substance, then the Regulation does not yet apply. Transitional legislation applies until the active substance has been included on the list of approved active substances for PT21.

Status active substances (cont'ed)

- The active substances in your product have not all been included on the list of approved active substances of the Biocidal Products Regulation:

1a) the active substance has been included in the European review programme, but the assessment of the substance has not yet been completed.

In this case, transitional legislation applies and you must follow the procedure

1b) the active substance has not been included in the European review programme. You cannot submit an application for authorisation of this product directly. First, you must submit a dossier for the active substance.

The active substance(s) are included on Annex I of the Biocidal Products Regulation (note that Annex I of the Regulation contains a list of low-risk active substances and must therefore not be confused with Annex I of the Directive).

In that case, after 1 September 2013 you can submit an application for a simplified authorisation.

EU has repealed guidance provided in the MoD

- However as the EU Biocides Regulation (EU BPR) has repealed and replaced the BPD, the guidance provided in the MoD is now obsolete as of 1 October 2015.
- If you have relied on the guidance previously provided by the MoD to conclude that your product(s) were out of the scope of the biocides legislation, but your product might now be within the scope of the EU BPR, there is an opportunity to support the relevant active substance/product type combination.
- The EU Commission has specifically identified the issue of products that only work by indirect means on the target organism.
- Due to a decision by the European Court of Justice such products may now be within the scope of the EU BPR and therefore the active substances will need to be supported.
- Additional information on the declaration, notification, submission processes can be found on the European Chemicals Agency website. Please note the deadline for the first step in the process to support the relevant active substance/product type combination is 1 October 2016.

  If you are unsure if your product now falls within the scope of the EU BPR please contact the National helpdesk or the ECHA helpdesk

Authorization procedures

- Since 1 September 2013, an application for authorisation of a biocidal product containing approved active substances or renewal of an authorisation under the Biocidal Products Regulation (EU) 528/2012 should be submitted through the information system provided by the European Chemicals Agency(ECHA).

  The application itself must be submitted via R4BP, but the dossier is created in IUCLID format.
- ECHA is responsible for the development of these systems, and has also prepared instructions for their use.
- To obtain an authorisation or extension of an authorisation for a biocidal product, you can choose from several types of applications.

An application for a national authorisation and the associated mutual recognition (WE)

Applications for mutual recognition of a national authorisation are submitted in accordance with the procedures 'sequential mutual recognition' or 'parallel mutual recognition'.

The authorisation process for biocidal products takes place accordingly and without prejudice in all Member States receiving applications for mutual recognition of a national authorisation of a biocidal product, under the same conditions.

Sequential mutual recognition

The Member State in which the application is first submitted (the evaluating Member State) conducts the primary assessment and provides a Product Assessment Report.

Based on the authorisation and the underlying assessment, you can then request mutual recognition in other Member States.

This short procedure (120 days) is called the ‘sequential mutual recognition’.

Requirements for an application for mutual recognition in sequence

- Applicants always need to submit their application via R4BP, the datasystem of ECHA including:

- The authorisation certificate of the evaluating MSCA;
- The Product Assessment Report by the evaluating MSCA;
- The summary of the product characteristics (SPC) in English;
- The composition of the product;
- The summary dossier (Doc I-III) for the product, as submitted to the evaluating MSCA, should be available in the IUCLID system for biocidal products. This should include SDS's of the biocidal product, the active substance(s) and the formulants (not older than 5 years, either in national language or English).

Furthermore:

- A covering letter confirming your application for mutual recognition of authorisation of the product, in which it is stated whether the application is similar to the authorised uses in the evaluating MSCA or whether there are differences, e.g. with respect to the category of users, the field of use, the target organisms, the packaging etc.
- You can upload this document in R4BP;
- A draft SPC
- Fee for mutual recognition according to the National fee system
- An invoice will be uploaded in R4BP.

