

**Decree 89/2004 (V.15.) FVM of the ministry of agriculture and rural development**

**on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products**

Authorised by Article 65 (2) c) and (3) a) of the Plant Protection Act 35 of 2000 (*hereinafter: Act*) – regarding paragraph (3) a), in agreement with the minister of health, social affairs and family and the minister of environment and water – I order as follows:

***General provisions***

**Article 1**

(1) This Decree shall apply to the authorization of placing on the market and use, as well as to packaging, labelling, storage and transport of plant protection products (*hereinafter: PPPs*)

(2) Within the scope of authorization, the particular rules are contained in the following Annexes

- a) *Annex 1*: Active substances authorized for use in plant protection products in Hungary.
- b) *Annex 2*: Requirements for the detailed and summary data to be submitted for the authorization of active substances,
- c) *Annex 3*: Requirements for the detailed and summary data to be submitted for the authorization of plant protection products,
- d) *Annex 4*: Standard phrases for special risks (R phrases) for humans or the environment,
- e) *Annex 5*: Standard phrases for safety precautions (S phrases) for the protection of humans or the environment,
- f) *Annex 6*: Uniform principles for the evaluation and authorization of plant protection products,
- g) *Annex 7*: The list and grouping of minor crops,
- h) *Annex 8*: Reduced data requirement for the authorization of plant protection products,
- i) *Annex 9*: Data to be submitted for the authorization of common materials, plant extracts, products of plant protection effect not qualified as plant protection products, as well as of equipment, materials and macro-organisms used for plant protection purposes,
- j) *Annex 10*: Active components of products of plant protection effect not qualified as plant protection products, as well as of materials and macro-organisms used for plant protection purposes authorized in Hungary,
- k) *Annex 11*: Groups of plants and plant products,
- l) *Annex 12*: Active substances of plant protection products, prohibited in Hungary,
- m) *Annex 13*: Requirements for the authorization document,
- n) *Annex 14*: Data to be submitted for parallel import,
- o) *Annex 15*: Deadlines for setting the supplementary R and S phrases for active substances and plant protection products.

## Article 2

For the purposes of this Decree the following definitions shall apply:

1) *Monograph*: Report prepared from the evaluation of the detailed and summary data submitted for the authorization procedure of an active substance and a PPP (*hereinafter*: detailed and summary data).

2) *Minor use*: use of a PPP in crops listed in *Annex 7* and over small areas in particular crops.

3) *Small unit formulation*: formulation or single unit without any commercial value (e.g.: ampule, tablet, pellet, etc.) which can be placed on the market by composing similar products in one package.

4) *Combined package*: package containing two or more authorized PPPs of different use patterns in separate units within a single package, marketed in this form generally for household gardens.

5) *Twin package*: package containing two or more authorized PPPs of generally similar use patterns, with or without adjuvant, in a single unit for one application.

6) *Collective package*: a single package (e.g. paper box) of PPPs of similar or different use patterns, the particular units of which can be placed on the market and used as individual marketing units in compliance with the authorization document.

7) *Parallel import*: import of a PPP from another Contracting Party to the Agreement on the European Economic Area (*hereinafter*: Contracting Party) to Hungary, which, under specified conditions, is identical to a PPP already authorized in Hungary (reference PPP).

8) *Substances*: chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

9) *Preparations*: mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as PPPs.

10) *Animals*: animals belonging to species normally fed and kept or consumed by man.

11) *Placing on the market*: any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of Hungary. Importation of a PPP into the territory of Hungary shall be deemed to constitute placing on the market.

12) *Authorization of a plant protection product*: administrative procedure by which the authority of Hungary specified in Article 3 authorizes, following an application submitted by an applicant, the placing on the market and use of a PPP in its territory or in a part thereof.

13) *Macro-organisms*: nematodes, parasitoids, predators and pollinating arthropods, at any of their developmental stages.

## *Official bodies participating in the procedure*

### **Article 3**

(1) Any tasks related to the authorization of active substances of PPPs (*hereinafter*: active substances) in the Community, as well as to the authorization of PPPs, products of plant protection effect, equipment, materials and macro-organisms used for plant protection purposes in Hungary are performed by the Central Service of Plant Protection and Soil Conservation (*hereinafter*: competent authority).

(2) The Chief Medical Office of Public Health (*hereinafter*: CMOPH) and the Ministry of Environment and Water (*hereinafter*: MEW) shall act as responsible official bodies in the procedure of authorization of PPPs.

(3) The official statement shall cover the following:

- a)* the official statement of CMOPH, prepared with the expertise of the National Institute of Chemical Safety, National Institute of Food Hygiene and Nutrition and the National Institute of Occupational Health of “Fodor József” National Center for Public Health, contains assessment of PPPs and active substances in respect of environmental and occupational health and of food hygienics, in particular the classification by properties imposing risk to humans, pre-harvest interval and re-entry time, establishing of maximum residue levels in plants and plant products, the necessary protective clothing and equipment to be worn by the users of PPPs and the first aid measures,
- b)* the official statement of MEW shall cover the environmental fate and behaviour of the PPP, its ecotoxicological properties, impacts on environment and nature protection, and conditions of its use required for environment and nature protection and classification as to environmental hazards.
- c)* both responsible official bodies make a proposal for grouping the PPP into a marketing category.

(4) The official statements of the responsible official bodies on the PPP are made considering the detailed and summary data submitted for the authorization and the monograph prepared by the competent authority.

## ***Council of PPP Authorization***

### **Article 4**

(1) The minister of agriculture and rural development (*hereinafter*: minister) establishes the Council of PPP Authorization with 9 members (*hereinafter*: CPA) in agreement with the ministers of health, social affairs and family and of the environment and water.

