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EXPLANATORY NOTE

COMPREHENSIVE INFORMATION ON MINOR USES PROCEDURES ACCORDING TO REGULATION (EC) No 1107/2009

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This document has been developed and peer-reviewed in co-operation with selected experts from several EU Member States (Belgium, Germany, Denmark, France, Hungary, Italy, Ireland, Lithuania, the Netherlands, Spain, and Sweden), the United Kingdom, Norway, Switzerland, and with support of DG SANTE's Legal Service.

The views expressed in this informative Explanatory Note on Minor Uses are those of the author(s).

With this pan-European team, it is hoped that the Explanatory Note on Minor Uses will be applicable and valuable on a European level.

Implementation schedule:

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The Note does not intend to produce legally binding effects and by its nature, the designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the MUCF concerning any measures taken by an EU Member State, the United Kingdom, Norway, and Switzerland.
The Note can be taken into consideration for applications submitted from 2022-04-12 onwards.

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Definitions, abbreviations, and terminology

In the framework of this Note, the following definitions apply:

Agronomic techniques are measures that can be used for the prevention and suppression of harmful organisms and are among other options:

- crop rotation,
- use of adequate cultivation techniques (e.g., stale seedbed technique, sowing dates and densities, under-sowing, conservation tillage, pruning and direct sowing),
- use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material,
- use of balanced fertilisation, liming and irrigation/drainage practices,
- preventing the spreading of harmful organisms by hygiene measures (e.g., by regular cleansing of machinery and equipment),
- protection and enhancement of important beneficial organisms, e.g., by adequate plant protection measures or the utilisation of ecological infrastructures inside and outside production sites.

(According to Annex III of Directive 2009/128/EC)[3]

The term **botanical active substance** or 'plant extract, botanicals' covers a highly heterogeneous group of substances ranging from simple plant powders to unprocessed and processed plant extracts. Furthermore, botanicals or plant extracts may be highly refined (e.g., one single active substance) or represent a complex mixture of components of which all or only some are biologically active.
(See Guidance Document on Botanical Active Substances and Plant Protection Products; SANCO/11470/2012 - rev. 8, 20 March 2014)[4]

Category 4 studies: According to the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009[5] 'category 4 studies' are data that are directly related to new guidance in place at the time of submission or to a new/revised endpoint decided at the time of the renewal of the approval of the active substance (endpoints as listed in the supporting information to the EFSA conclusions) and for which the time is too short from the publication of the EFSA conclusion to produce the requested study.

CIRCABC is a collaborative platform of the European Union, which offers easy distribution and management of documents (e.g., draft Registration Reports); distribution and management of documents on CIRCABC is restricted to competent authorities: https://circabc.europa.eu/ui/welcome

The MUCF **Commodity Expert Groups (CEG)** work to close, as a joint effort, minor use gaps at the EU level by finding chemical or non-chemical solutions within an Integrated Pest Management (IPM) framework. A link to the CEGs Terms of Reference is provided in Chapter 9.

Under the European Economic Area Agreement[6], three of the four EFTA states: Iceland, Liechtenstein and Norway, have implemented Regulation (EC) No 1107/2009[7]. Norway and Iceland are part of Zone A – North, and Liechtenstein is part of Zone B – Central. They can be part of the zonal system and operate as an EU Member State regarding the evaluation and assessment of plant protection products[8]. Switzerland is not a part

[3] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0128

[4] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_botanicals-rev-8.pdf

[5] https://ec.europa.eu/food/system/files/2016-11/pesticides_aas_guidance_renewal_1107-2009.pdf

[6] https://www.efta.int/eea/eea-agreement

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0675&from=EN

[8] With the exception of Liechtenstein.

of the European Economic Area Agreement, and it has not implemented Regulation (EC) No 1107/2009. However, the Swiss authorisation procedures are aligned with the EU procedures, and Switzerland participates actively in the MUCF.

EPPO Codes are computer codes developed for plants and pests (including pathogens) and uses of plant protection products in agriculture and plant protection. This harmonised coding system aims to facilitate the management of plant, pest and PPP usage names in computerised databases and data exchange between IT systems. EPPO Codes are available in the EPPO Global Database (https://gd.eppo.int/PPPUse/).

EUMUDA is the European Minor Uses Database. It is an essential tool to collect minor use needs from EU Member States, the United Kingdom, Norway and Switzerland, to follow-up on these needs, manage all MUCF collaborative projects, and provide additional information on minor uses in Europe (www.eumuda.eu). According to Article 51 (8) of Regulation (EC) No 1107/2009), EU Member States shall establish and regularly update a list of minor uses.