Parallel mutual recognition

- It is also possible to submit applications for primary assessment and mutual recognition simultaneously.
- When submitting the application in the evaluating Member State, you indicate the countries in which you want to request mutual recognition.
- The evaluating Member State will then consult with these other Member States about the assessment and the conditions for authorisation.
- With this 'parallel mutual recognition', the authorisation goes into effect simultaneously in all Member States concerned

Requirements for an application for mutual recognition in parallel

Applicants always need to submit their application via R4BP, the datasystem of ECHA containing:

- The Product Assessment Report by the evaluation MSCA;
- The draft summary of the product characteristics (SPC) in English;
- The composition of the product;
- The summary dossier (Doc I-III) for the product, as submitted to the evaluating MSCA, should be available in the IUCLID system for biocidal products. This should Include SDS's of the biocidal product, the active substance(s) and the formulants (not older than 5 years).

Once the evaluating MSCA has finalised their assessment they will upload a draft SPC in R4BP. This SPC will be evaluated by CAs.

Furthermore:

- A letter confirming your application for mutual recognition of authorisation of the product, in which it is stated whether the application is similar to the authorised uses in the evaluating MSCA or whether there are differences, e.g. with respect to the category of users, the field of use, the target organisms, the packaging etc.

You can upload this document in R4BP;

- Fee for mutual recognition according to the National fee system.
- An invoice will be uploaded in R4BP.

Application for a Union authorisation

- If all active substances in your biocidal product are approved for the product types relevant for that product, and you wish to place your biocidal product on the market in the entire European Union, it is now possible to apply for authorisation at Union level.
- For biocidal products, this type of application is initially possible only for Product Types 1, 3, 4, 5, 18 and 19, provided that the circumstances and method of use are the same in all European Member States.

  Applications for Union authorisation are submitted to ECHA; the applicant shall thereby that confirm that similar conditions of use for the biocidal product exist in the entire Union, state the name of the competent authority of the Member State which he or she proposes should assess the application and provide written confirmation that this competent authority has agreed to assess the application.
- That competent authority then becomes the evaluating competent authority. Based on the Product Assessment Report of the evaluating Member State, ECHA submits an opinion to the European Commission.

  Following an authorisation decision of the Commission, the product can be placed on the market in all Member States. Member States can make requests to modify certain conditions in the authorisation that are specific to their country.

Simplified authorization

- The simplified authorization is possible only for biocidal products that are based on low-risk substances included in Annex I of the new Biocidal Products Regulation (the 'new Annex I').

  * Please note: Annex I of the Regulation is not the same as Annex I of the Directive. Substances from Annex I of the Directive are now included in the Union list of approved active substances.

  See for more information the practical guide on biocidal products regulation from ECHA

Simplified authorization (cont'ed)

To qualify for a simplified authorization, biocidal products must comply with the following conditions:

a) all active substances in the biocidal products are listed in Annex I and comply with any restrictions specified in that Annex;

b) the biocidal product does not contain any substance of concern;

c) the biocidal product does not contain any nanomaterials;

d) the biocidal product is sufficiently effective;

e) personal protective equipment is not required for handling the product and using it as intended

Additional substances in the new Annex I of the Biocidal Products Regulation

- Upon entry into force of the Biocidal Products Regulation, 19 low-risk substances were included in the new Annex I.
- Additional substances will be eligible for inclusion in the new Annex I. These must not be substances of concern.

  European Commission will publish a guidance document that provides more information about the procedure for including a substance in the new Annex I and about the dossier requirements, on the basis of which it can be demonstrated that a substance is not of concern.

The Summary of Product Characteristics (SPC)

- The Summary of Product Characteristics (SPC) is a standard component of an authorisation decision for applications submitted under the Regulation.
- The Summary of Product Characteristics (SPC) is an integral part of an authorisation decision for applications subject to Biocidal Products Regulation (EU) 528/2012.
- The Biocidal Products Regulation applies to biocidal products that are based on approved substances.

  For authorisations issued under the Regulation, it has been concluded that the SPC is sufficient and that it is no longer desirable to adopt legal conditions for use/instructions.

This means that for biocidal products that are authorised under the Regulation, a SPC will be adopted in which the authorised use is described.

SPC

Authorisation holders must ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of product characteristics of the biocidal product.

