### MINISTRY OF RURAL DEVELOPMENT AND FOOD



### LAW 4036/2012

# "Pesticide marketing, sustainable use and other provisions"

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-Consolidated version-

#### Amended by:

		Official Journal	Date
1	Law 4152/2013	A' 107	9-5-2013
2	Law 4235/2014	A' 32	11-2-2014
3	Law 4351/2015	A' 164	4-12-2015
4	Law 4384/2016	A'78	26-4-2016
5	Law 4472/2017	A'74	19-5-2017

#### **UNOFFICIAL TRANSLATION**

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PLANT PROTECTION PRODUCTS & BIOCIDES
DEPARTMENT

DIRECTORATE OF PLANT PRODUCE PROTECTION (C.N.A.)

### PART ONE GENERAL PROVISIONS

### Article 1 Scope - Subject

- 1. Scope of the present law is:
- a) The establishment of necessary supplementary measures for the implementation of the provisions of
  - aa) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC,
  - bb) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC and its implementing regulations,
- b) The incorporation in the Greek laws of the provisions of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, of the supplementary measures of the directive and the adoption of national measures in compliance with Directive requirements,
- c) The establishment of other provisions in relation to pesticides.

#### **PART TWO**

## NECESSARY SUPPLEMENTARY MEASURES FOR THE IMPLENTATION OF REGULATION (EC) 1107/2009, REGULATION (EC) 396/2005 AND DIRECTIVE 2009/128/EC

## CHAPTER I IMPLEMENTATION AREA – COMPETENT AUTHORITY

#### Article 2 Implementation area

This part of the present law is applied to the pesticides that are plant protection products.

## Article 3 Coordinating National Authority and Competent Authorities

- The Plant Protection Produce Directorate of the Ministry of Rural Development and Food is designated as the Coordinating National Authority (CNA) for the implementation of the provisions of:
  - a. The Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC,
  - b. The Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC and its implementing regulations,
  - c. The Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
- 2. The Coordinating National Authority is designated for the coordination of competent authorities regarding the implementation of the present law, the cooperation with EU Commission, with EFSA, with the competent Authorities of the other Member States, with the manufacturers, producers, farmers, professional users and other involved in pesticide matters.

- 3. By a Decision of the Minister of Rural Development and Food or a Common Decision of the Minister of Rural Development and Food and the case by case responsible Minister the competent authorities for the implementation of the present law are designated as well as and their responsibilities.
- 4. ¹The Benaki Phytopathological Institute is designated as the competent authority for the evaluation of the submitted data, which are required for the placing of plant protection products on the market, according to the provisions of article 4 as well as for active substances other substances apart from additives regulated by the Regulation (EC) 1107/2009. By a Decision of the Minister of Rural Development and Food or Common Ministerial Decisions in case of common competencies, more competent authorities may be designated, which satisfy the scientific specifications, if it is necessary.

# CHAPTER II: NECESSARY MEASURES FOR THE IMPLEMENTATION OF REGULATION (EC) NO 1107/2009 AND REGULATION (EC) NO 396/2005 AND THEIR IMPLEMENTING REGULATIONS

### Article 4 Authorization

- 1. For the placing of plant protection products on the market, an authorization by the Coordinating National Authority (CNA) is required.
- 2. The applicant who wishes to place a plant protection product on the market of Greece, should submit an application to CNA either by himself or by his representative. If he headquartered abroad, he should appoint a responsible physical or legal person for placing of the plant protection products on the Greek market.
- An application for parallel trade permit or trial permit by CNA is submitted by a physical or legal person headquartered in any Member State of the European Union.

<sup>&</sup>lt;sup>1</sup> Amendment 4-12-2015: Paragraph 1, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 4 of article 3 of the law 4036/2012 is modified as following: ..."

- 4. <sup>2</sup>The authorization for the placing of plant protection products on the market in relation to the Regulation (EC) No 1107/2009 is issued and recalled or, in those cases when an evaluation is conducted by the competent authority of article 3 renewed and modified by a decision of the Minister of Rural Development and Food.
- 5. The submission by the applicant of a dossier, containing the application and all the technical data and studies, according to the provisions of the Regulation (EC) No 1107/2009 and its implementing regulations and also the national requirements that are in force on the date of submission, is required for issuing the authorization for the placing of plant protection products on the market.
- 6. The applications for issuing authorizations for the placing of plant protection products on the market are posted on the C.N.A. website available on the internet. The applications are examined according to a priority list in applications category (like new products, similar products) based on the applications submission date.
- 7. The evaluation of the submitted data is made by the competent authority designated on the paragraph 4 of article 3, in order to examine the fulfilling of the safety criteria for the human and the environment.
- 8. The evaluation of the plant protection products and the issue of the authorization for the placing of plant protection products on the market is completed within the time period defined in the article 37 of the Regulation (EC) No 1107/2009 starting on the date of fulfilling for each application category and the applicant is informed.
- 9. Prior to the completion of the evaluation and the issue of the authorization for the placing of plant protection products on the market, the CNA gives the applicant the opportunity to express or to submit in a certain time period comments.
- 10. The CNA keeps Registry of the authorization holders for the placing of plant protection products on the market and publishes it on its website. A special registry code number is supplied to each authorization holder. The authorization holders for the placing of plant protection products on the market are obliged to write this special code number on every document communicating with the CNA, the
- <sup>2</sup> Amendment 4-12-2015: Paragraph 2, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 4 of article 4 of the law 4036/2012 is modified as following: ..."

- competent authorities or the competent authorities of other Member States of the European Union.
- 11. All authorizations for the placing of plant protection products on the market are posted on the C.N.A. website available on the internet. The authorizations and also the evaluation reports except the confidential information are available, after submitting a relative application. The expenses for the reproduction of the evaluation reports are paid by the applicants.

### Article 5 Scientific Pesticides Committee

- 1. A Scientific Pesticides Committee (S.P.C.) is established in the Ministry of Rural Development and Food, in order to supply opinion to pesticides related matters.
- 2. The S.P.C. consists of:
  - a. The head of the competent General Directorate as the president of the committee,
  - b. The head of the Plant Produce Protection Directorate as a member,
  - The head of Biological Agriculture Directorate as a member,
  - d. An expert holding a doctorate degree and at least three years experience in toxicology and user exposure as a member,
  - e. An expert holding a doctorate degree and at least three years experience in ecotoxicology as a member,
  - f. An expert holding a doctorate degree and at least three years experience in fate and behaviour in the environment as a member,
  - g. An expert holding a doctorate degree and at least three years experience in residues on food and feed as a member,
  - h. An expert holding a doctorate degree and at least three years experience in efficacy as a member,
  - i. An expert holding a doctorate degree and at least three years experience in chemical controls as a member,
  - j. A representative of the environmental organizations as a member,
  - k. A representative of farmer organizations and
  - I. A representative of the Hellenic Crop Protection Association (HCPA) or a representative of the

professional body of biocides, competent to the Ministry of Rural Development and Food, authorizations holders if appropriate, as a member.

- m. <sup>3</sup>A representative from the Geotechnical Chamber of Greece (GEOTEE), as a member.
- 3. One of the employees of the Plant Produce Protection Directorate performs as a secretary of the S.P.C.
- 4. The president and the members of the S.P.C. with their deputies and the secretary are defined with a decision of the Minister of Rural Development and Food. The members of the paragraphs d. j. preferred to be University's professors.
- 5. <sup>4</sup>The incumbency of the members of the Committee shall be two years. The participation of each member should not exceed two terms, except of the representatives of the bodies.
- 6. The competencies of the S.P.C. are:
  - a. To supply a scientific opinion on pesticides general interest matters after a relative request of the Minister of Rural Development and Food and a proposal by CNA.
  - b. To supply a scientific opinion on claims upon authorizations for the placing of plant protection products on the market, related to the evaluation of the efficacy and the safety for the human and the environment conducted by the Competent Authority of paragraph 4 of the article 3 of the present law.
- 7. The Scientific Committee shall meet at the call of the President and is a quorum of at least five members.
- 8. The Commission shall decide on the agenda following a recommendation from the C.N.A. Decisions are taken by a majority of members present.
- 9. The President may invite the Commission before anyone else who may have a valid opinion on the issues of pesticides.
- 10. The issues related to the operation of the S.P.C. are defined by a decision of the Minister of Rural Development and Food.

### Article 6 Authorization fees

- The application for the authorization of an active substance, safener or synergist, as well as the application for an authorization for the placing of plant protection products on the market, according to the Regulation (EC) No 1107/2009 should be accompanied by the relative fee for its examination.
- The categories for the fees for authorizations and maximum residue limits definition are defined in Annex A.
- 3. <sup>5</sup>The fees are proportionate and recovery and their amount is determined and adjusted by the joint decision of the Ministers of Economic and Rural Development and Food. Special fee forms are issued for the recovery of the sums of the fees, nominal value equal to a percentage: a) 70% of the nominal fee value for the benefit of Benaki Phytopathological Institute, which, according to paragraph 4 of the article 3, is defined as the competent authority for the evaluation of the data required and submitted for the authorization for the placing of plant protection products on the market and b) 30% of the nominal fee value for the benefit of the Fund for Agriculture and Livestock of the Ministry of Rural Development and Food.

The method of acquisition and issuance of these specific fee forms, the type, the mode of use, the disposal and management of these, the way of cancellation and all related matters are determined by a joint decision of the Ministers of Economic and Rural Development and Food.

Up to the completion of the procedure for the acquisition of the above special fee forms, the recovery of fee amounts of the present article is made by the issuance of equal amount duplicate forms by the Public Financial Services for the benefit of those beneficiaries. These amounts shall be used exclusively for the purposes of this Act.

4. The imposition of any other fee in any form for the same purpose is forbidden.

<sup>&</sup>lt;sup>3</sup> Amendment 4-12-2015: Paragraph 12, article 18 of law num. 4351/2015 (O.J. A'164): "The case m is added after the case I of article 5, paragraph 2 of the law 4036/2012 as following: ..."

<sup>&</sup>lt;sup>4</sup> Amendment 4-12-2015: Paragraph 3, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 5 of article 5 of the law 4036/2012 is modified as following: ..."

<sup>&</sup>lt;sup>5</sup> **Amendment 11-2-2014**: Paragraph 1, article 44, of law num. 4235/2014 (O.J. A'32): "The paragraph 3 of article 6 of the law 4036/2012 is replaced as following: ..."

### Article 7 Controls on plant protection products

The C.N.A. is planning and coordinating annual or multiannual control programs of plant protections products in order to check if in practice the conditions of the authorizations are met and ensure the safety of users, consumers and environment.

