Additional measures for the implementation of Regulation (EC) num. 1107/2009 concerning the official controls of plant protection products

Unofficial translation in English of the Common Ministerial Decision num 1/32/2-1-2015 (Government Gazette B' 26)

The present Decision describes all the applied official procedures for the official controls of plant protection products in Greece

Ministry of Reconstruction of Production, Environment & Energy, Directorate of Plant Produce Protection
GREECE

Additional measures for the implementation of Regulation (EC) num. 1107/2009 concerning the official controls of plant protection products

Common Ministerial Decision Num. 1/32/2-1-2015 (Government Gazette B' 26)

Minister of Development and Competiveness

Minister of Rural Development and Food

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CONTENTS

CHAPTER A

OBJECTIVE – SCOPE – TYPES OF CONTROLS

Article 1
Objective - Scope

1. This Decision sets out the additional measures necessary for the implementation of the Regulation (EC) No. 1107/2009 (the Regulation) on the control of plant protection products with regard to formulations (in particular the content, the active substances and the additives), their packaging and their labeling.

2. The provisions of this Decision apply to the plant protection products which have been granted an authorization or a parallel import permit under Article 52 of Regulation (EC) No. 1107/2009 (hereinafter authorized plant protection products).

Article 2
Controls on authorized plant protection products

1. a) The authorized plant protection products are subject to laboratory tests of samples. In cases of plant protection products with a parallel import permit an additional similarity test is conducted between parallel import product and the reference product.

   b) The laboratory testing of authorized pesticides is carried out to examine the guaranteed composition as well as any toxicological significant impurity and their physicochemical properties, in comparison to those of the granted authorization and the FAO specifications, where these exist. When there are no specific FAO specifications for a certain active substance and formulation type, then the general specifications are the rule, as mentioned in the "Manual on development and use of FAO and WHO specifications" in the current version.

   c) The laboratory testing of the active substances of authorized plant protection products, is carried out to examine identity, to check their purity, and where necessary to detect and quantify any unacceptable impurities. Where there are specific FAO specifications, they are also checked.

2. The controls on the packaging of authorized plant protection products are carried to investigate the legality of the packaging in which each a plant protection product is marketed compared to the corresponding granted authorization or parallel import permit.

3. The control of labelling of authorized plant protection products is carried to investigate the legality of this, including those referred on the label, compared to the corresponding authorization or parallel import permit.

Article 3
Frequency of controls

1. Each authorized plant protection product can be checked for its content, up to five (5) times per year, since each control refers to a different batch of the formulation. More controls for the same purpose, may only be made if deemed necessary by the Coordinating National Authority.

2. Each authorized plant protection product can be checked for packaging and labelling according to paragraphs 2 and 3 of Article 2, up to ten (10) times per year, since each control refers to a different batch of formulation and packaging size. More controls for the same purpose, may only be made if deemed necessary by the Coordinating National Authority.

3. Each competent authority of Articles 3 and 8 paragraph 1 of law 4036/2012, as valid, may select which of the formulations included in the annual programs of the five-year control program for plant protection products of Article 7 of Law 4036 / 2012, as valid, will check, as long as the number of controls of paragraphs 1 and 2 of the present article is not exceeded, for the same purpose.

CHAPTER B

CONTROL PROGRAM AND CONTROL RECORDING

Article 4
Plant protection products Control Program

1. The five-year plant protection products control program (the Program) of the Article 7 of Law 4036/2012, as valid, includes annual control programs, taking into account:

   a) The statistical data of plant protection products sales for a period of twelve (12) months,

   b) The recommendations of the competent control authorities,

   c) The proposals and efficiencies of the competent chemical control laboratories for plant protection products,

   d) The infringements that were detected over a period of twelve (12) months prior to the drafting of the program,

   e) The changes in the authorizations during the two (2) previous years, which imposed changes on the labeling of plant protection products.

2. The program is communicated to the competent authorities and the control laboratories by the Coordinating National Authority.

