

## **Act Concerning the Protection of Crop Plants**

### **(Plant Protection Act - PflSchG)**

Version according to the notification of 14 May 1998 (BGBl. I, p. 971), last amended by Article 3 of the Act of 19 August 2004 (BGBl. II p. 1154)

amended by:

amendment of the notification of the revised version of the PflSchG of 16 June 1998 (BGBl. I p. 1527)

amendment of the first act to amend the PflSchG and the notification of the latest version of the PflSchG of 27 November 1998 (BGBl. I p. 3512)

article 14 of the act on the conversion of provisions for agriculture and forestry to the Euro (fifth act to introduce the Euro) of 25 June 2001 (BGBl. I pp. 1215, 1217)

article 186 of the seventh ordinance to rearrange competencies of 29 October 2001 (BGBl. I pp. 2785, 2822)

article 3 (4) of BnatSchNeuregG of 25 March 2002 (BGBl. I pp. 1193, 1217)

article 4 of the biocide act of 20 June 2002 (BGBl. I pp. 2076, 2088)

article 4 of the act on the reorganisation of consumer health protection and food safety of 6 August 2002 (BGBl. I pp. 3082, 3087)

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<sup>1</sup> The last official notification concerning the Plant Protection Act (PflSchG) is from 14 May 1998. This version was compiled by the Federal Office of Consumer Protection and Food Safety (BVL) for internal use on the basis of the amendments listed above. No liability is assumed for the correctness and completeness of the text.



**Section Ten  
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**Section One  
General Provisions**

**Article 1  
Purpose**

The purposes of this Act are:

1. to protect plants, particularly crop plants, against harmful organisms and non-parasitic impairments,
2. to protect plant products against harmful organisms,
3. (deleted)
4. to avert dangers that may result from the use of plant protection products or other plant protection measures, especially those relevant to human and animal health and the natural balance,
5. to enforce legal instruments issued by the European Community in the field of plant protection.

**Article 2  
Definitions**

(1) For the purpose of this Act

1. *plant protection* means:
  - a) the protection of plants against harmful organisms and non-parasitic impairments,
  - b) the protection of plant products against harmful organisms (protection of stored plant products)including the use and protection of animals, plants and micro-organisms by means of which harmful organisms may be controlled;
2. *integrated plant protection* means:

a combination of methods in which the use of chemical plant protection products is limited to the essential minimum with particular attention being paid to biological, biotechnical, plant-breeding and cultivation-related measures;

3. *plants* means: living plants and living parts of plants, including fruits and seeds;
4. *plant products* means:

products of plant origin which have not been processed or which have undergone only simple processing such as drying or crushing, with the exception of treated wood;
5. *plant species* means:

plant species and plant varieties, as well as combinations and subdivisions thereof;
6. *natural balance* means:

environmental components such as soil, water, air, flora and fauna and the interactions between them;
7. *harmful organisms* means:

animals, plants and micro-organisms which, at any stage of development, can cause serious damage to plants or plant products. Viruses and similar pathogens shall be treated as micro-organisms. Diseases not caused by harmful organisms shall be treated in the same way as harmful organisms;
8. *infested objects* means:

plants, plant products or other objects which are or may be carriers of specific harmful organisms;
9. *plant protection products (PPPs)* means:

substances designed

  - a) to protect plants or living parts of plants and plant products against harmful organisms,
  - b) to protect plants or living parts of plants and plant products against animals, plants or micro-organisms which are not harmful organisms,
  - c) to influence the life processes of plants, other than as nutrients (growth regulators),
  - d) to inhibit the germination of living parts of plants and plant products,except for water, fertilisers as defined in the Fertilizer Act, and plant resistance improvers; substances designed to destroy plants or to inhibit or prevent the growth of plants shall also be classified as plant protection products, even if they do not come under clauses a or c;
- 9a. *active substances* means:

chemical elements or compounds that occur naturally or are manufactured for commercial purposes, including impurities that exert effects on:

  - a) harmful organisms or
  - b) plants or plant products;micro-organisms, including viruses and similar

organisms as well as components thereof shall be treated as chemical elements;

9b. *residues* means:

substances present in or on plants, plant products, edible animal products or substances otherwise present due to the use of plant protection products, including their metabolites and degradation or reaction products;

10. *plant resistance improvers* means substances:

- a) solely intended to enhance the resistance of plants to harmful organisms,
- b) intended to protect plants against non-parasitic impairments,
- c) intended for use on cut ornamental plants except for planting material;

11. *plant protection equipment* means:

equipment and devices intended for the application of plant protection products;

12. *culture substrates* means:

soils and other substrates in solid or liquid form providing plants with root space;

13. *marketing* means:

supplying, keeping in stock for delivery, offering for sale and any kind of delivery to third parties;

13a. *field of application* means:

specific plants, plant species or plant products together with those harmful organisms against which plants and plant products shall be protected or any other purpose for which the plant protection product shall be used;

14. *member state* means:

member state of the European Union;

15. *outdoor areas* means:

areas not permanently covered by buildings or roofing, irrespective of their structure or use; this also includes any kind of traffic area such as tracks, streets, roads, farms and factory premises as well as any other land areas transformed by civil engineering measures.

## **Section Two Plant Protection**

### **Article 2a Implementation of plant protection**

(1) Plant protection must be carried out according to good professional practice. The main goals of good professional practice are

1. to keep plants healthy and assure the quality of plants and plant products through
  - a) preventive measures,
  - b) prevention of the importation and dispersal of harmful organisms,
  - c) prevention or control of harmful organisms and
2. to prevent hazards that may arise from the use, storage and other means of handling plant protection products or through other plant protection measures, especially those relevant to human and animal health and for the natural balance.

Good professional practice must also take into account the principles of integrated plant protection and the protection of groundwater

(2) In collaboration with the Länder and in consideration of the latest scientific findings as well as the experience of plant protection services and persons implementing plant protection measures, the Federal Ministry of Consumer Protection, Food and Agriculture shall elaborate principles for the implementation of good professional practice in plant protection. The Federal Ministry of Consumer Protection, Food and Agriculture shall publish these rules in the Bundesanzeiger (German federal gazette) in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.

### **Article 3 Plant protection measures**

(1) Insofar as this is necessary for attaining the purposes set forth in Article 1, the Federal Ministry for Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat (Federal Council), be empowered

1. to order that the responsible authority be notified of any occurrence or suspected occurrence of harmful organisms, the cultivation or presence of specific plant species, any other facts relevant to the occurrence or control of harmful organisms or the use of specific plant protection products, plant protection equipment or plant protection procedures;
2. to commit persons with a right of disposal and land owners to monitor or inspect infested objects, plots of land, buildings or premises for the occurrence of harmful organisms or to have them inspected;
3. to commit persons with a right of disposal and land owners to control specific harmful organisms or to have them controlled, as well as to prescribe

or prohibit the use of specific plant protection products, plant protection equipment or processes for this purpose;

4. (deleted)
5. to order the responsible authorities to monitor plants and plots of land for the occurrence of specific harmful organisms and to control specific harmful organisms;
6. to order the destruction, disinfection or disinfestation of infested objects and the disinfection or disinfestation of soil, culture substrates, buildings or premises, as well as to prescribe or prohibit the use of specific products, equipment or procedures for this purpose;
7. to prescribe or prohibit the use of specific culture substrates for the breeding or cultivation of specific plants;
8. to restrict the use of land that is infested, suspected of being infested or in danger of being infested and to lay down regulations governing the banning of such plots of land;
9. to prohibit or limit the use of unsuitable seed or planting stock or of unsuitable parts of plants intended for graftage;
10. to prohibit or limit growing specific plant species;
11. with regard to the marketing of specific plants to be used for plant production or otherwise for growing plants (cultivation material),
  - a) to prohibit or limit such marketing if the material is infested or suspected of being infested with specific harmful organisms,
  - b) to make such marketing dependent on the results of inspection of the material for infestation with specific harmful organisms or resistance to specific harmful organisms or to make such marketing subject to approval;
12. to order that land which is infested, suspected of being infested or in danger of being infested should be cleared or kept clear of specific plants;
13. to prohibit or limit the transportation, marketing and storage of specific harmful organisms and infested objects or to make such transportation and marketing subject to approval or notification;
14. to prohibit or limit the breeding, cultivation and utilisation of specific harmful organisms or to make such breeding, cultivation and utilisation subject to approval or notification;
15. to order the disinfection, disinfestation or cleaning of land, buildings, premises or containers used for

the storage of plants or plant products and to prescribe or prohibit the use of specific products, equipment or processes for that purpose;

16. to lay down regulations for the protection of animals, plants or micro-organisms
  - a) against dangers arising from the use of plant protection products, plant protection equipment or any other implements and facilities used in plant protection or
  - b) in view of their usefulness for controlling harmful organisms;
17. to lay down regulations governing the marketing and use of animals, plants or micro-organisms for controlling specific harmful organisms; the Ministry may thereby make the marketing and the use of animals, plants or micro-organisms subject to approval and specify the prerequisites and procedure for this.

(2) Ordinances pursuant to paragraph (1) nos. 3, 6, 15, 16 and 17 require the agreement of the Federal Ministry of Labour and Social Affairs and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in as much as they refer to the use of specific plant protection products or other substances.

(3) The governments of the Länder shall be empowered

1. to issue ordinances pursuant to paragraph (1) in as much as the Federal Ministry of Consumer Protection, Food and Agriculture does not exercise its own powers,
2. by means of ordinances in as much as this is necessary to achieve the purposes set forth in Article 1,
  - a) to prohibit growing specific plant species or to prescribe the use of specific seed or planting stock as well as specific cultivation methods in regions that are particularly well suited for the cultivation of specific plant species and
  - b) to prescribe that plants or plant products may be stored only in a specific manner.

They may, by ordinance, delegate these powers to other authorities stipulating that such authorities may in turn delegate their power by ordinance to subordinate authorities or authorities under their supervision.

#### **Article 4** **Measures to prevent the importation** **and dispersal of harmful organisms**

Insofar as it is necessary to prohibit or restrict the transportation, marketing, importation and exportation of harmful organisms and infested objects by ordi-

nance, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to issue ordinances

1. to prevent
  - a) the introduction of harmful organisms in the member states and
  - b) the dispersal of harmful organisms within the European Community or into a third country or
2. to protect specific regions from harmful organisms and infested objects.

It may in particular

1. make the transportation, marketing, importation and exportation of harmful organisms and infested objects subject to
  - a) approval or notification,
  - b) an inspection or proof of disinfection, disinfection or other treatment,
  - c) specific certificates,
  - d) specific packaging or labelling requirements,
  - e) licensing or registration of the company having produced or grown the plants or having marketed, imported or stored the plants, plant products, culture substrates or other infested objects;
2. lay down regulations regarding
  - a) inspection and sampling procedures,
  - b) the observation, use or treatment of infested objects, including their destruction,
  - c) the keeping of records, especially those on past inspections, harmful organism occurrence and control, and the fate of infested objects,
  - d) the contents, form and issuance of certificates pursuant to 1c,
  - e) the closure and sealing of packaging and containers,
  - f) the safekeeping of certificates and records as well as their submission to the responsible authority,
  - g) the prerequisites and procedure for the licensing or registration of companies under 1e, including license suspension, restrictions for licensed or registered enterprises in plant production, plant cultivation or transportation, marketing or storage of infested objects as well as the processing and use of data gathered in the procedure,
  - h) the licensing requirements and procedure for institutions that inspect plants, plant products or culture substrates for infestation with harmful organisms, including license suspension or restriction of inspection activity as well as the processing and use of the data gathered in the procedure.

## **Article 5** **Urgent cases**

(1) In case of imminent danger or if there is a need for immediate implementation of legal instruments by the European Community, the Federal Ministry of Consumer Protection, Food and Agriculture may issue ordinances in accordance with Article 3 (1) and (2) and Article 4 without the consent of the Bundesrat and without the approval of the other federal ministries. Such ordinances shall cease to have effect six months from their effective date at the latest. The period of their validity may be extended only with the consent of the Bundesrat.

