Technical procedures for the chemical control of plant protection products and evaluation of chemical control results

Unofficial translation in English of the Ministerial Decision num 5878/69892/23-6-2015 (Government Gazette B' 1372)

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

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

Technical procedures for the chemical control of plant protection products and evaluation of chemical control results

Decision Num. 5878/69892/23-6-2015 (Government Gazette B' 1372)

Deputy Minister of Reconstruction of Production, Environment and Energy

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CHAPTER A

OBJECTIVE – SCOPE – COMPETENT AUTHORITIES

Article 1
Objective

1. The purpose of this Decision is to establish the technical procedures for chemical control and evaluation of the results of chemical control of plant protection products
2. The official chemical control of the plant protection products is intended to control the content of active substance or active substances, the other substances contained in the formulation other than the active substance and the physicochemical properties of each formulation in relation to the provisions of marketing authorization or folder data and studies concerning the granting of marketing authorization or of the requirements in the parallel trade permit.
3. In the case of plant protection products, for which authorization has not been granted or the authorization has been revoked or has not received a parallel permit or has not been granted permission for trials, the official chemical control is intended to the qualitative and quantitative evaluation of the contained active substance or active substances.

Article 2
Scope

The provisions of this Decision shall apply to official controls carried out in our country by the competent authorities pursuant to those specified in article 68 of Regulation (EC) Num. 1107/2009 of the European Parliament and of the Council (EE L 309 of 24.11.2009, p. 1), as applicable to the chemical control and evaluation of the results of chemical control of plant protection products.

Article 3
Competent authorities

1. The competent official control laboratories for plant protection products are set in accordance with the provisions of paragraph 3 of Article 3 of law 4036/ 2012 (Government Gazette A8). The competent official control laboratories of plant protection products should be accredited according to ELOT EN ISO/IEC 17025:2005 on 'General requirements for the competence of testing and calibration laboratories' for the scope and implement the accreditation procedures. If necessary, other methods of analysis are developed, validated and applied.
2. Competent authorities to evaluate the results of chemical control of plant protection products are the laboratories carrying out official controls on plant protection products. This assessment includes compliance or not of the test sample or of the consignment with the legislation in force as regards the identity of the test material, packaging, contained chemical substancess and physicochemical properties.
3. If during a counter-analysis, opinions or objections are presented concerning the methods or the results of the chemical analysis, the laboratories performing official controls of plant protection products are responsible for submitting to the Coordinating National Authority (C.N.A.) of paragraph 1 of Article 3 of law 4036/2012 (Government Gazette A8) relevant views on the opinions or objections.

CHAPTER B

CHEMICAL CONTROL PROCEDURES

Article 4
Receipt of samples

1. The competent official chemical control laboratories of plant protection products in receipt of the samples check the following items:
   a. In case the sample refers to a plant protection product for which marketing authorization has been granted, sample identification data are checked and recorded, such as trade name, batch number and a brief description of the sample packaging including its size is given, considering those mentioned in sampling protocol that accompanies the sample.
   b. In case the sample refers to a plant protection product for which authorization has not been granted, spray material or soil or plant protection product packaging material or poisoned bait or any other material, a brief description of the packaging is recorded including the sample of this size, and any available identification, considering those mentioned in sampling protocol that accompanies the sample.
2. The samples of plant protection products which when received by the competent official control laboratories have dents or leaks or they are not accompanied by the necessary official documents are not accepted for laboratory analysis and the competent authority which carried out the sampling is properly informed.
3. The samples of plant protection products for which when received by the competent official control laboratories the expiry date indicated on the packaging or the label has passed or is less than six (6) months from the date of receipt are not accepted for laboratory analysis and the competent authority which carried out the sampling are properly informed.
4. By derogation, samples bearing an expiry date of less than six (6) months from the sampling date may be accepted for analysis, only if required to investigate a written complaint or upon command of C.N.A.
5. Upon receipt, samples that have not been rejected are kept in storage conditions that do not contradict the requirements specified on the packaging or the label. The rejected during receipt samples are returned to the competent authority which carried out the sampling or destroyed.

Article 5
Preparing samples for laboratory analysis

1. The preparation of samples for laboratory analysis is in accordance with the provisions in the manual of test methods of official control laboratories for plant protection products included in their accreditation.
2. The method of preparation of samples in the initial and counter analysis should be the same.

