

1. Chemical Control of Plant Protection Products (PPPs)

For the Chemical Control of PPPs, there aren't any additional national requirements, beyond those required for inclusion of the active substance in Annex I to Regulation (EC) No. 1107/09.

2. Biological control of Plant Protection Products (PPPs)

The legislation in force, enacted by the European Commission and the National Coordinating Authority, as well as the available General and Specific EPPO Standards should be taken into consideration for the evaluation of the biological data of PPPs in accordance with the Regulation (EC) No 1107/2009.

Specifically, regarding the extrapolation of efficacy and phytotoxicity data, the relevant documents to be taken into consideration are a) the EPPO Standard PP1/257 along with the EPPO extrapolation tables and b) the document of the European Commission *Sanco Technical Report: Proposals for extending and harmonizing efficacy and crop safety extrapolations to reduce the need for efficacy trials on minor crops* (DG SANCO/D3/SI2.395857).

This document sets the National Requirements concerning the Biological Control of PPPs, according to which, the submission of experimental data from Greek trials is considered necessary. In particular, efficacy or/and phytotoxicity trials carried out in Greece, are required in the following cases:

I) Differentiations in national agricultural practices or/and soil-climatic conditions, affecting the biology of the target organisms and consequently the effectiveness of the PPP under evaluation. These cases include national crops of major importance (e.g. cotton, olive trees) or specific crops of minor importance (e.g. pistachio trees, saffron/crocus), as referred in Appendix I.

In the specific cases of Appendix I the following data set must be submitted:

- a) 2-4 efficacy/phytotoxicity trials for uses (crops and pests) of major importance.
- b) 1-2 efficacy/phytotoxicity trials for uses (crops or/and pests) of minor importance.

Specifically, as regards PPPs intended for the control of the olive fruit fly by means of bait application(s) or mass trapping, the methodology to be followed in the Greek efficacy trials is defined by the Specific EPPO Standard under development and the relevant document in Appendix II in case of bait application, and the National Experimental Protocols of Hellenic Ministry of Rural Development and Food (MRDF) in case of mass trapping.

Additionally, in case of PPPs intended for use in crops that include cultivars of national importance, as those specified in Appendix III, at least 2 Greek phytotoxicity trials must be submitted to support the safe use of the PPP under evaluation in at least one of the listed cultivars for each crop.

II) Compatibility of the PPP under evaluation with other registered products in spraying programs. In case that tank mixing with another PPP is requested in the proposed label of a PPP, the biological compatibility of these products must be demonstrated with at least 1 trial in representative major/minor crops in the absence of pest/pathogen (non-replicated trials can also be accepted). In case where a PPP is intended for use in specific spraying programs, the efficacy must be demonstrated considering the Greek agricultural practices.

III) Integrated Plant Protection Programs (IPM). In case of specific IPM recommendations in the proposed label of a PPP or in case of crops in which indigenous natural enemies are established or beneficial arthropods have been released, experimental/bibliographic data demonstrating the absence of negative effects on these beneficial arthropods as well as recommendations for the management of potential risk must be submitted.

IV) Crops/cultivars of national importance [e.g. table grapes (var.: Soultanina), olive trees (var.: Koroneiki, Kalamon, Konservolia), peaches, industrial tomato etc.] **in order to support the absence of negative effects of the PPP under evaluation on the quality/sensory characteristics of fresh or/and processed plants and plant products.** In this case, data following the General (PP1/135, PP1/242, PP1/243 and PP1/268) and Specific EPPO Standards must be submitted. If such data are not available, a scientifically justified statement based on the physicochemical properties of the product, the residue studies etc. must be submitted.

3. Toxicological Evaluation and Risk Assessment for Humans

For the operator, bystander, worker and resident Exposure Assessment, it is strongly recommended to follow the EFSA's «Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents» (EFSA Journal 2010;8(2):1501. [65 pp.]. doi:10.2903/j.efsa.2010.1501). In addition, the following approaches are acceptable:

Operator exposure – Field application	- UK predictive operator exposure model (UKPOEM, revised UK MAFF, 2003) - German BBA model (Lundehn <i>et al.</i>, 1992, or the revised PSD version) For the intended uses not covered by the UKPOEM and the German models, other calculations or exposure data must be submitted, to be evaluated on a case-by-case basis.
Operator exposure – indoor applicaton	- DUTCH Greenhouse model: Van Golstein Brouwers Y.G.C., Marquart J., Van Hemmen J.J. (1996) Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120 - EUROPOEM data: EUROPOEM Operator Exposure data Base; EUROPOEM II Project FAIR3-CT96-1406, 2002 - Combination of different scenarios from the available models, e.g. mixing/loading: use the tractor scenario (boom sprayer) data available in German BBA model & UK POEM application: use the handheld equipment scenario data available in German BBA model (high crop) or UK POEM (low crop) - Field or greenhouse studies conducted with the same or similar product and the same application method, e.g. Mich, G. (1996): Operator Exposure in Greenhouses During Practical Use of Plant Protection Products; Project EF 94-02-03; June 6, 1996; ECON GmbH Ingelheim.
Worker, bystander and resident exposure	Calculations based on acceptable data (published or not) concerning the spray drift and the dislodgeable foliar residues. The submitted studies must be followed by complete justification of all the assumptions that have been made. As far as the bystander and resident exposure is concerned, the approach described by the «Chemicals Regulation Directorate (UK authorities) guidance» or the use of data derived from Martin <i>et al</i> (2008) are acceptable after appropriate justification.

4. Residues Control of Plant Protection Products (PPPs)

For the Evaluation of Residues in or on treated products, food and feed, in addition to the requirements mentioned in Regulation 544/2011 and in the relevant Guidance Documents, the following national requirements apply:

- 1) Grapes (Table and wine grapes): In cases where this is required (in accordance with Annex Point 6.5 of Regulation 544/2011), processing studies are necessary to be submitted on the effects on the nature of residues in raisins produced from the processing of grapes, in order to estimate the corresponding transfer factors from grapes to raisins.
- 2) Cotton: In cases where this is required (in accordance with Annex Point 6.5 of Regulation 544/2011), processing studies are necessary to be submitted on the effects on the nature of residues during processing of cotton seed for production of cotton oil and cotton cake, in order to estimate the corresponding transfer factors from cotton seed to cotton oil and cotton cake.
- 3) Vine leaves: Supervised residue trials are necessary to be submitted in accordance to the requirements set for minor crops supporting the critical Good Agricultural Practice (cGAP) which is related to vine leaves.
- 4) Finally, Regulation 396(2005) provides for the establishment of the Maximum Residue levels (MRLs) for feed for which the determination of data requirements is pending at EU level.

5. *Fate and behavior in the environment*

There are no particular specific national requirements for this section, other than the standard data package assessed for active substance Annex I inclusion. This should include:

- For PEC groundwater calculations, using both FOCUS PELMO and PEARL tools, 5 out of 9 scenarios should be < 0.1 µg/L including Piacenza, Porto, Sevilla και Thiva.
- R3, R4, D4 and D6 FOCUS SW scenarios are more representative for the Hellenic conditions.
- Registered active substances with high probability of leaching to ground waters, due to increased soil mobility and / or the high half-life in soil (soil DT₅₀) and applied to vulnerable soils, will be included in national monitoring programs in cooperation with competent bodies. The results of these programs may cause changes in the registration of the products containing these active substances

6. Ecotoxicology

Risk assessment for non target organisms at Hellenic National level is performed according to the relevant Directives and/or to relevant EFSA Opinions which are currently into force

Birds and mammals

The risk assessment (RA) should be performed according to:

- EFSA, 2009 (Risk Assessment for Birds and Mammals, EFSA Journal 2009; 7(12): 1438), for applications submitted after the 14th of June 2011
- SANCO, 2000 (SANCO/4145/2000, 25 September 2002) for applications submitted before the 14th of June 2011

General issues

- For more than one applications, MAF (multiple application factor) may take the value of 1 (food items: seeds, plant matter, arthropods) when application interval is sufficiently high. This will be examined on a case by case basis
- Vole scenario issues: Acceptable risk to mice and to lagomorphs for the species-relevant BBCH is of high importance. Regarding voles, risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons
 - *High fecundity and population recuperation of the vole*
 - *Primary source of food outside crops fields for the vole*
 - *Necessity of population control measures since the vole is considered a crop pest when high population levels are reached*
 - *Other agricultural techniques being also means of population control*

Refinement of RUD values (plant matter, arthropods)

- An extended database in EFSA GD, 2009 exists for RUD for monocotyledonous plants, thus its replacement with other experimental values is not advised.
- RUD replacement by experimental values should be supported with at least two trials of which at least one should have been performed in South Zone

- Bridging RUD values for plant matter between different crops is acceptable according to SANCO 7525/VI/95-rev.9, March 2011)

The following remarks should also been taken into account:

- Use of Body Burden Model for higher Tier assessment is acceptable
- Use of Population Modeling for higher Tier assessment is not acceptable unless accompanied by relevant Expert Opinion position paper

Acute Toxicity

- Use of geomean is acceptable only for acute toxicity and only across different species of birds or mammals. When more than one value are available for the same species, the geomean of these values may be used as an acute toxicity endpoint for this species
- When reassessed RUD and PT values are utilized, the 90th percentile of these values will be used if the studies submitted are considered reliable. When the studies are not considered reliable enough, values are to be finalized on a case by case basis
- For substances and products of high acute toxicity, reassessment of PT, PD and use of mixed diet (omnivorous) scenario is not advised, unless further and sufficient justification is provided. In these cases, the worst case scenario (highest ETE) is considered

Chronic Toxicity

- When reassessed RUD and PT values are utilized, the 50th percentile (mean value) of these values will be used if the studies submitted are considered reliable. When the studies are not considered reliable enough, values are to be finalized on a case by case basis
- Refined PT values <1 but also >0.5 are generally acceptable for all crops
- Refined chronic toxicity endpoints may be represented not only by the lowest toxicological endpoint (Section 3) but also by the ecotoxicologically relevant endpoint (see also 5.7, SANCO/4145/2000, 25 September 2002).

Focal species

- In case of refined RA by using focal species, its representativeness for the Hellenic conditions should be justified according to GD EFSA, 2009 §6.1.3.2.

- Table I includes focal species which are not considered acceptable for various crops for Hellenic situations (for spring and summer period), unless additional supportive data are provided by the applicant which unequivocally show the presence of these species in relevant Hellenic crop fields. Bridging data between species of Table I and focal species representative of Hellenic conditions are also acceptable. Table I will be updated according to new available knowledge.
- Table II contains focal species of birds and mammals which are acceptable for various crops and Hellenic national level. Table II will be updated according to new available knowledge.

Aquatic organisms

Water bodies protected:

- All water bodies except those which fall dry over longer periods in the year. The routes of exposure for the aquatic organisms should be reported.

The RA should be performed according to PEC_{sw} initial values. The use of PEC_{sw} two values, the presence of the sediment in trials and the reduction of uncertainty should be justified according to (EFSA J., 2005, 178, 1-45 and EFSA J., 2005, 301, 1-45)). Proposals from the E-link project are accepted. Evaluation of RA for all scenarios Focus SW steps 3 and 4 should be performed. For the final decision, emphasis should be given on R3, R4, D4 and D6 scenarios.

Risk mitigation measures proposed:

- Buffer zones from surface waters: As buffer zone is defined the distance between the limit of the cultivated field/ orchard and the surface waters.
- For approval of the formulation, the maximum buffer zone proposed is **40** m for orchards, vines and leafy crops and **20** m field crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2.
- FOCUS modeling (step 4) is accepted and the FOCUS Landscape and mitigation factors in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage.

Bees

For insecticides in seed treatment applications the RA through the dust should be addressed.

Non target arthropods

Risk mitigation measures proposed:

- Use of not sprayed buffer zones: As buffer zone is defined the safety distance between the limit of the cultivated field (fences included) and the inner side of the cultivated field/ orchard. Buffer zone distance needed to ensure acceptable risk to non-agricultural land is **10** m for orchards and vines and **5** m for field crops and leafy crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2.

Soil organisms

There are no additional national requirements, other than the standard data package assessed for active substance for the Annex I inclusion.

Non target plants

Risk mitigation measures proposed:

- Use of no sprayed buffer zones: As buffer zone is defined the safety distance between the limit of the cultivated field (fences included) and the inner side of the cultivated field/ orchard. Buffer zone distance needed to ensure acceptable risk to non-agricultural land is **10** m for all crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2.

General

The submitted folder should include:

- The GAP, which should include all the relevant details, including the growth stages (BBCH code), application rate (in Kg or gr a.s./ha) and intervals, remarks.
- The original reports from relevant trials which have been used for the support of RA for non-target organisms, if these have not been evaluated during the procedure for the inclusion of the

a.s. in Annexe I. These should be given preferably in electronic form, and if not available in such, as a hard copy.

- The representativeness for the Hellenic conditions of the data provided in order to support the risk assessment should be clarified by the applicant (for the relevant intended uses and growth stages).
- Information on the necessity of performing additional studies with the formulation or the metabolites, according to aforementioned guidelines (GD on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Dir 91/414/EEC, SANCO/221/2000 –rev.10, 25 February 2003).
- For the case of mixtures of substances, the potential synergistic effect should be clarified by the applicant (e.g. birds and mammals).
- Update table with the studies using the formulations (references relied on, Annex III).