(2) In case of imminent danger, the responsible authorities can order measures in accordance with Article 3 (1) and Article 4, sentence 1 in conjunction with Article 4, sentence 2, nos. 1a-d and 2 a-f if immediate intervention is necessary.

## **Section Three** **Use of Plant Protection Products**

### **Article 6** **General information**

(1) Plant protection products should be used according to the rules of good professional practice. Plant protection products must not be employed if the user must expect that their use in individual cases will have a harmful effect on human and animal health or on groundwater or have any other serious adverse effects, especially on the natural balance. The responsible authority may order measures necessary for meeting the requirements specified in sentences 1 and 2.

(2) Plant protection products may be applied in outdoor areas only if such land is used for agricultural, forestry or horticultural purposes. However, they must not be applied to surface and coastal waters or in the immediate vicinity of such waters.

(3) The responsible authority may grant exceptions from paragraph (2) if the intended purpose is urgent and cannot be achieved with reasonable input in any other way and if it does not conflict with overriding public interests, particularly with regard to the protection of plant and animal species.

### **Article 6a** **Special provisions governing use**

(1) Plant protection products may be used individually or in combination with other PPPs only if they have been authorised and

1. only in the fields of application specified in the authorisation and in the instructions for use approved under Article 18 (1) sentence 1,

published under Article 18a (4), or approved under Article 18b (1) sentence 1;

2. only according to the directions for use specified in the authorisation and stated in the instructions for use or published under Article 18a (4).

They may be used in amateur gardening only if the label states "authorised for amateur gardening".

(2) Paragraph (1) sentence 1 shall apply *mutatis mutandis* to plant protection products whose marketing or importation has been approved under Article 11 (2) sentence 1 nos. 2 and 3.

(3) In derogation of paragraph (1) sentence 1, plant protection products whose authorisation expires under Article 16 (1) or (2) sentence 1 may still be used until the end of the second year after expiry of the authorisation. They may not be used if the application is restricted by an ordinance issued in accordance with this Act or if the Federal Office of Consumer Protection and Food Safety ascertains by general order upon expiry of the authorisation that conditions for withdrawal or revocation would have existed.

(4) Paragraph 1 sentence 1 does not apply to

1. plant protection products used for research, investigation and experimental purposes,
2. plant protection products whose use has been ordered under Article 3 (1) nos. 3, 6 and 15 or under Article 4, sentence 1 in conjunction with sentence 2, no. 2b, in each case in conjunction with Article 5 (2),
3. plant protection products manufactured for agricultural, forestry or horticultural use within one's own company, provided the products do not contain substances or preparations that were marketed or imported for commercial purposes or within the scope of any other business undertakings unless the substances and preparations
  - a) may be used to produce organic produce in accordance with European Community regulations and
  - b) are included in a list maintained by the Federal Office of Consumer Protection and Food Safety,
4. Products used to control plant micro-organisms
  - a) in closed premises or pipe systems in companies and plants subject to supervision under trade, mining, nuclear or health legislation; this shall not apply to the use on premises for plant production or marketing of plants or plant products,
  - b) in sanitary facilities.

The Federal Office of Consumer Protection and Food Safety shall include substances and preparations in the list mentioned in sentence 1, no. 3b if there is no evidence that, when used properly or as a result of such use, adverse effects, especially with regard to human and animal health, groundwater and the natural balance, occur from their use. The Federal Office of Consumer Protection and Food Safety shall publish the list in the *Bundesanzeiger*.

## **Article 7 Prohibition of use**

(1) Acting in agreement with the Federal Ministries of Economic Affairs and Technology, Labour and Social Affairs, and, in the case of no. 1, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to issue ordinances prohibiting or limiting or making subject to approval or notification

1. the application
  - a) of specific plant protection products or plant protection products containing specific substances,
  - b) of plant protection products requiring the use of specific equipment or processes,
2. the cultivation of specific plant species on land where the soil has been treated with specific plant protection products as well as the use of specific plants or plant products grown there,
3. the sale to the user of plant protection products regulated pursuant to no. 1a,
4. the marketing, importation or use of seed, planting stock or culture substrates in or on which specific plant protection products are present,

to the extent necessary for the protection of human or animal health or for averting harm, particularly where the natural balance is concerned; this can be made subject to the provision that the approval must be granted by and notification made to the Federal Office of Consumer Protection and Food Safety.

(2) In cases where the use of plant protection products is restricted by an ordinance pursuant to paragraph (1) no. 1, details such as the purpose, type, time, place and method of application of a plant protection product can be prescribed or prohibited, and the dose to be applied and the waiting period to be observed after application can be prescribed.

(3) Ordinances pursuant to paragraph (1) no. 1 may not exclude a field of use specified in the authorisation of a plant protection product unless the authorisation was previously withdrawn or revoked

upon order of immediate enforcement. If the withdrawal or revocation of the authorisation is incontestably rescinded, the ordinance shall no longer be applicable.

(4) In case of imminent danger, the Federal Ministry of Consumer Protection, Food and Agriculture may issue ordinances pursuant to paragraph (1) without the consent of the Bundesrat and without the agreement of other federal ministries. Such ordinances shall cease to be in force six months from their effective date at the latest. The period of their validity may be extended only with the consent of the Bundesrat.

(5) The governments of the Länder shall be empowered to issue ordinances pursuant to paragraph (1) no. 1b if the Federal Ministry of Consumer Protection, Food and Agriculture does not exercise its own powers in the matter.

### **Article 8 More extensive regulations issued by the Länder**

The powers of the Länder

1. to lay down regulations to prohibit, to restrict or make subject to approval or notification
  - a) the use of plant protection products in protected areas governed by provisions under water or nature conservation law,
  - b) details of the application of plant protection products next to surface or coastal waters or
  - c) the use of plant protection products on outdoor areas not used for agriculture, forestry or commercial horticulture or
2.
  - a) the application of plant protection products using specific equipment or methods or
  - b) the cultivation of specific plant species on land where the soil has been treated with specific plant protection products as well as the use of specific plants or plant products grown there

shall remain unaffected

### **Article 9 Notification**

Any person intending to apply plant protection products for other persons - except in the case of occasional neighbourly help - or to give advice to others on the application of plant protection products for commercial purposes or within the scope of any other business undertaking shall notify the authority responsible for the company and the place where the work is to be performed before commencing such

work. The governments of the Länder shall be empowered to issue, by ordinance, the necessary detailed rules concerning notification and the notification procedure. They may by ordinance delegate these powers to supreme state authorities.

### **Article 10 Personal requirements**

- (1) Any person
1. applying plant protection products
    - a) in agricultural undertakings, including horticultural or forestry undertakings or
    - b) in a company for purposes of the protection of stored products,
  2. performing work subject to compulsory notification under Article 9 or
  3. instructing or supervising persons applying plant protection products within the scope of their training, if this is part of their training

must possess the necessary reliability and the required knowledge and skills for this and must also guarantee that no avoidable harmful effects on human or animal health or no other avoidable harmful effects, in particular on the natural balance, shall arise from the use of plant protection products.

(2) The designated authority may completely or partially prohibit the activities described in paragraph (1) if facts justify the assumption that the person performing these activities does not meet the prerequisites specified there.

(3) Proof of the necessary specialist knowledge and skills shall be furnished to the responsible authority on request. With the consent of the Bundesrat, the Federal Government shall be empowered to issue by ordinance detailed provisions on the nature and scope of the required specialist knowledge and skills as well as on the procedure of furnishing proof of these qualifications. The governments of the Länder shall be empowered

1. to issue ordinances under sentence 2 unless the Federal Government exercises its powers,
2. by ordinance, as far as this is required for attaining the purposes referred to in Article 1, to extend the scope of paragraph (1) to persons using plant protection products on land owned by legal persons under public law.

The governments of the Länder may delegate these powers to other authorities by ordinance.

**Article 10a**  
**Application for experimental purposes**

(1) Plant protection products may only be used for experimental purposes if their application is not expected to have any harmful effects on human and animal health or on groundwater nor any other harmful effects, especially on the natural balance. Furthermore, they may only be applied if the user has furnished proof of the necessary specialist knowledge and skills. Proof of the necessary specialist knowledge and skills shall be furnished to the responsible authority by presenting the certificates provided for by ordinance under paragraph (3). The responsible authority may upon request in individual cases approve the application of plant protection products for experimental purposes, by way of derogation from the second sentence, if no harmful effects on the protected goods referred to in the first sentence can be expected to arise from this. The second and third sentences shall not apply to experiments performed by the Federal Biological Research Centre or by the authorities designated under Article 34.

(2) The responsible authority may completely or partially prohibit the use of plant protection products for experimental purposes if certain facts justify the assumption that the person applying plant protection products for experimental purposes does not possess the necessary reliability or the required specialist knowledge and skills.

(3) The Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered to issue, by ordinance, with the consent of the Bundesrat, and acting in agreement with the Federal Ministries of Labour and Social Affairs, and for the Environment, Nature Conservation and Nuclear Safety, detailed rules regarding the nature and scope of the application of plant protection products for experimental purposes and the necessary specialist knowledge and skills as well as the procedure for furnishing proof of such knowledge and skills.

**Section Four**  
**Trade with Plant Protection Products**

**Article 11**  
**Need for authorisation**

(1) Plant protection products may be marketed or imported in the formulation envisaged for the sale to the user only if they have been authorised by the Federal Office of Consumer Protection and Food Safety. This shall not apply to

1. plant protection products which are intended for exportation or which, in the case of importation, are subject to customs supervision in a free port or as dutiable goods,

2. products intended for the control of plant micro-organisms
  - a) in closed premises or pipe systems in companies and plants subject to supervision under mining, nuclear or health legislation or
  - b) in sanitary facilities.

(2) The Federal Office of Consumer Protection and Food Safety may approve the marketing or importation of a specific quantity of unauthorised plant protection products

1. for experimental purposes,
2. for the purpose of controlling specific harmful organisms in the case of imminent danger, or
3. for use on plants or plant products intended for export if different requirements apply to them in the country of destination

for a specific period of time, which must not exceed 120 days in the cases specified in nos. 2 and 3. In doing so, the Federal Office of Consumer Protection and Food Safety shall specify the fields of application as well as the directions for use of the PPP in order to protect human and animal health and prevent harmful effects, especially those affecting the natural balance, which include provisions concerning the persons entitled to use the plant protection products. The Federal Office of Consumer Protection and Food Safety shall also issue any necessary restrictions. The approval is subject to revocation and can be renewed. In the case of sentence 1, no. 3, the approval may be granted after consultation with the Federal Institute for Risk Assessment, the Federal Biological Research Centre and the Federal Environmental Protection Agency.

(3) Seed, planting stock and culture substrates containing plant protection products or to which plant protection products are adherent may be marketed or imported only

1. if the plant protection products have been authorised in a member state, if the authorisation meets the requirements of Article 4 (1) b to e of Council Directive 91/414/EEC of 15 July 1991 regarding the marketing of plant protection products (OJ EC no. L 230, p.1) as amended and if the application of plant protection products has not been prohibited by ordinance under Article 7 (1) or
2. if the Federal Office of Consumer Protection and Food Safety has, upon request, stated that the plant protection products correspond in composition and effect to a plant protection product authorised in the Federal Republic of Germany.

Paragraph (1) sentence 2 and paragraph (2) shall apply *mutatis mutandis*.

## **Article 12**

### **Application for authorisation**

(1) An authorisation may be applied for by persons intending to market or import plant protection products for the first time.

(2) A person having neither a residence nor a place of business in a member state may apply for authorisation only if he has appointed a representative having a residence or business premises in the area in which this Act is in force. This person shall be authorised to represent him in the authorisation procedure.