Article 6
FAO Specifications for pesticides

1. The plant protection products available in our country's market are required to comply with the requirements of the Food and Agriculture Organization (FAO). The FAO specifications define the permissible variations in content and physicochemical properties of plant protection products.
2. The FAO specifications for active substances and preparations apply to the manufacturers that have provided data from the evaluation of which emerged the specifications and may not be suitable for products of other manufacturers. Any differentiation in the products of other manufacturer is permitted if it has been submitted in the folder for the authorization for placing on the market and has been evaluated by the competent authority assessing the data.
3. In any case the plant protection products that are available in our country's market are required to comply with the provisions in the current edition of the Manual on the development and use of FAO and WHO specifications on pesticides.

Article 7
Methods of analysis

1. The analytical methods used by the official control laboratories of plant protection products are:
   a. The analytical methods published by CIPAC (Collaborative International Pesticides Analytical Council) or the AOAC (Association of Official Analytical Chemists) or
   b. The analytical methods that are validated according to the document SANCO/3030/99 (1999), which the holder of the marketing authorization shall submit to the competent authority during the approval process or
   c. In the absence of internationally recognized rules or protocols, including those that the European Committee for Standardisation (CEN) has accepted, the relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; or
   d. In the absence of the above methods, the methods comply with the relevant rules established at the national level, developed or recommended by the Central Plant Protection Products Control Laboratory of Greece and validated in accordance with internationally accepted scientific protocols or
   e. In the absence of the above methods, the methods are validated in accordance with internationally accepted scientific protocols.
2. 2. Where there is an urgent need for laboratory analyzes, tests or diagnoses, and there is none of the methods mentioned in paragraph 1, the Central Plant Protection Products Control Laboratory in Greece, can use methods other than those referred to in paragraph 1 of this Article until the validation of appropriate method in accordance with internationally accepted scientific protocols.

Article 8
Chemical test parameters

1. The samples are tested for the identity of the contained active substance or active substances and the concentration or the corresponding concentrations of the active substances of plant protection products.
2. If required, the samples of plant protection products are tested for the type of formulation and / or the physicochemical properties of the preparation.
3. The samples of parallel trade plant protection products, in addition to their compliance with the above paragraphs, are tested for their similarity to the reference samples, to determine the degree of their compliance with the provisions of the parallel trade permit that has been granted, their compliance with EU and national legislation regarding plant protection products parallel trade.
4. The samples of plant protection products that are not unauthorized or samples investigated as counterfeit plant protection products are tested as to the identity of the contained active substance or active substances and the concentration or the corresponding concentrations of the active substances of plant protection products.
5. The test parameters that are investigated in each sample are determined by the official control laboratories of plant protection products, taking into account:
   a. The control requirements set by the purpose of the investigation as stated in the sampling protocol.
   b. The needs for the verification of the results and the evaluation of the compliance of test samples with the relative law in force.
   c. Any special knowledge or specific requirements for a sample as for example if it is an impurity of the technical active substance with a concentration limit or a control of toxicological significant or other impurities.

Article 9
Reference samples

1. Where necessary for the chemical control of plant protection products, a reference sample is used. A reference sample is a sample of a plant protection product which complies with the data laid down at authorisation.
2. Reference samples are needed, mainly, for comparative chromatography methods used for the control of plant protection products for parallel trade, according to the provisions of Article 52 of Regulation (EC) No. 1107/2009.
3. The reference samples may originate:
   a. From the Member State of origin at the request of the C.N.A. and sampling (administrative assistance) the competent authority of the Member State of origin or
   b. From the authorization holder in our country at the request of the C.N.A., referring to two (2) at least batches and accompanied by a written statement of the authorization holder of the marketing authorization that are corresponding to batches marketed in our country or

c. From official sampling from the market referring to two (2) at least batches of the authorized plant protection product.

In any case to characterize a sample as a reference sample, the controlled properties between the two batches should not show any permissible variations both between themselves and the relevant dossier for the authorization that has been granted.

4. In the case where the reference samples are not derived from an official sampling at the member state of origin the following conditions must be cumulatively fulfilled in order to be used in comparative chromatographic methods:

   a. The concentration of the contained active substance or active substances are within the permissible deviation limits for both batches.

   b. The physicochemical properties (at least pH and specific gravity) must be within the permissible deviation limits for both batches.

   c. The comparative chromatograms of the two batches do not show significant quality deviations.