APPENDIX I

PESTS		
Crop	Pest	Pest-scientific name
Olive tree	Olive fruit fly ^{1, 2}	<i>Bactrocera oleae</i>
Pistachio tree	Pistachio seed wasp ³	<i>Eurytoma plotnikovi</i>
Cotton	Cotton bollworm ²	<i>Heliothis armigera</i>
Vegetables	Root-knot nematodes ^{4, 5}	<i>Meloidogyne</i> spp.
Saffron/crocus	Experimental efficacy data to support the intended uses are required.	
DISEASES		
Crop	Disease	Causal agent-scientific name
Pistachio tree	<i>Botryosphaeria</i> canker ³	<i>Botryosphaeria dothidea</i>
Saffron/crocus	Experimental efficacy data to support the intended uses are required.	
MICROBIAL PESTICIDES		
Experimental efficacy data to support the use on representative crops (nationally important) are required.		
SUBSTANCES CAUSING INDUCTION OF PLANT RESISTANCE (Elicitors)		
Experimental efficacy data to support the use on representative crops (nationally important) are required.		
¹ Insect control using bait application(s) or mass trapping		
² Major pest on major crop		
³ Major pest on minor crop		
⁴ Major pest on major or minor crop		
⁵ Estimation of the level of the nematode population in soil is required in the experimental data set.		

APPENDIX II

Concerning efficacy evaluation trials of PPPs intended for the control of the olive fruit fly using ground spraying bait applications, the following are proposed, supplementary to the EPPO Standard:

In point 1.3 Design and lay-out of the trial, the plot size recommended by EPPO in cases of high population pressure, i.e. 5 ha (1.000 trees), must be followed for safer conclusions due to the behavior of this insect (biology, mobility etc.). In addition, in this case, untreated control is not required due to the large size of plots. Regarding the number of trials, the EPPO Standards PP1/181 and PP1/226 should be taken into account, thus the trials should be done across a range of climatic and environmental conditions likely to be encountered, and over at least two years. In case of olive trees, due to alternate bearing, trials carried out at the same year but in different areas can be accepted, provided that they satisfy the prerequisites of a large fruit bearing and high level of olive fruit fly population.

In point 2.3.1 Type of application, taking into account the total large size of the experimental olive orchard, the spraying of the entire experimental area should be completed in five (5) days *at the latest*. In addition, marking of the treated trees is recommended.

In point 2.3.3 Time and frequency of application, following the EPPO Standard “*Bactrocera oleae* – bait application”, which mentions that, where available, locally established thresholds, monitoring practices and warning systems should be used, it is noted that monitoring of the olive fruit fly population in bait applications in Greece is carried out with Mc Phail traps (1/500-600 trees or 2/500-600 trees in areas with high population pressure); the applications is foreseen to be carried out based on the number of captured adults in Mc Phail traps as well as on the application thresholds existing in each specific area, provided that the environmental conditions are suitable (temperature < 28oC, wind speed < 4 bf). Especially for the first application, the following criteria should also be taken into account: reproductively mature females > 5%, ratio of females to males > 1, the beginning of hardening of the olive fruit kernel.

In point 3.2.1 Type (of assessment),

Large plots (Sampling olive fruit to assess infestation), the sampling is recommended to be carried out at the center of each plot and the sampled trees to be marked. Double sample size (20 olive fruits per tree) is recommended for samplings in September-November.

During these samplings, both active (live) infestation (eggs, live L1-3, nymphs and exit holes) and dead infestation (non hatched eggs, infertile oviposition stings, suberized mines and dead L1-3) are estimated. The sum of active and dead infestation is the total infestation.

In point 3.2.2 Time and frequency, the olive fruit infestation is estimated by five samplings of the tree canopy during the first 10 days of July, August, September, October and November.

In point 3.5 Quantitative and qualitative recording of yield, the estimation of yield decrease due to the olive fruit fly infestation is an additional indication of the efficacy of the test product and it can be performed as follows: The initial yield is estimated by an initial sampling at the end of June-beginning of July. Thereafter monthly samplings of fallen fruits are conducted from four random trees located at the center of each plot from August until the beginning of harvest.

APPENDIX III

Crop	Cultivars ¹
Olive trees	Kalamon, Koroneiki
Pear trees	Krystalli, Kontoula
Vine ²	Soultanina, Corinthian raisin
¹ FEK 468/2011, regarding determination of promoted species, tree crop cultivars and other activities	
² Decision of MRDF (protocol number: 247771, 04/03/2010), concerning the classification of vine cultivars (FEK 381/B/6-4-2010)	

TABLE I

Birds and mammals species **NOT** accepted as “focal species” for all the crops in Hellas **for spring and summer**.