### Article 8 Control authorities and their responsibilities

- Controls on plant protection products are implemented by the competent authorities of the Regions, Regional Unities and with parallel capability for controls by the Regional Centers for Plant Protection and Quality Control of the Ministry of Rural Development and Food.
  - The C.N.A. keeps registry of inspectors appointed by Regions, Regional Unities and Regional Centers for Plant Protection and Quality Control of Ministry of Rural Development and Food.
  - The C.N.A. sets a training system for controls on plant protection products. This training system consists on initial courses and ongoing education in order to acquire and update the competence of inspectors who are implementing the controls. This training program is been planned and applied according to the relevant national and EU legislation.
- 2. With the exception of specific laws for confidentiality, all persons or companies are obliged to cooperate with inspectors during controls and supplying any requested information.
- 3. For the purpose of controls and to prove any infringements, inspectors:
  - a. Have the legal power to control any kind of documentation related to manufacture and marketing of plant protection products and other company's documents, such as management or staff's e-mails regardless the way they are saved, and the place they are kept, and can take copies of them
  - b. Have the legal power to carry out investigations at the company's offices and the rest facilities and at the forwarding vehicles.
  - c. Have the legal power to seal the company's facilities or documentation, during the investigation up to what is required.

- 4. The relevant control order is supplied by the head of the control service and contains the scope of the control and the consequences for not cooperating with the inspectors.
- Inspectors who are responsible for an investigation, are making a report, copy of which is given to the controlled company.
- In case of not cooperating with the inspectors, administrative assistance can be asked by the police or justice. This assistance can be asked even in advance.

#### Article 9

### Administrative sanctions for plant protection products infringements

- 1. If fake or misleading documents are submitted for the authorization of a plant protection product, or data known at the time of submission are hidden, or potentially harmful or unacceptable effects on humans, animal helath or environment are not notified according to article 56 of Regulation (EC) 1107/2009, a fine of 1,000 € up to 30,000 € is posed to the responsible and marketing of the plant protection product is prohibited for at least one year, depending on the severity of the case.
- 2. A fine of 10,000 € up to 50,000 € is posed to the responsible for importing, producing, packaging, forwarding or marketing not authorized plant protection products or active substances for the purpose of exporting to third countries or marketed to another Member State. Plant protection products are set under official detention and in case of imported plant protection products, they are reexported to the country of origin, in case of EU origin, they are return to the MS of origin or destructed. All expenses are paid by the owner of the products.
- 3. A fine of 1,000 € up to 30,000 € is posed to the responsible for importing, producing, packaging, holding, forwarding, exchanging, marketing, using or advertizing not authorized plant protection products, or plant protection products which authorization has been recalled, or plant protection products not covered by a parallel import permit, or plant protection products not cover by a trial permit. Plant protection products are set under official detention and in case of imported plant protection products, they are re-exported to the country of origin, in case of EU origin, they are return to the MS of origin or

- destructed. All expenses are paid by the owner of the products.
- 4. In the case that unacceptable discrepancies are discovered to the guaranteed composition or the physicochemical properties in relation to those stated to the authorization dossier, a fine of 1,000 € up to 30,000 € is posed to the responsible person or company and marketing of the plant protection product can be prohibited for at least one year, depending on the severity of the case. The related quantity of the batch or the total quantity of the product if the batch cannot be identified is set under official detention and in case of imported plant protection products, they are re-exported to the country of origin, in case of EU origin, they are return to the MS of origin or destructed. All expenses are paid by the responsible.
- 5. In the case that unacceptable discrepancies are discovered to the label or package, relation to those stated to the authorization valid at the time of control, a fine of 300 € up to 50,000 € is posed to the responsible person or company and marketing of the plant protection product can be prohibited, depending on the severity of the case. The related quantity of the batch or the total quantity of the product if the batch cannot be identified is set under official detention and labeling or packaging is corrected. All expenses are paid by the responsible for the infringement.
- 6. <sup>6</sup>A fine of 300 € up to 30,000 € is posed to the responsible for importing, using for professional use, transporting or marketing even if it is without price, plant protection products later than the expiry date that can be concluded by the label of packaging and which have unacceptable discrepancies to the guaranteed composition or the physicochemical properties in relation to those stated to the authorization dossier. Plant protection products are set under official detention and destructed. All expenses are paid by the responsible for the infringement.
- 7. A fine of 300 € up to 30,000 € is posed to the responsible for advertising plant protection product to a not allowed media or in case that a pesticide advertisement includes information that are not in accordance to the ones in the relevant plant protection product authorization. Advertising

- material is set under official detention and its use is prohibited.
- 8. A fine of 1,000 € up to 50,000 € is posed to the responsible for placing on the market seeds treated with plant protection products not authorized in any Member State and the seed batch is taken out of market. All expenses are paid by the responsible for the infringement.
- 9. A fine of 1,000 € up to 10,000 € is posed to the responsible for placing on the market seeds treated with plant protection products without keeping the measures for marketing stated by the competent authority or without proper labeling and the seed batch is taken out of market. All expenses are paid by the responsible for the infringement.
- 10. A fine of 1,000 € up to 10,000 € is posed to the responsible for placing on the market seeds treated with plant protection products without keeping the measures for marketing stated by the Member State of origin or measures stated by the competent authority and the seed batch is set under official detention and taken out of market. All expenses are paid by the responsible for the infringement.
- 11. <sup>7</sup>A fine of 1,000 € up to 10,000 € is posed to the responsible for placing on the market plant protection products containing macro-organisms not officially registered and the macro-organisms batch is taken out of market. All expenses are paid by the responsible for the infringement.
- 12. Anyone denies or delays by any manner the controls by the competent authority or denies to submit data or information or submits false data or information or hides data or information is punished with a fine of 1,000 € up to 50,000 €.
- 13. For any other infringement of the Regulation (EC) 1107/2009 and the implementation acts, a fine of 1,000 € up to 5,000 € is posed to the responsible.
- 14. In case of a second infringement from the same responsible:
  - a. The limits of fines are doubled and the second fine cannot be less than the double of the first fine.
  - Authorization of the plant protection product is recalled for a time period of one to ten years.

<sup>&</sup>lt;sup>6</sup> **Amendment 4-12-2015**: Paragraph 4, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 6 of article 9 of the law 4036/2012 is replaced as following: ..."

<sup>&</sup>lt;sup>7</sup> **Amendment 4-12-2015**: Paragraph 5, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 11 of article 9 of the law 4036/2012 is replaced as following: ..."

- 15. For the estimation of the fine, the following parameters are taken into account:
  - The risk caused by the infringement to human and environment.
  - b. The deviation from the authorization.
  - c. The consequences caused by the infringement
  - d. The repetition of the infringement. As repetition, it is considered the discovery of another same or similar infringement by the same person or company in a three years period, beginning from the date of issue of the previous decision for administrative sanctions.
- 16. The service that has made the investigation communicates with a document (with proven receipt) the infringement to the responsible, which is called to submit in writing his opinion in a 15 days period. After this period and regardless of submitting or not his opinion, the service forwards the file to the competent authority.
- 17. Fines are posed by decision of the Minister of Rural Development and Food, after a relevant proposal of the Coordinating National Authority (CNA). An authorization is recalled by decision of the Minister of Rural Development and Food.
- 18. If the owner of the bonded plant protection products refuses to destroy them, or to re-export them, or to return them to the Member State of origin, this work is made by the competent authority, with the cooperation of competent state services. All expenses are charged to the responsible.
- 19. Fines are assessed as public incomes and they are paid to the Account for Agriculture and Cattle Breeding. The competent Economic service of the Ministry of Rural Development and Food is responsible for the fine assessment.
- 20. With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the fines of the present article can be readjusted.

#### Article 10

### Punitive sanctions for plant protection product infringements

1. If fake or misleading documents are submitted for the authorization of a plant protection product, or data known at the time of submission are hidden, the

- responsible is punished with imprisonment for three months up to one year.
- Imprisonment for three months up to one year is posed to the responsible for import, producing, packaging, forwarding or marketing not authorized plant protection products or active substances for the purpose of exporting to third countries or marketed to another Member State.
- 3. Imprisonment for three months up to one year is posed to the responsible for importing, producing, packaging, holding, forwarding, exchanging, marketing, using or advertizing not authorized plant protection products, or plant protection products which authorization has been recalled, or plant protection products not covered by a parallel import permit.
- 4. In the case that unacceptable discrepancies are discovered to the guaranteed composition or the physicochemical properties in relation to those stated to the authorization dossier, the responsible is punished with imprisonment for three months up to two years.
- 5. In the case that unacceptable discrepancies are proved to the label or package, relation to those stated to the authorization valid at the time of control, the responsible is punished with imprisonment for three months up to one year.
- 6. 8Imprisonment for three months up to one year is posed to the responsible for importing, using for professional use, transporting or marketing even if it is without price, plant protection products later than the expiry date that can be concluded by the label of packaging.
- 7. Anyone denies or delays by any manner the controls by the competent authority or denies submitting data or information or submits false data or information or hides data or information is punished with imprisonment for three months up to one year.
- 8. For second infringements, Punitive Law Code is applied.

### Article 11 Responsible for sanction persons

The prosecution is made and penalties are imposed on those responsible for compliance with the provisions of

<sup>&</sup>lt;sup>8</sup> Amendment 4-12-2015: Paragraph 6, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 6 of article 10 of the law 4036/2012 is replaced as following: ..."

the Regulation (EC) No 1107/2009 and implementing such acts of the European Union and in this chapter. These are: in personal business entrepreneurs the businessmen, in personal companies the partners, in limited liability companies and cooperatives the managers and in anonymous companies the board members. No other responsible against law is allowed to be defined. For decisions taken by majority, the responsibility lays those who voted. The same individuals who are responsible with their personal property, are also responsible jointly and severally liable with each other and with the relevant legal entity for the payment of fines to be imposed in accordance with the provisions of this Chapter.

### Article 12 Pesticide residue controls

- 1. The C.N.A. prepares control programs for pesticide residues and coordinates the bodies responsible for their implementation.
- 2. A training system for controls on pesticide residues control is established. This training program consists on initial courses and ongoing education in order to acquire and update the competence of inspectors of competent bodies and services that are implementing the control programs. The training programs are designed and implemented by the Education Institute of the National Centre for Public Administration & Local Government (EKDDA) in cooperation with C.N.A.

## Article 13 Administrative sanctions for pesticide residue infringements

1. A fine of 1,000 € up to 50,000 € is posed to the responsible for producing, importing or exporting plant products with pesticide residues in concentrations higher than the Maximum Residue Limits (MRLs), as defined by the Regulation (EC) No 396/2005 of the European Parliament and the Council and the plant products are set under official detention. The induced costs are paid by the person responsible for the infringement. Next batch placement in the market of same origin plant products is only allowed if prior to marketing the batch is controlled by the Competent Authority and found that residues do not exceed the Maximum Residue Limits (MRLs), as defined by the Regulation (EC) No 396/2005. If the plant products are placed on the market before been controlled for pesticide

- residues, a fine of  $1,000 \in \text{up to } 60,000 \in \text{is posed to the responsible.}$
- 2. If it is found out that the professional user produces and places on the market plant products with pesticide residues in concentrations higher than the Maximum Residue Limits (MRLs), the Competent Authority also poses sanctions that are provided in the Council Regulation (EC) No 1782/2003 of 29 September 2003 "establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers".
- 3. A fine of 1,000 € up to 30,000 € is posed to anyone who distributes plant products on the market with pesticide residues in concentrations higher than the Maximum Residue Limits (MRLs), as defined by the Regulation (EC) No 396/2005 of the European Parliament and the Council and does not provide accurate and traceable information about the producer or supplier of the plant products.
- 4. A fine of 1,000 € up to 60,000 € is posed to anyone who denies or impedes in any way the controls of the authorized control bodies or refuses to provide data and information, or providing false information or conceals information and data and information regarding pesticide residue control.
- In case of a second infringement from the same responsible, the limits of fines are doubled and the fine imposed may not be less than double the previous fine imposed.
- 6. For the estimation of the fine, the following criteria are taken into account:
  - a. The risk caused by the infringement to human, as estimated by a dietary risk analysis,
  - b. The divergence against the Maximum Residue Limits,
  - c. The concentration of the residues and the number of illegal active substances that are detected.