3. At the end of the five (5) years, the Coordinating National Authority assesses the results from the implementation of the program and re-establish a five-year program, which defines the objectives and actions to be taken each year, taking into account the elements of para. 1.

Article 5
Electronic records of the controls

1. The Coordinating National Authority shall maintain an electronic application in which the controls performed in plant protection products are recorded, according to the annual programs of the five-year plant protection products control program of the Article 7 of Law 4036/2012, as valid.

2. The competent control authorities of the Articles 3 and 8 paragraph 1 of law 4036/2012, as valid, entry the plant protection products and batches controlled in a specific electronic service, before delivering each sample to the competent official control laboratories defined by the Num. 11324/113170/11.01.2012 Common Ministerial Decision (Government Gazette B 3225/

12.04.2012), as valid (the competent control laboratories) as well as prior to any control of the packaging or labelling of the plant protection products, in order to avoid repeating such controls and to maximize their number.

3. The electronic application is updated with the results of laboratory tests by the competent control laboratories.

4. Until the launch of the electronic service for recording the control data in authorized plant protection products, the competent control authorities of Articles 3 and 8 par. 1, law 4036/2012, as valid, shall select randomly the plant protection products for the official controls according to the annual programs of the five year control program of Article 7 of Law. 4036/2012, as valid.

5. Access to the electronic service is given only to the competent control authorities, the competent control laboratories and the Coordinating National Authority.

CHAPTER C
OFFICIAL PROCEDURES FOR THE CONTROL OF PLANT PROTECTION PRODUCTS

Article 6
Sampling of plant protection products

Where sampling plant protection products with a parallel import permit, following a claim, an additional sample of the reference product of two different batches is received. If the authority that sampled the parallel import product is not possible to take samples of the batches of the reference products, the control authority takes samples of the parallel import products and notes the lack of reference products to the official control laboratory. The official control laboratory uses the reference products that were taken by another competent authority or reports the lack to the Coordinating National Authority for taking appropriate measures. The official control laboratory may test only the properties for which it is claimed dissimilarity, for the direct use of the most appropriate technique and for saving resources.

Article 7
Sampling procedure for authorized plant protection products

1. a) The sampling of the authorized plant protection products is conducted in market at any point after their production, import or entry into the country before opening the packaging for the purpose of use.

   b) The sampling of the authorized plant protection products from batches that have already been supplied to wholesale or retail shops is conducted by taking two packages of the same batch of the plant protection product under control (sample - counter sample). The same procedure applies for sampling plant protection product imported, intra EC acquired, manufactured or stored, where they are in the final sealed packaging with which they are supplied to the end user.

   c) The sampling from consignments of authorized plant protection products, which should be repacked in smaller packages before being made available to the end user is conducted in accordance with the procedure set out in Annex B.

2. a) The competent control authorities of Articles 3 and 8 par. 1 of law 4036/2012, as valid, take samples with as most recent date of manufacture in order to be enough time to conduct the laboratory analysis, to submit any appeal for counter-analysis and to take the necessary measures if any infringements are found.

   b) The samples that are taken should not have an expiry date of less than six (6) months from the date of sampling.

   c) By derogation to the case b), the samples having an expiry date of less than six (6) months from the date of sampling, may be taken only if required to investigate a written claim or upon a relative request of the Coordinating National Authority.

Article 8
Sampling protocol

1. During sampling, the competent inspectors complete the Sampling Protocol of Annex A and take a digital photo of the test sample. The relevant files, if no infringement of legislation is found, are kept for a period of two (2) years or until the end of the expiry period of the formulation. If an infringement is found, the relevant records are kept for at least ten (10) years. The counter sample, if no infringement of legislation is found, is kept until the completion of the laboratory analysis. Each sample is numbered uniquely from the competent control body, to allow its traceability.

2. The sampling protocol is completed in quadruplicate and signed by the holder of the plant protection product or his refusal to sign is recorded. One copy shall accompany the sample, one the counter sample and one delivered to the holder of the plant protection product, from which the sample was taken. The fourth copy is kept in the archives of the competent authority. Instead of the quadruplicate completion of the sampling protocol, it is possible to complete on the spot duplicate forms and make two additional exact photocopies in the offices of the authority.

