Chemicals Act (Chemikaliengesetz, ChemG) - *Excerpts*

Long title: **Act on the Protection Against Hazardous Substances (Gesetz zum Schutz vor gefährlichen Stoffen)**

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Section One Purpose, Scope of Application and Definition of Terms

Article 1 Purpose of the Act

The purpose of this Act is to protect man and the environment from the harmful effects of dangerous substances and preparations, in particular to identify them, avert them and prevent their occurrence.

Article 2 Scope of Application

(1) The provisions contained in Sections Two and Three, Articles 16, 16a, 16b para. 1, sentence 1, subpara. 2, Articles 16e, 17, para. 1, subpara. 2, letters a and b and Article 23, para. 2 shall not apply to

1. tobacco products and cosmetic agents within the meaning of the Foodstuffs and Commodities Act (Lebensmittel- und Bedarfsgegenständegesetz),

2. pharmaceuticals which are subject to an approval or registration procedure in accordance with the Drugs Act (Arzneimittelgesetz) or in accordance with the Epizootic Diseases Act (Tierseuchengesetz), as well as other pharmaceuticals, insofar as under Article 21, para. 2 of the Drugs Act such pharmaceuticals do not necessitate approval or are delivered to the consumer in a specific packaging,

2a. medical products within the meaning of Article 3, subparas 1, 2, 6, 7 and 8 of the Medical Products Act (Medizinproduktegesetz),

3. wastes to be disposed of within the meaning of Article 3, para. 1, sentence 2, clause 2 of the Closed Substance Cycle Act (Kreislaufwirtschafts- und Abfallgesetz),

4. radioactive wastes within the meaning of the Atomic Energy Act (Atomgesetz),

5. waste water within the meaning of the Waste Water Charges Act (Abwasserabgabengesetz), insofar as such water is discharged into waters or waste water treatment plants.

(2) The provisions contained in Sections Two to Four, Article 17, para. 1, subpara. 2, letters a and b and Articles 23, para. 2 shall apply neither to foodstuffs within the meaning of the Foodstuffs and Commodities Act nor to animal feedstuffs and additives within the meaning of the Feedstuffs Act (Futtermittelgesetz). The provisions contained

in Section Three and Article 16b, para. 1, sentence 1, subpara. 1 and Article 16e shall, however, apply to

1. foodstuffs which are not intended for delivery to the consumer within the meaning of Article 6, para. 1 of the Foodstuffs and Commodities Act,

2. animal feedstuffs which, in a prepared, modified or processed state, are intended for feeding to animals, as well as to additives within the meaning of the Feedstuffs Act.

(3) The provisions contained in Section Two and Articles 16, 16a, 16c, 16d and 23, para. 2 shall not apply to substances and preparations

1. which are exclusively intended for use as an active substance in pharmaceuticals subject to approval or registrations under the Drugs Act or the Epizootic Diseases Act or as an active substance in medical products in accordance with Article 3, subpara. 2 and subpara. 7 in conjunction with subpara. 2 of the Medical Products Act, or

2. insofar as they are subject to an approval procedure that are solely designed to be placed on the market as active agents within the meaning Article 31d para.1 of the Plant Protection Act..

Article 17, para. 1, subparas 1 and 3 shall not apply to substances and preparations of the type specified in sentence 1, subpara. 2, insofar as appropriate regulations can be implemented on the basis of the Plant Protection Act.

(4) The provisions contained in Section Three and Articles 16c, 16d, 17 and 23 shall apply to the manufacture, putting into circulation or use of substances or preparations of the type specified in Article 3a, para. 1, subparas 2 to 5 and 15 as well as of such products which are capable of releasing or contain such substances and preparations insofar as this takes place on a commercial basis, within the scope of other economic activities or involves the services of employed persons. This restriction shall not apply to

1. regulations and orders

a) on the handling of commodities,

b) on waste disposal and clean air conservation, nor to

2. environmentally harmful substances and preparations if measures are taken to protect human health.

(5) The provisions contained in Sections One to Four, Articles 17 and 18 and the provisions contained in Sections Seven and Eight shall not apply to the transport of

dangerous goods by rail, road, inland waterway, sea and air, with the exception of transport within works premises.