EU Pesticides Database contains information on the approval status of active substances according to Regulation (EC) No 1107/2009, and Pesticides EU-MRLs according to Regulation (EC) No 396/2005Error! Hyperlink reference not valid. (https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en)

Homologa is a Global Crop Protection Database about plant protection products and their Maximum Residue Limits (MRLs) (https://v5.homologa.com/en/).

The MUCF **Horizontal Expert Group (HEG)** discusses general issues related to minor uses, as identified by the MUCF Commodity Expert Groups, the Minor Uses Steering Group or its members, aiming at harmonised procedures and at creating a level playing field among the EU Member States, UK, Norway and Switzerland. A link to the HEG's Terms of Reference is provided in Chapter 9.

Interregional Research Project No. 4 (IR-4) is a programme of minor uses in the USA, federally funded and established in 1963. IR-4 conducts the research necessary for obtaining registrations of pest control agents needed to grow minor crops. The Mission Statement for the IR-4 Project is to 'Facilitate Registration of Sustainable Pest Management Technology for Specialty Crops and Minor Uses' (https://www.ir4project.org/).

The abbreviation **IPM** stands for Integrated Pest Management. Additional information on IPM is given in Appendix II.
(According to Article 3(6) of Directive 2009/128/EC)[9]

A **micro-organism** is any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replicating or transferring genetic material.
(*According to Article 3(15) of Regulation (EC) No 1107/2009)*[10]

A **minor use need** is an identified plant protection problem on minor/speciality/niche crops or against plant protection problems that are not routinely encountered on major crops. These needs are compiled in a 'minor use needs table' in EUMUDA.

The **MUCF**, established in 2015 and based in Paris (France), is the European Minor Uses Coordination Facility (https://www.minoruses.eu/) and is hosted by the European and Mediterranean Plant Protection Organization (EPPO).

National Minor Uses Contact Points of the MUCF are appointed by their EU Member States or the UK, Norway, and Switzerland. The responsibility of the National Minor Uses Contact Point is related to:

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0128-20091125&from=EN

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN

- The appointment of experts to Commodity Expert Groups (CEG) and the Horizontal Expert Group (HEG).
- Adding information to the European Minor Uses Database (EUMUDA).
- Setting priorities in the 'table of needs'.
- Replying to requests from the European Minor Uses Coordination Facility (MUCF).
- The coordination of responses within their EU Member State or the UK, Norway or Switzerland.

Non-chemical methods are alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC, or physical, mechanical or biological pest control methods.
(according to Article 3(8) of Directive 2009/128/EC)[11]

The **Pest Management Centre (PMC)**, established in 2003, is the Canadian equivalent of the USA IR-4 programme. The PMC is a partnership between the grower community, federal and provincial governments, and the crop protection industry to improve Canadian growers' access to new and reduced-risk tools and approaches for crop protection (https://agriculture.canada.ca/en).

PPPAMS is the EU Plant Protection Products Application Management System. The PPPAMS is developed by the European Commission to enable industry users to create applications for PPPs and submit these to EU countries for evaluation. PPPAMS can currently be used for the following applications: 'First authorisation of a PPP', 'Mutual Recognition' and 'Emergency authorisations'. In the future the following applications will also be possible with PPPAMS: 'Amendment or withdrawal of an existing authorisation', 'Renewal of authorisation', 'Application for Minor Uses' and 'Parallel trade permits' (Information based on the situation on 2022-02-14). EU countries then manage these applications within the system, concluding with authorisation of the PPP or refusal of the application (https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en).

A **MUCF project** is a minor use need with agreed on actions to be taken by a Commodity Expert Group to solve this minor use need. Projects are entered in EUMUDA (European Minor Uses Database).

A **MUCF project plan** is a document that contains some basic information on the minor use need, the possible solution, the project, the project leader and parties involved to clarify the role of the parties participating /involved in the project.

A **MUCF project leader** will coordinate the work on a project and be responsible for the communication between the pesticide company/registration holder and the participating EU Member States, the UK, Norway, Switzerland and stakeholders.

MUCF project members support the work of the project leader according to the arrangements laid down in the project plan.

Public interest reflects the national view on the usefulness of granting authorisation and is defined by an individual EU Member State.

SCoPAFF is the Standing Committee on Plants, Animals, Food and Feed. It plays a crucial role in ensuring that Union measures on food and feed safety, animal health & welfare, and plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt.

(https://ec.europa.eu/food/horizontal-topics/committees/paff-committees_en)

Semiochemical active substances refer to active substances emitted by plants, animals, and other organisms and are used by these organisms for communication.