(2) The members of CPA are one designated representative of each of the following institutions: the Ministry of Agriculture and Rural Development (*hereinafter*: ministry), the Ministry of Health, Social Affairs and Family (*hereinafter*: MHSAF), the MEW, the Hungarian Chemical Industry Association, the Hungarian Food Safety Office, the Association of Hungarian Pesticide Producers, the Plant Protection Research Institute and the Hungarian Chamber of Professionals and Doctors of Plant Protection, furthermore a member jointly designated by the environmental civil organizations.

(3) CPA

- a) discusses the technical issues arising from the use of PPPs,
- b) gives opinion on the technical draft guidelines related to the authorization of PPPs and active substances,
- c) upon request, makes proposals and takes up its position in issues related to the authorization of PPPs and active substances.

(4) Only the official bodies involved in the authorization procedure may take part in the discussion of issues related to data protection.

(5) CPA's chairman is the representative of the ministry. The head of the competent authority acts as the secretary.

(6) CPA meets according to its own agenda and work plan or as needed.

(7) CPA works out its rules on organization and operation.

## **Article 5**

(1) The competent authority may involve external experts or groups of experts in the risk assessment of active substances and PPPs.

(2) During the co-operation with the CPA and the expert groups as well as with external experts, provisions on the protection, handling and confidentiality of data laid down in Article 22 of the Act shall be observed.

### *Authorization of active substances*

## **Article 6**

(1) The competent authority shall take part in the Community authorization of active substances according to Council Directive 91/414/EC concerning the placing of PPPs on the market (*hereinafter*: Directive), in the frame of the procedure described in this article.

(2) An active substance may be authorized if a PPP manufactured from that active substance and its residues, following good plant protection practice, do not have any harmful effects on human or animal health or the environment.

(3) For the evaluation of the active substance, the following shall be taken into consideration:

- a) an acceptable daily intake (ADI) for man;
- b) an acceptable operator exposure level (AOEL);
- c) an estimate of its fate and distribution in the environment as well as its impact on non-target species.

(4) Authorization of an active substance may be subject to requirements such as:

- a) the minimum degree of purity of the active substance, the nature and maximum content of certain impurities,
- b) restrictions arising from the evaluation of the information submitted for the authorization, taking into account of the agricultural, plant health and environmental (including climatic) conditions in question,
- c) type of the PPP,
- d) manner of use.

(5) Authorization, amendment and withdrawal of the authorization shall be decided in accordance with the procedure laid down in Article 6 of the Directive.

(6) For the authorization of an active substance, detailed and summary data, in compliance with the requirements of *Annex 2*, as well as, for at least one PPP containing the particular active substance, the data according to *Annex 3* and to the related chapters of the Plant Protection Methodology (*hereinafter*: Methodology), shall be submitted in English, at the request of the competent authority, also in Hungarian, to the competent authority in printed and electronic versions, which, at the same time, shall be sent by the applicant to the competent authorities of the Member States and the Commission of the European Union (*hereinafter*: Commission).

(7) *Annex 1 Part A* contains the active substances included in the Community list and the specific provisions applying to them. *Annex 1 Part B* contains the active substances under review in compliance with the Community Regulations which can be authorized in Hungary for use in PPPs.

(8) An active substance may be authorized for a period of not more than 10 years, which, at request, can be extended several times for other periods of maximum 10 years if the active substance meets the requirements of authorization. The authorization may be withdrawn if the requirements of the *Annex* are not fulfilled.

(9) If the active substance is not authorized, the competent authority shall take the necessary measures for withdrawing the authorization of the PPP containing the active substance and lays down the conditions for further placing on the market and use of the remained stocks.

(10) Article 22 of the Act shall apply to the protection of data submitted for the authorization.

### *Authorization of plant protection products*

#### **Article 7**

(1) Authorization of PPPs in Hungary may be granted if:

- a) the active substance is included in *Annex 1*, or
- b) the applicant acts according to the procedure laid down in Article 15 (2) of the Act.

(2) Taking paragraph (10) and Article 10 (1) to (3) into consideration, *Annex 2* and *Annex 3* data, as well as the detailed and summary data according to the Methodology shall be submitted in Hungarian or English, together with the application for authorization, to the competent authority. If the application is submitted in English, at special request of the competent authority, the summary data shall be submitted also in Hungarian language.

(3) The applicant shall submit the following test samples to the competent authority:

- a) sample of the analytical standard of the active substance, or in justified cases, sample of the breakdown products, inactive isomers and impurities of human toxicological and environmental importance,
- b) sample of the technical active substance in compliance with the submitted specifications,
- c) sample of the PPP.

(4) The quantity of samples shall be determined to ensure sufficient substance for at least ten replicates and five parallel measurements (maximum 1 g for a), maximum 200 g for b) and maximum 0.5 kg for c).

(5) The competent authority shall carry out completion check of the submitted data within 60 days and shall inform the applicant thereof.

(6) The competent authority shall keep records of the applications containing at least one copy of the application, one copy of the official statement on the application, data and *Annexes 2* and *3*, as well as one copy of the official decisions, furthermore, the summaries of each document. The competent authority shall store the detailed and summary data together and make the data available for the other Contracting Parties and the Commission. At their request, the competent authority provides the necessary information on the application.

(7) Concerning the active substances, the applicant meets his obligation for declaration specified in Article 7 of the Act 25 of 2000 on Chemical Safety (*hereinafter*: Chemical Safety Act) by submitting the application for authorization in compliance with the provisions.

(8) If an active substance has been included in *Annex 1*, the competent authority shall revise the authorization of the marketed PPPs containing the particular active substance to check if they meet the requirements specified in *Annex 1 Part A*. In this procedure

- a) the holder of the authorization shall declare, before the specified deadline, that he possesses the data under *Annex 2* or has access to them,
- b) it shall be certified that the purity and the nature of impurities of the active substances do not differ from those given in the detailed and summary data attached to the original application,
- c) if the application meets the requirements under paragraphs a) and b), the applicant shall submit the detailed and summary data in compliance with *Annex 3*, before the specified deadline,

d) if conditions specified under paragraph b) are not fulfilled, the procedure under paragraph (2) shall be followed.