Article 9
Storage of sample and counter-sample

If no infringement of legislation is found the sample and the counter sample are kept for a period of four (4) months, unless otherwise is stated in the accreditation manual of the official control laboratory. If an infringement is found in the tested sample, the counter sample is kept until it becomes clear if a counter analysis is requested and nevertheless for a period of one (1) year.

Article 10
Packaging, sealing, labeling, shipment and delivery of samples

1. The packaging, sealing and labeling of samples are conducted at the place of sampling by the presence of the owner of the plant protection products. In case of a refusal from the owner to attend sampling, this is noted in the additional observations of the Sampling Protocol.

2. The samples are packed and sealed in such a way as to ensure their safety and against any possible alteration of their ingredients during transport to the laboratory. Before packing, the

sample is re-tested for leaks that may make it inappropriate. The sample and the counter sample are individually packed in a plastic bag, preferably with air bubbles which closes and they are wrapped and sealed.

3. The sample and the counter sample are sent to the competent control laboratory as soon as possible after sampling. The delivery of samples is conducted with a relevant document of the competent authority, which is copied to the Coordinating National Authority and in electronic form. The document of the preceding paragraph shall indicate the trade name of the plant protection product (where applicable), the active substance, its content in the formulation, the type of formulation and the batch number. All necessary measures to avoid accidents are taken for the delivery of the sample and the counter sample.
4. The competent control laboratory upon receipt of the samples checks their condition and records the regularity of incoming samples.

Article 11

Sampling procedure for plant protection products to control their similarity

1. The sampling of plant protection products for the purpose to control their similarity is applied to parallel import plant protection products, following a claim or under a special provision of the control program of Article 7 of law 4036/2012, as valid.
2. Samples of the test batch of the parallel import plant protection product are taken and also samples from two different batches of the reference product. The competent control authority may take the samples of the three (3) batches (one batch from the parallel import plant protection product and two batches of the reference product) from the same or different area, simultaneously or at different times,. The control laboratory may use batches of the reference product shipped from another or other competent authorities for control of the parallel import plant protection product or request the assistance of the Coordinating National Authority. The packaging, sealing, labeling, shipment and delivery of samples of each batch should be in accordance with Article 10.

Article 12

Sampling procedure of PPP active substances

1. The sampling of active substances from consignments is conducted in accordance with the procedure set out in Annex B.
2. During sampling, the control authority, receive copies of procurement documents of the active substance (invoices etc), which checks in relation to the provisions of the marketing authorization of the formulations intended to be produced from the active substance.

CHAPTER D

LABORATORY CONTROLS OF PLANT PROTECTION PRODUCTS

Article 13

Laboratory analysis of plant protection products and record keeping

1. The competent control laboratories for plant protection products conduct the laboratory analysis of the received samples the soonest possible. Where appropriate, they prioritize the laboratory analysis of the received samples, taking into account:

   a) The date of receipt of the sample,

   b) The laboratory analysis of similar samples in order to save resources and

   c) The availability of laboratory instruments and laboratory substances.

2. During the chemical testing, the analytical method that is applied:

   a) An internationally recognized method of analysis or

   b) The analytical method proposed by the authorization holder of the plant protection product in the authorization dossier or

   c) The analytical method that is scientifically adequate and feasible for the needs of each analysis, according to the judgment of the competent control laboratory.

3. In case of small size samples and particular in samples smaller than one hundred milliliters (100 ml), the specific weight of the formulation may be considered equal to that which exists in the authorization dossier that was submitted in order to obtain the authorization of the formulation.

4. Upon the completion of the analysis, a control report is drawn up, which is sent to the competent control authority which carried out the sampling and notified to the Coordinating National Authority. This report contains at least:

   a) Full details of the sample collected and tested,

   b) The applied analysis method,

   c) Laboratory results and

   d) The conclusion on the legality of the sample tested.

