Wichtige Änderungen durch die EU-Biozid-Produkte-Verordnung

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Chapter I (Scope and Definitions)

- Article 1
  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, animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

Chapter I

This Regulation lays down rules for:
(a) the establishment at Union level of a list of active substances which may be used in biocidal products;
(b) the authorisation of biocidal products;
(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;
(e) the placing on the market of treated articles.

Chapter I

- Article 2
  This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

  Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments: …
  … (a) to (j): list updated

Chapter I

- Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.
- Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the following instruments: … … (a) to (q): list updated……

Chapter I

- This Regulation shall not apply to:

(a) food or feed used as repellents or attractants;

(b) biocidal products when used as processing aids.

Chapter I

- Definitions
  For the purposes of this Regulation, the following definitions shall apply:
  (a) "biocidal product" means any substance, mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Chapter I

- “biocidal product” means any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;
  A treated article that has a primary biocidal function shall be considered a biocidal product.

Chapter I

- (i) "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;
  (j) "placing on the market" means the first making available on the market of a biocidal product or of a treated article;
  (l) "treated article" means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;
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Chapter I

- (m) "national authorisation" means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;
  (n) "Union authorisation" means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;
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Chapter I

- (r) "single biocidal product" means a biocidal product with no intended variations as to the percentage of the active or non-active substances it contains;
  (s) "biocidal product family" means a group of biocidal products having similar uses, the active substances of which have the same specifications, and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products;
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Chapter I

- (x) "Agency" means the European Chemicals Agency established by Regulation (EC) No 1907/2006;
  (w) "technical equivalence" means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;
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Chapter I

- (z) "nanomaterial" means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

  Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials…..

Chapter I

- For the purposes of the definition of nanomaterial, "particle", "agglomerate" and "aggregate" are defined as follows:
  - "particle" means a minute piece of matter with defined physical boundaries;
  - "agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
  - "aggregate" means a particle comprising strongly bound or fused particles;

Chapter I

- (aa) "administrative change" means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

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Chapter I

- (ab) "minor change" means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;
  (ac) "major change" means an amendment of an existing authorisation which is neither an administrative change nor a minor change;
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Chapter I

- (ae) "small and medium-sized enterprises" or "SMEs" means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.
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- The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial , and whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Chapter I

- The Commission shall be empowered to adopt delegated acts in accordance with Article 83 in order to adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress and taking into account the Recommendation 2011/696/EU.

Chapter II (Approval of active substances)

Conditions for approval

- An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding 5 years.
- The approval of an active substance shall be restricted to those product-types for which relevant data have been submitted in accordance with Article 6.

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Chapter II

Exclusion criteria

- Subject to paragraph 2, the following active substances shall not be approved:
  (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;
  (b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;
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Chapter II

- (c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;
  (d) active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;
  (e) active substances which meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006.
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Chapter II

- Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:
  (a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;
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Chapter II

- (b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or
  (c) not approving the active substance would have a disproportionate negative impacts on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

  When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.
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Chapter II

- The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. The use of the biocidal product with the active substances concerned shall be restricted to Member States in which at least one of the conditions set out in this paragraph is met.

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Chapter II

Data requirements for an application

- An application for approval of an active substance shall contain at least the following elements:
  (a) a dossier for the active substance satisfying the requirements set out in Annex II;
  (b) a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and
  (c) if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

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Chapter II

- Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:
  (a) the data are not necessary owing to the exposure associated with the proposed uses;
  (b) it is not scientifically necessary to supply the data; or
  (c) it is not technically possible to generate the data.

Chapter II

- However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or 10(1), if required by the evaluating competent authority under Article 8(2).
- An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

Chapter II

Submission and validation of applications

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Evaluation of applications

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Approval of an active substance

- The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either:
  (a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or ...

Chapter II

- (b) in cases where the requirements of Article 4(1) or, where applicable, Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.

  Approved active substances shall be included in a Union list of authorised active substances. The Commission shall keep the list up to date and make it electronically available to the public.

Chapter II

Active substances which are candidates for substitution

- An active substance shall be considered a candidate for substitution if any of the following conditions are met:
  (a) it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);
  (b) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

Chapter II

(c) its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;

(d) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;

Chapter II

(e) there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;
(f) it contains a significant proportion of non-active isomers or impurities.

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Chapter II

- […], the approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.
- Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in the relevant Regulation adopted in accordance with Article 9.

Chapter IV (General Principles concerning the Authorisation of Biocidal Products)

Making available on the market and use of biocidal products

- Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.
- Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder. Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State ("the receiving competent authority"). Applications for Union authorisation shall be submitted to the Agency.