(9) The competent authority shall send the decision and the data, taken into consideration when making the decision, to the Commission.

(10) If the authorization procedure of a PPP, the active substance of which is included in *Annex I*, is initiated,

- a) the applicant for authorization of a PPP shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority whether the PPP for which the application is to be made is the same as a PPP for which authorization has been granted, and as to the name and address of the holder or holders of the authorization. The enquiry shall be supported by evidence that other information necessary for the application is available for the prospective applicant,
- b) the competent authority shall provide the requested information and shall at the same time inform the interested holder of the authorization of the given information,
- c) the holder or holders of previous authorizations and the applicant shall take all reasonable steps, with the eventual participation of the competent authority, to reach agreement on sharing of information so as to avoid the duplication or to limit the duplication of testing on vertebrate animals.

(11) In the authorization procedure, all data on physical, chemical, toxicological, ecotoxicological, fate and behaviour tests and pesticide residue analysis or particular data specified by the competent authority, other than data in paragraph (12), shall originate from test facilities following good laboratory practice for that particular test or working in an approved quality management system (*hereinafter*: accredited test facility).

(12) Taking the data in *Annexes 2* and *3* into consideration, the competent authority shall decide on the acceptance in the authorization procedure of data, generated before the coming into force of the Decree, originating from a non-accredited test facility.

(13) As for the additives and adjuvants of the PPPs, the following data shall be provided:

- a) chemical name of the material
- b) the registry number at the Chemical Abstract Service (*hereinafter*: CAS number)
- c) major impurities.

(14) If the additive or adjuvant or their impurities are qualified as dangerous substances specified in other order of legislation, the registry number of the dangerous substances as listed in Hungary, the safety sheet, classification according to hazards, the sign and the R and S phrases specified in other order of legislation shall be given.

## **Article 8**

Differing from Article 7, the PPPs containing active substances listed in *Annex I Part B* shall be placed on the market and used in compliance with the authorization and amendment for

authorization granted. Their authorization may be extended until the inclusion of the active substance(s) in *Annex 1 Part A* and in compliance with the provisions concerning the inclusion.

### **Article 9**

(1) The following data shall be submitted with the application for authorization of PPPs to be distributed in combined, twin and collective packages:

- a) the declaration of the holder of authorization, stating that he approves to the joint packaging of the PPPs
- b) draft labels of the particular PPPs and the collective package
- c) data of the applicant and the formulator.

(2) The competent authority evaluates the application for authorization under paragraph (1) within 60 days.

### **Article 10**

(1) Data under *Annex 8*, meeting the requirements for reduced data supply, shall be submitted attached to the application for authorization of PPPs not covered by data protection in Hungary, containing existing active substances not included in *Annex 1 Part A*, authorized at least 10 years ago.

(2) In case of PPPs containing common substances (e.g. copper sulphate, sulfur, natural minerals, plant extracts) not included in *Annex 1 Part A*, the applicant shall submit data under *Annex 9 Part A*.

(3) Data, other than the unnecessary toxicological ones, as specified in *Annex 9 Part A* shall be submitted with applications for authorization of aqueous or alcoholic solutions of plant extracts, the active substances of which are not included in *Annex 1 Part A* and are listed in the Hungarian Vademecum of Pharmaceuticals.

(4) For the authorization of aerial application of PPPs, the applicant shall submit data on the advantages, justifications and possible environmental and health risks of such treatment.

### **Article 11**

Data under *Annex 9* shall be submitted for the application for authorization of products of plant protection effect not qualified as PPPs, as well as of equipment, materials and macro-organisms used for plant protection purposes. The list of the active components of such products (other than equipment) bound to authorization is contained in *Annex 10*.

### **Article 12**

The application for authorization shall be submitted and the trials carried out taking the crop groups under *Annex 11* into consideration.

## *Evaluation of the application*

### **Article 13**

(1) In case of application for Community authorization of an active substance, the competent authority shall evaluate the data submitted with the application in compliance with Article 6 and prepare a monograph thereof for the Commission.

2) The evaluation of the detailed and summary data submitted for the authorization of PPPs and the preparation of the decision shall be made according to *Annex 6* and the Methodology, in compliance with the relevant Community guidelines regarding active substances, as well as with *Annexes 3, 8 and 9* regarding the data requirements for PPPs.

The Methodology shall be prepared by the competent authority, involving the responsible official bodies and it shall be approved by the ministry.

(4) The key chapters of the Methodology:

- a) authorization guidance
  - 1) methods for taking and preparing samples,
  - 2) methods of pesticide residue analysis ,
  - 3) methods of quality control of PPPs,
  - 4) methods of efficacy trials with PPPs,
  - 5) requirements for the content and format of submitting the data for PPP authorization,
  - 6) requirements for the content and format of the monographs
- b) labelling guidance
- c) conditions of grouping into marketing categories,
- d) guidance for carrying out efficacy trials,
- e) guidance for carrying out trials with PPPs necessary for establishing maximum residue levels of PPPs.

(5) The chapters of the Methodology, referred to in paragraph (4) a) points 5 and 6, as well as in points b) to e) are published by the competent authority on the website of the ministry, while the other chapters of the Methodology are available at the competent authority.

(6) In compliance with Article 15 (2) of the Act, a PPP may be authorized if, based on the evaluation, it meets the requirements under Article 16 (1) b) to k). If, after the period of three years, no decision has been made on the inclusion of the active substance in *Annex 1 Part A*, the validity of the authorization may be extended.