(3) The application for authorisation shall contain the information, documents and samples required for the examination of the requirements for authorisation. With the consent of the Bundesrat, the Federal Ministry for Consumer Protection, Food and, Agriculture - acting in agreement with the Federal Ministries of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety - shall be empowered to issue ordinances governing the contents and scope of the application as well as the nature and scope of the information, documents and samples to be enclosed with the application, observing the European Community provisions regarding the placing on the market of plant protection products. It may prescribe specific experiments and their methodology, including the methods of analysis to be used.

(4) If required for immediate implementation of European Community legal instruments, the Federal Ministry for Consumer Protection, Food and Agriculture may issue ordinances pursuant to paragraph (3) sentence 2 without the consent of the Bundesrat and without the agreement of the other federal ministries. They shall cease to be in force six months from their effective date at the latest. Their period of validity may only be extended subject to the requirements of paragraph (3) sentence 2.

## **Article 13**

### **Use of findings from third party documents**

(1) Documents to be enclosed with applications under Article 12 (3) are not necessary if the Federal Office of Consumer Protection and Food Safety is already in possession of sufficient knowledge drawn from documentation submitted by another applicant (previous applicant) and if

1. the previous applicant has given his written consent to its utilisation or
2. more than ten years have elapsed in a member state since the first authorisation of the previous applicant's plant protection product to which the intended use refers.

If Annex I of Directive 91/414/EEC does not include any active substances contained in the plant protection

product, the ten-year period under sentence 1, no. 2 shall commence with the first authorisation granted after 1 July 1998.

(2) In derogation of paragraph (1) sentence 1, no. 2, the ten-year period regarding the documentation to be enclosed with the application for the evaluation of an active substance shall commence with its first inclusion in Annex I of Directive 91/414/EEC.

(3) Documentation submitted to the Federal Office of Consumer Protection and Food Safety for the evaluation of an active substance under Article 15a (1) and (2) may be used for the benefit of other applicants or authorisation holders (third parties) only after the previous applicant or authorisation holder who submitted the documentation has given written consent. Sentence 1 shall not apply if more than five years have passed since the Commission decision referred to in Article 13 (3) d of Directive 91/414/EEC according to which the knowledge drawn from this documentation could be taken into account for the first time. In derogation of sentence 2, documentation may be used under Article 15a (1) and (2) only upon expiry of the period specified in paragraph (2) if the period for the same active substance expires at a date later than the five-year period specified in sentence 2.

## **Article 14**

### **Use of findings from experiments on vertebrates**

(1) Documents to be enclosed with applications in accordance with Article 12 (3) and which presuppose experiments involving vertebrates shall not be required if the Federal Office of Consumer Protection and Food Safety is already in possession of sufficient findings from documentation submitted by a previous applicant. In this case, the Federal Office of Consumer Protection and Food Safety shall inform the previous applicant and the applicant in question on which documents submitted by the previous applicant are to be used for the benefit of the current applicant and shall inform each of these two parties of the name and address of the other party. Sentence 2 shall not apply if more than ten years have elapsed in a member state since the initial granting of authorisation regarding the previous applicant's plant protection product to which the intended use refers. Article 13 (1) sentence 2 and Article 13 (2) shall apply *mutatis mutandis*.

(2) In the case of paragraph (1) sentence 1, the previous applicant may file an objection to the utilisation of his documentation in accordance with paragraph (1) sentence 2 within three months of receiving notification. In the event of an objection, the authorisation procedure shall be suspended for a period of five years following submission of the application for authorisation, but no longer than ten years from the initial granting of authorisation for the previous applicant's plant protection product in a

member state. If Annex I of Directive 91/414/EEC does not include any of the active substances contained in the plant protection product, the ten-year period specified in sentence 2 starts on the date specified in Article 13 (1) sentence 2, in the case of Article 13 (2) with the initial inclusion of the active substance in Annex I of Directive 91/414/EEC. If the time required for the applicant to furnish his own documentation is shorter than the period specified in sentence 2 or 3, the authorisation procedure shall be suspended only for the duration of this period. The applicant and the previous applicant shall be heard prior to the suspension of the authorisation procedure.

(3) If, in the case referred to in paragraph (2), the plant protection product is authorised on the basis of the previous applicant's or authorisation holder's documentation prior to expiry of the 10-year period specified in Article 13 (1) sentence 1 and in conjunction with sentence 2 and paragraph (2), the previous applicant shall have a claim towards the current applicant for payment of 50 per cent of the costs saved by the applicant due to utilisation of the previous applicant's documentation. The previous applicant may forbid the applicant to market the plant protection product as long as the latter has not effected the payment or provided an adequate security for it.

**Article 14a**  
**Use of new findings from**  
**experiments on vertebrates**

(1) Documents that presuppose experiments involving vertebrates and which were submitted to the Federal Office of Consumer Protection and Food Safety for examination of the active substance in accordance with Article 15a (1) and (2) may be used for the benefit of third parties only if the Federal Office of Consumer Protection and Food Safety has notified this party, and the previous applicant or authorisation holder who submitted the documents, as to which of these documents it intends to use for the benefit of the third party, as well as the name and address of the other party respectively.

(2) The previous applicant or authorisation holder who submitted the documents may file an objection to the utilisation of his documents pursuant to paragraph (1) within three months after receipt of the notification pursuant to paragraph (1) sentence 1. If an objection is raised, the authorisation procedure shall be suspended for five years following submission of the application for authorisation but, at the latest, until the period specified in Article 13 (3) sentence 3 has expired. Article 14 (2) sentences 4 and 5 shall apply *mutatis mutandis*.

(3) If, in the case specified in paragraph (2), the plant protection product is authorised prior to expiry of the time specified under Article 13 (3) sentences 2 and 3, on the basis of the documentation submitted by

the previous applicant or authorisation holder, the previous applicant shall have a claim towards the third party, for whose benefit the documentation was used, for payment of 50 per cent of the costs saved by the third party due to utilisation of the documentation. The previous applicant or authorisation holder who submitted the documents may forbid the third party to market the plant protection product as long as the latter has not effected the payment or provided an adequate security for it.

**Article 14b**  
**Requesting supplementary documentation**  
**at a later date**

If documentation of identical content, presupposing experiments involving vertebrates, is requested at a later date from several authorisation holders under Article 15a (1), in order to prove compliance with the authorisation requirements in the case of plant protection products which are already authorised, the Federal Office of Consumer Protection and Food Safety shall inform each authorisation holder which documentation is required for further evaluation and shall also notify him of the names and addresses of the other authorisation holders involved. The Federal Office of Consumer Protection and Food Safety shall give the authorisation holders involved the opportunity to reach an agreement among themselves within a period to be specified by the Federal Office of Consumer Protection and Food Safety as to who shall submit the documentation. If no agreement is reached, the Federal Office of Consumer Protection and Food Safety shall make a decision in this matter according to its own judgement and shall inform all parties involved of this decision without delay. Unless they request revocation of the authorisation for their plant protection product, these parties shall each be required to bear part of the expenditure involved in the elaboration of the documentation, that is, the corresponding fraction in accordance with the number of authorisation holders involved; they shall be liable as joint and several debtors. Sentences 1 to 4 shall apply *mutatis mutandis* if documentation of identical content is requested from several applicants in the course of current authorisation procedures.

**Article 15**  
**Authorisation**

(1) The Federal Biological Research Centre shall grant authorisation of a plant protection product if

1. the application meets the requirements specified in Article 12 (3) sentence 2 or Article 12 (4) or (5),
2. The active substances of the plant protection product are listed in Annex I of Directive 91/414/EEC.
3. an examination of the plant protection product

shows that, in the light of current scientific findings and technology, given its intended and proper application or as a result of such application, this product

- a) is satisfactorily effective,
  - b) does not have any unacceptable effects on the plants and plant products to be protected,
  - c) does not cause any avoidable pain or suffering for vertebrates intended to be controlled by the plant protection product,
  - d) does not have any harmful effects on human and animal health nor on groundwater and
  - e) does not have any other unacceptable effects, particularly on the natural balance as well as on the hormonal balance of man and animals,
4. a) the active substances as well as formulants and impurities of the plant protection product relevant to health or the natural balance according to type and quantity and
- b) the residues relevant to human and animal health and the natural balance that arise from the intended and proper use of the plant protection product

can be reliably ascertained without unreasonable expenditure and

5. the plant protection product can be stored satisfactorily.

(2) Within the scope of the authorisation procedure and with regard to the restrictions specified in Annex I of Directive 91/414/EEC, the Federal Office of Consumer Protection and Food Safety shall decide on

1. the fields of application of the plant protection product,
2. the directions for use required for the protection of human and animal health and the prevention of any other harmful effects, in particular on the natural balance, including those concerning
  - a) the application rate,
  - b) the waiting period,
  - c) the distancing requirement necessary for the protection of waters and
  - d) the persons authorised to apply plant protection products, and
3. the suitability of the plant protection product for application in amateur gardening, especially taking into account the properties of the active substances, their suitability for dosing, form of the plant protection product and the size of the packaging.

(3) In each case, the Federal Office of Consumer Protection and Food Safety shall decide whether or not the conditions have been met in conjunction with

paragraph (2),

1. pursuant to paragraph (1) in agreement with the Federal Biological Research Centre in as much as nos. 2 and 3 do not stipulate otherwise,
2. pursuant to paragraph (1) no. 3d and e and no. 4b regarding health, in the case of paragraph (1) no. 3e regarding the prevention of health hazards through soil contamination, acting in agreement with the Federal Institute for Risk Assessment,
3. pursuant to paragraph (1) no. 3d and e regarding the prevention of damage resulting from strain on the natural balance as well as from waste from the plant protection product, in agreement with the Federal Environmental Protection Agency.

The authorities named in sentence 1 nos. 1 to 3 shall combine their decision with a written assessment which must be submitted to the Federal Office of Consumer Protection and Food Safety.

A decision on authorisation shall be made within a period of twelve months upon receipt of the application and the data, documents and samples to be submitted under Article 12 (3) sentence 2 and Article 12 (4) as well as paragraph (5).

(4) The Federal Office of Consumer Protection and Food Safety shall make the authorisation in compliance with the restrictions laid down in Annex I of Directive 91/414/EEC subject to the conditions necessary for

1. proper application as well as
2. for the protection of human and animal health and the prevention of any other harmful effects, in particular on the natural balance,

if regulations pursuant to paragraph (2) have not been issued. Furthermore, the Federal Office of Consumer Protection and Food Safety shall make the authorisation subject to the proviso that restrictions may be adopted, amended or supplemented at a later date.

(5) The Federal Office of Consumer Protection and Food Safety may request further information, documents and samples from the applicant during evaluation if this is required to prove compliance with authorisation requirements.

(6) Legal remedies against the requirements stipulated in paragraph (4) do not have any suspensive effect.

(7) The Federal Office of Consumer Protection and Food Safety may, to the extent that this is necessary for achieving the purpose of protection set out in Article 1 no. 4, impose conditions during the period of authorisation to the effect that specific findings regarding the application of the plant protection product shall be made, collected and analysed and that it shall be informed about the results

within a specific period. The relevant documents and samples must be submitted to the Federal Office of Consumer Protection and Food Safety upon request.

#### **Article 15a New findings**

(1) If new findings necessitate a review of authorisation, the Federal Office of Consumer Protection and Food Safety may request information, documents and samples from the authorisation holder within specific periods to prove continuous compliance with authorisation requirements.

(2) The applicant and the authorisation holder shall notify the Federal Office of Consumer Protection and Food Safety without delay of

1. changes to the data and documentation since the application was submitted and
2. new findings on effects of the plant protection product on human and animal health as well as on the natural balance.

The notification shall include information, documents and samples showing these changes or new findings.