Chapter IV

- An authorisation for a biocidal product may be granted for a single biocidal product or a biocidal product family.
- An authorisation shall be granted for a maximum period of 10 years.
- Biocidal 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.

  Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.

Chapter IV

Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

- The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

Chapter IV

- The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products marketed under difference names by the same or different enterprises under the same terms and conditions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Chapter IV

Measures geared to the sustainable use of biocidal products

- By [1.9.2016] the Commission shall, on the basis of experience gained with the application of this Regulation, submit to the European Parliament and the Council a report on how this Regulation is contributing to the sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human health, animal health and the environment by biocidal products. That report shall, inter alia, examine:

Chapter IV

(a) the promotion of best practices as a means of reducing the use of biocidal products to a minimum;
(b) the most effective approaches for monitoring the use of biocidal products;
(c) the development and application of integrated pest management principles with respect to the use of biocidal products;

(d) the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater and whether additional measures are needed to address those risks; ……

(e) the role that improved performance of the equipment used for applying biocidal products could play in

Chapter IV

(e) the role that improved performance of the equipment used for applying biocidal products could play in sustainable use.

On basis of that report, the Commission shall, if appropriate, submit a proposal for adoption in accordance with the ordinary legislative procedure.

Chapter IV

Conditions for granting an authorisation

Requirements for applications for authorisation

Waiving of data requirements

Content of authorisation

Comparative assessment of Biocidal Products

Chapter V

Simplified Authorisation Procedure

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please see the next presentation given by Dr. Fassold

Chapter VI
National Authorisations of Biocidal Products

Chapter VII
Mutual Recognition Procedures

Chapter VIII
Union Authorisations of Biocidal Products

Chapter IX
Cancellation, Review and Amendment of Authorisations

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please see the next presentation given by Dr. Fassold

Chapter X (Parallel Trade)

- A competent authority of a Member State ("Member State of introduction") shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ("Member State of origin") to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ("the reference product").

Chapter X

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The application shall be accompanied by the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

Chapter X

- Where the competent authority of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 80(2). […]
- A biocidal product shall be considered as identical to the reference product only if all the following conditions are met:
  (a) they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process;

Chapter X

(b) they are identical in specification and content in respect of the active substances and the type of formulation;
(c) they are the same in respect of the non-active substances present; and
(d) they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.
[…]

Chapter X

- The parallel trade permit shall prescribe the same conditions for making available on the market and use as the authorisation of the reference product.

  The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.
  If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 49 and the requirements of Article 19 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired.

Chapter X

- The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

Chapter XI (Technical Equivalence)

Assessment of technical equivalence

- Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ("the applicant") shall submit an application to the Agency and pay the applicable fee in accordance with Article 80(1).
- The applicant shall submit all data that the Agency requires to assess technical equivalence.
- The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Chapter XI

- Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.
- Where appropriate, the Agency may consult the competent authority of the Member State which acted as the evaluating competent authority for the evaluation of the active substance.

Chapter XII (Derogations)

Derogation from the requirements

- By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

Chapter XII

- The competent authority referred to in the first subparagraph shall, without delay, inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall, without delay, inform the other competent authorities and the Commission of the revocation of such action.
  On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Chapter XII

- By way of derogation from point (a) of Article 18(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

  Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product may be expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

Chapter XII

- If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

  Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the requirements of Article 4(1) or, where applicable, Article 5(2). Competent authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

Chapter XII

- By way of derogation from point (a) of Article 19(1), the Commission may, by means of implementing acts, allow a Member State to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). A Member State wishing to obtain such a derogation shall apply to the Commission, providing due justification.

Chapter XII

Research and development

- By way of derogation from Article 17, an experiment or a test for the purposes of research or development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ("experiment" or "test") may take place only under the conditions laid down in this Article.

Chapter XII

Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.

Chapter XII

- Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the competent authorities.

Chapter XII

In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.

Chapter XII

- If the experiments or tests could have harmful effects, whether immediate or delayed, on human or animal health, in particular on vulnerable groups, or any unacceptable adverse effect on the environment, humans or animals, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. […]

Chapter XIII (Treated Articles)

Placing on the market of treated articles

- This Article shall apply exclusively to treated articles that are not biocidal products. It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

Chapter XIII

- A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.
- The person responsible for the placing on the market of such a treated article shall ensure that the label provides the information listed in the second subparagraph, where:
  - in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or

Chapter XIII

- in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.