(7) The competent authority shall withdraw the authorization granted according to paragraph (6), if

- a) the residues of the PPP have harmful effect on human and animal health or groundwater and constitutes an unacceptable risk to the environment and the toxicologically or environmentally relevant residues cannot be detected with generally used methods

- b) in spite of the application of the principles of good plant protection practice, the PPP has harmful effect on human and animal health or on the environment especially on drinking and groundwater.

(8) The competent authority shall refuse the application for authorization of PPPs containing active substances listed in *Annex 12* or withdraw the authorization granted for any PPPs containing such active substances. The competent authority shall inform the Contracting Parties and the Commission of the prohibited active substances.

#### *Mutual recognition, mutual acceptance of data*

### **Article 14**

(1) In case of application for authorization based on the mutual acceptance of data, the applicant shall prove comparability for use in Hungary with documentary evidence. Then repetition of tests and analyses, having already been made for the authorization of the PPP in an other Contracting Party, shall not be required to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product (*together hereinafter: comparability conditions*) are similar in the regions concerned.

(2) Authorization may be subject, with the agreement of the applicant, to changes in the conditions of use, considering the technically justified conditions of comparability.

(3) Authorization may also be accompanied by restrictions on use, taking dietary patterns into consideration in order to protect consumers.

(4) The competent authority shall inform the Commission of cases where it has required repetition of a test and of cases where it has refused to authorize a PPP already authorized in another Contracting Party, irrespective of which the applicant had claimed that the important comparability conditions relevant to the use of the product are similar in the territory of Hungary and the Contracting Party where the test was carried out or for which authorization was granted. The Commission shall be notified of the grounds on which repetition of the test was required or authorization was refused.

(5) According to the agreement concluded with a particular Contracting Party, in addition to paragraphs (1) to (4), mutual recognition of an authorization may only take place if authorization has been granted following uniform principles in that Contracting Party and if the active substance is included in *Annex 1 Part A*.

(6) In cases where the competent authority refuses to recognize comparability and to accept tests and analyses or to authorize a PPP in the relevant regions of the territory of the country, the applicant may take the matter to the Commission to decide whether or not comparability exists.

(7) Where the competent authority has valid reasons to consider that a PPP it has authorized under mutual recognition constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on the territory of the country.

It shall immediately inform the Commission and the other Contracting Parties thereof and give reasons for its decision.

### *Decision-making*

#### **Article 15**

(1) Based on the official statements, and the guidelines on decision-making, the competent authority shall make preliminary decision on the authorization for placing on the market and use of PPPs and, by sending the draft authorization document, calls upon the applicant to submit the draft label in Hungarian.

(2) The competent authority shall approve the draft label before granting the authorization.

(3) The decision shall respect the application of the principles of good plant protection practice and wherever possible, the principle of integrated control.

#### **Article 16**

(1) The competent authority shall grant the authorization for placing on the market and use of a PPP if

- a)* the active substance of the PPP is included in *Annex 1*,
- b)* the evaluation was made according to *Annex 6*,
- c)* the PPP has no unacceptable effect on the plants and plant products,
- d)* the PPP has no direct or indirect harmful effect on human or animal health (via e.g. drinking water, food or feed) or on groundwater,
- e)* the PPP does not influence, in an unacceptable way, the environment, with particular attention to the fate and behaviour of the PPP in the environment (including drinking and groundwater) and the non-target species,
- f)* the nature and quantity of the active substance and, if necessary, its all, toxicologically or ecotoxicologically relevant contaminants and other elements can be determined with suitable methods,
- g)* the residues of PPPs originating from the authorized use and of toxicological or environmental relevance can be determined with suitable methods,
- h)* the physical and chemical properties of the PPP were determined and the PPP is adequate for the envisaged use and storage,
- i)* the competent authority has fixed the residue levels of PPPs in plants and plant products specified in the authorization and informed the Commission thereof,
- j)* the conditions of the recommended use were specified in such a way to ensure that the provisional maximum residue levels are not exceeded, and
- k)* the PPP meets the requirements of Article 14 of the Act.

(2) The requirements for the use of PPPs shall be stipulated in such a way that conditions specified in paragraph (1) k) are fulfilled.

(3) Tests and analyses in relation to the requirements specified in paragraph (1) shall be made with approved methods adequate for the agricultural, plant health and environmental conditions relevant for the envisaged use of the PPP.

#### **Article 17**

(1) The competent authority shall grant the authorization by issuing a document in compliance with *Annex 13*.

(2) The authorization document shall be made out in two original copies. One copy shall be sent to the applicant, the second one shall be placed in the archives of the competent authority.

#### *Modification and withdrawal of the authorization*

#### **Article 18**

(1) In compliance with Article 16 (1) of the Act, beside the holder of the authorization, modification of the authorization may be applied for by any natural persons, holdings, social organisations, public boards and state budget institutions interested in the use. The competent authority obtains, if necessary, the consent of the holder of the authorization regarding the modification of the authorization. If the modification of the authorization for use is not applied for by the holder of the authorization, the authorization may be modified if

- a) the applicant submitted the documentation and data to support the modification, furthermore
- b) the PPP does not
  - 1) cause unnecessary pain or suffering to vertebrates against which the product is intended to be used
  - 2) have any direct or indirect harmful effect on human or animal health (via e.g. drinking water, food or feed) or on groundwater,
  - 3) influence, in an unacceptable way, the environment, with particular attention to the fate and behaviour of the PPP in the environment and the effect to water pollution (including drinking and groundwater) and effect to non-target species.

(2) By the completion of the label, the users shall be informed on the mode of application of the PPP.

(3) The rules on the authorization procedure shall apply to the modification of the authorization. Data submitted in the procedure need not be submitted again.

(4) No modification is to be applied for if detailed and summary data on the PPP concerned differ from the previously evaluated ones only to such extent which does not modify risks involved by the product and its use. The holder of the authorization shall inform the competent authority of the modification in writing.