(3) The Federal Office of Consumer Protection and Food Safety may require the authorisation holder to submit data and documents pursuant to paragraphs (1) and (2) to the Commission of the European Community and the responsible authorities in the other member states within specific periods and to inform it about the submission.

#### **Article 15b Authorisation of plant protection products authorised in other member states**

(1) The Federal Office of Consumer Protection and Food Safety may authorise a plant protection product authorised in another member state in accordance with the requirements of Article 4 of Directive 91/414/EEC in derogation of Article 15 if

1. the application and application documents meet the requirements set out in paragraph (6),
2. the active substances of the plant protection product are listed in Annex I of Directive 91/414/EEC and
3. the conditions which are important for the application of the plant protection product on national territory, in particular with respect to
  - a) plant protection as well as other agricultural concerns, including horticulture and forestry,
  - b) the effects on human and animal health and on groundwater as well as
  - c) other effects, in particular on the natural

balance,

correspond to those of the member state in which the plant protection product has been authorised and it can thus be refutably assumed that the plant protection product meets the requirements stipulated in Article 15 (1) nos. 3 to 5.

(2) Article 15 (2) shall apply mutatis mutandis to authorisations pursuant to paragraph (1). Within the scope of the decision on the fields of and directions for use, those fields of and directions for use that correspond to those specified in the plant protection product authorisation issued by the other member state shall be stipulated subject to the provisions of paragraph (3).

(3) If the domestic conditions relevant to the application of the plant protection product do not fully correspond to those in the member state where the plant protection product has been authorised, the Federal Office of Consumer Protection and Food Safety may, in derogation of paragraph (2) sentence 2, exclude or restrict fields of use or stipulate other directions for use if this is necessary to compensate for differences in the relevant conditions. If these restrictions or stipulations relevant to the application of the plant protection product, as described in sentence 1, do not suffice to compensate for differences in the conditions relevant to use of the plant protection product, no authorisation will be granted.

(4) The Federal Office of Consumer Protection and Food Safety shall decide whether or not the conditions have been met, in conjunction with the paragraphs 2 and 3 respectively,

1. pursuant to paragraph (1) no. 3 in agreement with the Federal Biological Research Centre in as much as nos. 2 and 3 do not stipulate otherwise,
2. pursuant to paragraph (1) no. 3b and c regarding the effects on health, in the case of paragraph (1) no. 3c, regarding the prevention of effects on health through soil contamination, acting in agreement with the Federal Institute for Risk Assessment,
3. pursuant to paragraph (1) no. 3b and c regarding effects due to strain on the natural balance and due to waste from the plant protection product in agreement with the Federal Environmental Protection Agency.

The authorities named in sentence 1 nos. 1 to 3 shall combine their decision with a written assessment which must be submitted to the Federal Office of Consumer Protection and Food Safety

(5) If regulations pursuant to paragraph (2) have not been issued, the Federal Office of Consumer Protection and Food Safety shall make the

authorisation subject to restrictions corresponding to those provisions which were envisaged for the authorisation of the plant protection product in the other member state for its intended and proper use, as well as for the protection of human and animal health and for the prevention of any other harmful effects, in particular on the natural balance. Paragraph (3) shall apply mutatis mutandis to restrictions. The Federal Office of Consumer Protection and Food Safety shall make the authorisation subject to the proviso that restrictions may be adopted, amended or supplemented at a later date.

(6) The applicant shall prove through appropriate data and documents that the plant protection product has been authorised in a member state and that the national conditions relevant for application of the plant protection product pursuant to paragraph (1) no. 3 correspond to those in this member state. The Federal Ministry for Consumer Protection, Food and Agriculture shall be authorised to regulate by ordinance the type and scope of the data and documents, in agreement with the Federal Ministries of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety, with the consent of the Bundesrat.

(7) If a decision of the European Community under Article 10 (3) of Directive 91/414/EEC prescribes the authorisation of a plant protection product which has been authorised in another member state, the Federal Office of Consumer Protection and Food Safety shall authorise the plant protection product within the scope specified in the decision.

(8) Article 15 (5), (6), (7) and Article 15a shall apply mutatis mutandis to authorisations pursuant to paragraphs (1) and (7).

**Article 15c**  
**Authorisation prior to a decision**  
**by the European Community**

(1) In derogation of Article 15 (1) nos. 2 to 5 and Article 15 (3), the Federal Office of Consumer Protection and Food Safety may authorise a plant protection product for a maximum period of three years

1. if the plant protection product contains an active substance for which no decision has yet been made on its inclusion in Annex I of Directive 91/414/EEC and
2. if there is no indication that
  - a) the plant protection product given intended and proper use or as a result of such use
    - aa) is not sufficiently effective,
    - bb) has unacceptable effects on plants and plant products,
    - cc) causes avoidable suffering and pain for

vertebrates for whose control the plant protection product is intended,

- dd) has harmful effects on human and animal health and on groundwater and
  - ee) has other unacceptable effects, in particular on the natural balance,
- b) aa) active substances, and formulators and impurities of the plant protection product that are relevant to human and animal health and the natural balance according to type and quantity and
- bb) the residues arising from the intended and proper use of the plant protection product relevant to human and animal health and to the natural balance
- cannot be reliably ascertained by reasonable expenditure and
- c) the plant protection product cannot be stored satisfactorily.

Article 15 (1) no. 1, Article 15 (2) and (4) to (7) as well as Article 15a (2) and (3) shall apply mutatis mutandis to authorisations pursuant to sentence 1.

(2) The Federal Office of Consumer Protection and Food Safety shall decide whether or not the conditions pursuant to paragraph (1) have been met in conjunction with

1. Article 15 (1) and (2) in agreement with the Federal Biological Research Centre in as much as nos. 2 and 3 do not stipulate otherwise,
2. Article 15 (1) no. 3d and e and no. 4b and Article 15 (2) regarding human health, in the case of Article 15 (1) no. 3e and Article 15 (2) with respect to the prevention of health hazards through soil contamination, in agreement with the Federal Institute for Risk Assessment,
3. Article 15 (1) no. 3d and e and Article 15 (2) with respect to the prevention of damage through strain on the natural balance as well as through waste from the plant protection product in agreement with the Federal Environmental Protection Agency.

The authorities named in sentence 1 nos. 1 to 3 shall combine their decision with a written assessment which must be submitted to the Federal Office of Consumer Protection and Food Safety.

(3) The Federal Office of Consumer Protection and Food Safety may, upon application, extend the authorisation pursuant to paragraph (1) subject to a decision of the European Community under Article 8 (1) sentence 5 of Directive 91/414/EEC up to the date when a decision is made on the authorisation of the plant protection product under Article 15.

**Article 16**  
**Termination of authorisation**

(1) Authorisations under Articles 15 and 15b shall expire ten years after the year in which they were granted and may be renewed. The Federal Office of Consumer Protection and Food Safety may grant an authorisation for a shorter term in individual cases. Authorisations under Article 15b (1) and (7) may, in derogation of sentence 1, be granted only up to the date of expiry in the member state of the authorisation to which the applicant referred in justifying the requirements stipulated in Article 15b (1).

(2) If no decision has been made on an application for renewal of authorisation before an authorisation granted under Articles 15 and 15b has expired, the Federal Office of Consumer Protection and Food Safety may extend the authorisation upon application up until the date when a decision is made on the renewal of authorisation. An extension of authorisation presupposes that

1. the renewed application is valid for three years at the most and is applied for at the latest one year before expiry of authorisation,
2. the application for renewed authorisation meets the set requirements and
3. there are no indications that the plant protection product does not meet the conditions stipulated in Article 15 (1) nos. 3 to 5.

**Article 16a**  
**Revocation, withdrawal and suspension  
of an authorisation**

(1) Except in the cases of Article 49 (2) sentence 1 of the Administrative Procedure Act, authorisations may be revoked

1. if the authorisation holder so requests or
2. if, subject to paragraph (2), one of the requirements for authorisation no longer applies.

(2) Authorisations shall be revoked if one of the requirements stipulated in Article 15 (1) nos. 2 to 5, Article 15b (1) nos. 2 and 3 or Article 15c (1) no. 2 is no longer fulfilled.

(3) Authorisations under Article 15c (1) shall be revoked if the European Community decides not to include the active substance of the plant protection product in Annex I of Directive 91/414/EEC or has imposed a restriction under Article 5 (4) of Directive 91/414/EEC on the inclusion of the active substance in the current version of Annex I which conflicts with the authorisation. There is no claim for compensation of a pecuniary loss in this case.

(4) Authorisations may be withdrawn if the applicant has obtained the authorisation

1. through fraudulent misrepresentation, threat or bribery or
2. intentionally or by gross negligence through essentially incorrect or incomplete information.

Article 48 of the Administrative Procedure Act shall remain unaffected.

(5) Instead of withdrawal or revocation, the Federal Office of Consumer Protection and Food Safety may, also in the cases specified in paragraphs (2) and (4), order the suspension of authorisation for a specific period until the reasons for withdrawal or revocation have been eliminated.

(6) Article 49 (6) of the Administrative Procedure Act shall apply mutatis mutandis to the cases specified in paragraph (1) no. 2 and paragraph (2).

**Article 16b**  
**Returning of plant protection products**

(1) Upon termination of the authorisation of a plant protection product, it may be returned to

1. the authorisation holder,
  2. the importer or his representative or
- a third party authorised by one of these individuals.

(2) The responsible authority may order the return if the Federal Office of Consumer Protection and Food Safety has withdrawn or revoked the authorisation or if it has established upon expiry of authorisation that the requirements for a withdrawal or revocation actually existed. The authorisation holder, the importer and his representative shall be obliged to accept returned plant protection products without delay in the case of sentence 1.

(3) Furthermore, in the case of withdrawal or revocation under Article 49 (2) sentence 1, nos. 3 to 5 of the Administrative Procedure Act or under Article 16a (2), the return of a plant protection product to a company that markets it for commercial purposes is admissible. In such a case, the company shall be obliged to accept returned plant protection products without delay if the responsible authority orders their return.

(4) Acting in agreement with the Federal Ministries of Economic Affairs and Technology and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered to regulate by ordinance, with the consent of the Bundesrat, precise details of return and acceptance and to stipulate who shall bear the costs of the return or acceptance.

(5) The Federal Office of Consumer Protection and Food Safety shall inform the designated

authorities on the reasons for withdrawal, revocation or that conditions actually existed for withdrawal or revocation.

### **Article 17 Empowerment**

(1) In agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs, and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to regulate by ordinance

1. the precise details of the requirements for authorisation under Article 15 (1) nos. 3 to 5, Article 15b (1) no. 3 or Article 15c (1) no. 2 in compliance with the provisions issued by the European Community on the marketing of plant protection products,
2. the procedure for the authorisation of plant protection products and,
3. if required to meet the purposes stipulated in Article 1, the requirements and the procedure of recognition of institutions that evaluate the efficacy of plant protection products for compiling data and documents for the authorisation of plant protection products.

(2) If required to meet the purposes referred to in Article 1, the Federal Ministry of Consumer Protection, Food and Agriculture acting in agreement with the Federal Ministry of Finance, shall be empowered to prescribe by ordinance without the consent of the Bundesrat that plant protection products may be imported into or exported from non-member states via specific customs offices only.

(3) The Federal Office of Consumer Protection and Food Safety shall publish notice of:

1. the authorisation of plant protection products and the expiry date of this authorisation,
2. the withdrawal, revocation or suspension of the authorisation, and
3. general orders under Article 6a (3) sentence 2.

in the Bundesanzeiger

### **Article 18 Approval**

(1) Upon application, the Federal Office of Consumer Protection and Food Safety may approve the use of an authorised plant protection product in a field of use other than those specified in the authorisation

1. if the use is in the interest of the public,

2. if the data and documents required to prove fulfilment of the approval requirements under no. 4 have been submitted,
3. if it is known that the plant protection product is effective in the fields of application applied for and that it does not have any unacceptable effects on the plants and plant products to be protected,
4. if the examination reveals that, given intended and proper use or as a result of such use, the requirements stipulated in Article 15 (1) no. 3c to e have been met, and
5. if the use is envisaged
  - a) for plants cultivated only on a minor scale or whose cultivation is of minor importance,
  - b) for plant products whose production is of minor importance,
  - c) against harmful organisms which only occasionally cause serious damage or only in specific areas or
  - d) in other cases solely in small quantities.