Article 3 Definition of Terms

Within the meaning of this Act, the following terms shall apply:

1. Substances:
chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve stability and any impurity deriving from the process used, but excluding any solvent which may be separated from the substance without affecting its stability or changing its composition;

2. Existing substances:

substances listed in the European Inventory of Existing Commercial Substances (EINECS) (OJ EC subpara. C 146 A of 15 June 1990) in the most recent respective version published in the Official Journal of the European Communities;

3. New substances:

substances which are not deemed to be existing substances within the meaning of number 2;

3a. Polymer:

a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consisting of less than a simple weight majority of molecules of the same molecular weight if such molecules are distributed over a range of molecular weights, whereby differences in the molecular weights are primarily attributable to differences in the number of monomer units; in the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer;

4. Preparations:

mixtures, blends or solutions composed of two or more substances;

5. Products:

substances or preparations which, in the course of their manufacture, are given a specific structure, surface or shape which determines their function to a greater degree than their chemical composition as such or in composite form;

6. Classification:

the assignment of a hazardous property;

7. Manufacturer:

a natural or legal person, or an unincorporated association of persons that manufactures or extracts a substance, preparation or product;

8. Importer:

a natural or legal person, or an unincorporated association of persons that brings a substance, preparation or product into the area of validity of this Act; anyone involved in transit supervised by the customs authorities shall not be classified as an importer insofar as the substance or preparation concerned does not undergo any treatment or processing;

9. Placing on the market:

the issue to third parties or the placement at the disposal of third parties; introduction into the area of validity of this Act shall be deemed as being put into circulation insofar as this does not merely involve transit as specified in number 8, clause 2;

10. Use:

utilisation, consumption, storage, keeping, treatment and processing, filling into containers, transfer from one container to another, mixing, removal, destruction and internal works transport;

11. Scientific research and development:

scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

12. Process-oriented research and development:

the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance.

Article 3a Dangerous Substances and Dangerous Preparations

(1) Dangerous substances or dangerous preparations shall be understood to mean substances or preparations which are deemed to be

1. explosive,

2. oxidising,

3. extremely flammable,

4. highly flammable,

5. flammable,

6. very toxic,

7. toxic,

8. harmful to health,

9. corrosive,

10. irritant,

11. sensitising,

12. carcinogenic,

13. toxic for reproduction,

14. mutagenic or

15. a hazard to the environment,

excluding the hazardous properties of ionising rays.

(2) Substances or preparations shall be deemed as being detrimental to the environment if they or their transformation products are capable of changing the natural balance of water, soil or air, climate, animals, plants or micro-organisms in such a way that immediate or delayed hazards to the environment may be caused.

...

Section Two Notification of New Substances

Article 4 Compulsory Notification

(1) Any manufacturer shall only be permitted to put a new substance as such or in the form of a constituent part of a preparation into circulation on a commercial basis or within the scope of any other economic activity in the Member States of the European Community and the other Contracting Parties to the Treaty on the European Economic Area if such is notified to the notification authority. Notification shall not be required if the manufacturer is already engaged in the production of the said substance in another Member State of the European Communities or a Contracting Party to the Treaty on the

European Economic Area and has notified it to the competent authority within that country on the basis of an equivalent procedure.

(2) Any importer shall only be permitted to bring a new substance as such or in the form of a constituent part of a preparation from any country which is not a Member State of the European Communities or a Contracting Party to the Treaty on the European Economic Area into the area of validity of this Act, either on a commercial basis or within the scope of any other economic activity, if he has notified it to the notification authority. Notification shall not be required if the importer is already engaged in the importation of said substance into another Member State of the European Communities or a Contracting Party to the Treaty on the European Economic Area and has notified it to the competent authority in that country on the basis of an equivalent procedure.

(3) Any person not domiciled within a Member State of the European Communities or in another Contracting Party to the Treaty on the European Economic Area shall not be permitted to introduce into the area of validity of this Act any new substance as such or any new substance in the form of a constituent part of any preparation on a commercial basis or within the scope of any other economic activity.