- (5) The authorization of the PPP shall be withdrawn if
- a) it does not meet the requirements under Article 7 (8),

- b) the applicant submitted falsified data used for the evaluation,
- c) the manufacturer repeatedly places on the market a PPP with composition different from the authorization.

(6) The use of the stored stocks of the PPPs with withdrawn authorization shall be approved at least for six months in the growing season, unless the competent authority prohibited its further use. The content of the decision on the withdrawal of the authorization shall be indicated on the label.

(7) At the time of withdrawing the authorization, the competent authority shall inform the holder of the authorization thereof.

### *Off-label uses*

#### **Article 19**

(1) Without prejudice to Article 20 (1) of the Act, the competent authority may approve in a separate decision, at the user's responsibility, minor uses or use of an already authorized PPP in non-labelled crops, not later than the validity of the authorization, if it is in compliance with Article 14 (1) c) points 3 and 4 of the Act, informing the manufacturer and the responsible official bodies thereof. The use approved by the decision shall not be indicated either in the authorization document or in the approved label of the PPP. In compliance with the issued decision, the PPP shall be used by the designated growers

(2) The approval of an off-label use may be applied for by natural persons, holdings, social organisations, public boards and state budget institutions interested in the use. The application shall be submitted to the competent authority through the regionally concerned county plant protection and soil conservation service (*hereinafter*: Service).

(3) The following data shall be attached to the application:

- a) justification of the application
- b) pesticide residue data (taking extrapolation and mutual recognition into consideration)
- c) information on safe use

(4) The approval of an off-label use may be modified or withdrawn according to Article 16 of the Act, also at the justified request of the holder of the original authorization.

(5) The off-label use of a PPP, approved in compliance with paragraph (1) shall not be advertised and shall not infringe rights obtained by the original authorization.

(6) The competent authority shall publish the decision under paragraph (1), or the modification and withdrawal of the decision in the official journal of the ministry and the website of the competent authority.

### *Parallel import*

## Article 20

(1) Parallel import of a PPP shall be applied for by the distributor of the particular PPP in such form in the country.

(2) The application for parallel import shall be submitted to the competent authority together with data specified in *Annex 14*.

(3) The competent authority shall check the identity and the common origin of the reference PPP and the PPP to be imported as laid down in paragraph (4).

(4) The PPP to be imported may be considered identical and of common origin with the reference PPP, if:

- a) the manufacturer of the active substance and the PPP is the same, or the active substance and the PPP are manufactured with the manufacturer's consent based on the same patent,
- b) formulation of the reference and the products to be imported is the same,
- c) specification and origin of the active substance are the same as of that authorized in Hungary.

(5) Guidance in *Annex 6* shall be taken into consideration during the decision on the acceptability of differences foreseeable in the manufacturing procedure.

(6) With regard to the classification and categories, signs of risks and hazards as well as to use, the label content of the PPP to be imported may differ from the label of the reference products only by taking the legal provisions into consideration. The eventual differences of classification and categories shall not influence the verification of the identity.

(7) The competent authority may require information necessary for the evaluation of the identity from the manufacturer of the PPP or his representative or the holder of the authorization of the reference PPP or the competent authority of the country of origin.

(8) The competent authority shall evaluate the application within six months of the arrival of the necessary data.

(9) The validity of the parallel import approval may not exceed that of the authorization of the reference PPP.

### *Experimental use*

## Article 21

(1) In compliance with paragraph (2), any experiment or test for research or development purposes involving the release into the environment of an unauthorized PPP may only be carried out after authorization for trial purposes has been granted by the competent authority

(*hereinafter*: authorization for trial), under controlled conditions and for limited quantities and areas.

(2) Paragraph (1) shall not apply to the preliminary and informative trials and trial places for which the manufacturers have obtained the right for carrying out the experiments and tests with the PPPs.

(3) If the experiments or tests under paragraph (1) are liable to have harmful effects on human and animal health or have an unacceptable adverse influence on to the environment, the competent authority may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.

(4) Experiments with products containing living organism not native in Hungary may be carried out – independently from paragraph (2) – only in possession of the authorization granted by the competent authority, considering the opinions of the CMOPH, MEW and the ministry. This authorization does not give an exemption from acquiring the import approval specified by nature conservation legislation.

(5) In the authorization for trial granted in compliance with paragraphs (1) and (4), the competent authority approves or designates the experimental site and the necessary specific conditions (isolation, destruction, safety measures).

## **Article 22**

(1) Trials for authorization may be carried out by official or officially recognized test facilities.

(2) The Central Service for Plant Protection and Soil Conservation recognizes and regularly inspects the test facilities. The rules on recognition are contained in the Methodology.

(3) The institution carrying out the biological efficacy trials for authorization shall not be in interest/property relations with the manufacturer or distributor of the tested PPP.

## *Restricted use*

## **Article 23**

(1) The competent authority may grant authorization in an area or way different from the labelled use of a PPP already authorized in Hungary, if

- a)* the use is justified by public interest or the plant protection situation, and
- b)* information is available on the evidence that the PPP concerned is effective for the requested uses.

(2) The authorization under paragraph (1) is valid for the area specified in the document and limited for one growing season. The application shall be submitted to the competent authority through the Service concerned at the place of use.

(3) The authorization under paragraph (1) shall contain the following data for fresh-market crops, food-industry and fodder plants on the

- a) pre-harvest interval for the approved treatment, specified by the responsible official body,
- b) rules on pesticide residue levels,
- c) provisions for the temporary distribution and restrictions on the crop harvested from the treated area

(4) Contamination of the produce harvested from an area treated according to the authorization under paragraph (1) shall be checked, before placing on the market, in the designated laboratory.

(5) If certain plants, plant products contain pesticide residues above the MRL, a decision on their further use shall be made in compliance with other order of legislation.