The documents specified in sentence 1, no. 2 are not required if the Federal Office of Consumer Protection and Food Safety has sufficient data for an examination pursuant to sentence 1, no. 4.

(2) Article 15 (2) no. 2, Article 15 (4) and (6), and Article 15a (2) sentence 1 shall apply to approvals pursuant to paragraph (1).

(3) The Federal Office of Consumer Protection and Food Safety shall decide whether the conditions stipulated in paragraph (1) sentence 1, no. 4 have been fulfilled in conjunction with

1. Article 15 (1) no. 3 and (2) no. 2 in agreement with the Federal Biological Research Centre in as much as nos. 2 and 3 do not stipulate otherwise,
2. Article 15 (1) no. 3 d and e and Article 15 (2) no. 2 regarding human health, in the case of Article 15 (1) no. 3e and Article 15 (2) no. 2 with respect to the prevention of health hazards through soil contamination in agreement with the Federal Institute for Risk Assessment,
3. Article 15 (1) no. 3d and e and Article 15 (2) no. 2 with respect to the prevention of damage through strain on the natural balance as well as through waste from the plant protection product in agreement with the Federal Environmental Protection Agency.

The authorities named in sentence 1 nos. 1 to 3 shall combine their decision with a written assessment which must be submitted to the Federal Office of Consumer Protection and Food Safety.

(4) The approval shall apply

1. only as long as the authorisation is valid and if the authorisation has not been suspended and

2. only for use in agricultural holdings, including horticulture and forestry.

Article 6a (3) shall apply mutatis mutandis.

#### **Article 18a** **Approval procedure**

(1) Apart from the authorisation holder, the approval may be applied for by:

1. those applying plant protection products for commercial purposes or within the scope of other economic undertakings on an agricultural holding, including horticulture or forestry,
2. legal persons whose members are legal persons pursuant to no. 1 or
3. official and scientific institutions engaged in fields of agriculture, including horticulture or forestry.

(2) If the applicant is not the authorisation holder, the authorisation holder shall be heard before a decision is made on approval. If the latter raises an objection against the granting of the approval because the plant protection product is only insufficiently effective in the proposed field of use or causes unacceptable damage to the plants or plant protection products to be protected, the Federal Office of Consumer Protection and Food Safety may grant the approval only if the objections raised by the authorisation holder can be proven to be unfounded.

(3) Acting in agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs, and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to lay down in detail by ordinance the approval procedure and, in particular, the type and scope of the data and documents specified in Article 18 (1) sentence 1, no. 2.

(4) The Federal Office of Consumer Protection and Food Safety shall publish the approval and its contents as well as the withdrawal or revocation of the approval in the Bundesanzeiger.

#### **Article 18b** **Approval in individual cases**

(1) In individual cases, the responsible authority may, upon application, approve the use of an authorised plant protection product in fields of use other than those specified in the authorisation

1. if application is planned
  - a) on plants grown only on a minor scale or

- b) against harmful organisms that cause serious damage only in specific areas, and

2. if the intended use corresponds to a field of use specified in the authorisation.

Article 18a (1) nos. 1 and 2 shall apply mutatis mutandis.

(2) An approval pursuant to paragraph (1) for the purpose of using the plant protection product on plants and plant products from which food may be produced may be granted only

1. if a maximum limit has been set for the residues to be expected from intended and proper use of the plant protection product in or on foodstuffs of plant origin under the Maximum Residue Limits Ordinance of 1 September 1994 (Bundesgesetzblatt<sup>2</sup> I, p. 2299) as amended and
2. if the food produced from these plants or plant products contributes only to a minor degree to the average daily intake.

(3) Before granting the approval, the Federal Office of Consumer Protection and Food Safety shall be given the opportunity to express its opinion.

(4) The approval shall be subject to

1. the necessary requirements for the protection of human and animal health and for the prevention of other harmful effects, in particular on the natural balance as well as
2. the proviso of revocation.

The approval shall be valid for a limited period. Article 18 (4) sentence 1, no. 1 shall apply mutatis mutandis.

#### **Article 18c** **Confidentiality**

(1) Data constituting or containing trade or business secrets may not be disclosed by the Federal Office of Consumer Protection and Food Safety if the applicant or authorisation holder has clearly indicated that the data is confidential. Sentence 1 shall not apply if the Federal Office of Consumer Protection and Food Safety ascertains an overriding public interest in the disclosure, taking into account the interest in confidentiality of the concerned parties. Articles 13 to 14 b shall remain unaffected.

(2) Trade and business secrets pursuant to paragraph (1) shall not encompass:

1. the trade name of the plant protection product and the name and address of the authorisation holder,
2. information on the type and quantity of the active

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<sup>2</sup> Federal Law Gazette

substances,

3. physicochemical data concerning the plant protection product and the active substance,
4. a summary of the results of the tests and trials to establish the efficacy and effects on human and animal health as well as other effects, in particular on the natural balance,
5. information on precautions as well as first-aid measures in case of accidents,
6. methods of analysis to determine active substances, formulants, impurities and residues under Article 15 (1) no. 4 and Article 15c (1) no. 2b,
7. information on methods of proper disposal or neutralisation of the plant protection product, its container or packaging as well as the active substance.

(3) Applicants and authorisation holders shall immediately inform the Federal Office of Consumer Protection and Food Safety of the self-initiated publication of data and documents which they had previously indicated as requiring confidentiality pursuant to paragraph (1) sentence 1.

#### **Article 19 Compulsory notification**

(1) By March 31st of each year,

1. any manufacturer of plant protection products,
2. any person who placed a plant protection product on the market for the first time, and
3. in cases where plant protection products are imported, any person who puts the goods into circulation or causes them to be put into circulation

shall submit an annual report to the Federal Office of Consumer Protection and Food Safety therein notifying the Federal Office of Consumer Protection and Food Safety of the type and quantity of the plant protection products sold or exported to purchasers with residence or place of business in Germany and of the active substances contained in these products. A separate report shall be submitted for each plant protection product, specifying its trade name. Sentences 1 and 2 shall not apply if plant protection products are sold pursuant to an approval in accordance with Article 11 (2).

(2) Acting in agreement with the Federal Ministries of Economic Affairs and Technology and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered by ordinance to lay down details regarding the content and form of these notifications without the consent of the Bundesrat.

(3) The Federal Office of Consumer Protection and Food Safety shall inform the responsible authorities of the Länder about the results of the notifications.

#### **Article 20 Labelling**

(1) The provisions of Articles 13 to 15 of the Chemicals Act concerning labelling shall apply *mutatis mutandis*

1. to the marketing of plant protection products which are not substances or preparations as defined in Article 3 (1) or (4) of the Chemicals Act,
2. to the marketing of plant protection products by distributors and
3. to the importation of plant protection products.

(2) Plant protection products may be marketed or imported only if, in addition to the labelling requirements specified in Articles 13 and 14 of the Chemicals Act, the following information is printed indelibly in German on the containers and commercial packaging in a clearly visible and legible fashion:

1. the trade name of the plant protection product,
2. the authorisation number,
3. the name and address of the authorisation holder and the person who packaged and labelled the plant protection product for sale to the user unless he is the authorisation holder,
4. type and quantity of active substances,
5. the expiry date in the case of plant protection products with a maximum shelf life of two years,
6. the instructions for use
  - a) with the fields of applications and directions for use specified in accordance with Article 15 (2), Article 15b (2) and (3), also in conjunction with Article 15 (2) or Article 15c (1) sentence 2 in conjunction with Article 15 (2),
  - b) in accordance with the restrictions stipulated in Article 15 (4) sentence 1, Article 15b (5) sentences 1 and 2, also in conjunction with Article 15b (3) or Article 15c (1) sentence 2 in conjunction with Article 15 (4) sentence 1,
  - c) with the field of application "authorised for use in amateur gardening" if the Federal Office of Consumer Protection and Food Safety has established its corresponding eligibility with authorisation in accordance with Article 15 (2) no. 3, also in conjunction with Article 15b (2) sentence 1 and Article 15c (1) sentence 2,
7. the prohibitions or restrictions issued under Article 3 (1) no. 3 and Article 7 (1) nos. 1 and 2.

(3) The fields of application and directions for use specified by the authority responsible for authorisation are to be included in the instructions for use under the heading "Fields of application and directions for use specified by the authority responsible for authorisation" and kept clearly separate from the other details and information.

(3a) Paragraphs (1) and (2) shall not apply with respect to the importation of a plant protection product by a manufacturer or distributor.

(4) Paragraph (2) shall not apply to plant protection products intended for exportation or which in the case of importation are kept in a free port or as dutiable goods under customs supervision.

(5) Acting in agreement with the Federal Ministries of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered to issue ordinances with the consent of the Bundesrat

1. if this is required to meet the purposes specified in Article 1
  - a) to specify in detail the contents of the information pursuant to paragraph (2),
  - b) to prescribe that further specific details must be attached to containers and commercial packaging in addition to the information pursuant to paragraphs (1) to (3) and to stipulate their contents,
  - c) to regulate in detail the type and form of labelling,
  - d) to prescribe the use of specific containers, packages or packaging materials as well as to regulate the closure of the containers or packages, including their seals,
  - e) to prescribe specific labelling for the marketing of culture substrates containing plant protection products or to which plant protection products are adherent;
2. insofar as the purposes referred to in Article 1 are not impaired, to stipulate that information pursuant to paragraphs (1) to (3) as well as information to be provided by virtue of an ordinance under no. 1a, b and e may be contained in a package insert accompanying the container or the package. In such cases, reference shall be made to the package insert on the container and the commercial packaging.

## **Article 21**

### **Prohibited data**

When marketing plant protection products for commercial purposes or within the scope of other business undertakings or advertising plant protection products, no use may be made of information indicating that these products may be used in larger quantities, higher concentrations, at other times or with shorter waiting periods than those specified in the instructions for use or in the approval published in the Bundesanzeiger under Article 18a (4). This shall not apply to plant protection products intended for exportation.

## **Article 21a**

### **Notification requirements**

Persons intending to market plant protection products for commercial purposes or within the scope of other business undertakings or to import them for commercial purposes must notify the authority responsible for the company address and the place of activity and, in the case of importation, the authority responsible for the company address or branch before initiating the activity. The governments of the Länder shall be empowered to issue detailed provisions by ordinance regarding notification and the notification procedure. They may delegate these powers to other authorities by ordinance.

## **Article 22**

### **Sales**

(1) Plant protection products may not be marketed by means of vending machines or other forms of self-service. Provisions on the sale of hazardous substances or preparations that were issued under Article 17 (1) no. 1a and c of the Chemicals Act shall apply mutatis mutandis to the sale of plant protection products.

(2) With respect to retail and mail-order businesses, the person engaged in a business or the person selling plant protection products on his behalf, shall inform the purchaser about the use of the plant protection product, in particular about prohibitions and restrictions.

(3) The responsible authority may completely or partially prohibit the retail or mail-order sale or offering for sale of plant protection products if certain facts justify the assumption that the person engaged in a business or the person selling plant protection products on his behalf does not possess the reliability and specialist knowledge necessary for informing the purchaser properly about the application of the plant protection products and the risks involved.

(4) Such persons shall, upon request, furnish the

responsible authority with proof that they possess the necessary specialist knowledge. Article 10 (3) sentences 2 to 4 shall apply mutatis mutandis.