CHAPTER C

EVALUATION OF THE RESULTS

OF THE CHEMICAL CONTROL OF THE PLANT PROTECTION PRODUCTS

Article 10

Decision criteria for the evaluation of chemical control results

1. The decision criteria for the evaluation of the results of chemical control are:

   a. The composition of the formulation which refers to the active substance contained and its concentration, the impurities, the co-formulants and the adjuvants in relation to the composition submitted in the authorization dossier. In case of modification of the guaranteed composition, the composition that were in force during the manufacturing date stated in the formulation label or package is examined. In case of parallel trade plant protection products, the composition of the formulation which refers to the active substance contained and its concentration, the impurities, the co-formulants and the adjuvants in relation to the composition in the Member State of origin, communicated to the C.N.A. for granting the parallel trade permit.

   b. The physicochemical properties, which should comply with the requirements specified in the authorization dossier with permissible deviations as set out in FAO corresponding specifications or in the absence thereof with the limits set out in the present Decision. Since certain physicochemical properties are subject to changes during storage, the results of the storage stability studies carried out by holders of marketing authorization, if available, are incorporated in the evaluation. In the case of parallel trade plant protection products, if the composition of a plant protection product parallel trade differs between the Member State of origin and the Member State of introduction, these differences are taken into particular

consideration when evaluating the physicochemical properties. In cases where the composition of the plant protection product parallel trade and the reference product are identical, the physical, chemical and technical properties of the parallel trade plant protection product and the reference product must not be different.

2. The failure of the sample to comply with the current legislation is documented if any non-permissible deviations exist in one or more criteria than those specified in paragraph 1 of this article.
3. If deemed necessary by the official control laboratory for plant protection products, the final assessment of the conformity of the sample with applicable law is carried out taking into account various parameters and laboratory test data submitted to the C.N.A.

Article 11
Concentration of active substance content

The permissible deviation from the declared content is determined by the provisions of the specifications of the Food and Agriculture Organization (FAO). The tolerances in the values of the FAO specifications refer to average value of the analysis due to the likelihood of discrepancies between batches, which can occur during manufacture, in samples and in analytical assessment. If the active substance content is outside the range of specifications, the controlled batch presents non-permissible deviations.

Article 12
Impurities of foreign substances regarding to manufacturing process

1. Not relevant impurities are not generally acceptable either in the plant protection product or on the technical grade active substance. Regarding a foreign substance present as an impurity of the active substance, a maximum concentration limit of 0.1% is applied generally for the active substance according to the Regulation (EC) num. 544/2011 and the Regulation (EC) num. 283/2013. If this substance consists an impurity classified as relevant to the technical active substance, the defined maximum limit is applied, if available. The intensional addition of a foreign substance in a plant protection product aiming an additional plant protection action is not allowed and the product is not allowed to be marketed. If a foreign substance is proved, or may be an unintentional impurity, the upper limit is set at 0.1%, in relation to the product, above which marketing of the product is not allowed.
2. When an unintentional impurity of a foreign substance in a plant protection product in concentrations of less than 0.1% is proved, a risk assessment to humans and the environment of the impurity is conducted, taking into account:

   a. Whether the impurity is related to an approved active substance in our country.

   b. Any data that are available from the authorization holder on the occurrence of impurities and the analysis that have been conducted.

   c. The use of the plant protection product where the impurity exists and the risk of the substance being detected as an impurity.

   During the evaluation of the analysis results, it is evaluated where feasible:

   a. The possibility of adverse effects on the health of the user of the plant protection product,

b. The possibility of causing any unacceptable concentrations of residues in crops, wherein the formulation is applied,

c. The possibility of contamination of underground and surface water,

d. The possibility of causing phytotoxicity symptoms to crops, wherein the formulation is applied.

3. When evaluating the results of the analysis, a range of tolerance of 15% is taken account for homogeneous formulations (liquid formulations such form SC, SL, EC, etc.) and 25% for heterogeneous formulations (solid formulations, such as form WG, GR, etc.) for dirt and impurities.

4. The test batch is considered to conform to the current legislation only if it is cumulatively fulfilled the conditions of existence of impurity less than 0.1% as regards the formulation and the absence of risk to human and the environment. If the batch in question does not comply with the current legislation, the person responsible for placing on the market must withdraw from the market directly the entire batch or the entire quantity of the formulation that was placed on the market, if it is not possible the precise determination of the contaminated batches.