The service that has made the investigation communicates with a document with proven receipt the infringement to the responsible, which is called to submit in writing his opinion in a 15 days period. After this period and regardless of submitting or not his opinion, the service forwards the file to the competent authority.

7. Fines are posed by decision of the Minister of Rural Development and Food, after a relevant proposal of the Coordinating National Authority (CNA).

- 8. Fines are assessed as public incomes and they are paid to the Account for Agriculture and Cattle Breeding. The competent Economic service of the Ministry of Rural Development and Food is responsible for the fine assessment.
- With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the fines of the present article can be readjusted.

## Article 14 Punitive sanctions for pesticide residue infringements

- Imprisonment for at least six (6) months is posed to the responsible for producing, importing or exporting plant products with pesticide residues in concentrations higher than the Maximum Residue Limits (MRLs), as defined by the Regulation (EC) No 396/2005 of the European Parliament and the Council.
- 2. Imprisonment for three (3) months up to one (1) year is posed to anyone who distributes plant products on the market with pesticide residues in concentrations higher than the Maximum Residue Limits (MRLs), as defined by the Regulation (EC) No 396/2005 of the European Parliament and the Council and does not provide accurate and traceable information about the producer or supplier of the plant products.
- 3. Imprisonment for at least one (1) year is posed to anyone who denies or impedes in any way the controls of the authorized control bodies or refuses to provide data and information, or providing false information or conceals information and data and information regarding pesticide residue control.

## PART THREE TRANSPOSITION OF DIRECTIVE 2009/128/EC TO NATIONAL LEGISLATION

## SECTION ONE IMMEDIATE IMPLEMENTATION MEASURES OF DIRECTIVE 2009/128/EC

### CHAPTER A' GENERAL PROVISIONS

#### Article 15

### (article 1 of directive 2009/128/EC) Subject matter

The present part of the law establishes provisions to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides.

## Article 16 (article 2 of directive 2009/128/EC) Scope

- Provisions of the present part apply to pesticides that are plant protection products as defined in point 10(a) of Article 17, point 10a and are applied having regard to any other relevant Community Act.
- 2. By stretching the provision of the present law precautionary principle can be applied in restricting or prohibiting the use of pesticides in specific circumstances or areas.

## Article 17 (article 3 of directive 2009/128/EC) Definitions

For the implementation of the third part of the present law, the following definitions are valid:

- "professional user" means any person who uses pesticides in the course of their professional activities, including operators, technicians, employers and self-employed people, both in the farming and other sectors;
- "distributor" means any natural or legal person who makes a pesticide available on the market, including wholesalers, retailers, vendors and suppliers;
- "advisor" means any person who has acquired adequate knowledge and advises on pest management and the safe use of pesticides, in the context of a professional capacity or commercial service, including private self-employed and public advisory services, commercial agents, food producers and retailers where applicable;
- "pesticide application equipment" means any apparatus specifically intended for the application of pesticides, including accessories that are essential for the effective operation of such equipment, such as nozzles, manometers, filters, strainers and cleaning devices for tanks;

- 5. "aerial spraying" means application of pesticides from an aircraft (plane or helicopter);
- 6. "integrated pest management" means careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment;
- 7. "risk indicator" means the result of a method of calculation that is used to evaluate risks of pesticides on human health and/or the environment;
- "non-chemical methods" means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques as well as physical, mechanical or biological pest control methods:
- the terms "surface water" and "groundwater" have the same meaning as in law 3199/2003 (A'280) in compliance to Directive 2000/60/EC;
- 10. "pesticide" means:
  - (a) a plant protection product as defined in Regulation (EC) No 1107/2009;
  - (b) a biocidal product as defined in Presidential Decree 205/2001 (A'160) in compliance to Directive 98/8/EC.

## Article 18 (article 4 of directive 2009/128/EC) National Action Plans

 The National Action Plan is set for defining quantitative and other targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. These targets may cover different areas of concern, for example worker protection, protection of the environment, residues, use of specific techniques or use in specific crops.

The National Action Plans also include risk indicators to monitor the use of plant protection products containing active substances of particular concern, especially if alternatives are available. Special attention is given to the plant protection products

containing active substances approved in accordance with Presidential Decree 115/1997 in compliance to the Council Directive 91/414/EEC of 15 July 1991 which, when subject to renewal of approval under Regulation (EC) No 1107/2009 will not fulfill the criteria relevant for approval laid down in Annex II, points 3.6 to 3.8 of that Regulation, regarding to their consequences to human health, environmental fate and behavior and ecotoxicity.

<sup>9</sup>On the basis of such indicators and taking into account where applicable, the targets related to the risk or use reduction targets achieved already prior to the application of the present law, timetables and targets for the reduction of use are also established, in particular if the reduction of use constitutes an appropriate means to achieve risk reduction with regard to data identified under in paragraph 2, Article 29.

When drawing up and revising the National Action Plans, the health, social, economic and environmental impacts of the measures envisaged, specific national, regional and local conditions and all relevant stakeholder group opinions are taken account. The National Action Plans describe how they will implement measures pursuant to Articles 16 to 26 in order to achieve the objectives referred to in the first subparagraph of the first paragraph of the present article.

<sup>10</sup>In the National Action Plans the implementation measures pursuant to Articles 19 to 29 are described, in order to achieve the objectives referred to in the first subparagraph of the first paragraph of the present article.

The National Action Plans take into account plans provided in other provisions related to the use of pesticides, such as planned measures under law 3199/2003 (A'280) in compliance to the Directive 2000/60/EC.

 <sup>11</sup>The C.N.A. communicates the National Action Plans to the Commission and to other Member States until 26 November 2012. The National Action Plans shall

<sup>&</sup>lt;sup>9</sup> **Amendment 11-2-2014**: Paragraph 2a, article 44, of law num. 4235/2014 (O.J. A'32): "aa) The fifth quotation is replaced by the following: ..."

<sup>&</sup>lt;sup>10</sup> **Amendment 11-2-2014**: Paragraph 2a, article 44, of law num. 4235/2014 (O.J. A'32): "bb) The ninth quotation is replaced by the following: ..."

<sup>&</sup>lt;sup>11</sup> **Amendment 11-2-2014**: Paragraph 2b, article 44, of law num. 4235/2014 (O.J. A'32): "b) The first quotation of paragraph 2 of article 18 of law 4036/2012 is replaced by the following: …"

- be reviewed at least every five years and any substantial changes to National Action Plans shall be reported to the Commission without undue delay.
- 3. <sup>12</sup>The provisions on public participation laid down in Article 2 of Directive 2003/35/EC shall apply to the preparation and the modification of the National Action Plans.

## CHAPTER B' TRAINING, SALES OF PESTICIDES, INFORMATION AND AWARENESS-RAISING

## Article 19 (article 5 and Annex I of directive 2009/128/EC) Training

- 1. C.N.A. take the necessary measures in order all professional users, distributors and advisors to have access to appropriate training by bodies designated decision of the Minister of Rural Development and Food. This shall consist of both initial and additional training to acquire and update knowledge as appropriate. The training is designed such a way to ensure that such users, distributors and advisors acquire sufficient knowledge, taking account of their different roles and responsibilities. Training subjects are provided in Annex B.
- 2. By 14 December 2013, certification system is established. These certificates shall, as a minimum, provide evidence of sufficient knowledge of the subjects listed in Annex B acquired by professional users, distributors and advisors either by undergoing training or by other means. Certification systems include requirements and procedures for the granting, renewal and withdrawal of certificates.

## Article 20 (article 6 of directive 2009/128/EC) Requirements for sales of pesticides

 Inland distributors are obliged to employ sufficient staff in their employment holding a certificate referred to paragraph 2 of article 19. Such persons shall be available at the time of sale to provide adequate information to customers as regards pesticide use, health and environmental risks and safety instructions to manage those risks for the

- products in question according to the Common Ministerial Decision 265/2002 (B'1214) in compliance to the Directive 1999/45/EC.
- 2. Pesticide sales authorised for professional use are restricted to persons holding a certificate referred to paragraph 2 of article 19.
- 3. Distributors selling pesticides to non-professional users are obliged to provide general information regarding the risks for human health and the environment of pesticide use, in particular on hazards, exposure, proper storage, handling, application and safe disposal in accordance with Community legislation on waste, as well as regarding low-risk alternatives. Pesticide manufacturers are obliged to provide such information.
- 4. The measures provided for in paragraphs 1 and 2 are valid by 14 December 2015.

## Article 21 (article 7 of directive 2009/128/EC) Information and awareness-raising

- 1. C.N.A. adopts measures to inform the general public and to promote and facilitate information and awareness-raising programs and the availability of accurate and balanced information relating to pesticides for the general public, in particular regarding the risks and the potential acute and chronic effects for human health, non-target organisms and the environment arising from their use, and the use of non-chemical alternatives.
- 2. C.N.A. takes care of establishing systems for gathering information on pesticide acute poisoning incidents, as well as chronic poisoning developments where available, among groups that may be exposed regularly to pesticides such as operators, agricultural workers or persons living close to pesticide application areas.
- C.N.A. follows relative recommendations of the Commission of the European Union, for the presentation of the information on monitoring and surveying of impacts of pesticide use on human health and the environment.

 $<sup>^{12}</sup>$  Amendment 4-12-2015: Paragraph 7, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 3 is added after the paragraph 2 of article 18 of the law 4036/2012 as following: ..."

### CHAPTER C' PESTICIDE APPLICATION EQUIPMENT

## Article 22 (article 8 and Annex II of directive 2009/128/EC)

### Inspection of pesticide application equipment in use

- The Directorate for Land Improvement Works
   Development and Mechanical Facilities is defined as
   the competent authority for the regular inspection of
   the professional pesticide application equipment. The
   interval between inspections is five years until 2020
   and three years thereafter.
- By 26 November 2016, pesticide application equipment has been inspected at least once. After this date only pesticide application equipment having successfully passed inspection shall be in professional use.
  - New equipment is inspected at least once within a period of five years after purchase.
- 3. By way of derogation from paragraphs 1 and 2 and, following a risk assessment for human health and the environment including an assessment of the scale of the use of the equipment, may:
  - a) apply different timetables and inspection intervals to pesticide application equipment not used for spraying pesticides, to handheld pesticide application equipment or knapsack sprayers and to additional pesticide application equipment that represent a very low scale of use, which shall be listed in the National Action Plan provided in the article 18 of the present law.
    - The following additional pesticide application equipment shall never be considered as constituting a "very low scale of use":
    - (i) Spraying equipment mounted on trains or aircraft;
    - (ii) Boom sprayers larger than 3 m, including boom sprayers that are mounted on sowing equipment;
  - b) Exempt from inspection handheld pesticide application equipment or knapsack sprayers. In this case the competent authority of paragraph 1 ensures that operators have been informed of the need to change regularly the accessories, of the specific risks linked to that equipment, and that operators are trained for the proper use of that

application equipment in accordance with Article 19.