### **Article 23 Export**

(1) Insofar as regulations have not been issued with other legal provisions, plant protection products may be exported for commercial purposes or within the scope of other economic undertakings to states other than member states only

1. if the trade name of the plant protection product, the active substances according to type and quantity and the expiry date of plant protection products with a maximum shelf life of two years are indicated on the containers and commercial packaging in clearly visible, legible and indelible print and
2. if the containers and commercial packaging are accompanied by instructions for use containing information on
  - a) the intended and proper application,
  - b) possible harmful effects on human and animal health as well as on the natural balance,
  - c) precautions as well as first-aid measures in case of accidents,
  - d) proper disposal or neutralisation.

International agreements and, in particular, the International Code of Conduct on the Distribution and Use of Pesticides of the Food and Agriculture Organisation of the United Nations, shall also be observed in the case of exportation.

(2) Plant protection products intended for exportation

1. which are not authorised under the provisions of this Act,
2. which are not labelled as prescribed in Article 20 (2) nos. 2, 6, and 7 and Article 20 (3) or
3. which do not bear information stipulated pursuant to Article 21

shall be kept separate from plant protection products intended for use in the territory where this Act is in force and shall be rendered recognisable as such. Sentence 1, no. 2 shall apply mutatis mutandis to culture substrates for which labelling has been prescribed in an ordinance as specified in Article 20 (5) no. 1e.

(3) Acting in agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs, for the Environment, Nature Conservation and Nuclear Safety and of Economic Co-operation and Development, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat,

be empowered to prohibit by ordinance the exportation of specific plant protection products or of plant protection products containing specific substances into non-member states to the extent that this is necessary for

1. the implementation of legal instruments of the European Community or
2. for averting serious hazards to human or animal health, which cannot be eliminated in any other way or any other dangers, particularly to the natural balance.

Article 5 (1) shall apply mutatis mutandis.

### **Article 23a Separate storage**

Foodstuffs or animal feed intended for exportation and which have been treated with plant protection products whose distribution or importation has been approved under Article 11 (2) sentence 1, no. 3 shall be kept separate from foodstuffs and animal feed intended for placing on the domestic market and shall be rendered recognisable as such.

## **Section Five Plant Protection Equipment**

### **Article 24 Marketing; importation**

Plant protection equipment may be placed on the market or imported only if it is designed in such a way that, when used properly and as intended for the application of plant protection products, it will not produce any harmful effects on human or animal health or on groundwater nor shall it have any other harmful effects, particularly on the natural balance, which can be avoided by using state of the art techniques.

### **Article 25 Declaration**

(1) Before plant protection equipment, with the exception of small devices, is placed on the market or imported for the first time, the manufacturer, the distributor (if he intends to market the plant protection equipment for the first time) or the person importing the plant protection equipment for the first time for commercial purposes shall declare to the Federal Biological Research Centre that the equipment type meets the requirements set out in Article 24.

(2) The declaration must contain:

1. the name and address of the manufacturer, distributor or importer,

2. the name of the equipment type and the area of use.

(3) The declaration must be accompanied by:

1. the instructions for use,
2. a description of the equipment type and
3. any other documents necessary for assessment.

(4) The documents referred to in paragraph (3) must be resubmitted or supplemented in the case of modifications to the equipment type influencing the application of plant protection products.

(5) The Federal Biological Research Centre may waive the declaration if the plant protection equipment is intended for research, investigation, trial or exhibition purposes.

#### **Article 26** **Plant protection equipment list**

(1) The Federal Biological Research Centre shall keep a list of the equipment types for which a declaration under Article 25 has been submitted (plant protection equipment list).

(2) The Federal Biological Research Centre shall announce entries in the plant protection equipment list and the deletion of such entries in the Bundesanzeiger.

#### **Article 27** **Evaluation**

(1) The Federal Biological Research Centre may test plant protection equipment to establish whether it meets the requirements of Article 24. It shall give priority to testing plant protection equipment whose declaration or accompanying documents give rise to doubts as to whether the plant protection equipment meets the requirements of Article 24.

(2) In specific cases, the Federal Biological Research Centre may order the manufacturer, distributor or importer to supply it with one plant protection machine for testing.

#### **Article 28** **Results of evaluation**

If testing reveals that the plant protection equipment does not meet requirements, the Federal Biological Research Centre shall delete the relevant entry from the plant protection equipment list. In case of minor shortcomings, the Federal Biological Research Centre may initially refrain from deleting the entry and set the manufacturer, distributor or importer a reasonable deadline for eliminating them. Until this period has elapsed, plant protection

equipment of this type may continue to be marketed with these shortcomings in derogation of Article 24.

#### **Article 29** **Instructions for use**

In the case of importation and marketing of plant protection equipment, the instructions for use must be supplied in German. They must also include:

1. the name and address of the manufacturer, distributor or importer,
2. the designation of the equipment and the area of use.

#### **Article 30** **Empowerment**

(1) The Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to issue ordinances

1. as far as this is necessary for attaining the purpose stated in Article 1 no. 4,
  - a) to specify in greater detail the requirements for plant protection equipment under Article 24,
  - b) to require holders of a right of disposal and owners to have plant protection equipment already in use tested,
  - c) to prohibit the use of plant protection equipment which does not meet the requirements laid down in an ordinance as specified in a) or which has not been tested as specified in b);
2. to define the term "small devices" as referred to in Article 25 (1),
3. to lay down details of the procedure for testing plant protection equipment, and in particular the nature and scope of documentation required under Article 25 (3).

(2) The governments of the Länder shall be empowered to issue ordinances requiring holders of rights of disposal and owners to have plant protection equipment already in use tested and to lay down details of this procedure if the Federal Ministry of Consumer Protection, Food and Agriculture does not exercise its own powers in the matter and insofar as this is necessary for attaining the purpose set forth in Article 1 no. 4. They may also stipulate that testing shall be carried out by officially recognised inspection facilities and may lay down the requirements to be met for approval, loss of approval and the procedure for granting approval. The governments of the Länder may, by ordinance, delegate these powers to supreme state authorities while stipulating that these authorities may in turn delegate the aforementioned powers, by ordinance, to subordinate authorities or authorities

otherwise under their control.

**Section Six  
Plant Resistance Improvers,  
Additives, Active Substances**

**Article 31  
Marketing of plant resistance improvers**

(1) Plant resistance improvers may be marketed only if

1. given the intended and proper use or as a result of such use they do not have harmful effects on human and animal health, groundwater or the natural balance,
2. they have been included in a list of plant resistance improvers issued by the Federal Office of Consumer Protection and Food Safety and
3. the wording "plant resistance improver" and the list number are stated on the containers and outer packaging or package inserts in accordance with Article 31a (1) sentence 2, nos. 1 to 5.

(2) Article 22 (1) shall apply mutatis mutandis to the sale of plant resistance improvers.

**Article 31a  
Inclusion in the list**

(1) Plant resistance improvers shall be included in the list under Article 31 (1) no. 2 if the manufacturer, distributor or importer has applied for the inclusion. The application must include:

1. the name and address of the applicant,
2. the trade name of the plant resistance improver,
3. information on its composition, specifying the nature and quantity of the substances using the commonly used scientific nomenclature,
4. information on the mode of action,
5. the instructions for use and
6. the labelling intended for the container and outer packaging or package inserts.

Furthermore, the application shall state that the plant resistance improver meets the requirements stipulated in Article 31 (1) no. 1. Acting in agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to regulate by ordinance the procedure of inclusion in the list of plant resistance improvers, especially concerning the contents and form of the application.

(2) If the submitted data and documents give rise to doubts as to whether the plant resistance improver meets the requirements stipulated in Article 31 (1) no. 1, the Federal Office of Consumer Protection and Food Safety may request that the applicant supplies the documents and samples necessary for assessment of the plant resistance improver.

(3) The Federal Office of Consumer Protection and Food Safety shall decide within four months upon receipt of the application on inclusion in the list of plant resistance improvers. The Federal Office of Consumer Protection and Food Safety shall make this decision in consideration of

1. potentially harmful effects on human and animal health in agreement with the Federal Institute for Risk Assessment,
2. potentially harmful effects on the natural balance in agreement with the Federal Environmental Protection Agency,
3. other harmful effects pursuant to Article 31 (1) no. 1 in agreement with the Federal Biological Research Centre for Agriculture and Forestry.

The authorities named in sentence 1 nos. 1 to 3 shall combine their decision with a written assessment which must be submitted to the Federal Office of Consumer Protection and Food Safety. If the Federal Office requests documents or samples pursuant to paragraph (2) before inclusion of the plant resistance improver in the list, it shall make a decision within four months upon receipt of the documents or samples.

(4) If the documents or samples reveal that a plant resistance improver does not meet the requirements stipulated in Article 31 (1) no. 1, the Federal Office of Consumer Protection and Food Safety shall refuse to include the plant resistance improver in the list.

(5) The applicant shall immediately notify the Federal Office of Consumer Protection and Food Safety of changes in the data and documents pursuant to paragraph (1) sentence 2 and paragraph (2).

**Article 31b  
Evaluation**

(1) The Federal Office of Consumer Protection and Food Safety may also test plant resistance improvers after their inclusion in the list, to determine whether they meet the requirements stipulated in Article 31 (1) no. 1. The Federal Office shall give priority to testing those plant resistance improvers where the application, the enclosed data or the documents and samples under Article 31a (2) give rise to doubts as to whether the plant resistance improver

meets the requirements stipulated in Article 31 (1) no. 1.

(2) If a subsequent examination should reveal that a plant resistance improver does not meet the requirements stipulated in Article 31 (1) no. 1, the Federal Office of Consumer Protection and Food Safety shall delete the plant resistance improver from the list. In this case the return of the plant resistance improver to the manufacturer or to a third party authorised by him shall be admissible.

(3) The Federal Office of Consumer Protection and Food Safety shall publish the inclusions and deletions in the list of plant resistance improvers in the Bundesanzeiger.

#### **Article 31c Additives**

(1) Substances intended for adding to plant protection products to change their properties or effects (additives), with the exception of water and fertilisers as defined in the Act on Fertilisers, may only be marketed in the formulation proposed for sale to the user if they meet the requirements stipulated in Article 31 (1) no. 1 and have been included in the list of additives kept by the Federal Office of Consumer Protection and Food Safety.

(2) The provisions on plant resistance improvers shall apply mutatis mutandis to additives. Acting in agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs, and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered to regulate by ordinance with the consent of the Bundesrat the procedure for inclusion in the list of additives, especially with regard to the contents and form of the application.

#### **Article 31d Marketing of active substances contained in plant protection products**

(1) Active substances used to manufacture plant protection products or used as plant protection products may be marketed or imported only

1. if the active substances have been classified, packaged and labelled in accordance with Articles 13 to 15 of the Chemicals Act and
2. if the necessary data and documents required pursuant to Annex II to Directive 91/414/EEC have been submitted to the member states and the Commission of the European Community along with a declaration that the active substances is intended for use in plant protection products or as a plant protection product. This shall not apply to

active substances marketed or imported for experimental purposes.

(2) Insofar as this is required for attaining the purposes referred to in Article 1, the Federal Ministry of Consumer Protection, Food and Agriculture, acting in agreement with the Federal Ministries of Economic Affairs and Technology, of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety, shall, with the consent of the Bundesrat, be empowered to regulate by ordinance the procedure for submitting documentation, including type and scope.

#### **Section Seven Compensation, Assignment of Claims**

#### **Article 32 Compensation**

(1) A reasonable pecuniary compensation shall be paid in the event of destruction pursuant to this Act of plants or plant products which are neither infested nor suspected of infestation or of other objects that are neither carriers of harmful organisms nor suspected of being carriers. The compensation shall be determined by equitably weighing the interests of the general public and those of the persons affected.