5. At the request of the Coordinating National Authority, a copy of the Control Report of paragraph. 4 above is sent to the competent authority for assessing the toxicological data of plant protection products, i.e. the Benaki Phytopathological Institute, which within ten (10) days of its receipt, give advice to the Coordinating National Authority on the risk of the tested batch of the plant protection product. Taking the preceding advice, the Coordinating National Authority takes the necessary immediate measures to protect public health and the environment.

6. The records of the laboratory tests are kept by the control laboratory for a period of ten (10) years unless relevant administrative or judicial review is pending and if so they are kept until its completion.

Article 14

Detecting infringements in matters of plant protection products by laboratory analysis

1. Where from the conclusion of the laboratory, a law infringement is found, the competent control authority which carried out the sampling, notifies immediately, in writing and with proof of delivery the holder of the authorization if he is based in the country or a natural or legal person who is designated as a representative or the holder of the parallel import permit.

2. This written notification of the persons of paragraph 1 includes:

   a) The relevant legislation and sanctions.

   b) Copies of the sampling protocol and the control report of the relevant official laboratory.

   c) A description of the infringement and

   d) The opportunity to appeal against the laboratory analysis, in accordance with Article 15.

Article 15

Appealing against laboratory analysis

1. The holder of the authorization or his legal representative or the holder of the parallel import permit, may submit an appeal to the Coordinating National Authority within fifteen (15) days after the delivery of the written notification in Article 14.

2. The applicant should justify in his appeal, the reasons why it is submitted and requiring repetition of the analysis of the second sample from the consignment of the plant protection product tested. In the case where risk of the plant protection product is documented and in particular, possibility to cause risk to human health or the environment, the appeal does not affect the obligation to withdraw the batch of the controlled formulation from the market or the whole marketed quantity of the formulation, if it is not possible to determine the batch.

3. After the submission of the appeal, the Coordinating National Authority forward immediately to the laboratory that made the first analysis, which within fifteen (15) days of receipt of the proceeds to repeat the analysis with another person - responsible analyst for the analysis. If the laboratory where the first analysis was conducted, does not employ more than one responsible analyst, the laboratory informs the Coordinating National Authority, which takes the proper actions for the direct transmission of the second sample with the relevant documentation to another plant protection product control laboratory, to carry out the second analysis.

4. A second chemist (expert), appointed by the applicant, may be present during the second analysis following an appeal request. The full details of the second expert (name, address and telephone number) are mentioned in the appeal and a copy of the title of studies is attached. The second expert of the previous paragraph, is notified by the laboratory which is to conduct

the analysis in writing with proof of delivery at least twenty-four (24) hours before the date of the second analysis and if fails to appear, then the second analysis takes place without his presence. The notification of the second expert may be performed, by the person who submitted the appeal.

5. After the completion of the second analysis, a review protocol is drawn up in which the second expert may record his comments or objections on chemical results and methods that have been applied in the second analysis, and it is forwarded to the Coordinating National Authority in order to proceed with the procedure laid down in law 4036/2012, as valid.

CHAPTER E

CONTROLS ON THE PACKAGING AND LABELLING OF PLANT PROTECTION PRODUCTS

Article 16
Controls on the packaging of plant protection products

When carrying out controls on the packaging of plant protection products, the competent control authorities complete the control report of Annex C on-site or afterwards at the offices of the control authority, after taking digital photographs of the packages. In this case, the check should be conducted within a period of one (1) month from the receipt of the photographic material.