- 4. The inspections verify that pesticide application equipment satisfies the relevant requirements listed in Annex C, in order to achieve a high level of protection for human health and the environment. Pesticide application equipment complying with harmonized by the Commission of the European Union standards is presumed to comply with the essential health and safety and environmental requirements.
- Professional users conduct regular calibrations and technical checks of the pesticide application equipment in accordance with the appropriate training received as provided for in article 19.
- 6. The bodies responsible for implementing the inspection systems are designated by a decision of the Minister of Rural Development and Food after a proposal of the competent authority of paragraph 1 and the Commission is informed thereof. With the same procedure certificate systems are established, designed to allow the verification of inspections and recognize the certificates granted in other Member States following the requirements referred to in paragraph 4 and where the time period since the last inspection carried out in another Member State is equal to or shorter than the time period of the inspection interval applicable in Greece. The aim is to recognize the certificates issued in other Member States provided that the inspection intervals referred to in paragraph 1.

### CHAPTER D' SPECIFIC PRACTICES AND USES

## Article 23 (article 9 of directive 2009/128/EC) Aerial spraying

- 1. Aerial spraying is prohibited in Greece.
- 2. By way of derogation from paragraph 1 aerial spraying may only be allowed in special cases provided the following conditions are met:
  - (a) there must be no viable alternatives, or there must be clear advantages in terms of reduced impacts on human health and the environment as compared with land-based application of pesticides;

- (b) the pesticides used must be explicitly approved for aerial spraying following a specific assessment addressing risks from aerial spraying;
- (c) the operator carrying out the aerial spraying must hold a certificate as referred to in Article 19(2). During the transitional period where certification systems are not yet in place, C.N.A. may accept other evidence of sufficient knowledge;
- (d) the enterprise responsible for providing aerial spray applications shall be certified by the competent in Greece authority for authorizing equipment and aircraft for aerial application of pesticides;
- (e) if the area to be sprayed is in close proximity to areas open to the public, specific risk management measures to ensure that there are no adverse effects on the health of bystanders shall be included in the approval. The area to be sprayed shall not be in close proximity to residential areas;
- (f) as from 2013, the aircraft shall be equipped with accessories that constitute the best available technology to reduce spray drift.
- 3. The C.N.A. establishes the specific conditions by which aerial spraying may be carried out, for examining requests pursuant to paragraph 4 and for making public information on crops, areas, circumstances and particular requirements for application including weather conditions where aerial spraying may be allowed.
  - The C.N.A. issues approval, where specifies the measures necessary for warning residents and bystanders in due time and to protect the environment in the vicinity of the area sprayed.
- 4. The professional user wishing to apply pesticides by aerial spraying submits in due time a request for approval of an application plan to C.N.A. accompanied by evidence to show that the conditions referred to in paragraphs 2 and 3 are fulfilled. The request for application of aerial spraying in accordance with the approved application plan is submitted in due time to C.N.A. It contains information about the provisional time of spraying and the amounts and the type of pesticides applied. C.N.A. replies positive or negative in two months time from the date of submission of the request for application. In case that the two months time has expired without an answer from C.N.A., the request is considered to be rejected.

- 5. The C.N.A. establishes that the conditions referred to in paragraphs 2 and 3 are met by conducting appropriate monitoring.
- 6. The C.N.A. keep records of the requests and approvals as referred to in paragraph 4 and shall make available to the public the relevant information contained therein such as the area to be sprayed, the provisional day and time of the spraying and the type of pesticide, in accordance with the applicable national or Community law.

## Article 24 (article 10 of directive 2009/128/EC) Information to the public

The National Action Plan includes on informing persons who could be exposed to the spray drift.

## Article 25 (article 11 of directive 2009/128/EC) Specific measures to protect the aquatic environment and drinking water

- The C.N.A. establishes the set up of appropriate measures to protect the aquatic environment and drinking water supplies from the impact of pesticides are adopted. Those measures shall support and be compatible with relevant provisions of the relevant provisions of law 3199/2003 (A'280), in compliance to the Directive 2000/60/EC and Regulation (EC) No 1107/2009.
- 2. The measures provided in paragraph 1 include:
  - a. giving preference to pesticides that are not classified as dangerous for the aquatic environment pursuant to the Common Ministerial Decision 265/2002 (B'1214) in compliance to the Directive 1999/45/EC nor containing priority hazardous substances as set out in the law 3199/2003 (A'280) in compliance to the Directive 2000/60/EC;
  - giving preference to the most efficient application techniques such as the use of lowdrift pesticide application equipment especially in vertical crops such as hops and those found in orchards and vineyards;
  - c. use of mitigation measures which minimize the risk of off-site pollution caused by spray drift, drain-flow and run-off. These shall include the establishment of appropriately-sized buffer zones for the protection of non-target aquatic

- organisms and safeguard zones for surface and groundwater used for the abstraction of drinking water, where pesticides must not be used or stored;
- d. reducing as far as possible or eliminating applications on or along roads, railway lines, very permeable surfaces or other infrastructure close to surface water or groundwater or on sealed surfaces with a high risk of run-off into surface water or sewage systems.

## Article 26 (article 12 of directive 2009/128/EC) Reduction of pesticide use or risks in specific areas

Having due regard for the necessary hygiene and public health requirements and biodiversity, or the results of relevant risk assessments, the C.N.A. ensures that the use of pesticides is minimized or prohibited in certain specific areas. Appropriate risk management measures are taken and the use of low-risk plant protection products as defined in Regulation (EC) No 1107/2009 and biological control measures are considered in the first place. The specific areas in question are:

- (a) areas used by the general public or by vulnerable groups as defined in Article 3 of Regulation (EC) No 1107/2009, such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities;
- (b) protected areas as defined in the law 3199/2003 (A'280) in compliance to the Directive 2000/60/EC or other areas identified for the purposes of establishing the necessary conservation measures in accordance with the provisions of the Common Ministerial Decision 414985/85 (B'757) as modified by the Common Ministerial Decisions 366599/1996 (B'1188) and 294283/1997 (B' 68) in compliance to the Directive 79/409/EEC and the Common Ministerial Decision 33318/1998 in compliance to the Directive 92/43/EEC;
- (c) recently treated areas used by or accessible to agricultural workers.

## Article 27 (article 13 of directive 2009/128/EC) Handling and storage of pesticides and treatment of their packaging and remnants

1. The C.N.A. establishes the adoption of the necessary measures to ensure that the following operations by

professional users and where applicable by distributors do not endanger human health or the environment:

- a. storage, handling, dilution and mixing of pesticides before application;
- b. handling of packaging and remnants of pesticides;
- c. disposal of tank mixtures remaining after application;
- d. cleaning of the equipment used after application;
- e. recovery or disposal of pesticide remnants and their packaging in accordance with the relevant legislation on waste.
- 2. The C.N.A. establishes the adoption of the necessary measures regarding pesticides authorised for nonprofessional users to avoid dangerous handling operations. These measures may include use of pesticides of low toxicity, ready to use formulations and limits on sizes of containers or packaging.
- 3. The C.N.A. establishes the adoption of the necessary measures to ensure that storage areas for pesticides for professional use are constructed in such a way as to prevent unwanted releases. Particular attention is paid to location, size and construction materials.

## Article 28 (article 14 and Annex III of directive 2009/128/EC) Integrated Pest Management

- 1. The Ministry of Rural Development and Food takes of the necessary measures to promote low pesticideinput pest management, giving wherever possible priority to non-chemical methods, so that professional users of pesticides switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem. Low pesticide-input pest management includes integrated pest management as well as organic farming according to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labeling of organic products.
- 2. The Ministry of Rural Development and Food establishes or supports the establishment of necessary conditions for the implementation of integrated pest management. In particular, they shall ensure that professional users have at their disposal information and tools for pest monitoring and decision making, as well as advisory services on integrated pest management.

- The C.N.A. reports to the Commission on the implementation of paragraphs 1 and 2 and, in particular, whether the necessary conditions for implementation of integrated pest management are in place by 30 June 2013.
- National Action Plan describes how it is ensured that the general principles of integrated pest management as set out in Annex D are implemented by all professional users by 1 January 2014.
- 5. The Ministry of Rural Development and Food establishes appropriate incentives to encourage professional users to implement crop or sector-specific guidelines for integrated pest management on a voluntary basis. Public authorities and/or organizations representing particular professional users may draw up such guidelines. The Ministry of Rural Development and Food refer to those guidelines that are considered relevant and appropriate in the National Action Plan.

## CHAPTER E' INDICATORS, REPORTING AND INFORMATION EXCHANGE

## Article 29 (article 15 and Annex IV of directive 2009/128/EC) Indicators

 The C.N.A. uses harmonized risk indicators, established by the Commission of the European Union, as referred to in Annex IV. However, competent authority may continue to use existing national indicators or adopt other appropriate indicators in addition to the harmonized ones.

#### 2. The C.N.A.:

- (a) calculates harmonized risk indicators as referred to in paragraph 1 by using statistical data collected in accordance with the Regulation 1185/2009 concerning statistics on plant protection products together with other relevant data;
- (b) Identify trends in the use of certain active substances;
- (c) identify priority items, such as active substances, crops, regions or practices, that require particular attention or good practices that can be used as examples in order to achieve the objectives of this Directive to reduce the risks and impacts of pesticide use on human health and the environment and to encourage the development

- and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.
- 3. The competent authority communicates the results of the evaluations carried out pursuant to paragraph 2 to the Commission and to other Member States and makes this information available to the public.

### CHAPTER F' FINAL PROVISIONS

## Article 30 (article 17 of directive 2009/128/EC) Penalties

The sanctions provided in the articles 45 and 46 of the present law are implemented to the responsible persons for infringements of articles 15-29.

<sup>13</sup>The C.N.A. is obliged to notify those provisions to the Commission by 26 November 2012 and to notify it without delay of any subsequent amendment.

## Article 31 (article 19 of directive 2009/128/EC) Fees and charges

- A recovery amount is paid to the Central Cashier of the Ministry of Rural Development and Food associated with any work pursuant to obligations under the article of the present law by means of a fee or charge.
- The C.N.A. ensures that the fee or charge referred to in paragraph 1 is established in a transparent manner and corresponds to the actual cost of the work involved.

## SECTION TWO NATIONAL COMPLIANCE MEASURES TO REQUIREMENTS OF DIRECTIVE 2009/128/EC

### Article 32 National Action Plans drawing up

 With a Common Ministerial Decision of the Minister of Rural Development and Food, the Minister of Environment, Energy and Climate Change and the

<sup>&</sup>lt;sup>13</sup> **Amendment 11-2-2014**: Paragraph 3, article 44, of law num. 4235/2014 (O.J. A'32): "3. The second quotation of article 30 of law 4036/2012 is replaced by the following: ..."