(2) If, as a result of a measure taken under this Act, the person affected suffers a pecuniary loss which cannot be compensated for pursuant to paragraph (1), a pecuniary compensation shall be granted insofar as this appears appropriate for preventing or compensating for any undue hardships.

(3) No compensation shall be paid in those cases where the person affected by the measure or his predecessor in title occasioned the measure by reason of an infringement of this Act or of an ordinance or order issued under this Act.

(4) Resort to the general courts of law shall be open in the event of disputes arising from claims for compensation.

#### **Article 32a Assignment of claims**

If compensation is paid under Article 32 (1) or (2) or is granted due to official measures to control or prevent the introduction of harmful organisms and if the European Community participates in the financing of the compensation or settlement, the Federal Ministry of Consumer Protection, Food and Agriculture may, with the consent of the Bundesrat, prescribe by ordinance that claims for compensation or damages made by a person entitled to claim compensation or a settlement from a third party shall be passed to the European Community to the amount

of the prorata financing of the compensation or settlement if this is required to implement the legal instruments of the European Community. Further details regarding the assignment of claims and an assignment of residual claims to the Länder, especially the scope and procedure of these claims, may be regulated in the ordinance stipulated in sentence 1.

## **Section Eight Authorities; Monitoring**

### **Article 33 Federal Biological Research Centre**

(1) The Federal Biological Research Centre is an autonomous superior federal authority under the jurisdiction of the Federal Ministry of Consumer Protection, Food and Agriculture.

(2) In addition to the tasks which have been or shall be assigned to it by this Act, by ordinances as specified in Article 30 (1) and Article 38b sentence 2 or by other legal provisions, the Federal Biological Research Centre shall have the following tasks:

1. to inform and advise the Federal Government in the field of plant protection,
2. to carry out research to the purpose of this Act, including the compilation of library and documentary records, the evaluation and provision of information,
3. (deleted)
4. to participate in the monitoring of plant protection equipment of the equipment types in the plant protection equipment list,
5. to test plant protection equipment,
6. to test and develop plant protection methods as well as participate in the closing of control gaps,
7. to test plants for resistance to harmful organisms,
8. to examine bees for damage caused by authorised plant protection products,
9. to analyse and assess risks in the area of introducing and dispersing harmful organisms and to participate in establishing national and international standards in the field of plant health,
10. to participate in and accompany programmes and measures, including monitoring, in the Länder and the European Community for preventing the introduction and dispersal of harmful organisms,
11. to participate in the evaluation of active substances contained in plant protection products in accordance with the provisions issued by the European Community.

(3) The Federal Biological Research Centre may

test equipment and devices used in plant protection which do not constitute plant protection equipment.

(4) The Federal Biological Research Centre shall publish a descriptive list of plant protection equipment registered in the plant protection equipment list, detailing the features and properties important for the use of plant protection equipment. Use may be made of test results from plant protection practice. It notifies standards which have been adopted in accordance with Article X of the International Plant Protection Convention.

(5) (deleted)

(6) (deleted)

### **Article 33a Federal Office of Consumer Protection and Food Safety**

(1) In addition to the tasks which have been or shall be assigned to the Federal Office of Consumer Protection and Food Safety by this Act, by ordinances as specified in Article 7, Article 17 (1), Article 18a (3), Article 19 (2), Article 31a (1) sentence 4, Article 31c (2) sentence 2, Article 31d (2) and Article 38b sentence 2 or by other legal provisions, it shall also have the following tasks:

1. to inform and advise the Federal Government in the field of plant protection products, plant resistance improvers and additives,
2. to participate in the monitoring of authorised plant protection products and plant resistance improvers and additives included in the respective lists,
3. to participate in the publication of the list under Article 18 of the Federal Law concerning the Prevention of Epidemics,
4. to participate in the Rotterdam Convention concerning the procedure for prior informed consent for specific hazardous chemicals, plant protection products and pesticides in international trade for the area of plant protection,
5. to evaluate active substances contained in plant protection products in accordance with the provisions issued by the European Community.

(2) The Federal Office of Consumer Protection and Food Safety may evaluate:

1. plant protection products which do not require authorisation,
2. substances for use in plant growing which are not plant protection products, plant resistance improvers or additives.

(3) The Federal Office of Consumer Protection and Food Safety may publish a descriptive list

1. of authorised plant protection products, detailing the features and properties important for their application, in particular the suitability of plant protection products for specific fields of use, soil and climatic conditions and for households and allotment gardens as well as the expiry date for the authorisation of the plant protection products,
2. plant resistance improvers and additives registered in the respective lists.

Use may be made of test results from plant protection practice.

(4) A scientific advisory committee comprised of members appointed by the Federal Ministry of Consumer Protection, Food and Agriculture shall be formed at the Federal Office of Consumer Protection and Food Safety. The expert committee shall be consulted

1. before the decision on the authorisation of a plant protection product is made as specified in Articles 15, 15b or 15c,
2. before the decision on approval under Article 18 is made,
3. before an authorisation or approval is withdrawn or revoked, except in cases of imminent danger.

(5) Acting in agreement with the Federal Ministries of Labour and Social Affairs and for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, be empowered to lay down by ordinance detailed regulations concerning the expert committee.

#### **Article 34 Implementation in the Länder**

(1) In the Länder, the enforcement of this Act, including the monitoring of compliance with its provisions as well as the ordinances issued and restrictions stipulated under this Act, shall be the responsibility of those authorities designated under state law.

(2) In their role as the plant protection services, the designated authorities shall have the following terms of reference in particular:

1. monitoring crop stands as well as stored plants and plant products for the presence of harmful organisms,
2. monitoring the transport, marketing, storage, importation and exportation of plants, plant products and culture substrates within the scope of plant protection as well as the issuing of certificates necessary for these activities,
3. providing advice, information and training in the field of plant protection, including the operation of a warning service, also using its own studies

and trials,

4. reporting on the occurrence and spread of harmful organisms,
5. testing plant protection products, plant protection equipment, plant protection methods, the resistance of plant species as well as co-operation in closing control gaps,
6. performing the studies and trials required for the tasks described in nos. 1 to 5.

#### **Article 34a Official directives**

In individual cases the designated authority may make arrangements for eliminating infringements of this Act or for preventing future infringements of this Act or of ordinances issued pursuant to this Act. It may, in particular, prohibit

1. the application of a plant protection product to prevent infringements of Article 6 (2) or Article 6a or
2. the marketing of a plant protection product, plant resistance improver or plant protection equipment if the required authorisation or approval cannot be submitted or if the plant resistance improvers or plant protection equipment have not been entered in the respective lists as required.

#### **Article 35 Co-operation with customs offices**

(1) The Federal Ministry of Finance and the customs offices it has designated shall be involved in the monitoring, importation, transport and exportation of harmful organisms and infested objects as well as the importation and exportation of plant protection products and plant protection equipment.

The specified authorities can interrupt the transport of harmful organisms and infested objects as well as accompanying items of this kind including their means of transport, containers, loading and packaging material during importation, transit and exportation for monitoring and, in the case of provisions for the fumigation of infested objects, dispatch them under customs control to the nearest fumigation facility.

(2) Acting in agreement with the Federal Ministry of Consumer Protection, Food and Agriculture, the Federal Ministry of Finance shall be empowered to lay down by ordinance the details of the monitoring procedure without the consent of the Bundesrat. It may, in particular, provide for compulsory notification, declaration, information and performance of ancillary services as well as the obligation to allow inspection of business papers and other documents and to permit inspections and the taking of samples and specimens without payment.

**Article 36**  
**Entry points**

Acting in agreement with the Federal Ministry of Finance, the Federal Ministry of Consumer Protection, Food and Agriculture shall announce in the Bundesanzeiger the customs offices through which

1. consignments of harmful organisms and infested objects for importation and exportation shall be cleared in cases where the importation or exportation is subject to an ordinance under Article 4 or
2. plant protection products for importation or exportation shall be cleared if the importation or exportation is subject to an ordinance under Article 17 (2).

**Article 37**  
**Charges**

(1) The Federal Office of Consumer Protection and Food Safety shall levy charges (fees and expenses) for

1. official acts pursuant to this Act and
2. reporting its activities within the framework of a work programme under Article 8 (2) of Directive 91/414/EEC in conjunction with the implementing regulations of the European Community specified by ordinance.

In calculating the amount of charges stipulated in sentence 1, the administrative effort involved in the co-operative acts of the Federal Institute for Risk Assessment, the Federal Biological Research Centre and the Federal Environmental Protection Agency shall be taken into account.

(1a) The Federal Biological Research Centre shall levy charges (fees and expenses) for its official acts pursuant to this Act.

(2) Acting in agreement with the Federal Ministries of Finance and of Economic Affairs, and of Technology, the Federal Ministry of Consumer Protection, Food and Agriculture shall be empowered to stipulate by ordinance, without the consent of the Bundesrat, the elements liable to charges and to provide for fixed or basic rates. Reasonable account shall be taken of the benefits of plant protection products, plant protection equipment, plant protection methods as well as of the devices and equipment used in plant protection for the general public. The expenses to be refunded may be regulated in derogation of the Administrative Expenses Act.

**Section Nine**  
**Obligation to Give Information; Submission of Data; Penal and Administrative Fine Provisions**

**Article 38**  
**Obligation to give information**

(1) Natural and legal persons as well as associations of persons not having legal capacity shall, upon request, provide the designated authority with the information necessary for carrying out the tasks assigned to the authority by this Act or by virtue of this Act.

(2) Within the scope of paragraph (1), persons acting on behalf of the designated authority may, during office hours, set foot upon land and enter business premises and workrooms and means of transport belonging to the party required to furnish information and

1. carry out inspections and examinations for the presence of harmful organisms and examine plant protection equipment,
2. take samples free of charge, issuing an acknowledgement of receipt and
3. examine business documents there.

They may be accompanied on these inspections by experts of the Commission of the European Community or other member states. In order to prevent imminent dangers to public safety and public order, such land, business premises and workrooms and means of transport may also be entered in cases where they are at the same time used for residential purposes by the party required to furnish information. The latter shall tolerate the measures, assist the persons charged with the monitoring activities and submit the necessary business documents.

(3) The persons charged by the designated authority with monitoring and control measures as specified in Article 3 (1) no. 5 may, within the scope of their mandate, set foot upon land in the daytime on working days and may carry out monitoring and control measures there. The holder of the right of disposal or the owner must tolerate such measures.

(4) The constitutional right of the inviolability of domicile (Article 13 of constitutional law) shall be limited within the scope of paragraphs 2 and 3.

(5) Any person required to furnish information may refuse to furnish answers to questions if, through answering the questions concerned, he would expose himself or a person as defined in Article 383 (1) nos. 1 to 3 of the Code of Civil Procedure to the risk of prosecution under criminal law or of proceedings under the Administrative Offences Act.

**Article 38a**  
**Submission of data**

(1) The Federal Biological Research Centre and the Federal Office of Consumer Protection and Food Safety may inform the designated authorities of other member states and the Commission of the European Community about decisions and measures insofar as this is prescribed by legal instruments of the European Community or required to implement the agreement on the European Economic Area. The Federal Office of Consumer Protection and Food Safety may also submit data and documents it has obtained in performing its tasks under Articles 15 to 16a and 18 to the places stated in sentence 1 insofar as this is prescribed by legal instruments of the European Community or required to implement the agreement on the European Economic Area.

(2) If this is required to fulfil legal requirements concerning plant protection or if prescribed by legal instruments of the European Community, the designated authorities may transmit data they have gathered during the enforcement of this Act to the designated authorities of other Länder, of the Federal Government or of other member states as well as to the Commission of the European Community.

**Article 38b**  
**Foreign relations**

The Federal Ministry of Consumer Protection, Food and Agriculture is responsible for relations with the responsible authorities of other member states and the Commission of the European Community. It may delegate these powers by ordinance to the Federal Biological Research Centre or the Federal Office of Consumer Protection and Food Safety without the consent of the Bundesrat. It may furthermore delegate these powers by ordinance, with the consent of the Bundesrat, to the responsible supreme state authorities. The supreme state authorities may delegate these powers to other authorities pursuant to sentence 3.