Hellenic bird and mammal name	English bird and mammal name	Scientific bird and mammal name	Source
Birds			
Σταρήθρα	Skylark	<i>Alauda arvensis</i>	1. Status in EU countries according to Birdlife International/European Bird Census Council 2000. 2. Killian Mullarney et al. 1999.
Mammals			
Αρουραίος της Μεσογείου	Common vole	<i>Microtus arvalis</i>	1. Zima 1999 2. Robert Luttic 2008
Αρουραίος	Mediterranean pine vole	<i>Microtus duodecimcostatus</i>	1. Robert Luttic 2008
Αρουραίος	Savi's Pine Vole	<i>Microtus savii</i>	1. Robert Luttic 2008
Αρουραίος	Field vole	<i>Microtus agrestis</i>	1. Zima 1999 2. Robert Luttic 2008
Μυγαλίδα	Common shrew	<i>Sorex araneus</i>	1.Anděra 1999, Hausser 1999 2. Robert Luttic 2008
Μυγαλίδα	Greater white toothed shrew	<i>Crocidura russula</i>	1. Robert Luttic 2008
Ποντίκι	Algerian Mouse, Western Mediterranean Mouse	<i>Mus spretus</i>	IUCN Red List of Threatened Species http://www.iucnredlist.org

Anděra, M. 1999. *Sorex araneus* Linnaeus, 1758. pp. 42-43. In: Mitchell-Jones, A. J.; Amori, G.; Bogdanowicz, W.; Krystufek, B.; Reijnders, P. J. H.; Spitzenberger, F.; Stubbe, M.; Thissen, J. B. M.; Vohralik, V. & Zima, J. (Eds.). The atlas of European mammals. Academic Press, London.

Killian Mullarney, Lars Svansson, Dan Zetterstrom and Peter J.Grand, 1999. Τα πουλιά της Ελλάδος, της Κύπρου και της Ευρώπης. (2007, Εκδοση Ελληνική Ορνιθολογική Εταιρεία).

Robert Luttic, 2008. Oral Presentation AgChem Forum (Berlin) 2008.

Zima, J. 1999. *Microtus arvalis* (Pallas, 1778). Pp. 228-229. In: Mitchell-Jones, A. J.; Amori, G.; Bogdanowicz, W.; Krystufek, B.; Reijnders, P. J. H.; Spitzenberger, F.; Stubbe, M.; Thissen, J. B. M.; Vohralik, V. & Zima, J. (Eds.). The atlas of European mammals. Academic Press, London

TABLE II

Birds and mammals species accepted as “focal species” for all the crops in Hellas.

Crop scenario	Hellenic bird and mammal name	English bird and mammal name	Scientific bird and mammal name	Source
Birds				
<i>Arable crops</i> (all BBCH levels) Spring (4 th -5 th yearly month)	Τσιφτάς	Corn bunting	<i>Miliaria calandra</i>	Foudoulakis et al., 2011
<i>Arable crops</i> (all BBCH levels) Summer (6 th -9 th yearly month)	Κατσουλιέρης Σπιτοσπουργίτης	Crested lark House sparrow	<i>Galerida cristata</i> <i>Passer domesticus</i>	Foudoulakis et al., 2011 Foudoulakis, 2012
<i>Winter cereals</i> BBCH <13 Winter (11 th -12 th yearly month)	Σταρήθρα Τσιφτάς	Skylark Corn bunting	<i>Alauda arvensis</i> <i>Miliaria calandra</i>	Foudoulakis et al., 2011
<i>Winter cereals</i> BBCH=30 Spring (3 rd yearly month; before arrival of migratory birds)	Λιβαδικελάδα Σταρήθρα	Meadow pipit Skylark	<i>Anthus pratensis</i> <i>Alauda arvensis</i>	Foudoulakis et al., 2011

Foudoulakis Manousos, Tzakos Dimitrios, Kostouros Nikolaos and Kaniastas Evaggelos, 2011. Hellenic scenarios for bird focal species: the case of the cotton fields. SETAC Europe 21st Annual Meeting, Milan, Italy.

Foudoulakis Manousos, 2012. Farmland bird communities vs crop specific focal species in a Mediterranean landscape: The case of arable crops in Hellas. 5th SETAC World Congress, Berlin, Germany.