- Minister of Health the National Action Plan for the implementation of Directive 2009/128/EC for human health and environment protection is established.
- 2. A committee for the submission of National Action Plan proposal is set in less than two months from the publication of the present law by a decision of the Minister of Rural Development and Food. The following are participating to the committee: Ministry of Rural Development and Food, other competent Ministries, Organizations and Institutions, scientists with special knowledge, farmer's representatives, distributors and pesticide producers, food processors and distributors, O.K.E., environmental and consumer organizations. The committee compiles a National Action Plan proposal in less than five months from the date that it was established. The Coordinating National Authority coordinates committee operation. The National Action Plan proposal is laid to public consultation for a month time and afterwards the Common Ministerial Decision of the paragraph 1 is issued.
- 3. The C.N.A is responsible to draw up and monitor the implementation of the National Action Plan, its review and its communication to European Council.
- 4. The results from the evaluation of statistical data received by the implementation of the pesticide sale procedure provided in article 36 plan are taken into account in addition to those mentioned in article 18; The National Action also comprises measures to encourage integrated pest management and actions for information to humans that can be exposed to spray drift.
- 5.The fees for funding National Action Plans, the procedure for their payment, as well as their readjust are defined by a common Ministerial Decision of the Minister of Rural Development and Food and the Minister of Regional Development and Competition.

#### **Article 33**

#### Training program on sustainable use of pesticides

- A training program on sustainable use of pesticides is established, to which all professional users, distributors and advisors have access, taking account of their different roles and responsibilities. This training consists of both initial and additional training to acquire and update knowledge as appropriate.
- 2. The C.N.A. in cooperation with other competent authorities of the Ministry of Rural Development and Food as well as legal entities of the Ministry draw up training programs on sustainable use of pesticides.

- 3. The training material is certified according to relevant notion and community provisions.
- 4. Certification procedure is defined up to 26 November 2013 the latest by a decision of the Minister of Rural Development and Food; the certificates provide evidence of sufficient knowledge of the subjects on sustainable use of pesticides.

### Article 34 Pesticide Plants Registry

- Manufacturing, formulating, repackaging and storage of pesticides is allowed only if the legal entity is registered in the Pesticides Plants Registry.
- 2. The C.N.A. checks the application with the dossier data of the applicant regarding the capabilities of manufacturing, formulating, repackaging and storage of the declared types of pesticides formulations and registers the entity in a six (6) months period from the application.
- The conditions and the procedure for registering in the Pesticides Plants Registry are defined by a decision of the Minister of Rural Development and Food.
- 4. The C.N.A. keeps the Pesticides Plants Registry and publishes it in its website.

#### <sup>14</sup>Article 35 Pesticide sales

- a. The pesticides sale is allowed only from specialty shops that meet certain standards and have responsible scientist.
  - b. Agronomists having a university degree or graduated from Technological Education Institutes as defined in the Presidential Decree 109/1989 (O.J. A 47) or in the Presidential Decree 312/2003 (O.J. A 264) for uses compatible with organic agriculture or equivalent degree or diploma holder corresponding specialty school of another Member-State of the EU or a third country based on the principle of reciprocity.
  - c. For the sale of pesticides, pesticide shops may be provided with employee-seller. The employee selling pesticides must either comply with the conditions of case b of this paragraph or hold a

<sup>&</sup>lt;sup>14</sup>**Amendment 11-2-2014**: Paragraph 4, article 44, of law num. 4235/2014 (O.J. A'32): "The article 35 of law 4036/2012 is replaced with the following ..."

- training certificate in accordance with paragraph 2 of Article 19 or to be equally proficient in another Member State of EU, in order to ensure the same level of human safety, the plant and animal health and the protection of the environment.
- d. The responsible scientist and / or employee-seller conduct the sales of pesticides and are responsible for the proper performance of the prescription of use, provided in paragraph 5, particularly regarding the approved dose - the quantity of the formulation that can be used and to provide guidance on how to implement the formulation - spray solution depending on the means of implementation of each producer, like the suitable pressure.

They have also the obligation to provide general information regarding the potential risks for human health and the environment of pesticide use, in particular on hazards, user exposure, proper storage, handling, application and safe disposal of tank mixtures remaining after application and packaging and remnants of pesticides, as well as regarding low-risk alternatives. Specifically, as to the prescribed active substance and approved formulations that can be used, the responsible scientist is only responsible.

2. The pesticide sales is divided into wholesale and retail. By submitting the notification of starting pesticide sales, the stakeholders declare: the type of pesticide sales they would carry, the name and the identification number of the person or the entity that will perform the selling, the company's headquarters, the storage areas and the responsible scientist. The competent authority may, within a period of three (3) months from the receipt of the notification, prohibit the exercise of the profession, if the legal requirements are not met or the data presented do not prove the contribution. Stakeholders freely exercise the pesticides sales after the period of three months from the receipt of notification, if there is no prohibition on the exercise as mentioned above and earlier if the competent authority notifies in writing for the completeness of the data. Pesticide sales is prohibited without the above mentioned notification to the competent authority and subsequent wait for three months or receipt of the relevant notification about the submitted data completeness, and in case of prohibition of pesticide sales by the competent authority.

- The wholesale sale of pesticides allowed to stakeholders who have submitted to the competent authority notification of starting pesticide sales, in accordance with paragraph 2 and it is addressed to other wholesalers or retailers.
- 4. The employment of the responsible scientist and / or employee-seller at the time of the sale of pesticides is required for pesticides wholesale or retail.
- 5. a. The issue of a prescription of use by a scientist qualified according to the case b of paragraph 1 is a prerequisite for retail sales of pesticides in professional users.
  - <sup>15</sup>b. Until November 26, 2016, the prescription may be issued at the time of sale of pesticides. In this case, the electronic record of the retail sale of pesticides in a special form, in accordance with paragraph 5 of Article 36, may be equated with a prescription of pesticide use, giving full details of the scientist issued.
  - c. After November 26, 2015, the retail sale of pesticides for professional use is conducted only by ensuring that their use is made by a person or under the supervision of a person, which has granted a certificate of knowledge regarding the issues of sustainable use of pesticides, in accordance with paragraph 4 Article 33 and Directive 2009/128/EC. The user supervisor takes the responsibility for the proper use of pesticides and is required immediately after using them to record with signature.
  - <sup>16</sup>,<sup>17</sup>d. In pesticide packaging sizes which: aa) are intended for use in open fields with area that does not exceed one thousand square meters (1,000 square meters) and bb) do not have hazard pictogram with skull and cross bones prescription, either a prescription is issued or at the time sale the electronic recording of the pesticides retailer sale in a special form, in accordance with paragraph 5 of Article 36, is equated with a prescription of pesticide use, giving full details of

<sup>&</sup>lt;sup>15</sup> **Amendment 26-4-2016**: Paragraph 1, article 48, of law num. 4384/2016 (O.J. A'78): "The case b. of paragraph 5 of article 35 of law 4036/2012 is replaced with the following ..."

<sup>&</sup>lt;sup>16</sup> **Amendment 26-4-2016**: Paragraph 2, article 48, of law num. 4384/2016 (O.J. A'78): "After the case b. of paragraph 5 of article 35 of law 4036/2012, a new case d. is added as the following ..."

<sup>&</sup>lt;sup>17</sup> **Amendment 19-5-2017**: Article 121 of law num 4472/2017 (O.J. A'74): "The case d of paragraph 5 of *article 35 of law 4036/2012 is replaced with the following ...*"

the scientist issued. In this case, the responsible scientist and / or employee-seller who carried out the sale is required to provide general information on the risks to human health and the environment from pesticide use, in particular on hazards, exposure, proper storage, handling and application and safe disposal in accordance with current legislation on waste, as well as on low-risk alternatives.

#### 6. a. The pesticide retail shops:

- a. are required to keep all the recipes of pesticide use for a period of five (5) years from the date of issue,
- b. are prohibited to hold unexecuted or unsigned recipes of pesticide use.
- b. The wholesale of pesticides is prohibited to stores that do not meet the requirements of this Article.
- c. The traders of pesticides are required to cooperate with the competent control authorities, to inform immediately of any change to the information declared to the competent authority and to provide access to any storage or handling of pesticides, as well as documents related to pesticides marketing, whether they are in paper or electronic form.
- d. The selling of either substances according to Regulation (EC) 1107/2009 or preparations among registration holders should be notified to the competent authority.

#### 7. a. The C.N.A. keeps:

- Registry of pesticide sellers companies, which is posted on the website available on the internet.
   Every pesticide seller grants a special code by the C.N.A.
- b. Registry of the scientists who can issue a prescription of pesticides use, which is posted on the website available on the internet.
- b. The authority responsible for pesticides sales is required to maintain a web site where it is posted: the requirements for pesticide sales, pesticide entities, pesticide stores addresses and their respective responsible scientists and to communicate these data to C.N.A. at the latest within fifteen (15) days after the three months period from the notification of starting pesticide sales. The obligations of the preceding paragraph shall also apply to any change in the data of existing pesticide sale stores that had already notified starting.

#### Article 36

#### Registry of approved pesticide preparations – Electronic sales' record

- A list of approved pesticides, which include formulations of pesticides for which authorization has been granted by the Ministry of Rural Development and Food, and the information mentioned on these authorizations is established.
- The list has the form of an electronic database and posted on the website of the Ministry of Rural Development and Food.
- The C.N.A. is responsible for editing, updating and the maintenance of the electronic application of the above list.
- 4. The formulations, which authorization have been expired or revoked, are listed with the mark: "Revoked" and a reference to the decision. In cases of approval, renewal, revocation or amendment of the authorization, the competent authority of the Ministry of Rural Development and Food updates the list immediately and at the latest within fifteen (15) days of the issue of the decision.
- 5. The professional user obtains pesticides included in the Registry only through official retailer shops. The retailer records electronically in a "Special Sale Form" for each professional user the following:
  - a. Name, surname and tax number of the professional.
  - b. The area/region of the field
  - c. The field code (if exists)
  - d. The quantity of the pesticide
  - e. The crop or the plant products that the pesticide is going to be used
  - f. The invoice/receipt number
  - g. The retailer special code issued by C.N.A.

The same data, except c) data, are recorded for amateur users.

- 6. Pesticide choice is made based on efficacy, mode of action, spectrum of action, selectivity for the crop, disease, pest or weed, special environmental targets, compatibility with other pesticides, application facility, expected residues on the crop, residual duration, toxicological classification, its compatibility in management programs of pest resistance as well as possible effects on next crop.
- 7. Priority is given to selective pesticides.

- 8. Retailer sales without completing the special form are forbidden.
- 9. Copy of the special form is given to the professional user.
- 10. An electronic application is created in the Ministry of Rural Development and Food where Special Sales Forms are entered. The registration is done electronically from pesticide retailers. The information is confidential and covered by the provisions on the protection of personal data legislation. <sup>18</sup>The C.N.A. may use the information to produce statistics on the marketing and use of plant protection products, the establishment of the National Action Plans, as well as to control the placing of pesticides on the market. Until the online application is completed, the pesticide retailers are required to record the data of paragraph 5 electronically.
- 11. The body for the creation, renovation and maintenance of the electronic application of paragraph 10 and any relevant details on the form and content of the Special Sale Forms is defined by a decision of the Minister of Rural Development and Food.
- 12. <sup>19</sup>An access permit to the electronic application of paragraph 10 is given to responsible scientists and the employee-sellers of pesticide shops by the Ministry of Rural Development and Food
- The marketing of non-recorded to the Approval Record pesticides, or against label indications is forbidden.