5. The person responsible for placing on the market of the plant protection product is required to notify the C.N.A. within fifteen (15) days from the date of detection of the impurity, any non-permissible impurities in a formulation that is marketed in our country. The notification is compulsory even if one of the samples tested from the same batch is detected with non-permissible impurities. The notification shall include consideration of the concentration of the impurity in a sufficient number of samples and the risk assessment of the results as indicated in paragraph 3. In the event of failure to notify, the sanctions of paragraph 1 of Article 9 of law 4036 / 2012 (Government Gazette 8) are applied.

Article 13
Type and appearance of the formulation

1. Where the type of the formulation according to GIFAP is investigated due to a claim or observations of the sample, examinations are conducted with proper methods, according to the official control laboratory for plant protection products.

2. The identity of the controlled batch of the plant protection product that is authorized or is evaluated from the results of the examinations Από τα αποτελέσματα των εξετάσεων αξιολογείται η ταυτότητα ή μη της εξεταζόμενης παρτίδας του δείγματος με το φυτοπροστατευτικό προϊόν στο οποίο έχει χορηγηθεί άδεια διάθεσης στην αγορά ή άδεια παραλλήλου εμπορίου.

3. Δεν υπάρχει διαδικασία μέτρησης για τον προσδιορισμό της εμφάνισης του φυτοπροστατευτικού προϊόντος. Ως εκ τούτου, μια οπτική εκτίμηση των κριτηρίων του χρώματος και της φυσικής κατάστασης διενεργείται και μόνο εφόσον οι παρατηρούμενες διαφορές είναι πολύ σαφής (π.χ. στερεά - υγρά , σκόνη – κόκκους, σαφής διαφορές στο χρώμα) τεκμηριώνεται η μη κανονικότητα του δείγματος, ως προς τις προδιαγραφές του FAO. Πιο μικρές διαφορές , για παράδειγμα στο χρώμα (κίτρινο ανοικτό - κίτρινο) δεν είναι επαρκείς αποδείξεις για το χαρακτηρισμό του δείγματος ως μη κανονικό.

4. Η μορφή του φυτοπροστατευτικού προϊόντος πρέπει να είναι σύμφωνη με την οριζόμενη στο φάκελο που αφορά την άδεια διάθεσης στην αγορά που χορηγήθηκε.

5. Τα ίδια κριτήρια εφαρμόζονται και για την αξιολόγηση των αποτελεσμάτων συγκριτικών χημικών ελέγχων μεταξύ δειγμάτων προϊόντων παραλλήλου εμπορίου και δειγμάτων αναφοράς.

Form and appearance of the formulation

1. Where the form at GIFAP formulation put under control of notice or observations on the sample tests carried out using appropriate methods,.

2. The results of the tests evaluated the identity or otherwise of the consignment of the sample with the plant protection product having been granted a marketing authorization or permit parallel trade.

3. No measurement procedure to determine the appearance of the plant protection product. Therefore, a visual assessment of the criteria of color and fitness effected only if the observed differences are very clear (eg, solid - liquid, powder - grain, clear color differences) documented irregularity of the sample, in specification of FAO. Most minor differences, for example in color (yellow light - yellow) is not sufficient evidence to characterize the sample as abnormal.

4. The form of the plant protection product must conform to that specified in the dossier for marketing authorization granted.

5. The same criteria apply to the evaluation of the results of comparative chemical controls between samples parallel trade products and controls.

Article 14
Specific gravity and flash point of the formulation

1. The specific gravity of the plant protection product sample is determined to liquid form preparations. The flash point of the plant protection product sample is determined in formulation types SL, EC, SE, CS, or other if necessary.
2. The result of the laboratory examination is compared primarily with the specifications of FAO, if exists. The sample is considered not complying as regards specific weight if the result of sample measurement differs from the value in the authorization dossier by more than ± 0.05 g/ml (acceptable deviation), if there are no specific FAO specifications.
3. The sample is regarded not complying regarding the flash point, if the result of sample measurement differs from the value in the authorization dossier t by more than ± 3°C, if there are no specific FAO specifications. In this case, the sample solvents should be identified and quantified where possible.
4. The same criteria apply to the evaluation of the results of comparative chemical controls between samples of parallel trade products and reference products.