#### **Article 24**

(1) Differing from Article 7 (1), the competent authority may authorize, for maximum 120 days, the use of PPPs not authorized in Hungary if

- a) conditions of Article 23 (1) are fulfilled, and
- b) if properly used, requirements of Article 14 (1) c) of the Act are fulfilled, or
- c) together with complying with b), the treated plant, plant product is intended for export on the basis of contracted production.

(2) The authorization under paragraph (1) for fresh-market crops, food-industry and fodder plants shall contain the data laid down in Article 23 (3).

(3) The competent authority shall inform the Contracting Parties and the Commission of granting the authorization under paragraph (1).

(4) The Commission shall decide on the conditions of extension or on withdrawal of authorization under paragraph (1).

#### *Handling of the documentation submitted for authorization*

#### **Article 25**

(1) The competent authority and the responsible official bodies concerned provide for the safe handling and storing of detailed and summary data submitted in printed and electronic versions for the authorization.

(2) After the evaluation of the application, one copy of the complete original documentation shall be archived by the competent authority. The applicant is required to take the other copies away at his own expense. If this is not done within six months of the notice, the documentation may be destroyed by the competent authority at the applicant's cost.

## *Import of treated seeds and growing media*

### **Article 26**

(1) In case of importing seeds and plant materials (*hereinafter*: propagating materials), as well as growing media under Article 12 (3) of the Act, other order of legislation and provisions of paragraphs (2) and (3), as well as of Article 27 (1) to (3) shall apply:

(2) Propagating materials treated with PPPs, the active substances of which are listed in *Annex I*, shall be imported without the special approval of the competent authority.

(3) Propagating materials treated with PPPs, the active substances of which are not listed in *Annex I*, shall be imported with the approval of the competent authority. The application for the approval shall be accompanied by the following data:

- a) volume of the treated propagating material
- b) safety data sheet of the used PPP
- c) list of the countries in which the PPP concerned is authorized
- d) name and address of the Hungarian distributor or user.

### **Article 27**

(1) Other orders of legislation provide for the authorization of placing on the market and use of growing media.

(2) No special import approval of the competent authority is required for the growing media contaminated with PPPs if they contain residue of active substance(s) listed in *Annex I* and the quantity of which does not exceed MRLs for geological media specified in other order of legislation, lacking this, 1 mg/kg.

(3) If a growing medium contains residue of active substance(s) not listed in *Annex I* or the quantity of the pesticide residue is higher than that defined under paragraph (2), the import approval of the competent authority shall also be obtained. The application for the approval shall be accompanied by the following data:

- a) volume of the growing medium to be imported
- b) safety data sheet of the PPP
- c) results of the tests made in an accredited laboratory
- d) name and address of the distributor/user.

## *Quality control*

### **Article 28**

(1) No PPP with expired shelf life shall be distributed without quality control.

(2) The quality control test – on his own cost – shall be the responsibility of the distributor or the owner of the PPP.

(3) If the quality control proves that a particular lot of the PPP fails to comply with the requirements specified in the authorization document or is unsuitable or dangerous for use, the Service concerned decides on the future thereof in compliance with the rules.

### *Classification of plant protection products*

#### **Article 29**

(1) During their evaluation in compliance with *Annex 6*, the PPPs shall be classified according to their properties presenting risks to humans and the environment in compliance with other order of legislation on the classification of dangerous substances and dangerous preparations, and characterized by the supplementary R and S phrases listed in *Annexes 4* and *5*, taking paragraph (2) into consideration. In justified cases, protecting human and animal health and the environment, further phrases may be required to be indicated on the label, of which the contracting Parties and the Commission shall be notified, supported with due justification. The eventual review may be done based on the decision of the Commission.

(2) Paragraph (1) shall apply to PPPs authorized in Hungary, the active substances of which are included in *Annex 1 Part A*. The supplementary R and S phrases shall be set for the active substances by the deadlines specified in *Annex 15*. If a PPP contains more than one active substance, the latest deadline shall be taken into consideration.

(3) PPPs according to their toxicity to bees, may be classified as dangerous to bees (R57); if no risk assessment is available, in order to take the necessary precautionary measures, the notes of highly dangerous and moderately dangerous to bees shall also be indicated in compliance with *Annex 5*,

- b)* may be classified according to their toxicity to: aquatic organisms (R50, R51, R52, R53, R50/53, R51/53, R52/53), flora (R54) and fauna (R55), soil organisms (R56), environment (R58) and the ozone layer (R59), as well as in compliance with *Annex 5* and other order of legislation.

(4) Based on the classification according to toxicity to aquatic organisms, in the vicinity of waters, watercourses and ponds created during the surface exploitation of mineral raw material, in addition to the restrictions specified in other order of legislation, any plant protection operation with PPPs is prohibited within the following safety distances:

- a)* PPPs highly dangerous to aquatic organisms (LC50/EC50 < 1 mg/l to fish or the most sensitive species): 200 m, if no risk assessment is available,
- b)* PPPs moderately dangerous to aquatic organisms (LC50/EC50 1-10 mg/l to fish or the most sensitive species): 50 m, if no risk assessment is available,
- c)* PPPs with low danger to aquatic organisms (LC50/EC50 10-100 mg/l to fish or the most sensitive species): 20 m, if no risk assessment is available,
- d)* safety distances of 5, 20, 50 m may be specified based on risk assessment.

(5) PPPs – other than those authorized for use in living waters – shall not be applied within the safety distance of 5m from waters, watercourses and ponds created during the surface exploitation of mineral raw material.

(6) The Methodology contains the conditions of grouping PPPs into marketing categories.

### *Packaging and labelling of plant protection products*

#### **Article 30**

(1) The appearance of the PPP packaging (*hereinafter*: container) shall ensure that the PPP may not be mistaken with other substances (pharmaceuticals, food, household chemicals). The label of the container shall bear the indication „Keep away from the reach of children!“ if the authorization document does not contain such S phrases, and the following phrase: ”In order to avoid risks to humans and the environment keep the instructions for use”.