The standard EU template contains the following components:

- Administrative information
- Product composition
- Authorised uses
- Classification and labelling
- Directions for use

SPC

- The SPC does not contain any confidential information. With respect to the composition of the product, only the active substance and the part of the formula (quantitative/qualitative data on excipients) that is needed for correct use are included in the SPC.
- When submitting an application under the Regulation, the applicant includes a proposal for a draft SPC (in the language/languages required by the Member State).
- Submission takes place with the aid of R4BP, the IUCLID Report Generator, which helps applicants to prepare the SPC.
- If SPC is not correct or not complete, it will be modified accordingly in consultation with the applicant. It is therefore crucial that the SPC is properly filled in by the applicant.

Different situations

- A single authorisation with multiple product names:

under the Regulation, it is possible to request multiple product names with a single authorisation.

In that case, there will be only a single SPC that includes all product names.

- An authorisation according to 'the same biocidal product' procedure:

if 'the same biocidal product' procedure is used to acquire an authorisation under the Biocidal Products Regulation, then the newly authorised product will be given its own SPC.

- Biocidal product family:

if a number of similar types of biocidal products are authorised as part of a biocidal product family, then each product within this family will be given its own SPC.

- The SPCs will be made public by ECHA in the Register for Biocidal Products (R4BP).

Digital access

- Based on the provisions in Biocidal Products Regulation (EU) 528/2012, information can be disclosed publicly only after an active substance has been approved or an authorisation is issued.
- ECHA provides digital access to all non-confidential information. Regarding applications for authorisation of biocidal products under transitional legislation, the previous arrangement remains in force: in Italy, data must be submitted directly to the MoH, both digitally (Certified email) and/or paper

Public disclosure of information through digital access under the Regulation

- Information that is part of an application for approval of an active substance or authorisation of a biocidal product based on included (approved) substances must be submitted digitally to ECHA from that time forward.
- Based on the provisions in Biocidal Products Regulation (EU) 528/2012, information can be disclosed publicly only after an active substance has been approved or an authorisation is issued.
- ECHA provides digital access to all information that is not confidential (this information is specified below).

Role of ECHA

ECHA is the agency for the implementation of REACH and CLP, and recently for the implementation of Biocidal Products Regulation (EU) 528/2012

ECHA is responsible for the implementation of the Biocidal Products Regulation (EU) 528/2012.

It has previous experience with the implementation of schemes such as REACH.

For the implementation of the Regulation, ECHA can rely on its experience with providing digital access in REACH.

In both REACH and the Biocidal Products Regulation, the basic premise is:
transparency and public disclosure, unless confidentiality is required. A fair balance between these conflicting interests is sought

Biocidal Products Committee (BPC) adopts opinions

- 50 opinions per year should be issued by BPC

Role of ECHA

The Biocidal Products Regulation (EU) 528/2012 provides that the European Chemicals Agency (ECHA) should carry out specified tasks with regard to the evaluation of active substances as well as the Union authorisation of certain categories of biocidal products and related tasks.

It also provides that Biocidal Products Committee is established within the Agency to carry out certain tasks conferred on the Agency by this Regulation (approval of opinions on active substances) Consequently, this is major change in the mode of operation under Directive 98/8.

Many tasks implemented by the Commission under the Directive will now be delegated to the Agency under the provisions in the Regulation.

In addition, a number of tasks will be coordinated by the Agency which were previously implemented by the Member States under the Directive.

Tasks assigned to the Agency

- ECHA is responsible for the coordination and facilitation of new applications for approval (also renewal and review) of active substances. Applications are submitted to ECHA, but the evaluation is performed by one of the Member States (Member State Competent Authority). In addition, ECHA (through the Committee for Biocidal Products) advises the Commission regarding the approval (including renewal and review) of active substances;
- Advises the Commission (through the Committee for Biocidal Products) about which active substances are candidates for substitution;
- Applications for a simplified authorisation are submitted to ECHA, the assessment and authorisation is performed by one of the Member States (Member State Competent Authority);
- Biocidal products are eligible for the simplified authorisation procedure if the active substances in these biocidal products are included in Annex I (list of substances that are not of concern) of the Regulation;
- Advises the Commission (through the Committee for Biocidal Products) on the inclusion of active substances in Annex I (list of substances that are not of concern);