**Article 39**  
**Penal provisions**

(1) Any person who spreads harmful organisms, thereby

1. endangering stands of particularly protected plant species as defined in Article 10a (2) no. 10 of the Federal Nature Conservation Act,
2. endangering plant stands of notable value which are not his own or
3. endangering plant stands of notable value for the natural balance or the landscape

shall be liable to imprisonment for a term of up to five

years or to a fine.

(2) Any attempt to commit such acts is punishable.

**Article 40**  
**Provisions concerning administrative fines**

(1) An administrative offence is committed by any person who, either intentionally or by negligence,

1. contravenes the provisions of an ordinance issued
  - a) under Articles 3, 4 and 5 (1), Article 9, sentence 2, Articles 17 (2) and 20 (1) in conjunction with Article 14 of the Chemicals Act, Article 20 (5) no. 1b to e, Article 23 (3) or Article 30 (1) no. 1c or under Article 3 of the Plant Protection Act repealed by Article 44 (1) no. 1 of this Act or

- b) under Article 7

in cases where the ordinance refers to this administrative fine provision for a specific act;

2. contravenes an enforceable order issued
  - a) under Article 5 (2), Article 6 (1) sentence 3, Article 10 (2), Article 10a (2), Article 16b (2) sentence 1, Article 22 (3) or Article 34a sentence 1,
  - b) under Article 15a (3), also in conjunction with Article 15b (8) or Article 15c (1) sentence 2 or
  - c) by virtue of an ordinance under Article 3 (1) or (3), Article 5 (1) in conjunction with Article 3 (1), under Article 7 (1) or (4) in conjunction with (1), under Article 10a (3), Article 21a, sentence 2 or Article 30 (1) no. 1c in cases where the ordinance refers to this administrative fine provision for a specific act,

3. (deleted)

4. uses a plant protection product contrary to Article 6 (2), Article 6a (1) sentence 1, also in conjunction with Article 6a (2) or Article 6a (1) sentence 2 or Article 10a (1) sentence 1 or 2, each in conjunction with an ordinance under Article 10a (3),

5. contrary to Article 9, sentence 1 or Article 21a, sentence 1, also in conjunction with an ordinance under Article 21a, sentence 2, fails to give notification or does not give notification in due time,

6. markets or imports an unauthorised plant protection product contrary to Article 11 (1) sentence 1 or who markets or imports seeds, planting material or a culture substrate contrary to Article 11 (3) sentence 1,

7. contravenes an enforceable restriction under

- Article 11 (2) sentence 2, Article 15 (4) sentence 1, also in conjunction with Article 15c (1) sentence 2 or Article 18 (2), under Article 15 (7) sentence 1, also in conjunction with Article 15b (8), under Article 15b (5) sentence 1 or Article 18b (4) sentence 1, no. 1 or who contravenes an enforceable obligation connected to an authorisation under Article 15b (7),
8. contrary to Article 15a (2) sentence 1, also in conjunction with Article 15b (8), Article 15c (1) sentence 2 or Article 18 (2) or contrary to Article 31a (5), also in conjunction with Article 31c (2) sentence 1, fails to give notification or who, contrary to Article 19 (1) sentence 1 or 2, fails to make a report or fails to do so correctly, completely or in the manner prescribed or not in due time,
  - 8a. contrary to Article 16b (2) sentence 2 or Article 16b (3) sentence 2, fails to accept a plant protection product or does not accept it completely or in due time,
  9. markets or imports a plant protection product without the prescribed labelling contrary to Article 20 (1) in conjunction with Article 13 or Article 15 of the Chemicals Act and contrary to Article 20 (2), also in conjunction with an ordinance under Article 20 (5) no. 1a,
  10. contravenes the provisions of Article 21, sentence 1 regarding prohibited details,
  11. markets a plant protection product, a plant resistance improver or an additive contrary to Article 22 (1) sentence 1, also in conjunction with Article 31 (2), also in conjunction with Article 31c (2) sentence 1,
  - 11a. contrary to Article 22 (2), fails to inform the purchaser about prohibitions or restrictions, does not inform him correctly, completely or in due time,
  12. exports a plant protection product contrary to Article 23 (1) sentence 1 or who, contrary to Article 23 (2), fails to keep a plant protection product or culture substrate intended for exportation separately or who fails to make it recognisable as such,
  13. contrary to Article 24, markets or imports plant protection equipment which does not comply with an ordinance issued under Article 30 (1) no. 1a,
  14. contrary to Article 25 (1) to (3) in conjunction with an ordinance issued under Article 30 (1) no. 2 or 3, fails to submit a declaration or fails to do so correctly, completely or in due time or, contrary to Article 25 (4), fails to submit or supplement documents,
  15. contrary to Article 29, sentence 1, fails to supply the instructions for use,
  16. contrary to Article 31 (1) no. 2 or 3, also in

conjunction with Article 31c (2) sentence 1, markets a plant resistance improver or an additive or, contrary to Article 31c (1), who markets an additive which has not been included in the list referred to there,

- 16a. markets or imports an active substance contrary to Article 31d (1) no. 1 or
17. contrary to Article 38 (1), fails to furnish information or fails to furnish it correctly or completely or, contrary to Article 38 (2) sentence 3, fails to tolerate a measure, assist a person charged with the task of monitoring or supply business documents, or contrary to Article 38 (3) sentence 2 fails to tolerate a measure.

(2) In the cases specified in paragraph (1) nos. 1, 2a, 2c, 4, 6, 7, 9, 10, 13 and 16a, the administrative offence may be punished by a fine of up to fifty thousand euros; in the cases specified in paragraph (1) nos. 2b, 5, 8, 8a, 11 to 12, 14 to 16 and 17, the offence may be punished by a fine of up to ten thousand euros.

(3) Plants, plant products, culture substrates, plant protection products, plant resistance improvers, additives, active substances and plant protection equipment in respect of which an administrative offence has been committed according to the terms of paragraph (1) nos. 1 to 4, 6, 7, 9, 13, 16 or 16a shall be liable to seizure.

(4) In the cases of paragraph (1) nos. 2b and 8, the Federal Office of Consumer Protection and Food Safety, and in the case of paragraph (1) no. 14 the Federal Biological Research Centre shall be the administrative authorities as defined in Article 36 (1) no. 1 of the Administrative Offences Act.

## **Section Ten Final Provisions**

### **Article 41**

#### **Clause concerning the non-effect of the provisions on other legislation**

This Act shall be without prejudice to the provisions of the

1. Foodstuff and Commodities Act,
2. Federal Emission Control Act,
3. Chemicals Act,
4. Equipment Safety Act and
5. Gene Technology Act

as well as to the ordinances based on these Acts.

**Article 42**  
**Special provisions for controlling**  
**grape phylloxera**

Control of grape phylloxera (*Daktulosphaira vitifoliae* Fitch) shall be the subject of an ordinance issued by the Federal Ministry of Consumer Protection, Food and Agriculture under Article 3 (1), issued with the consent of the Bundesrat. In addition, the Länder may

1. make further arrangements for controlling grape phylloxera which go beyond the ordinances issued under Article 3 (1),
2. make arrangements in derogation of Article 32 (1) to (3) with regard to compensation for measures aimed at controlling grape phylloxera,
3. in derogation of Article 34 (2), set up a special vine protection service and delegate its tasks relating to the protection of vines.

**Article 43**  
**General administrative provisions**

The Federal Ministry of Consumer Protection, Food and Agriculture shall, with the consent of the Bundesrat, issue the general administrative provisions required for the implementation of this Act. The general administrative provisions for the implementation of Article 15 (3), Article 15b (4), Article 15c (2) and Article 18 (3) shall require the agreement of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.

**Article 44**  
**Repealing provisions**

If Article 3 is insufficient warrant, the governments of the Länder are empowered to repeal the published amended version of legal provisions already issued based on the Act governing the Protection of Crop Plants and published in the Bundesgesetzblatt, part III, 7823-1. They can transfer their powers via legal provisions to other authorities.

**Article 45**  
**Transitional provisions**

(1) Article 6a (1) sentence 1, no. 1 shall not apply until 1 July 2001 for plant protection products that were authorised

1. by 1 July 1998 or
2. in accordance with Article 15.

(2) Article 6a (1) sentence 2 shall apply as of 1 July 1999.

(3) Article 10a (1) and (2) as well as the ordinances by virtue of Article 10a (3) shall not be applied until 1 July 2000, the general requirements regarding application under Article 6 (1) sentence 2 with respect to the application of plant protection products for experimental purposes shall remain unaffected.

(4) Articles 13 to 14b shall not apply to the use of documents in favour of an applicant if the Federal Biological Research Centre has already used the documents in his favour under Articles 13 and 14 of this Act as amended until 30 June 1998. Articles 13 and 14 of the Plant Protection Act as amended until 30 June 1998 shall apply to the use of documents presupposing experiments on animals other than vertebrates if the Federal Biological Research Centre has made the notifications under Article 13 (1) sentence 2 or Article 14 (2) sentence 1 or 5 in conjunction with sentence 1 of the Plant Protection Act as amended until that date.

(5) Until a decision has been made on the inclusion of an active substance in Annex I of Directive 91/414/EEC, Article 15 (1) no. 2 shall not apply to plant protection products containing this active substance and which had been marketed in a member state before 27 July 1993 for commercial purposes or within the scope of other economic undertakings. Upon request of the Federal Office of Consumer Protection and Food Safety, the applicant must prove that the plant protection product had been marketed in a member state before 27 July 1993 pursuant to sentence 1.

(6) Article 15c shall not apply to plant protection products which contain active substances which were contained in plant protection products which were marketed in a member state prior to 27 July 1993 for commercial purposes or within the scope of other economic undertakings.

(7) Authorisations for plant protection products that were marketed in a member state prior to 27 July 1993 for commercial purposes or within the scope of other economic undertakings, shall be revoked if the European Community, under Article 8 (2) sentence 7 of Directive 91/414/EEC, has decided not to include an active substance in Annex I of Directive 91/414/EEC or to impose a restriction under Article 5 (4) of Directive 91/414/EEC on the inclusion of the active substance in the current version of Annex I if this conflicts with the authorisation.

(8) Article 31d (1) no. 2 shall not apply to active substances that were marketed in a member state prior to 27 July 1993 for commercial purposes or within the scope of other economic undertakings.

(9) Plant protection products that were authorised prior to 1 July 1998 under Article 15 of this Act as amended at this date may continue to be marketed, imported and used until 30 June 2001 under the

provisions of this Act as amended prior to 1 July 1998. If the expiry date of the authorisation is after 30 June 2001, the plant protection product may be marketed, imported and used until the expiry of authorisation only

1. if the Federal Biological Research Centre has specified the fields of application and directions for use under Article 15 (2) beforehand and
2. if the plant protection product has been labelled under Article 20 (1) to (3) or by virtue of an ordinance issued under Article 20 (5).

The authorisation holder shall submit an application for the specification of fields of application and directions for use to the Federal Biological Research Centre by 1 February 1999.

(10) Plant resistance improvers that were marketed prior to 1 July 1998 under the provisions of this Act as amended at this date may continue to be marketed until 30 June 2000. Plant resistance improvers under Article 2 (10b) and additives may continue to be marketed until the authorisation expires if they have been authorised as plant protection products and if the authorisation expires after the period referred to in sentence 1.

(11) Plant protection products which were labelled before 1 November 2002 according to current provisions may be marketed or imported until supplies are depleted but not after 29 July 2004. Containers and consumer packaging manufactured before 1 November 2002 according to current provisions, may be used until supplies are depleted but not after 29 July 2004

**Article 46**  
**(Entry into force)**