(2) The competent authority may restrict or prohibit the form and volume of containers and the use of certain materials for the manufacturing PPP containers.

(3) The label shall bear the data of the approved draft label, but at least the requirements of the authorization document other than points 4, 18 and 20 of *Annex 13*, the net content of the package, the date of manufacturing and indication of the envisaged use. Active substances and other components shall be indicated with the name listed in *Annex 1*, or if not found there, the ISO common name. If the latter one is not available, the chemical name according to IUPAC (International Union of Pure and Applied Chemistry) standards shall be used. For combined packages, the manufacturing date of either all the PPPs contained in the package, or the oldest manufacturing date shall be indicated on the outside package. The wording of the label shall comply with the requirements for content and format as specified in the chapter on labelling of the Methodology.

(4) The container of the PPPs placed on the market in small units must bear the name, active substance, manufacturer and function of the PPP, risk phrases or hazard symbols and the manufacturing date. The collective package shall bear a label in compliance with paragraph (3) and separate recommendations for use with identical content must be attached to all units. In this case the following wording shall be indicated: “Read the attached information before application”. The recommendation for use is an integral part of the label and they shall be provided by the formulator and distributor.

(5) Outside the container of a liquid, the PPP shall bear indications (an arrow) of transport and storage.

(6) The container of the PPPs classified as highly toxic, toxic and caustic materials (toxic materials) intended for use by the general public shall be sealed in a children-safe way as specified in Act on Chemical Safety.

#### **Article 31**

(1) In case of damage of the original container and repackaging of the product, rules on packaging shall apply. Only containers properly cleaned inside and outside, providing safety the same as the original, may be used for repackaging the PPPs.

(2) It is forbidden to fill and package PPPs in containers intended for other purposes (e.g., food, pharmaceuticals, cosmetics, feeds).

(3) Container of the repackaged PPPs shall bear: name, authorization number, active substance(s), classification as to hazard, marketing category, date of repackaging, expiry date of the PPPs as well as the name of the repackaging person. Article 30 shall apply for placing on the market of a repackaged PPP.

(4) The shelf-life of PPPs repackaged or filled in smaller units may not differ from the original shelf-life of the product due the repackaging and filling.

(5) If there is not enough space in the label on the container, the required data shall be attached in detailed recommendation for use to all packaging units.

(6) In addition to the required information, only those data may be put on the label, which are not in contradiction with the authorization.

(7) In no circumstances may the label of the packaging of a PPP bear the indications 'non-toxic', 'harmless', or similar indications or those leading to the underestimation of the risks of the PPP concerned. Information to the effect that the PPP may be used when bees or other non-target species are active, or when crops or weeds are in flower, or other such phrases to protect bees or other non-target species may be given on the label, if the authorization relates explicitly to use during the season for bees or other specified organisms and presents minimal hazard to them.

(8) For the packaging and labelling of PPPs, in cases not provided for in the Act and this Decree, the Act on Chemical Safety and the decrees on its implementation shall apply.

(9) If, for the protection of human health and the environment, the competent authority deems it justified to indicate further phrases on the label, it shall inform the Contracting Parties thereof and ask the position of the Commission.

(10) Guidance for labelling shall contain the practical requirements on labelling.

### *Manufacturing, formulation and packaging*

#### **Article 32**

(1) For the purposes of domestic distribution and use, only PPPs authorized in the Hungarian procedure may be manufactured, formulated and packaged, with the exception of PPPs under Article 21.

(2) Those active substances can be placed on the domestic market for plant protection purposes, which are included in *Annex 1* and comply with provisions specified in other order of legislation on labelling.

(3) The Service shall check the PPPs under Article 11 (5) of the Act in compliance with this Decree and other order of legislation.

### **Article 33**

(1) The holder of authorization or, by his written approval, the contracted formulator of the PPP from the active substance and the contracted packaging company are required to inform the competent authority on the domestic contracted formulation and packaging at least 15 days prior to the start of the activity. The competent authority shall keep records of the declaration.

(2) The holder of the authorization is responsible for the contracted formulation and packaging.

### *Storage of the plant protection products at the users*

### **Article 34**

(1) Any activity and facility related to storage of PPPs shall meet the requirements specified in other order of legislation on the protection of surface- and groundwater and the conservation of geological media.

(2) PPPs may only be stored in a storage place separated from any premises used for staying of humans and animals and for storage of food and feeds as well as in cabinets in a place and way not accessible for unauthorized persons, in a way avoiding risks of explosion and inflammation and imposing no risk to health and the environment, ensuring complete cleaning of the surroundings in case of contamination.

(3) Storehouse of PPPs, except for stocks not exceeding 50 kg product of individual users, may not be established on the protected area of waterworks or area exposed to flood and standing water.

### **Article 35**

(1) A notice saying „Storehouse of poisons”, „Storehouse of plant protection products” or „Plant protection products” shall be fixed on the door of any storehouses of PPPs in a visible way.

(2) The door of the cabinet and the storehouse must have safety locks, the keys of which may only be handled by authorized persons.

(3) At the site of application, PPPs prepared and measured for a single-day use may also be stored in safely lockable occasional storehouses. These storehouses may only be used for other purposes after the removal of the eventual contamination from PPPs.

(4) In the storehouse for PPPs only activities in connection with the storage and weighing in of the PPPs necessary for the application may be performed.

(5) Any storage facilities subject to licence specified in other order of legislation shall comply with the provisions on retail and wholesale trade of PPPs.

### **Article 36**

(1) PPPs may be stored in original sealed packaging or in original packaging resealed after use.

(2) For the storage, transport and use of PPPs containing microbial active substances and macro-organisms, the provisions for PPPs shall apply unless otherwise specified in the authorization document.