(4) The provisions of this Act and of statutory ordinances based on this Act which refer to the importer shall apply mutatis mutandis to natural or legal persons or to unincorporated societies with habitual residence or place of business in the Federal Republic of Germany who/which transport a new substance as such or as a component of a preparation from a country which is neither a Member State of the European Communities nor a Contracting Party to the Treaty on the European Economic Area to another Member State or Contracting Party unless it is merely a question of transit pursuant to Article 3, subpara. 8, clause 2.

Article 5 Exemptions from Compulsory Notification

(1) Notification shall not be required for

1. polymers, provided their total mass weight contains two per cent or less of a new substance in combined form;

2. substances placed on the market in the Member States of the European Communities or a Contracting Party to the Treaty on the European Economic Area exclusively for the purpose of scientific research and development in amounts not exceeding 100 kg per manufacturer per year, under the proviso that the manufacturer or importer provides labels showing the identity of the substance, designation of the amount delivered and the name and address of the recipient;

3. substances which are placed on the market exclusively for the purposes of process-oriented research and development for the maximum period of one year in a quantity necessary for that purpose, if the said substance is

only issued to a limited number of persons verifiable by the manufacturer or importer and assurance is given that the said substance as such or in the form of a constituent part of any preparation, is not issued to any other party;

4. substances placed on the market within Member States of the European Communities and the other Contracting Parties to the Treaty on the European Economic Area in annual quantities not exceeding 10 kg per manufacturer.

....

(3) In the case of para. 1, subpara. 3 the notification authority shall be able,

1. upon completion of process-oriented research and testing, to prohibit the substance, whether in the form of a constituent part or actual product, from being delivered to other parties if any danger to life, human health or to the environment is to be feared.

2. on application of the manufacturer or the importer, to extend the validity of the exemption for a period of one year if

a) the applicant furnishes proof that the aim of the process-oriented research and development cannot be achieved within a year, or if other extraordinary circumstances obtain justifying an extension and

b) no danger to life, human health or to the environment is to be feared.

Article 6 Contents of Notification

(1) The party required to notify shall submit in writing to the notification authority his name and address, and, in the case of import, also the name and address of the manufacturer, location of the production site, as well as

1. identifying characteristics, including nature and percentage by weight of the auxiliary agents, the main impurities and the other impurities and decomposition products of which he is aware,

2. methods of detection and determination,

3. methods of analysis known to him to determine human exposure and levels found in the environment,

4. information on manufacture, application, exposure and retention,

5. hazardous effects in application,

6. information on toxicokinetics,

7. the planned classification, packaging and labelling,

8. recommendations on the precautions to be taken during application and emergency measures in the case of accident,

9. the amount of the substance which he wishes to place on the market or import per year,

10. procedures for the proper disposal, possible reuse or other means of rendering the substance harmless and

11. evidence of testing as required under Article 7 (basic testing).

(1a) In the event that the party required to notify is in possession of additional findings on the effects of the substance on humans or the environment, that party shall be required to submit relevant documents in this regard, together with the notification and, at the request of the notification authority, the complete documentation.

(2) In the case of a dangerous substance, the party required to notify shall furthermore be required to submit the safety data sheet provided for.

(3) It shall not be necessary to submit documentation pursuant to para. 1, subparas 6, 10 and 11 if corresponding documentation has already been submitted within the preceding ten years by another manufacturer or importer pursuant to this Act or to equivalent provisions of another Member State of the European Communities or Contracting Party to the Treaty on the European Economic Area.

Article 7 Evidence of Basic Testing

Evidence of basic testing shall be required to cover:

1. physical, chemical and physio-chemical properties,

2. acute toxicity,

3. reasons to suspect carcinogenic or mutagenic properties,

4. evidence of properties toxic for reproduction,

5. irritant and corrosive properties,

6. sensitising properties,

7. sub-acute toxicity,

8. abiotic and slight biological degradability,

9. toxicity in relation to water organisms after short-term exposure,

10. stunting of algae growth,

11. bacterial inhibition,

12. adsorption and desorption.