## Article 37 Procedures for public information regarding pesticides

 Local and regional plant protection competent authorities, in cooperation with the C.N.A., are responsible for public information and awareness raising about the pesticide use, particular regarding the risks and the potential acute and chronic effects for human health, non-target organisms and the

- environment arising from their use, and the use of non-chemical alternatives.
- Information is given in paper and with electronic means as well as through internet. It is regularly reviewed to take account of scientific and technical progress. Information procedures are included in the National Action Plan.
- 3. The Poisoning Center of the Ministry of Health gathers information and data and records in a systemic way, acute poisoning incidents, or other effects caused by pesticide use. A copy of this report is dispatched to the C.N.A., in order to be evaluated and to take the necessary measures as public information, information to registration holders and distributors, modification or recall of the pesticide approval. These data are used for National Action Plan drawing up.

## Article 38 Inspection system for pesticide application equipment

- An inspection system for professional use pesticide equipment is established, which leads to suitability certificate granting.
- 2. The Directorate for Land Improvement Works Development and Mechanical Facilities of the Ministry of Rural Development and Food is defined as the competent authority for supervising the inspection system for professional use pesticide equipment. Local competent authorities belonging to Regions and Regional Units keep a Pesticide Application Equipment Registry, where professional use pesticide application equipment is recorded per category, geographical area and user. The new pesticide application equipment, which is marketed for use after the date of valid of the present law, is recorder with the responsibility of the buyer to the Pesticide Application Equipment Registry of the relevant Region.
- The inspection procedures for pesticide application equipment are defined with a decision of the Minister of Rural Development and Food.

### Article 39 Pesticide aerial spraying

 The Directorate of Plant Produce Protection of the Ministry of Rural Development and Food is defined as the competent authority for the implementation of article 34 regarding aerial spraying.

<sup>&</sup>lt;sup>18</sup> **Amendment 11-2-2014**: Paragraph 5a, article 44, of law num. 4235/2014 (O.J. A'32): "5. a. *The fourth quotation of paragraph 10, article 36 of law 4036/2012 is replaced with the following "* 

 $<sup>^{19}</sup>$  Amendment 11-2-2014: Paragraph 5b, article 44, of law num. 4235/2014 (O.J. A'32): "5. b. The paragraph 12, article 36 of law 4036/2012 is replaced with the following ..."

 Pesticide aerial spraying is forbidden. By deviation it is allowed only in special cases and provided that all requirements and specifications of paragraph 2 of article 23 are fulfilled. The agreeing statement of the Region is even required for issuing the deviation decision.

## Article 40 Specific measures establishment for aquatic resources protection

Specific measures in order to protect the aquatic environment and drinking water, compatible to the article 25, are issued by a common decision of the Minister of Rural Development and Food, the Minister of Environment, Energy and Climate Change and the Minister of Health.

## Article 41 Measures for the reduction of pesticide use or risks in specific areas

The measures for the reduction or prohibition of pesticide use or possible risks in specific areas, compatible with the provisions of article 26, are incorporated to the National Action Plan of Article 32.

### Article 42 Handling and storage of pesticides

- 1. The sustainable use of pesticides by the professional users and especially:
  - handling, application and storage;
  - disposal of tank mixtures remaining after application;
  - cleaning of the equipment used and the personal protective equipment after application;
  - management of empty pesticide packaging after use

should be done without risks for human, animals and environment.

2. The procedures for awareness raising and keeping of users obligations as well as commitments of distributors, especially in safe storage and disposal matters are incorporated to the National Action Plan of Article 32.

### Article 43 Integrated Pest Management

Provisions for the encouragement of the integrated pest management, according to article 28, are incorporated to the National Action Plan of Article 32.

### Article 44 Controls on sustainable use of pesticides

The Directorate of Plant Produce Protection of the Ministry of Rural Development and Food draws up and coordinates annual and multi-annual control programs on sustainable use of pesticides aiming to the reduction of the pesticide risks to human and to the environment, except the control programs of the pesticide application equipment, which are drawn up and coordinated by the Directorate for Land Improvement Works Development and Mechanical Facilities of the Ministry of Rural Development and Food.

#### Article 45

### Administrative sanctions for infringements on sustainable use of pesticides

- A fine of 1,000 € up to 100,000 € is posed to the responsible for manufacturing, formulating, packaging or storing for the purpose of sale pesticides without been registered to the Pesticide Plant Registry kept by the competent authority.
- 2. A fine of 300 € up to 5,000 € is posed to the responsible for infringements of articles 38-44 of the present law.
- 3. A fine of 300 € up to 30,000 € is posed to the responsible for using pesticides not in accordance with labeling.
- 4. A fine of 1,000 € up to 30,000 € is posed to the responsible retailer or wholesaler for selling pesticides without the sale notification of starting and fulfilling of the data. The pesticides are set under official detention.
- 5. A fine of 1,000 € up to 30,000 € is posed to the responsible for selling pesticides without keeping the notified conditions of sale which may cause risks to human health or to pesticides stability. The shop operation is suspended until the conditions are fixed and confirmed by a control of the competent authority. A fine of 1,000 € up to 30,000 € is posed to the responsible for selling not authorized pesticides and depending on the severity of the case: a) the shop operation is suspended for at least one year, and b) pesticides can be set under official detention.

- 6. <sup>20</sup>A fine of 1,000 € up to 30,000 € is posed to the responsible of a pesticide store if he conducts retail sales without a prescription or without recording electronically the sale on the Special Sale Form of the paragraph 5 of Article 36, which serves as a prescription of use when it is issued by a qualified scientist or in case of holding unexecuted or unsigned recipes of pesticide use or without the presence of the responsible scientist of employee seller, appointed for the execution of pesticide prescriptions.
- 7. A fine of 1,000 € up to 30,000 € is posed to the responsible for selling pesticides without keeping the provisions of the article 35 of the present law.
- 8. A fine of 1,000 € up to 30,000 € is posed to the responsible for selling pesticides to professional users without registering the sale in the Special Sale Form according to Article 36.
- 9. A fine of 1,000 € up to 30,000 € is posed to the responsible for denying or obstructing by any way an investigation or denying giving information or supplying false data or information or hiding data or information.
- <sup>21</sup>9.a. a. A fine of 1,000 € up to 30,000 € is posed to the responsible scientist of a pesticide store if he conducts retail sales without a prescription or without recording electronically the sale on the Special Sale Form of the paragraph 5 of Article 36, which serves as a prescription of
  - b. A fine of 1,000 € up to 30,000 € is posed to the employee-seller of a pesticide store if he conducts retail sales without a prescription, or with a prescription issued by himself without been qualified as a scientist to issue it.
  - c. A fine of 300 € up to 5,000 € is posed to the responsible for issuing prescriptions without fulfilling the conditions of case b., paragraph 1 of Article 35.
  - d. A fine of 300 € up to 10,000 € is posed to the professional user who uses pesticides without the issue of a relative prescription or applying

- them without following the directions of the relative prescription.
- e. A fine of 1,000 € up to 30,000 € is posed to the wholesaler who sell pesticides to stores not fulfilling the conditions of article 35.
- 10. If infringements of the present article are repeated, the fine limits are doubled and the second fine cannot be less than the double of the previous one. As repetition, it is considered the discovery of another same or similar infringement by the same person or company in a three years period.
- 11. For the estimation of the fine, the following parameters are taken into account:
  - a. The risk caused by the infringement.
  - b. Consequences that may rise by the infringement.
- 12. The service that has made the investigation communicates with a document (with proven receipt) the infringement to the responsible, who is called to submit in writing his opinion in a 15 days period. After this period and regardless of submitting or not his opinion, the service forwards the file to the competent authority.
- 13. Fines are posed by a decision of the Minister of Rural Development and Food, after a relevant proposal of the Coordinating National Authority (CNA), with the exception of infringements of article 38, where there is a proposal by the Directorate of the Exploitation of Ground Improvement Projects and Machinery.
- 14. Fines are assessed as public incomes and they are paid to the Account for Agriculture and Cattle Breeding. The competent Economic service of the Ministry of Rural Development and Food is responsible for the fine assessment.
- 15. With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the fines of the present article can be readjusted.

#### Article 46

### Punitive sanctions for infringements on sustainable use of pesticides

 Imprisonment for at least six months is posed to the responsible for manufacturing, formulating, packaging or storing for the purpose of sale pesticides without been registered to the Pesticide Plant Registry kept by the competent authority.

<sup>&</sup>lt;sup>20</sup> **Amendment 11-2-2014**: Paragraph 6a, article 44, of law num. 4235/2014 (O.J. A'32): "a. The paragraph 6, article 45 of law 4036/2012 is replaced with the following ..."

<sup>&</sup>lt;sup>21</sup>Amendment 11-2-2014: Paragraph 6b, article 44, of law num. 4235/2014 (O.J. A'32): "b. After the paragraph 9, article 45 of law 4036/2012, a new paragraph 9a is added with the following "

- 2. Imprisonment for at least one year is posed to the responsible retailer or wholesaler for selling pesticides without the proper sale registry.
- 3. Imprisonment for at least one year is posed to the responsible registered pesticide retailer or wholesaler for selling not authorized pesticides.
- Imprisonment for three months up to one year is posed to the responsible pesticide retailer or wholesaler for infringements against article 35 of the present law.
- Imprisonment for at least one year is posed to the responsible for denying or obstructing by any way a residue investigation or denying giving information or supplying false data or information or hiding data or information.

### SECTION FOUR PESTICIDE RELEVANT PROVISIONS

### Article 47 Pesticide price monitoring

To enhance the competitiveness and transparency in the marketing of plant protection products the following are established:

- a. The responsible of pesticide stores write the selling price on pesticide packaging.
- b. Retailers post prominently and make public the price list of available plant protection products
- c. The authorization holders of plant protection products submit each year to the C.N.A. the official wholesale price lists and annual price changes of plant protection products and formulations containing macro-organisms that they place in the market no later than March 31 of each year.
- d. An observatory for monitoring retail prices of plant protection products is established. Its operation and coordination with relevant bodies of the Ministry of Rural Development and Food or other Ministries is defined by a decision of Minister of Rural Development and Food.