(3) In the storage facility

a) empty, properly cleaned inside and outside, sealable container, which may be used for repackaging of PPPs,

b) damaged, unidentifiable, contaminated and expired products, as well as containers to be decontaminated

shall be stored separately from the PPPs.

### *Transport*

### **Article 37**

(1) PPPs shall be transported in containers, properly fixed in compliance with the requirements, as specified in the related provisions. Only persons possessing appropriate knowledge may be charged with this job.

(2) It is forbidden to transport humans, animals, feeds, food and pharmaceuticals together with PPPs on the loading area of the vehicle. Any other goods may only be transported in a way that they could not be in contact with the PPPs. PPPs shall be placed so as to prevent contamination of the vehicle and the environment.

(3) In case of eventual contamination of the vehicle, it shall be cleaned without delay, observing provisions on health, environment protection and nature conservation. Waste water and wastes produced during the cleaning of the contaminated vehicle must be treated and decontaminated in compliance with the related environmental provisions.

(4) During transport of various PPPs, the protective equipment adjusted to the most dangerous PPP shall be ensured.

### *Fee of authorization and charge for maintaining the authorization*

### **Article 38**

Fees must be paid for the evaluation of active substances, the authorization procedure of PPPs, the modification of authorization, the approval of parallel imports, the restricted use authorization, the off-label use approvals, recognition and inspection of the test facilities, carrying out the trials and for maintaining the authorization as specified in other order of legislation.

#### *Reporting obligation*

### **Article 39**

The competent authority shall inform the Commission and Member States by reporting as follows:

- a) authorized and withdrawn PPPs, quarterly, indicating the following data:
  1. the name or business name of the holder of the authorization,
  2. the trade name of the PPP,
  3. the function of PPP,
  4. the name and quantity of each active substance it contains,
  5. the envisaged use or uses,
  6. the maximum residue levels provisionally established where they have not already been set by Community rules, for the active substances listed in *Annex I Part A*,
  7. where relevant, the reasons for the withdrawal of an authorization,
  8. the data necessary for establishing provisional MRLs
- b) list of the PPPs authorized in Hungary, annually
- c) list of PPPs containing the active substances included in *Annex I Part A*, the active substances of which are produced by manufacturers other than those indicated in the Annex, providing the information on the identity and impurities of the active substance.
- d) new data submitted by the holder of the authorization on the risk of the PPP and the active substance.

#### *Final clauses*

### **Article 40**

(1) This Decree will enter into force 8 days after its publication

(2) At the time of entering into force of this Decree,

- a) the Ministerial Decree 6/2001.(I. 16.)FVM on the authorization of placing on the market and use, as well as on the packaging, storage and transport of plant protection products and

b) Article 10 and Annex 5 of Ministerial Decree 5/2001. (I. 16.) FVM on Plant Protection Activity as well Article 7 and Annex 4 of 81/2003. (VII. 9.) FVM amending it.  
will be repealed.

#### **Article 41**

The competent authority may extend the validity of the authorization of PPPs on the market until the review in compliance with the Community Regulations.

#### **Article 42**

(1) The holder of the authorization shall submit, to the competent authority for approval before 30 July 2005, any proposal for classification and grouping of PPPs in compliance with other order of legislation on detailed rules of certain procedures and activities in relation to dangerous substances and dangerous preparations.

(2) Labels made in compliance with provisions effective before the coming into force of this Decree may be used till the evaluation of the applications submitted in compliance with paragraph (1) and according to the provisions of the related authorization documents. After this date, only such labels may be used, the draft of which was made and approved in compliance with this Decree and the valid authorization documents.

#### **Article 43**

(1) For PPPs authorized before entering into force of this Decree, classification as to hazard and toxicity to fish may be used until the expiry of the authorization or till the reclassification.

(2) PPPs classified “non-toxic to fish” (LC50/EC50 >100 mg/l) shall be considered non-classified as to toxicity to fish/aquatic organisms and a safety distance of at least 5 m from surface waters shall be observed.

#### **Article 44**

The ministry shall hand over the accomplished and in-procedure documents of the issues related to authorization under the scope of this Decree to the competent authority after entering into force of this Decree. The deadline for handing over of the documents is 31 October 2004.

#### **Article 45**

This Decree is intended to comply with the following directives::

- a) Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC), as well as Council Directive 1997/57/EC and Commission Directives 1993/71/EEC, 1994/37/EC, 1994/79/EC, 1995/35/EC,

1995/36/EC, 1996/12/EC, 1996/46/EC, 1996/68/EC, 1997/73/EC, 1998/47/EC, 1999/1/EC, 1999/73/EC, 1999/80/EC, 2000/10/EC, 2000/49/EC, 2000/50/EC, 2000/66/EC, 2000/67/EC, 2000/68/EC, 2000/80/EC, 2001/21/EC, 2001/28/EC, 2001/36/EC, 2001/47/EC, 2001/49/EC, 2001/87/EC, 2001/99/EC, 2001/103/EC, 2002/18/EC, 2002/37/EC, 2002/48/EC, 2002/64/EC, 2002/81/EC, 2003/5/EC, 2003/23/EC, 2003/31/EC, 2003/39/EC, 2003/68/EC, 2003/70/EC, 2003/79/EC, 2003/81/EC, 2003/82/EC, 2003/84/EC, 2003/112/EC, 2003/119/EC, 2004/20/EC, 2004/30/EC on its amendment

- b) Council Directive of 21 December 1978 on prohibiting the placing on the market and use of plant protection products containing certain active substances (79/117/EEC), as well as Council Directives 1986/214/EEC, 1986/355/EEC, 1987/181/EEC, 1989/365/EEC, 1990/533/EEC and Commission Directives 1983/131/EEC, 1985/298/EEC, 1987/477/EEC, 1990/335/EEC, 1991/188/EEC on its amendment.
- c) Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.