Article 7a Reduced Notification

Article 8 Procedure Following Receipt of Notification, Placing on the Market of the Notified Substance

(1) The notification authority shall inform the party required to notify, in the case of a notification pursuant to Article 6 within a period of 60 days, in the case of notification pursuant to Article 7a within a period of 30 days after the notification has been received, of whether the notification has been accepted as proper. The subsequent submission of notification documentation pursuant to Article 7a, para. 1, sentence 3 shall be deemed to be notification pursuant to the requirements which are met by the subsequent submission. Where notification is accepted, the notification authority shall issue the notification with a notification number and shall inform the party required to notify of this number together with information pursuant to sentence 1, unless this has already been done earlier in a notification for the same substance and the same party is required to notify. Acceptance of notification shall not prejudice further demands pursuant to Article 20, para. 2.

(2) In the event that the notification authority requires a correction or supplement to the notification specified in Article 20, para. 2 within the deadlines set pursuant to para. 1, para. 1 shall apply under the proviso that the receipt of the correction or supplement replaces the receipt of the notification.

(3) The party required to notify shall be permitted to put the substance on the market 60 days at the earliest following receipt of the notification by the notification authority in the case of a notification pursuant to Article 6, and 30 days following receipt of the same in the case of a notification pursuant to Article 7a. Where the notification authority demands a correction or supplement to the notification specified in Article 20, para. 2 during these deadlines, the date of receipt of the notification shall be replaced by the date of the receipt of the correction or supplement by the notification authority. Where, in the case of a notification pursuant to Article 7a, the notification authority has already recognised the notification before the 30-day deadline has expired, the party required to notify shall be permitted to place the substance on the market in the amount specified from the day of

receipt of the confirmation of acceptance, at the earliest, however, 15 days following receipt of the notification by the notification authority.

Article 9 Additional Testing, Level 1

(1) If any notified substance is put into circulation within the Member States of the European Communities and the other Contracting Parties to the Treaty on the European Economic Area by the party required to notify, in a quantity reaching 100 tonnes annually or in a quantity totalling 500 tonnes since commencement of its manufacture or introduction into these states, the party required to notify shall be required, upon request of the notification authority, to provide additional evidence within a period specified by the authority verifying that the substance concerned has been tested for

1. physical, chemical and physio-chemical properties to the extent to which this is deemed to be required by the evidence of basic testing,

2. sub-chronic and chronic toxicity to the extent to which this is deemed to be required by the evidence of basic testing,

3. properties toxic to reproduction,

4. carcinogenic and mutagenic properties,

5. basic toxicokinetic properties,

6. potential biological degradability, as well as further abiotic degradability insofar as proved necessary by the results of basic testing,

7. adsorption and desorption to the extent to which this is deemed to be required by the evidence of basic testing,

8. bio-accumulation,

9. toxicity in relation to water organisms after long-term exposure,

10. toxicity in relation to soil organisms and plants.

Where deemed to be required by the evidence of basic testing, the notification authority may also order the development of analysis methods which allow the substance and its conversion products to be pursued and determined, and also investigations into the decomposition products arising from thermal treatment.

(2) At the request of the notification authority, the party required to notify must, within a period set by this authority, submit evidence of testing as specified in para. 1 even if

1. the quantity of a notified substance put into circulation within the European Communities or another Contracting Party to the Treaty on the European Economic Area by the party required to notify has reached 10 tonnes annually or a total of 50 tonnes since commencement of its manufacture or importation into these states and

2. the submission of evidence is necessary in the light of previous knowledge of the substance and its conversion products, its known or foreseeable uses or the results of the tests performed in accordance with Article 7.

Article 9a Additional Testing, Level 2

(1) If any notified substance is put into circulation within the Member States of the European Communities or another Contracting Party to the Treaty on the European Economic Area by the party required to notify, in a quantity reaching 1,000 tonnes annually or in a quantity totalling 5,000 tonnes since commencement of its manufacture or introduction into these states, the party required to notify shall be obliged, upon request of the notification authority, to provide further additional evidence within a period specified by that authority verifying that the substance concerned has been tested for

1. toxicokinetic properties including biotransformation,

2. chronic toxicity,

3. carcinogenic properties,

4. properties disturbing behaviour,

5. properties toxic to reproduction,

6. perinatal and postnatal effects,

7. organic and system toxicity,

8. mobility, in particular adsorption and desorption,

9. abiotic and biological degradability,

10. bio-accumulation,

11. toxicity in relation to fish,

12. toxicity in relation to birds,

13. toxicity in relation other organisms and

14. further properties which alone, or in conjunction with other properties of the substance, present a hazard to the environment.