Article 15
Other physicochemical properties of the formulation

1. Additional physicochemical properties of the sample are examined, if necessary, and the results are evaluated in relation to the corresponding FAO specifications.

2. The criteria applied for the evaluation of the results of comparative chemical controls between samples of parallel trade products and reference products with regard to specific physicochemical properties are:

   a. **Persistent foam**: The amount of persistent foam after one minute is determined in accordance with CIPAC Method MT 47.2. If the reference product has no persistent foam, the test sample of the relevant parallel trade product is considered to conform if it has maximum 5 ml foam. In all other cases, the acceptable deviation between the values of the reference product and the sample of parallel trade is 20 ml maximum. The foam should not exceed the value of 60 ml after one minute.

   b. **pH value**: The evaluation of the pH value of the sample should refer to the data from the storage stability studies on the registered product and the ensuing fluctuation range. The pH value of the sample must not deviate from the pH values before or after storage by more than one unit.

   c. **Suspensibility**: The suspensibility must be at least 60%. If the suspensibility determined is above this minimum requirement, the difference between the parallel trade sample and the reference product must not be more than 20% in all. The measurements may have to be repeated several times so as the laboratory of official controls to be able to estimate the acceptable tolerances.

   d. **Surface tension**: The surface tension values between the parallel trade sample and the reference product must not differ by more than 20%.

Article 16
Comparative chromatography and other screening methods

1. If no deviations occur, or deviations which are still permissible when determining these examination parameters, further studies must be carried out. These examinations should include both comparative chromatographic or other analytical methods (so-called screening methods) as well as examinations of the physicochemical properties. The choice of method is always dependent on the type of formulation and the composition. Preferably, laboratory equipment GC/MS-MS and LC/MS-MS to be used as a screening method. Gas chromatography mass spectrometry (GC/MS-MS) is a suitable method for documentation of volatile compounds (such as solvents) and liquid chromatography mass spectrometry (LC/MS-MS) is particularly suitable for non-volatile compounds. If specific findings are detected in the sample, additional analytical methods such as HPLC/UV or infrared spectroscopy (if a corresponding database is available) can be used if required. If the results of these measurements show deviations from the reference sample, it is concluded that the sample tested is not identical to the reference sample. If necessary, further analytical examinations are carried out to evaluate the results and contents of co-formulants and/or impurities are determined. These examinations can also prove necessary if the technical active substance in the plant protection product to be examined contains a relevant impurity.
2. The method of preparation and the method of analysis of samples of plant protection products and trade parallel samples of the reference product must be the same.
3. If the chromatogram of the examined sample shows additional or less signals than the reference sample or if big differences, at least 20 times are witnessed in the intensity of identical signals, it is assumed that there is no chemical identity and the samples are not identical. Especially in the

case of new signals it is possible that the sample contains further substances which were not assessed with regard to their risk for humans and the environment compared to the plant protection product evaluated in the authorization procedure.

4. However, the composition of the examined sample must be taken into consideration when evaluating the chromatograms and especially:
   a. Solvent mixtures which are fractionally distilled exist and
   b. At high active substance concentrations, where significant concentrations of impurities of the technical active substance exist.
5. If corresponding findings or databases are available, a clear signal detected with one of the screening methods mentioned can be allocated to a defined chemical substance.
6. For other oligomers, above all polymeric co-formulants, additional chromatographic separation techniques are necessary as spectroscopic methods in order to make statements on possible deviations from the reference sample. In these cases the kinds of methods or techniques used depend to a large degree on the specific composition and the substance classes contained in the formulation and defined by the competent official control laboratory for plant protection products. Examples, which in combination with GC/MS and/or LC/MS screening can also lead to a statement on the identity of the sample, are techniques like atom spectroscopy (e.g. ICP), thin-layer chromatography (TLC), gel permeation chromatography (GPD), infrared spectroscopy (IR), nuclear resonance spectroscopy (NMR), and microscopic methods.
7. If special product findings are available, priority can be given to one or more specific analysis methods which serve the same purpose, rather than one or more screening methods. This applies in particular to co-formulants or impurities of the technical active substances in the formulation. To this end, chromatographic techniques such as GC/MS, LC/MS, GC/FID and HPLC/UV are used as well as spectroscopic methods such as IR and NMR or x-ray diffractometry.