Article 17
Controls on the labeling of plant protection products

1. The control of the labels of the plant protection products is conducted on-site, where the plant protection product is found, by comparing the controlled points of the label with the relevant of the authorization or at the offices of the control authority when a sample or a photo of the label of the formulation is taken. If a sample is taken, it should be returned to the holder if no infringement is established when checking the label.
2. In all labels of the plant protection products, the competent authority checks the application instructions (spectrum of action, doses, application time, pre-harvest period, etc.) in comparison to the relevant provisions of the authorization, as valid at the time of the control and completes the relevant fields of Annex C. It also checks and records the trade name of the formulation, the content of active substance and the batch number.
3. As a percentage of eighty percent (80%) of the sampled labels of plant protection products, the competent authority checks the classification, the risk and safety phrases and the instructions in case of accident, in comparison to the relevant provisions of the authorization, as valid at the time of the control and complete the relevant fields of Annex C.
4. As a percentage of twenty percent (20%) of the sampled labels of plant protection products, the competent authority verifies the identity data (approval number, holder of the authorization, responsible for the final packaging and labeling, etc.), in comparison to the relevant provisions of the authorization, as valid at the time of the control and complete the relevant fields of Annex C.

5. Each phrase, statement or representation, which gives false or misleading information in contradiction to those phrases or indications mentioned in the authorization is defined as a deviation from the provisions of the relevant authorization.

Article 18
Exceptional plant protection product controls

1. Exceptional controls are carried out in plant protection products other than those specified in the monitoring program under Article 7 of Law 4036/2012, as valid, if:

a) There is a claim to the competent control authority for the investigation of which a control is necessary,

b) The control is requested from the Coordinating National Authority to investigate cases,

c) The control is requested by the police or judicial authorities to investigate cases and

d) Where it is found necessary for the purposes of placing on the market of plant protection products and their proper use.

2. The provisions of this Decision are applied for carrying out the exceptional checks of paragraph 1.

CHAPTER F
FINAL PROVISIONS

Article 19
Cooperation with control authorities

The suppliers, distributors, importers, exporters and users of plant protection products are obliged to facilitate the control authorities, giving all relevant information and corresponding purchase invoices or bills of lading or any document relating to the controlled nature of the sample.

Article 20
Repealing- Transitional provisions

1. From the entry into force of this Decision, the provisions of Num. 155501/7.7.1983 decision of the Minister for Agriculture "Specifying the reception mode official samples for testing of pesticides" (Government Gazette B 353 / 23.6.1983) are repealed.

2. The samples of plant protection products obtained before the entry into force of this Decision and whose examination by the Control Laboratories is still pending are tested in accordance with the provisions of the above mentioned repealed Decision.

Article 21
Annexes

Three (3) Annexes are annexed to this Decision, which form an integral part of and are as follows:

Annex A.

Plant protection products sampling protocol

GREEK REPUBLIC

Sending authority

PROTOCOL FOR SAMPLING THE PLANT PROTECTION PRODUCT

Sample number .....

Today .... / .... / .... and time .... : .... We, the undersigned ....ordered for the sampling of plant protection products, officials of the competent authority, took a sample of the plant protection product / active substance (delete as appropriate) with the following identity data:

1. Trade name:
2. Authorization number/ parallel import permit:
3. Active substance - content - form:
4. Packing size:
5. Batch number:
6. Document supply:

Sampling was conducted in compliance with the following control command:

.....

Sampling was done by the following sampling point:

.....

Samples sent to the following official control Lab:

.....

Sampling was done:

- For the purposes of the annual monitoring program 201 ... ..
- Other reason (specify):

  .....

  .....

The holder of the people conducting the
plant protection product sampling

Annex B

Sampling procedure of active substances or bulk plant protection products

A. Definitions

1. Batch: A defined and homogeneous quantity of a plant protection product or a substance derived from a production cycle. The key feature of the lot is homogeneity.

2. Primary sample: A quantity taken from a single part in the batch.

3. Composite sample: The total of the primary samples taken from the same batch. A composite sample is achieved by integrating and mixing the primary samples.

4. Laboratory sample: a representative fraction of the composite sample intended for laboratory analysis.

B. General guidelines for sampling of plant protection products

1. Plant protection products in liquid form (solutions, concentrated solutions, emulsifiable and other relative formulations of plant protection products)

Due to the physicochemical constants reversible changes can happen under abnormal conditions of transport and storage (e.g. low temperatures). Therefore, before sampling and use, it should be ensured that any changes in the physicochemical characteristics have disappeared. Where it is not possible to remix or re-dilute the separated ingredients, the temperature of the sample should be recorded and the thickness of the sediment that is remained should be measured. The sediment should be separately sampled.