The label referred to in the first subparagraph shall provide the following information:

(a) a statement that the treated article incorporates biocidal products;

(b) where substantiated, the biocidal property attributed to the treated article;

Chapter XIII

(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

(d) the name of all nanomaterials contained in the biocidal product(s), followed by the word "nano" in brackets;

(e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

Chapter XIII

(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.
This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.

- Notwithstanding the labelling requirements set out in paragraph 3, the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment.

Chapter XIII

- Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article.
- The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise. In the case of treated articles that are not produced as part of a series but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

Chapter XIV (Data Protection and Data-Sharing)

Protection of data held by competent authorities or the Agency

- Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:
  (a) the subsequent applicant has a letter of access; or
  (b) the relevant time limit for data protection has expired.

Chapter XIV

- When submitting data to a competent authority or to the Agency for the purposes of this Regulation the applicant shall, where relevant, indicate the name and contact details of the data owner for all data submitted. The applicant shall also specify whether it is the data owner or holds a letter of access.
- The applicant shall, without delay, inform the competent authority or the Agency about any changes to the ownership of the data.
  […]

Chapter XIV

Data protection periods

- Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.

  Data protected under Directive 98/8/EC or under this Article or for which the protection period expired under Directive 98/8/EC or under this Article shall not be protected again.

Chapter XIV

- The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.
- The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

Chapter XIV

The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end 5 years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

- The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).

Chapter XIV

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), 34(6) or 44(4).

The protection period for new data submitted with a view to the renewal or amendment of the authorisation of a biocidal product shall end 5 years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.

Chapter XIV

Letter of access

- A letter of access shall contain at least the following information:

  (a) the name and contact details of the data owner and the beneficiary;
  (b) the name of the active substance or biocidal product for which access to the data is authorised;
  (c) the date on which the letter of access takes effect;
  (d) a list of the submitted data to which the letter of access grants citation rights.

- Revocation of a letter of access shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

Chapter XIV

Data sharing

- In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation.
- Any person intending to perform tests or studies ("the prospective applicant")
  (a) shall, in the case of data involving tests on vertebrates, and
  (b) may, in the case of data not involving tests on vertebrates,

Chapter XIV

submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant.

Chapter XIV

The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner.

Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant:

(a) shall, in the case of data involving tests on vertebrates, and

(b) may, in the case of data not involving tests on vertebrates,

request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.

Chapter XIV

Compensation for data sharing

- Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.

Chapter XIV

- Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation.

Chapter XIV

- Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof, at the earliest one month after the prospective applicant receives the name and address of the data submitter from the Agency.
  Within 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred.

Chapter XIV

Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.
The data owner shall not refuse to accept any payment offered pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court, in accordance with the second subparagraph.

Chapter XIV

- Compensation for data sharing shall be determined in a fair, transparent and non discriminatory manner, having regard to the guidance established by the Agency . The prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of this Regulation.
- An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Chapter XV (Information and Communication)

Compliance with requirements

- Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products shall apply accordingly.

Chapter XV

- Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.
  In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

Chapter XV

(a) safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

(b) records of the various manufacturing operations performed;

(c) results of internal quality controls;

(d) identification of production batches.

Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3).

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and Member States.

Chapter XVII (Final Provisions)

Transitional measures

- The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 14 May 2014. To that end, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme.
  Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period.

Chapter XVII

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt either implementing regulations providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.

Chapter XVII

- By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until two years after the date of approval of the last of the active substances to be approved in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing existing active substances which have been or are being evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC , but which have not yet been approved for that product-type.

Chapter XVII

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to twelve months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1.

Chapter XVII

- Following a decision to approve a particular active substance for a specific product type Member States shall ensure that authorisations for biocidal products of that product type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years of the date of approval.

Chapter XVII

- Following a decision to approve a particular active substance for a specific product type Member States shall ensure that authorisations for biocidal products of that product type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years of the date of approval.

Chapter XVII

To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product type.

Chapter XVII

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

(a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and

(b) disposal and use of existing stocks of the biocidal product may continue until 365 days after the date of approval of the active substance(s).

Chapter XVII

- Where a Member State's competent authority rejects the application for authorisation of a biocidal product submitted under paragraph 3 or decides not to grant authorisation, that biocidal product shall no longer be made available on the market 180 days after the date of such rejection or decision. Disposal and use of existing stocks of such biocidal products may continue until 365 days after the date of such rejection or decision.