Article 17
Co-formulants of the product

1. If comparative chromatographic methods and physical, chemical and technical examinations do not lead to clear results with regard to the identity or non-identity of a plant protection product sample, an analysis of the co-formulants and/or the impurities is necessary for the evaluation of the sample to be able to make a reliable statement on identity. If feasible, quantitative determination of the content of individual co-formulants is carried out.
2. Co-formulants can be classified according to their functionality or chemical structure. Consequently, grouping substances together according to their mol weight into lower molecular, oligomeric and polymeric substances is preferred because this classification means that the time needed for analysis for the purpose of identification and quantification increases as the molecular weight increases. If suitable comparative or reference materials for quantification are missing for the quantitative determination of the co-formulants, only qualitative analysis of them is carried out.
3. Typical lower molecular co-formulants include solvents, anti-freezing agents, oils, inorganic substances, alkylaryl sulfonate, pigments, stabilisers, preservative agents and water.

4. Formaldehyde and naphthalene are lower molecular substances which, due to their toxicological assessment, are of special interest in the process of identifying plant protection product samples. The majority of lower molecular substances can be determined clearly using chromatographic techniques such as GC and HPLC in conjunction with corresponding detectors. Detectors must be selected depending on the substance to be analyzed.
5. Surfactants belong to oligomeric co-formulants. Ειδικές τεχνικές ανάλυσης εφαρμόζονται, εφόσον είναι διαθέσιμες, για τις δύο αυτές ομάδες. Adhesives, organic and inorganic thickeners and resins are typical polymeric co-formulants. Special analysis techniques are applied, if are available for these both groups.
6. Special attention should be paid to examining undesired or forbidden co-formulants, which can be done at the same time as other measurements are taken.
7. The permitted range of quantifiable co-formulants is seen as being double the range stated in the FAO/WHO Manual for active substances, because the contents of the co-formulants vary more for manufacturing reasons than those of the active substances, and the analytics can be more difficult. The tolerable deviations between the declared and the actual co-formulant content in a plant protection product are:

Declared content in g/kg or g/l at 20±2°C	Admissible deviation from the declared content
Up to 25 (corresponds to content up to 2,5%)	±15% for homogeneous formulations (EC, SC, SL etc.) or ±25% for heterogeneous formulations (GR, WG, etc.)
More than 25 up to 100 (corresponds to content more than 2,5% to 10%)	±10%
More than 100 to 250 (corresponds to content more than 10% to 25%)	±6%
More than 250 to 500 (corresponds to content more than 25% to 50%)	±5%
More than 500 (corresponds to content more than 50%)	±25 g/kg ή g/l

CHAPTER D

OTHER MATTERS

REGARDING CHEMICAL CONTROL OF PLANT PROTECTION PRODUCTS

Article 18
Other matters regarding Chemical Control of Plant Protection Products

1. The counter analysis is carried out by the same methods of the initial analysis. By derogation, it is allowed to perform additional or different methods than those of the initial analysis provided that:
   a. The provisions of article 7 of the present Decision are met.
   b. They are requested by the expert- representative of the opposing and evaluated by the official control laboratory that is feasible and practical in time to carry out and give supporting evidence to assess the results.
   c. They are evaluated by the official control laboratory as more suitable methods than those applied for the initial analysis of the sample.
2. Samples which were in normal condition when received but up to the laboratory analysis they leak, are analyzed only if deemed feasible by the laboratory. In this case the official control laboratory records in the analysis report in addition to other elements and time and sample storage conditions.
3. Additional evaluation of the results of the chemical control of plant protection products may be performed:
   a. From the official control laboratory itself, if taken note further data or information that alter the initial evaluation and
   b. At the request of the C.N.A., which is appropriately justified.
4. The used analytical standards should be certified reference materials (CRMs), manufactured and certified in accordance with ISO Guide 34: 2009 and ISO/IEC 17025: 2005 and accompanied by a certificate of analysis and certificate of origin. If such standards are not commercially available, it is possible to supply other analytical standards, accompanied by a certificate from appropriately accredited laboratory or any other internationally recognized quality system.

CHAPTER E
FINAL PROVISIONS

Article 19
Entry into force

This Decision shall be effective from the date of publication in the Government Gazette.
This Decision shall apply to samples taken by the competent authorities after the entry into force of this Decision.
This Decision shall be published in the Official Gazette.

(*This Decision was published in the Government Gazette in July 3rd, 2015*)