1.1. Preparation for sampling

a) Heat the sample at a temperature which will not affect the active ingredients, if this appears not to be homogeneous.

b) Shake the container package, or, if packed in large containers, stir the content.

1.2. Equipment and instruments used for sampling

a) A long tube glass or of a suitable plastic or stainless steel

b) Pipette or other volumetric instruments.

1.3. Sample size

The sample size is determined by three important factors:

a) The nature of the active ingredient and method of analysis

b) The percentage of active ingredient in the final product

c) The size of the packaging container

It should be observed that the lower the content of active ingredient (b) and the greater the volume of the container (c), the larger sample must be taken.

1.4. Containers for Storage of samples

Preferred glass containers with suitable caps to close tightly.

2. Plant protection products in powder form (dusting powders, wettable powders, etc.)

The plant protection products that are in powder form, as opposed to liquids, they are not susceptible to low temperatures (freezing), although often affected by high temperature and humidity. The samples that have been stored for a long time, may afterwards not be representative of the respective batches.

2.1. Preparation of the sample

Any special preparations prior to sampling, as shaking the sample does not usually have practical significance.

2.2. Sampling

The sample should always be taken from various parts of the product, using a long tube (sampling saber) suitable for plant protection products powders.

2.3 Sample size

The sample size is determined by the following factors:

a) Nature of the active ingredient and method of analysis

b) Percentage of active ingredient in the final product

c) Form of the pesticide

d) Size of the packaging container

It should be observed that the lower the content of active ingredient (b), the coarser product (granular) (c), and the larger the size of the container (s), the larger sample must be taken

2.4. Division of the sample for analysis

Because plant protection products in powder or granular form may undergo change in the size of the particles during transport or when transferred to other containers, care should be taken that the laboratory sample is representative of the composite sample.

2.5 Sample containers

Containers able to be closed tightly are recommended. The glass is usually the most suitable material.

C. Size and method of making composite sample

It is common practice to form the composite sample from the primary samples, which will be analyzed. The composite sample should be so much that it can provide at least three (3) analytical samples of which one is used for the first formal analysis (control). The remaining two are counter samples from which the one sent with the sample to the appropriate Official Laboratory for use in case of analysis after an appeal. The second counter sample remains the owner of the sampled plant protection product but it cannot be used in case of disputes in court.

1. Liquid products (solutions or emulsifiable concentrates)

a) Minimum size of composite sample: 650 mL

b) Number of samples per consignment: maximum 20 primary samples of which one composite sample is derived for each 5 tons of plant protection products to be repacked or for each 20 tons of bulk shipments of plant protection products.

c) The number and the size of the primary samples depending on the size of packages and the sampled volume.

Unit Size	Primary sample quantity
> 1 liter to at least 50 liters	20 to 50 ml each obtained from 2 to 5 units per 100 units of packaging
> 50 liters to at least 200 liters	50 to 100 ml each at 2-5 package units

Tanker car or wagon: From each wagon three samples of 100 ml each taken from various parts of the wagon or a sample of 300 ml with a suitable probe which enters slowly and vertically into the liquid. An additional sample of 100 to 200 ml should be taken a few centimeters above the bottom of the wagon and analyzed separately.

d) When sampling, it is important to check if it has been separation of ingredients or not. If you have crystals settled as a sediment, then they should be diluted carefully at a suitable temperature (usually 30 to 40°C) and any variations in concentration should be dissapeared with stirring or shaking. If the product cannot be made homogeneous before sampling, eg tank car, an additional sample should be taken very close to the bottom and analyzed separately.

2. Plant protection products in powder form (dusting powders, wettable powders and other similar formats)

a) Minimum size of the composite sample for products with an active substance content in content as following:

Content	Quantity (grams)
Less than 2%	800
2% to 10%	600
Greater than 10%	500

b) Number of samples per consignment: Maximum number of primary samples 20 of which is one composite sample is derived for every 5 tons, or every 20 tons (bulk shipments).