Article 10 Special Provisions for Importer Notifications

(1) Where a substance is notified by an importer, the authoritative amount pursuant to Articles 7a, 9 and 9a shall be the total amount in which the same substance from the same manufacturer is brought into the Member States of the European Community and the other Contracting Parties to the Treaty on the European Economic Area. The notification authority shall check, following the receipt of a notification pursuant to sentence 1,

1. whether the same manufacturer has notified the same substance to this notification authority or to the notification authorities of other Member States or Contracting Parties and

2. whether the total amount pursuant to sentence 1 is given in the notification documents,

and shall keep this information up to date. Where the total amount exceeds the range of amounts on which the notification is based, the notifying authority shall inform the party responsible for notification of this fact.

(2) The manufacturer of a substance to be notified under the terms of this Act or under equivalent provisions of another Member State of the European Communities or another Contracting Party to the Treaty on the European Economic Area may himself notify the substance by a sole agent domiciled or with place of business in the Federal Republic of Germany according to the terms of this Act. The sole agent shall be deemed to be the importer pursuant to Article 4, para. 2. On submission of the notification documents, he shall in addition be obliged

1. to present a power of attorney from the manufacturer which indicates that the manufacturer has entrusted the agent, as sole agent for the territory of the Member States of the European Community and the other Contracting Parties to the Treaty on the European Economic Area, with the notification of the substance, and

2. to give the names and addresses of all persons and associations represented by him who/which are bringing the substance into the Member States and Contracting Parties.

The information provided by the sole agent on the amount of the substance shall comprise the total amount brought into the Member States and Contracting Parties by the persons and associations pursuant to sentence 3, subpara. 2 and indicate separately the amount brought in by each person and association named.

(3) An importer who is expressly considered in the notification of the sole agent pursuant to para. 2 or under other equivalent provisions in another Member State of the European Communities or Contracting Party to the Treaty on the European Economic Area need not submit his own information and evidence of testing pursuant to Articles 6, 7, 9, 9a and 16 provided the sole agent has submitted adequate information. Where the importer refrains from submitting his own documentation, he shall keep the sole agent up to date on the amount imported by him and on the information he has pursuant to Article 6, para. 1a; the state of notification by the sole agent is the decisive criterion for the deadlines pursuant to Article 8, para. 3.

Article 11 Powers of the Notification Authority

Article 12 Notification Authority, Evaluation

Section Three Classification, Packaging and Labelling of Hazardous Substances, Preparations and Products

Article 13 Compulsory Classification, Packaging and Labelling

(1) Any manufacturer or importer who puts a substance into circulation shall be required to package and label such in accordance with the statutory ordinance specified in Article 14. Insofar as the substance is not specified in the statutory ordinance stated in Article 14, he shall be required to

1. establish the information to which he has access on the properties of the substance, and

2. classify, package and label any substance which is found to present a hazard on the basis of a test performed in accordance with Article 7, Article 9 or Article 9a or on the basis of reliable scientific findings.

If a substance is exempt from notification pursuant to Article 5, para. 1, subparas 2 to 4 or is subject to reduced notification pursuant to Article 7a, and for which the results of the tests pursuant to Article 7 are not available in their entirety, he shall be required to add an additional label to the substance with the warning "Achtung - noch nicht vollständig geprüfter Stoff" (Caution - substance not yet fully tested).

(2) Para. 1 shall apply accordingly to preparations insofar as they are classified as being hazardous in the statutory ordinance under Article 14, or insofar as this statutory ordinance prescribes calculations of hazardous preparations performed by the manufacturer or importer on the basis of the results of tests performed in accordance with Article 7, Article 9 or Article 9a, or on the basis of reliable scientific findings within the meaning of para. 1, sentence 2, shall take precedence over classifications performed on the basis of calculation procedures.

(3) Labelling and packaging regulations above and beyond those stipulated in other legislation shall remain unaffected.