Chapter XVII

Transitional measures concerning active substances evaluated under Directive 98/8/EC

- The Agency shall be responsible for coordinating the process of evaluation of dossiers submitted after 1 September 2012 and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission.

Chapter XVII

- Applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No 1451/2007.
  That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC.
  Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Chapter XVII

Every effort shall be made to avoid additional testing on vertebrates and to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements.

Notwithstanding paragraph 1, the Agency shall also be responsible for coordinating the evaluation process of dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission from 1 January 2014.

Chapter XVII

Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC

- Applications for biocidal product authorisations submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with that Directive.
  Notwithstanding the first paragraph, the following shall apply:

Chapter XVII

- where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5(1) is met, the biocidal product shall be authorised in accordance with Article 19;
- where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Chapter XVII

Transitional measures concerning biocidal products authorised/registered under Directive 98/8/EC

- Biocidal products for which an authorisation or registration in accordance with Articles 3, 4, 15 or 17 of Directive 98/8/EC was granted before 1 September 2013 can continue to be made available on the market and used subject, where applicable, to any conditions of authorisation or registration stipulated under that Directive until the expiry date of the authorisation or registration or its cancellation.
- Notwithstanding paragraph 1, this Regulation shall apply to biocidal products referred to in that paragraph from 1 September 2013.

Chapter XVII

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

- Without prejudice to Article 89, applications for authorisation of biocidal products not covered by the scope of Directive 98/8/EC and falling within the scope of this Regulation and which were available on the market on 1 September 2013 shall be submitted at the latest by 1 September 2017.
- By way of derogation from Article 17(1), biocidal products referred to in paragraph 1 of this Article for which an application was submitted in accordance with paragraph 1 of this Article may continue to be made available on the market or used until the date of the decision granting the authorisation.

Chapter XVII

In the case of a decision refusing to grant the authorisation, the biocidal product shall no longer be made available on the market 180 days after such a decision.

By way of derogation from Article 17(1), biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article may continue to be made available on the market or used until 180 days after 1 September 2017.

Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the first subparagraph or twelve months after the date referred to in the second subparagraph, whichever is the later.

Chapter XVII

Transitional measures concerning treated articles

- By way of derogation from Article 58 and without prejudice to Article 89, treated articles that were available on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the application for the approval of the active substance(s) for the relevant product type is submitted at the latest by 1 September 2016.

Chapter XVII

- In the case of a decision not to approve an active substance for the relevant product type, treated articles which were treated with, or which incorporate, biocidal product(s) containing that active substance shall no longer be placed on the market 180 days after such a decision or as of 1 September 2016, whichever is the later, unless an application for the approval has been submitted in accordance with paragraph 1.

Chapter XVII

Transitional measures concerning access to the active substance dossier

- As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the "relevant person") shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

(a) a dossier complying with the requirements of Annex II or, where appropriate, with Annex IIA to Directive 98/8/EC; or

(b) a letter of access to a dossier as referred to under point (a); or

(c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

Chapter XVII

If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph.

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrates.

The relevant person to whom a letter of access to the a dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1).

Chapter XVII

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

- The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1) or have taken over the role of the participant.

Chapter XVII

- Without prejudice to Article 93, as of 1 September 2015, a biocidal product shall not be made available on the market if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product, is not included in the list referred to in paragraph 2. Without prejudice to Articles 52 and 89, disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until 1 September 2016.
- This Article shall not apply to active substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such active substances.

Annex IV (Biocidal product-types and their descriptions as reffered to in Article 2(1)

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.

- **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 purpose 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.

Annex IV

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.

Annex IV

- **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.

Annex IV

- **Product-type 5**: Drinking water

Products 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.

- **Product-type 6**: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.

Annex IV

- **Product-type 7**: Film preservatives

Products 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.

- **Product-type 8**: Wood preservatives

Products 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.

Annex IV

- **Product-type 9**: Fibre, leather, rubber and polymerised materials preservatives

Products 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.

- **Product-type 10**: Construction material preservatives

Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.

Annex IV

- **Product-type 11**: Preservatives for liquid-cooling and processing systems

Products 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.

- **Product-type 12**: Slimicides

Products 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.

Annex IV

- **Product-type 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

- **Product-type 14**: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

- **Product-type 15**: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Annex IV

- **Product-type 16**: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.

- **Product-type 17**: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

- **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.

Annex IV

- **Product-type 19**: Repellents and attractants

Products 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.

- **Product-type 20**: Control of other vertebrates

Products 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.

Annex IV

MAIN GROUP 4: Other biocidal products

- **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.

- **Product-type 22**: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.