When a consignment consists of several batches, each batch is sampled separately and the number of primary samples making up the composite sample depends on its size in relation to the size of the entire consignment.

c) Number and size of primary samples for each different size packaging unit

Unit size	Sample Quantity
> 100 to 2000 g	At least 50 g. each obtained from 3 to 5 units per 500 units of packaging
> 2 kg to 10 kg	At least 50 g. each obtained from 3 to 5 units per 100 units of packaging
> 10 kg to 50 kg	At least 50 g. each obtained from 3 to 5 units of packaging

Large packages which are destroyed during sampling (eg bags). In this case, random samples are taken e.g. a sample of 250 g. every fifty units. If there is a special agreement between buyer and supplier, it should be considered.

3. Granular formulations:

a) Minimum size of the composite sample for products with an active substance content in content as following:

Content	Quantity (grams)
Less than 2%	1000
2% to 5%	800
5 to 10%	600
Greater than 10%	500

b) Number of samples per consignment:

Maximum number of primary samples 20 of which one composite sample is derived for every 5 tons (packaged products) or every 20 tons (bulk).

c) Number and size of primary samples for each different size packaging unit

Unit Size	Primary sample quantity
> 1 kg to 10 kg	At least 100 g. each obtained from 3 to 5 units per 100 units of packaging
> 10 kg to 50 kg	Primary sample size of at least 100 g. from 3-5 package units

Large packages which are destroyed during sampling (eg bags). In this case, random samples are taken e.g. a sample of 250 g. every fifty units. If there is a special agreement between buyer and supplier, it should be considered.

d) Points to note:
In large packagess, each primary sample should be taken from different parts of the package.
During dividing the composite sample in the sample and counter samples ,, care should be taken for the representativeness of the samples to be analyzed.

4. Suspensions, pastes and emulsions.

a) Maximum size of the composite sample for products with an active substance content in content as following:

Content	Quantity (grams)
Less than 1%	1000
1 to 10%	600
Greater than 10%	400

b) Number of samples per consignment: maximum number of primary samples 30 of which one composite sample is derived for each 5 tons (repacked) or every 20 tons (bulk shipments). When a consignment consists of more than one batch, each batch is sampled separately and the number of primary samples making up the composite sample depends on its size in relation to the size of the entire mission.

c) Number and size of primary samples depending on the size of packages and the sampled volume.

Unit Size	Quantity of primary sample
> 100 to 1000 g	40 to 100 g. each obtained from 5 units per 1000 packaging units
> 1 kg to 10 kg	40 to 100 g. each obtained from 5 units per 100 units of packaging
More than 10 kg	From each unit at least two samples are taken of 10 to 40 g. each from various parts of the package

d) When sampling, it is important to check if there is a separation of the ingredients (e.g. precipitation). The contents of the package must be homogeneous before sampling.

D. Closure and sealing of the samples

The capping must be handled with care so as to ensure tightness. The seals should be clean, dry, odorless, cork or rubber or metal which surrounded from a waterproof material. If the sampled species is hygroscopic or there is a possibility of evaporation or sublimation, insulating films should additionally be used on the closure point of contact with the package. The sealing of the sample after wrapping, the tying with string and attachment of the sampling protocol, should be made in such a way that the inviolability is ensured. The sealing is made with Spanish wax, and special stamp preferably metal which states the identity of the

sampling authority in a way that reflected the distinctive points. Lead seals can be used for sealing instead of Spanish wax.

After wrapping the samples, a sampling card of the type described below is bound to the ends of the twine tie, which must necessarily writes where appropriate "*for the first examination*" or "f*or the examination on appea*l".

The counter sample that is sent to the competent laboratory is accompanied by two sampling cards, one placed inside the wrapping paper and the second bound as described above.

The packing, sealing and labeling of the samples are conducted at the place of sampling and by the presence of the owner or holder or representative or the transporter of the good. In case of their refusal to attend, this is written in the sampling protocol.