[11] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0128

(see Guidance Document on Semiochemical Active Substances and Plant Protection Products; SANTE/12815/2014 rev. 5.2, May 2016)[12]

Zones (Definition of different zonal systems):

Definition of **EPPO climatic zones** for performing efficacy trials. For the efficacy evaluation of plant protection products Europe has been divided by the European and Mediterranean Plant Protection Organization (EPPO) into 4 EPPO climatic zones. These EPPO zones consider different agro-climatic subareas for the purpose of comparability of efficacy evaluation trials on PPPs. These zones are the Mediterranean zone, the Maritime zone, the North-East zone and the South-East zone (https://pp1.eppo.int/standards/PP1-241-2).

Definition of **regulatory zones** for the authorisation of plant protection products as referred to in Article 3(17) of Regulation (EC) No 1107/2009 (*According to Annex I of Regulation (EC) No 1107/2009*).

- Zone A - North

The following Member States belong to this zone: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden.

- Zone B - Central

The following Member States belong to this zone: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom.

- Zone C - South

The following Member States belong to this zone: Bulgaria, Croatia, Greece, Spain, France, Italy, Cyprus, Malta, Portugal.

Definition of **residue zones** for performing residue field trials. Residue field trials should represent the zones where an EU authorisation is granted or envisaged. Concerning the pesticide residue assessment, the EU is divided into the two geographical zones that are considered to represent comparable conditions, Northern and Central Europe (NEU) and Southern Europe and the Mediterranean (SEU).

- Northern and Central Europe (NEU)

The following Member States belong to this zone: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France*, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, and Sweden. As part of the Northern Zone under Regulation (EC) No 1107/2009, Iceland, Liechtenstein and Norway are considered part of the NEU under the EEA Agreement.

- Southern Europe and the Mediterranean (SEU)

The following Member States belong to this zone: Bulgaria, Croatia, Cyprus, France*, Greece, Italy, Malta, Portugal and Spain.

(*)The French metropolitan territory is divided between the two geographical zones

For crops grown in greenhouses, one residue zone applies across the EU.

(https://ec.europa.eu/food/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf)

All references in this section of the Minor Use Explanatory Note were last accessed and checked for validity in November 2021.

[12] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_semiochemicals-201605.pdf

1 Introduction & Background

Minor uses of plant protection products are uses on minor crops against harmful organisms[13]. A minor use can be likewise a harmful organism that on occasion is damaging in a major crop. In addition, growth regulation of a minor crop is also considered a minor use.
Minor crops have a high economic value for farmers but may be of low economic interest for the crop protection industry. Applicants may face difficulties gaining authorisation for 'minor uses' due to the extensive data packages required for authorisation to market plant protection products. This leads to a lack of authorised products on the market for farmers to be used on these crops, which can lead to loss of crop production with a severe economic impact on the farmers. Not only does a lack of efficient crop protection solutions (e.g., limited pesticide options) hinder the development of minor crop production, as described in a French study, other interconnected obstacles create a socio-technical lock-in in favour of the dominant major crop species. Challenges occur at every link of the production chain for the minor crop: poor availability of improved varieties (lower breeding investments than for major species), scarcity of quantified information on crop rotations, the complexity of the knowledge to be acquired by farmers to produce speciality crops, logistical constraints concerning the collection and the storage and the processing and distribution of the minor crop produce, and difficulties of coordination of all involved stakeholders within the emerging value chain[14].

However, minor crops in Europe include, for example, most vegetables, fruits, hops, berries, mushrooms, nursery & ornamental plants, rice, tobacco, herbs & spices, most seeds, and some arable crops. It is estimated that overall, they represent more than EUR 60 billion per year, which equates to 20% of the total European Union plant production value[15]. Minor crops are not only of great economic importance for European agriculture (economic impact), but their production also enriches the biodiversity of the agroecosystems at the regional level (environmental impact). Crop diversification is considered a significant lever to increase the sustainability of arable farming systems, allowing reduced inputs, increasing the heterogeneity of habitats or reducing the yield gaps associated with too frequent returns of the same crop species [14]. Minor crops which are largely produced in highly specialised (e.g., labour and capital-intensive) production systems create jobs in rural areas and thus counteract rural depopulation (socio-economic impact). Finally, consumption of edible minor crops can diversify the diet of Europeans, and increased consumption of certain fruits and vegetables are considered to reduce the risk of some types of cancer and coronary heart disease (health impact)[16].

Due to the multifactorial importance of these crops in Europe, the term 'speciality or niche crop' could be used rather than 'minor crop' as this better reflects the relevance of these crops. The term minor crop, speciality crop or niche crop are proposed to be used interchangeably, as to date, no harmonised definition for 'minor crop' exists in Europe, and national definitions vary. A European-wide applicable definition criteria for a minor crop would be useful and should be developed.