Article 14 Power to Issue Classification, Packaging and Labelling Provisions

Article 15 Obligations of Distributors

Hazardous substances, preparations or products which have been put into circulation by the manufacturer or importer in accordance with the packaging and labelling provisions contained in this Act or in accordance with a statutory ordinance adopted on the basis of this Act may only be reintroduced into circulation if

1. the packaging and labelling are intact or

2. the distributor has repackaged and relabelled the substance, preparation or product in line with the given provisions.

If the distributor wishing to reintroduce a substance, preparation or product into the market is aware that the packaging and labelling do not conform to the given provisions, he shall be obliged to carry out labelling and packaging which do conform to the given provisions.

Article 15a Indications of Dangerous Properties in Advertising

It shall be prohibited to advertise a dangerous substance without giving notice of its dangerous properties pursuant to Article 3a, para. 1.

Section Four Duties to Inform

Article 16 Duties to Inform in the Case of Notified Substances

Article 16a Duties to Inform in the Case of New Substances Exempted from Compulsory Notification

Article 16b Duties to Inform in the Case of New Substances which are not put into Circulation or only put into Circulation within the European Economic Area

Article 16c Duties to Inform in the Case of Existing Substances

Article 16d Duties to Inform in the Case of Preparations

Article 16e Information for the Information and Treatment Centres for Toxic Contaminations

Section Five Powers to Impose Bans and Restrictions, as well as Measures to Protect Employed Persons

Article 17 Bans and Restrictions

(1) After consulting those involved, the Federal Government shall be authorised by statutory ordinance approved by the Bundesrat, insofar as necessary for the purpose laid down in Article 1, to

1. prescribe that specific hazardous substances, specific hazardous preparations or products which are capable of releasing or contain any such substance or preparation,

a) may not, only in a certain state or only for specific purposes, be manufactured, put into circulation or used,

b) may only be used in a specific manner or

c) may only be issued under certain conditions or only to specific persons,

2. prescribe that anyone who manufactures, puts into circulation or uses specific hazardous substances, specific hazardous preparations or products capable of releasing or containing such a substance or preparation,

a) be required to furnish notification of such,

b) require a licence,

c) satisfy specific requirements placed on his reliability and health or

d) verify his expertise in a procedure to be defined more closely,

3. ban manufacturing or application processes involving specific hazardous substances.

(2) On the basis of the statutory ordinance specified in para. 1, it shall also be possible to impose bans and restrictions, taking into consideration the development of substances, preparations, products or processes whose manufacture, use, disposal or application are associated with a lesser risk to man and the environment.

(3) Para. 1 shall also apply to substances, preparations and products specified in Article 19, para. 2, as well as to substances, preparations or products, the transformation products of which are deemed to be hazardous within the meaning of Article 3a, para. 1, subparas 1 to 14.

(4) Para. 1, subparas 1 and 2 shall also apply to substances, preparations or products for which there are reasons, in particular justified suspicion founded on latest scientific findings, to believe that such a substance, preparation or product is hazardous.

(5) Within the scope of the statutory ordinances specified in para. 1, the Federal Government shall also be able to define methods to monitor their observance. In this context, it shall, in particular, also be possible to include sampling and the methods to be applied for this purpose, as well as methods required to analyse individual substances or substance groups.

(6) In the case of imminent danger, the Federal Government shall be able to issue a statutory ordinance on the basis of para. 1, subparas 1 and 3 without the approval of the Bundesrat and without consulting those involved. This statutory ordinance shall become ineffective twelve months at the latest after taking effect. Its period of validity may only be extended with the approval of the Bundesrat.

(7) Those involved shall comprise representatives to be selected from the field of science, from consumer protection associations, trade unions and employers' liability insurance associations, from the industry concerned, the health service as well as from environmental, animal protection and nature conservation associations.

Article 18 Poisonous Animals and Plants

Article 19 Measures to Protect Employed Persons

Section Six Good Laboratory Practice

Article 19a Good Laboratory Practice (GLP)

Article 19b GLP Certification

Article 19c Reporting

Article 19d Supplementary Provisions

Section Seven General Provisions

Article 20 Submission of Evidence of Testing

(1) The evidence of testing to be submitted by the party required to notify or inform, and the other documents to be presented together with such evidence, must permit an assessment of whether the relevant substance or preparation is to be associated with detrimental effects on man or the environment.