E. Sampling card and protocol

The sampling officers complete and sign two sampling cards, which are placed on the samples. Sample cards are cardboard with dimensions 6 x 9 cm and indications on it having the following type:

.....
(Sampling authority)
.....
SAMPLING CARD
For the first or on appeal examination
Sample number: .....
Sampled good: .....

Sampled amount: .....

Sampling Location: .....
Date: dd / mm / yyyy
Signatures
....
....
....

After sampling, a special protocol is drawn up in quadruplicate which mentions the sample number of the sampling card. The protocol is kept by the sampling authority, and a copy of this is submitted with the cover letter to the competent laboratory for the requested examination and one is left to the one where the sampling took place.

E. Packaging - Transportation - receipt and examination of samples

Two of the samples together with the relevant cover letter and the attached sampling protocols are packed so as to ensure security and the stability of the ingredients during transport and shipped immediately by the sampling authority to the competent Official control laboratory. Upon receipt, the regularity of the samples is checked.

The samples that the normal sealing is compromised or destroyed, or they are not protected due to improper packaging or it is not ensured the irreplaceable content or leaking of the contents is noticed due to lose or irregular closure or mechanical damage (cracking etc.) during transport of sampling bottles or the samples that contain insufficient quantity, even if one of the two samples shows any of these aberrations, they not accepted for examination.

The samples that are not accepted are well packed and sent back by letter with acknowledgment to the sampling authority or returned to the official who has provided them with a cover letter which states the reasons of the return.

The one of the samples that meets the above requirements, labeled 'For the on appeal examination" is kept sealed by the competent control laboratory at the best possible storage conditions to avoid alteration for a period of four months after the dispatch of the analysis report to the sampling authority.

ANNEX C

Competent authority
conducting the control

CONTROL REPORT ON THE PACKAGING / LABELING OF PLANT PROTECTION PRODUCTS

Today dd / mm / yyyy at hour ..... the control group of officials of the authority ……
……
…… consisting of the employees:
……
……
acting after the num. .... control order issued by authority controlling the packaging and the label of the plant protection product with the following data:

Authorization number/ Parallel trade permit number:	
Tradename:	
Active substance – content – form:	
Batch number:	
Expiry date (if exists):	

Place where the plant protection product was found: ……

……

Place where the control of packaging or labeling of the plant protection product was made:

◯ In the place where found

◯ A sample was taken / photos and the control was made on the authority premises.

Holder of the controlled formulation (name - signature):

Parts of the label controlled:

Identity data	**Application instructions**	**Classification** **Risk-safety phrases**
◯ Authorization number	◯ Instructions for use	◯ Risk symbol
◯ Tradename	◯ Category and mode of action	◯ R-phrases
◯ Active substance, content, form	◯ Spectrum of action	◯ S-phrases
◯ Batch number	◯ Special conditions for use	◯ First aid – antidote
◯ Holder of the authorization	◯ Pre harvest interval	◯ Phrases for bees, fish and productive animals
◯ Responsible for repacking and classification	◯ Phytotoxicity	
◯ Expiry date		
◯ Storage conditions – storage stablity		

The packaging / labeling of the plant protection product was controlled in comparison to the provisions of the num. …… Ministerial Decision. The results of the control were (delete as appropriate):

☐ No infringements found in comparison to the provisions of the authorization

☐ The following infringements werefound in comparison to the provisions of the authorization:

……

……

……

……

The inspectors :

Note: In case of law violation, a copy of the control report is sent to the person responsible for the infringement found. Any additional notes are listed in an extra page attached to the control report.

Article 22
Entry into force

1. The validity of this Decision starts from its publication in the Government Gazette.
2. The provisions of this Decision shall apply until the adoption and implementation, by the competent bodies of the European Union, the Regulation that is provided for in Article 68 of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 (EU L 309 / 24.11.2009), in accordance with the regulatory procedure set out in that Article.

This Decision shall be published in the Official Gazette.

Athens 01/02/2015

(*This Decision was published in the Government Gazette in January 14th, 2015*)