### Article 48 Products containing macro-organisms

 As plant protection formulations containing macroorganisms are defined those containing only organisms that are visible to the naked eye and are used in integrated pest management programs

- 2. The Directorates of Plant Produce Protection and Organic Agriculture of the Ministry of Agriculture are responsible for compiling a national list of plant protection formulations containing macro-organisms, which entered the formulations, the macro organism, the action spectrum and the holder of data. The national list is posted on the website of the Ministry of Rural Development and Food.
- 3. The application for entry in the national list is submitted to the Directorate of Plant Produce Protection of the Ministry of Rural Development and Food, either in person by the applicant who wishes to market the product once he is established in Greece, or through a representative. The entry in the national catalog of place is conducted when, after evaluating the evidence presented, it is found that the criteria of safety for humans and the environment, and the efficacy are fulfilled.
- 4. The information and studies that the applicants should submit regarding registration on the national list of plant protection formulations containing macroorganisms, the competent authority for assessing the application and the conditions for licensing units manufacturing plant protection formulations containing macro-organisms are specified by a decision of the Minister of Rural Development and Food.

#### <sup>22</sup>Article 49

## Sanctions for infringements on matters of professional use of biocides that the Ministry of Rural Development and Food is competent

- 1. <sup>23</sup>A fine of 300 € up to 30,000 € is posed to the responsible of using professionally biocides that the Ministry of Rural Development and Food is competent without the special prior notification of starting the profession.
- 2. A fine of 300 € up to 30,000 € is posed to the responsible of using professionally biocides that the Ministry of Rural Development and Food and their use is prohibited for a period of three (3) months up to five (5) years, depending on the severity of the case, if:

<sup>&</sup>lt;sup>22</sup>Amendment 11-2-2014: Paragraph 7a, article 44, of law num. 4235/2014 (O.J. A'32): "7. The article 49 of law 4036/2012 is amend as the following: a. The title of the Article is amended as the following ...".

<sup>&</sup>lt;sup>23</sup>Amendment 11-2-2014: Paragraph 7b, article 44, of law num. 4235/2014 (O.J. A'32): "b. The paragraphs 1 and 2 of Article 49 of law 4036/2012 are replaced with the following …"

- a. uses unregister for the specific purpose biocides,
- b. does not take all necessary measures for the safety of biocide application, among which the presence of a responsible scientist is included to supervise the work of the professional use of biocides
- 3. If infringements of the present article are repeated, the fine limits are doubled and the second fine cannot be less than the double of the previous one.
- 4. For the estimation of the fine, the following parameters are taken into account:
  - The risk caused by the infringement to human.
  - b. The duration of the infringement.
- 5. The service that has made the investigation communicates with a document (with proven receipt) the infringement to the responsible, who is called to submit in writing his opinion in a 15-day period. After this period and regardless of submitting or not his opinion, the service forwards the file to the competent authority.
- 6. Fines are posed by a decision of the Minister of Rural Development and Food, after a relevant proposal of the competent authority. The license is recalled by a decision of the Head of Plant Produce Protection Directorate.
- 7. Fines are assessed as public incomes and they are paid to the Account for Agriculture and Cattle Breeding. The competent Economic service of the Ministry of Rural Development and Food is responsible for the fine assessment.
- 8. With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the fines of the present article can be readjusted.

#### <sup>2425</sup>Article 49a Right to appeal

1. Against decisions imposing fines, in accordance with articles 9, 13, 45, and 49, except those involving violations of article 38, and in front of the Minister of Rural Development and Food, offenders have the right to appeal. The appeal is submitted to the

<sup>24</sup>Amendment 11-2-2014: Paragraph 8, article 44, of law num. 4235/2014 (O.J. A'32): "After Article 49, a new Article 49a is added with the following ..."

Directorate of Plant Produce Protection within a period of ten (10) days from the notification of the decision to impose the fine.

A committee of five members is set up in the Ministry of Rural Development and Food for the examination of the appeals, consisted of two representatives of the Ministry of Rural Development and Food with their deputies and one representative from a university related to the subject, one from the Benaki Phytopathological Institute and one from Geotechnical Chamber of Greece (GEOTEE) with their deputies, appointed by their bodies. One of the representatives of the Ministry of Rural Development and Food is appointed as the president of the committee and an employee of the Plant Produce Protection Directorate of the Ministry of Rural Development and Food is appointed as the secretary of the committee. The members of the committee and every topic related to the mode of its operation is defined by a decision of the Minister of Rural Development and Food.

2. Especially for the examination of the appeals against decisions imposing fines for infringements of Article 38, and in front of the Minister of Rural Development and Food, offenders have the right to appeal. The appeal is submitted to the Directorate of Land Reclamation Works and Mechanical Equipment of the Ministry of Rural Development and Food within a period of ten (10) days from the notification of the decision to impose the fine.

A tripartite committee is set up in the Ministry of Rural Development and Food, defined by a decision of the Minister of Rural Development and Food where it is set out the composition, the properties of members, mode of operation and all related matters.

- 3. The committees of paragraphs 1 and 2 shall meet at the call of the President and recommend to the Minister of Rural Development and Food, after examining the legality and merits of the appeals, to cancel in whole or in part or modify the decision imposing a fine or rejection of the appeal.
  - The decision of the Minister of Rural Development and Food on the objection is final, irrevocable and enforceable and shall be communicated to the person concerned on receipt.
- 4. The submission of a fee with a value of 10% of the amount of the fine is a necessary prerequisite for the evaluation of fines. The fee is submitted to the Account for Agriculture and Cattle Breeding. In case

<sup>&</sup>lt;sup>25</sup> **Amendment 4-12-2015**: Paragraph 8a, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraphs 1 and 2 of article 49a of the law 4036/2012 are replaced as following: ..."

of total or partial success of the appeal, the value of the fee is refunded to the person concerned.

#### Article 50

#### **Empowering measures**

- 1. The following are defined by decision of the Minister of Rural Development and Food:
  - a. The national data requirements (par. 5, article 4).
  - b. The composition of the Scientific Pesticides Committee (par. 4, article 5) and its operation matters (par. 10, article 5).
  - c. The allowed media for advertising plant protection products.
  - d. The bodies for training of professional users (par.1, article 19).
  - e. The composition of the committee for drafting a proposal for the National Action Plan (par. 1, article 32).
  - f. The procedure for granting a certificate of adequate knowledge on sustainable use of pesticides (par. 4, article 33).
  - g. The procedures for registering in Pesticides Plants Registry (par. 3, article 34).
  - h. The body for the creation, renovation and maintenance of the electronic application of recording the Pesticide Sales Forms (par. 11, article 36).
  - i. The inspection procedures for pesticide application equipment (par. 6 of article 22 and article 38)  $\alpha\rho\theta$ 0 38).
  - k. The operation mode of the observatory for monitoring retail prices of plant protection products (case d. of article 47).
  - The information and studies that the applicants should submit regarding registration on the national list of plant protection formulations containing macro-organisms (par. 4 of article 48).
  - m. The other competent authorities for the evaluation needed for the authorization of the plant protection products (par. 4 of article 3).
  - <sup>26</sup>n. The processes for detention and managing for plant protection products, active substances and

<sup>26</sup> **Amendment 11-2-2014**: Paragraph 9a, article 44, of law num. 4235/2014 (O.J. A'32): "Article 50 of law num 4036/2012 is amended as the following: a. In paragraph 1, Article 50 after

- treated with plant protection products seeds by the competent authorities in accordance with the provisions of paragraphs 2, 3, 5, 6, 7 and 9 of Article 10 and paragraphs 4 and 5 of Article 45.
- The competent authorities and the verification procedures and audit to verify the effectiveness of official controls on pesticide and pesticide residues in plant products or products of primary processing.
- p. <sup>27</sup>The technical procedures, the mode and any other necessary technical measure for the implementation of Regulation (EC) 396/2005, Regulation (EC) No 1107/2009 and Directive 2009/128/EC as well as the procedures for the parallel trade and the procedures and the training material and certification of knowledge regarding sustainable use of pesticides.
- q. The terms and conditions to ensure that the use of pesticides authorized for professional use is conducted only by a person or under the supervision of a person, which has granted a certificate of knowledge regarding sustainable use of pesticides, in accordance with paragraph 4 of Article 33.
- <sup>28</sup>r. The content and the type of pesticide prescription, the procedure and the way of issue, the duration, the scientific methodology for the issue and the selection of active substances and any other relative matter for the implementation of cases a. and b. of paragraph 5 of Article 35.
- s. The terms, the conditions the procedure and the required documents for the notification of starting for bodies supplying initial and additional training to professional users, distributors (sale responsible are included) and pesticide advisors, the system for granting certificate regarding initial and additional training and any other relative matter for the implementation of article 19, with which Article 5 of Directive 2009/128/EC and Annex I were transposed.

the case m, the cases n., o., p. q. and r. are added as the following ..."

<sup>&</sup>lt;sup>27</sup> **Amendment 4-12-2015**: Paragraph 9, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 1p of article 50 of the law 4036/2012 is replaced as following: ..."

<sup>&</sup>lt;sup>28</sup> **Amendment 26-4-2016**: Paragraph 3, article 48, of law num. 4384/2016 (O.J. A'78): "The case r. of paragraph 1 of article 50 of law 4036/2012 is replaced with the following ..."

- 2. By Common Decision of the Minister of Rural development and Food and any other competent Minister:
  - a. Additional competent authorities for the implementation of the law are defined (par. 3, Article 3).
  - b. The competent control authorities for pesticide residue controls (par. 1, Article 12).
- 3. With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the following are defined:
  - a. The determination and adjustment of the amount of the fees for plant protection products authorization (par. 3, Article 6).
  - b. The fines for administrative sanctions on plant protection products (par. 21, Article 9), pesticide residues (par. 8, Article 13) and sustainable use of pesticides (par. 16, article 45) infringements are adjusted.
  - c. The amount of the recovery fee or charge (par. 2, Article 31).
  - d. The fines for pest control infringements are adjusted.
  - <sup>29</sup>e. The determination and adjustment of the amount of the fee for the notification of starting wholesale or retail sale of pesticides.
- 4. With a Common Decision of the Minister of Rural Development and Food, the Minister of Environment, Energy and Climate Change and the Minister of Health the following are defined:
  - a. The establishment of the National Action Plan (par.1, Article 32)
  - b. The specific measures in order to protect the aquatic environment and drinking water (Article 40).
- <sup>30</sup>5. With a Presidential Decree, issued after a proposal of the Minister of Rural Development and Food they are

<sup>29</sup> **Amendment 11-2-2014**: Paragraph 9b, article 44, of law num. 4235/2014 (O.J. A'32): "Article 50 of law num 4036/2012 is amended as the following: b. After the case d. of paragraph 3, Article 50, a new case e. is added as the following ..."

defined: the procedure for the control of the documentation regarding the notification of starting wholesale and retail sale of pesticides and pesticide logistics intended for wholesale, the local authorities, the terms and conditions that the pesticide shops require to fulfill, the responsible scientists and the employee-sellers of pesticides, the type of their employment, the control procedure for pesticide sales, the competent authorities for the first and second level controls on pesticide sales and the type and content of the price list of marketed plant protection products posted in pesticide stores.