(2) If evidence of testing and other documents do not permit adequate assessment for reasons of incompleteness or incorrectness, or if presentation of further test evidence,

documentation or supplementary information is necessary on the basis of a legal instrument of an organ of the European Communities, the party required to notify or inform shall, at the request of the notification authority, be required to submit the necessary corrections and supplements within a period stipulated by that authority. Article 11, para. 3 shall apply accordingly. Appeals against the orders specified in sentences 1 and 2 shall have no suspensory effect.

(3) If evidence of testing and other documents do not permit adequate assessment, despite their being neither incomplete nor incorrect, the notification authority shall be able to inform additional information concerning the evidence of testing and other documents presented by that party within a reasonable, set deadline. Appeals against the request to furnish information under sentence 1 shall have no suspensory effect.

(4) Insofar as the submission of evidence of testing is not necessary on the basis of latest scientific findings, or testing is not technically possible, the reasons underlying the failure to submit evidence must be presented in writing.

(5) Anyone required to submit notification documents, evidence of testing or information documents under Articles 6, 7, 7a, 9 and 9a and 16 to 16e shall be required to retain a duplicate of these documents or of this evidence for a period of five years after the substance or preparation was first put into circulation or manufactured.

...

Article 20a Application of Evidence of Testing from a Third Party, Obligation of Advance Enquiry

(1) The notification authority shall be able to permit that the party required to notify or inform make reference to evidence of testing in the possession of a third party insofar as the party required to notify or inform is given written approval by that third party and the notification authority has been furnished with evidence of such testing.

(2) Before animal experiments are carried out to prepare notification or information, the party required to notify or inform shall submit an enquiry to the notification authority asking whether the said animal experiments are necessary, giving the identification characteristics of the substance, the amount he intends to place on the market or manufacture and certification of his justified interest in carrying out the experiments. The submission of evidence of testing involving animal experiments shall not be required insofar as the notification authority is in possession of adequate findings. If these findings are derived from test evidence received from a third party, such evidence having been submitted within the last ten years, the notification shall without delay inform the latter, as well as the party required to notify or inform, of which test evidence received from the third party it intends to assess, as well as the name and address of the other parties concerned. Where evidence of testing has been submitted as notification documentation by a third party pursuant to Article 6 and where the third party made an application to this end, information shall be submitted to the notification authority pursuant to sentence 3

within the first year after submission of the notification, in the first instance without mentioning the names and addresses of those involved and without any other details which could reveal indications of the identity of the other party; the details shall be expanded once the year's deadline has expired.

(3) The third party shall, within a period of one month after receipt of information specified in para. 2, sentence 3, be able to object to its test evidence being utilised. In the case of objection, the period specified in Article 8, para. 3 shall be extended by the time the party required to notify would need to procure test evidence of his own. This period shall, at the request of one of the parties concerned, be determined by the notification authority after consulting the third party.

(4) If, in the case of para. 2, sentences 3 and 4, evidence of testing is utilised by the notification authority within a period of ten years after such evidence was submitted by the third party, the third party shall have claim to remuneration from the party required to notify or inform in the amount of 50 per cent of the expenditure saved by its utilisation and the party required to notify or inform shall have claim to a copy of the assessed evidence of testing. In the case of notification as specified in Article 4, the third party shall be able to prohibit the person required to notify from putting the substance into circulation, insofar as the latter fails to pay the remuneration or to furnish security of an appropriate amount.

(5) If evidence of testing concerning identical subjects is to be submitted simultaneously by several parties required to notify or inform, the notification authority shall inform those parties required to notify or inform who are known to it which testing evidence is to be submitted by them jointly, as well as the names and addresses of the other parties involved. The notification authority shall give those parties required to notify or inform the opportunity within a set period to reach agreement as to who submits evidence of testing. In the event of failure to reach agreement, the notification authority shall make a decision and immediately inform all those concerned accordingly. These shall, insofar as they do not withdraw their notification or insofar as the conditions underlying their duty to notify or furnish information otherwise cease to exist, be obliged to share on an equal basis the expenses incurred for the compilation of documents; they shall be jointly and severally liable.

Article 20b Committees

Article 21 Monitoring

Article 21a Assistance from Customs Offices

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