Tasks assigned to the Agency

- Applications for a Union authorisation (including renewal, withdrawal and amendment of an authorisation) are submitted to ECHA; the assessment is performed by one of the Member States (Member State Competent Authority); Furthermore, ECHA advises the Commission (through the Committee for Biocidal Products) on the authorisation of these applications;
- Advises the Commission (through the Committee for Biocidal Products) on technical or scientific issues;
- ECHA is the office of the Coordination Group (a body formed by representatives of the Member States and the Commission to discuss, among other things, objections concerning the handling of mutual recognition requests);
- Technical Equivalence Assessment of active substances;
- ECHA coordinates access to previously submitted animal studies;
- ECHA provides electronic public access to information (as specified in the Regulation) as soon as a substance is approved or a biocidal product is authorised;
- ECHA is responsible for the Register for Biocidal Products (R4BP). ECHA monitors whether applicants have submitted applications in the correct format;
- R4BP is already being used under the Directive, but further development is in full swing to make the system suitable for the Regulation. Moreover, it is now clear that the applications and dossiers must be submitted in IUCLID format;
- Preparing a list of manufacturers and importers of active substances. This concerns the owners of the active substance dossiers as well as alternative suppliers

Tasks assigned to the Agency

- ECHA will charge the applicant for its services directly. Furthermore, ECHA will charge an annual fee for products that are authorised by means of a Union authorisation. The rates have not yet been finalised. These rates will soon be established in a separate Regulation (the ECHA Fee Regulation).

  ECHA also plays an important role in the development of various forms, procedures and guidance documents regarding the Regulation. Refer to ECHA's website for more information about Biocidal Products Regulation (EU) 528/2012 and the role of ECHA. Also see the ECHA leaflet.

- If you are unsure if your product now falls within the scope of the EU BPR please contact the National helpdesk or the ECHA helpdesk

ECHA encourages companies to apply now to stay on the market

- From 1 September 2015, biocidal products consisting of, containing, or generating a relevant substance cannot be made available on the market unless either the substance supplier or the product supplier is included in the Article 95 list for the relevant product-type(s).
- ECHA reminds applicants not to underestimate the preparation time needed for Article 95 applications, and to allow sufficient time to provide additional data should the draft decision be negative.

http://echa.europa.eu/biocides-2015

ECHA updates on the Registry for Biocidal Products (R4BP)

- ECHA and Member State competent authorities plan to correct and complete information in R4BP regarding product authorisations that have expired in error.
- A new version of the software is also available, which allows product authorisation change requests to be made in parallel, and enhances synchronisation between related applications.

- Member States and ECHA to update information on biocidal product authorisations. ECHA/NA/15/11. http://echa.europa.eu/view-article/-/journal_content/title/member-states-and-echa-to-update-information-on-biocidal-product-authorisations
- New version of the Registry for Biocidal Products (R4BP 3) available. ECHA/NI/15/13. http://echa.europa.eu/view-article/-/journal_content/title/new-version-of-the-registry-for-biocidal-products-r4bp-3-available

ECHA redefines biocidal active substances generated *in situ*

- Active substances generated *in situ* have been redefined so that their precursors are specified. Companies are invited to notify ECHA within one year if they wish to have their precursor-active substance system included in ECHA's review programme.
- European Chemicals Agency (2015). *In situ* generated biocidal active substances redefined. ECHA/NA/15/13. http://echa.europa.eu/view-article/-/journal_content/title/in-situ-generated-biocidal-active-substances-redefined

Commission published its Report on the Sustainable use of Biocides

- **March 17, 2016**

The report published today concludes that processes laid down in the Regulation, such as the active substance approval, product authorisation, or the comparative assessment of biocidal products which aims the phasing-out of dangerous substances where less hazardous alternatives are available, are important contributions to the objective of fostering the sustainable use of biocidal products. The report also concludes that the completion of this on-going assessment of all active substances and the authorisation of biocidal products containing these active substances shall be the main priority in view of promoting the sustainable use of biocidal products.

The report also highlight best practices for the use of biocidal products can also be achieved through the development of appropriate guidance and standards.

Thanks for your attention!

maristella.rubbiani@iss.it