#### Article 51

### Modification of law 721/1977 regarding biocides that the Ministry of Rural Development and Food is competent

- 1. After the case d., Article 26 of law num 721/1977 (O.J. A-298) a new case e. is added, as the following:
  - «e. The biocide products of product types 14 and 18, according to par. 2, Article 26 of Presidential Decree 205/2001 (O.J. A-160), as valid regarding terms and conditions of their authorizations".
- After the case kst., Article 14 of law num 721/1977 (O.J. A-298), the new cases kz. and kh. are added, as the following:
  - «31kz. With Common Decisions of the Minister of Rural Development and Food and the Minister of Health and Solidarity they are defined: the additional organizational and executive measures to implement the provisions of the regulations and decisions of the institutions of the European Union and the necessary regulatory and administrative provisions to directives of those same transpose the institutions for biocide products. establishment of competent authorities, the definition of competencies and administrative procedures, and the adoption of administrative sanctions are included in these normative acts.
  - Kh. With a Common Decision of the Minister of Rural Development and Food and the Minister of Development, Competiveness and Shipping the terms and conditions for the authorization of biocides of case e., Article 26 of law num 721/1977 (O.J. A-298) are defined.

<sup>&</sup>lt;sup>30</sup> **Amendment 11-2-2014**: Paragraph 9c, article 44, of law num. 4235/2014 (O.J. A'32): "Article 50 of law num 4036/2012 is amended as the following: c. The paragraph 5, Article 50 is replaced as the following ..."

<sup>&</sup>lt;sup>31</sup> **Amendment 11-2-2014**: Paragraph 1a, article 45, of law num. 4235/2014 (O.J. A'32): "Article 14 of law num 721/1977 as valid is amended as the following: a. The case kz., Article 14 is replaced as the following ...".

- <sup>32</sup>Kth. With a Decision of the Minister of Rural Development and Food, the terms and conditions of professional use for the biocides, that the Ministry of Rural Development and Food is competent, are defined.
- 3. Article 5 of the present law is also valid for the biocides that the Ministry of Rural Development and Food is competent.
- $4.^{33}$  The sub-case iziz of case a, paragraph 1, Article 27 of the law num 721/1977 (O.J. A-298) is replaced as the following:

"iziz. For the notification of starting the professional use of the biocides that the Ministry of Rural Development and Food is competent, and also its renewal and amendment".

## SECTION FIVE Article 52 Repeal- transitional provisions

- 1. By the date of entry into force of the present law, the following are repealed:
  - a. Law-Decree 220/1973 (O.J. A-170).
  - b. The provisions of the law num 721/1977 (O.J. A-298) related to plant protection products and any other provision which is contrary or otherwise regulate the issues of plant protection products.
  - c. The provisions of Article 18 of the law num 721/1977 (O.J. A-298) and any reference to the Superior Pesticide Council in this law and the Presidential Decree 205/2001 (O.J. A-160) regarding biocides that the Ministry of Rural Development and Food is competent.
- 2. Until the date of entry into force of implementing Presidential Decrees and Ministerial Decisions of the present law the relative provisions remain in valid.
- 3. <sup>34</sup>For those who have a permit for distributing pesticides, in accordance with the provisions of law

<sup>32</sup> **Amendment 11-2-2014**: Paragraph 1b, article 45, of law num. 4235/2014 (O.J. A'32): "Article 14 of law num 721/1977 as valid is amended as the following: b. After the case kh., Article 14, a new case kth. is added as the following ...".

<sup>33</sup> **Amendment 11-2-2014**: Paragraph 2, article 45, of law num. 4235/2014 (O.J. A'32)

220/1973 (OJ A'272) and Presidential Decree 353/1974 (OJ A'138), the provisions of paragraph 32 of article 20 of law 3399/2005 (OJ A'255) still apply after the entry into force of this law. The same individuals are entitled to issue pesticide prescriptions in accordance with paragraph 5 of Article 35, until their retirement.

#### Article 53

The Common Decision num. 392169/20.10.1999 of the Ministers of Economy and Agriculture "General Regulations for the use of the term Local Wine as a descriptive data of table wine (B-1985), as amended and valid is ratified and acquires the force of law.

#### Article 54 Entry into force

The validity of this law begins its publication in the Official Gazette, unless otherwise specified in its individual provisions.

#### **ANNEX A**

Fees for approval [Analytical list of fees categories]

### ANNEX B Training content

- All relevant legislation regarding pesticides and their use.
- The existence and risks of illegal (counterfeit) plant protection products, and the methods to identify such products.
- 3. The hazards and risks associated with pesticides, and how to identify and control them, in particular:
  - (a) risks to humans (operators, residents, bystanders, people entering treated areas and those handling or eating treated items) and how factors such as smoking exacerbate these risks;
  - (b) symptoms of pesticide poisoning and first aid measures;
  - (c) risks to non-target plants, beneficial insects, wildlife, biodiversity and the environment in general.
- Notions on integrated pest management strategies and techniques, integrated crop management strategies and techniques, organic farming principles, biological pest control methods, information on the

 $<sup>^{34}</sup>$  Amendment 4-12-2015: Paragraph 10, article 18 of law num. 4351/2015 (O.J. A'164): "The paragraph 3 is added after the paragraph 2 of article 52 of the law 4036/2012 as following: ..."

- general principles and crop or sector-specific guidelines for integrated pest management.
- 5. Initiation to comparative assessment at user level to help professional users make the most appropriate choices on pesticides with the least side effects on human health, non-target organisms and the environment among all authorised products for a given pest problem, in a given situation.
- 6. Measures to minimise risks to humans, non-target organisms and the environment: safe working practices for storing, handling and mixing pesticides, and disposing of empty packaging, other contaminated materials and surplus pesticides (including tank mixes), whether in concentrate or dilute form; recommended way to control operator exposure (personal protection equipment).
- 7. Risk-based approaches which take into account the local water extraction variables such as climate, soil and crop types, and relieves.
- Procedures for preparing pesticide application equipment for work, including its calibration, and for its operation with minimum risks to the user, other humans, non-target animal and plant species, biodiversity and the environment, including water resources.
- 9. Use of pesticide application equipment and its maintenance, and specific spraying techniques (e.g. low-volume spraying and low-drift nozzles), as well as the objectives of the technical check of sprayers in use and ways to improve spray quality. Specific risks linked to use of handheld pesticide application equipment or knapsack sprayers and the relevant risk management measures.
- 10. Emergency action to protect human health, the environment including water resources in case of accidental spillage and contamination and extreme weather events that would result in pesticide leaching risks.
- 11. Special care in protection areas established under law 3199/2003 (A'280), in compliance to Directive 2000/60/EC.
- 12. Health monitoring and access facilities to report on any incidents or suspected incidents.
- 13. Record keeping of any use of pesticides, in accordance with the relevant legislation.

#### **ANNEX C**

Health and safety and environmental requirements relating to the inspection of pesticide application equipment

- a) The inspection of pesticide application equipment covers all aspects important to achieve a high level of safety and protection of human health and the environment. Full effectiveness of the application operation should be ensured by proper performance of devices and functions of the equipment to guarantee the following objectives are met.
- b) The pesticide application equipment must function reliably and be used properly for its intended purpose ensuring that pesticides can be accurately dosed and distributed. The equipment must be in such a condition as to be filled and emptied safely, easily and completely and prevent leakage of pesticides. It must permit easy and thorough cleaning. It must also ensure safe operations, and be controlled and capable of being immediately stopped from the operator's seat. Where necessary, adjustments must be simple, accurate and capable of being reproduced.
- c) Particular attention should be paid to:

#### 1. Power transmission parts

The power take-off driveshaft guard and the guard of the power input connection shall be fitted and in good condition and the protective devices and any moving or rotating power transmission parts shall not be affected in their function so as to ensure protection of the operator.

#### 2. Pump

The pump capacity shall be suited to the needs of the equipment and the pump must function properly in order to ensure a stable and reliable application rate. There shall be no leakages from the pump.

#### 3. Agitation

Agitation devices must ensure a proper recirculation in order to achieve an even concentration of the whole volume of the liquid spray mixture in the tank.

#### 4. Spray liquid tank

Spray tanks including indicator of tank content, filling devices, strainers and filters, emptying and rinsing systems, and mixing devices shall operate in such a way as to minimise accidental spillage, uneven concentration distribution, operator exposure and residual content.

#### 5. Measuring systems, control and regulation systems

All devices for measuring, switching on and off and adjusting pressure and/or flow rate shall be properly calibrated and work correctly and there shall be no leakages. Control of pressure and operation of

pressure adjustment devices shall be easily possible during application. Pressure adjustment devices shall maintain a constant working pressure at constant revolutions of the pump, in order to ensure that a stable volume application rate is applied.

#### 6. Pipes and hoses

Pipes and hoses shall be in proper condition to avoid disturbance of liquid flow or accidental spillage in case of failure. There shall be no leakages from pipes or hoses when run with the maximum obtainable pressure for the system.

#### 7. Filtering

In order to avoid turbulence and heterogeneity in spray patterns, filters shall be in good condition and the mesh size of the filters shall correspond to the size of nozzles fitted on the sprayer. Where applicable the filter blockage indication system shall operate correctly.

8. Spray boom (for equipment spraying pesticides by means of a horizontally positioned boom, located close to the crop or the material to be treated).

The spray boom must be in good condition and stable in all directions. The fixation and adjustment systems and the devices for damping unintended movements and slope compensation must work correctly.

#### 9. Nozzles

Nozzles must work properly to control dripping when spraying stops. To ensure homogeneity of the spray pattern, the flow rate of each individual nozzle shall not deviate significantly from the data of the flow rate tables provided by the manufacturer.

#### 10. Distribution

The transverse and vertical (in case of applications in vertical crops) distribution of the spray mixture in the target area must be even, where relevant.

11. Blower (for equipment distributing pesticides by air assistance)

The blower must be in good condition and must ensure a stable and reliable air stream.

#### **ANNEX D**

#### General principles of integrated pest management

- 1. The prevention and/or suppression of harmful organisms should be achieved or supported among other options especially by:
  - crop rotation,

- use of adequate cultivation techniques (e.g. stale seedbed technique, sowing dates and densities, under-sowing, conservation tillage, pruning and direct sowing),
- use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material,
- use of balanced fertilisation, liming and irrigation/drainage practices,
- preventing the spreading of harmful organisms by hygiene measures (e.g. by regular cleansing of machinery and equipment),
- protection and enhancement of important beneficial organisms, e.g. by adequate plant protection measures or the utilisation of ecological infrastructures inside and outside production sites.
- Harmful organisms must be monitored by adequate methods and tools, where available. Such adequate tools should include observations in the field as well as scientifically sound warning, forecasting and early diagnosis systems, where feasible, as well as the use of advice from professionally qualified advisors.
- 3. Based on the results of the monitoring the professional user has to decide whether and when to apply plant protection measures. Robust and scientifically sound threshold values are essential components for decision making. For harmful organisms threshold levels defined for the region, specific areas, crops and particular climatic conditions must be taken into account before treatments, where feasible.
- 4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.
- The pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment.
- 6. The professional user should keep the use of pesticides and other forms of intervention to levels that are necessary, e.g. by reduced doses, reduced application frequency or partial applications, considering that the level of risk in vegetation is acceptable and they do not increase the risk for development of resistance in populations of harmful organisms.
- 7. Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action.

8. Based on the records on the use of pesticides and on the monitoring of harmful organisms the professional user should check the success of the applied plant protection measures.

### ANNEX E Harmonized risk indicators

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