[13] "harmful organisms" means any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products, according to Article 3(7) of Directive 2009/128/EC.

[14] Meynard, JM., Charrier, F., Fares, M. et al. (2018). Socio-technical lock-in hinders crop diversification in France. Agron. Sustain. Dev. 38, 54. https://doi.org/10.1007/s13593-018-0535-1

[15] Lamichhane, Jay Ram & Arendse, Wilma & Dachbrodt-Saaydeh, Silke & Kudsk, Per & Roman, Johan & Bijsterveldt-Gels, José & Wick, Mario & Messean, Antoine. (2015). Challenges and opportunities for integrated pest management in Europe: A telling example of minor uses. Crop Protection. 74. 42-47. 10.1016/j.cropro. 2015.04.005.

[16] Kendall, Cyril W.C. & Esfahani, Amin & Jenkins, David J.A (2010). The link between dietary fibre and human health. Food Hydrocolloids. Volume 24. Issue 1. Pages 42-48. ISSN 0268-005X.

As the economic incentive for industry to apply for an authorisation is limited for certain uses and to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules have been established for minor uses.

These specific provisions are laid down in Article 51 of Regulation (EC) No 1107/2009 (see page 22). Other incentives are related to extended data protection (Article 59), and minor uses should be considered when applying comparative assessment (Article 50). The provision of Article 53 (emergency authorisation in plant protection) should not be used as a standard solution for minor uses problems. However, it is recognised that the withdrawal of authorisations due to non-renewal of active substances, combined with increasing resistance problems, leads to increased applications for Article 53 as a short-term measure whilst alternatives are sought.

To address the 'minor uses' problem more coherently, the European Commission has made specific provisions in the Regulation (EC) No 1107/2009 and assisted in establishing the European Minor Uses Coordination Facility (MUCF), providing a financial contribution to its funds. The MUCF serves as an information exchange platform to support the identification of solutions to plant protection issues for speciality crops in an Integrated Pest Management (IPM) framework (General principles of IPM, as laid down in the Sustainable Use of Pesticide Directive 2009/128/EC are summarised in Appendix II, page 23). This enables farmers in the European region to produce high-quality crops through improved availability of crop protection tools, thus contributing to sustainable European agriculture.

The mission of the MUCF is to support Members in closing minor uses gaps through efficient collaboration to improve the availability of chemical and non-chemical solutions within an IPM framework to enable European farmers to produce high-quality crops.

Although, in general, the application for an extension for minor uses according to Article 51 follows the same (zonal) procedure as other applications, there are currently differences in the implementation of the minor use provisions of Regulation (EC) No 1107/2009. This creates uncertainty and divergence between the EU Member States and some MUCF Member Countries. Whilst different approaches may be consistent with the Regulation, greater harmonisation would support the authorisation of minor uses on a national and zonal level.

One of the outcomes of the consultation performed as part of the REFIT[17] process is that the availability of plant protection products for minor uses is negatively affected by a lack of clarity regarding the rules for authorisation and harmonisation between the EU Member States.

For this Note, 'minor uses' refers to 'minor uses' as defined in Article 3(26)[18] of Regulation (EC) No 1107/2009:

A Minor Use means use of a plant protection product in a particular EU Member State on plants or plant products which are:

(a) not widely grown in that Member State; or

(b) widely grown, to meet an exceptional plant protection need.

[17] The Refit programme (Regulatory Fitness and Performance Programme) was established by the European Commission to verify if existing legislation is (still) fit for purpose and to improve existing EU legislation. https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en

[18] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN

2 Objectives & Scope

2.1 Objectives

This 'Explanatory Note on Minor Uses' on the implementation of Article 51 and other provisions related to minor uses (hereinafter referred to as the 'Note') has been developed to encourage EU Member States, the United Kingdom, Norway and Switzerland to take a consistent approach in the evaluation of dossiers, the use of the risk envelope approach, and in the use of relevant extrapolation tables, e.g. EPPO efficacy extrapolation tables[19] and extrapolation possibilities for residues (as listed in the Technical Guideline on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin[20] [Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 REV. 10.3]).

The Note is intended to stimulate the practical implementation of Regulation (EC) No 1107/2009, to reduce obstacles and other impediments for mutual recognition of minor uses between EU Member States, the United Kingdom, Norway, Switzerland and to encourage harmonisation.

The Note explains the application procedures to professional users, agricultural organisations, official or scientific bodies involved in agricultural activities and other stakeholders.

2.2 Scope

The Note has been developed to provide comprehensive information on minor uses procedures in the context of the implementation of Article 51 and other provisions related to minor uses for different parties such as authorisation holders, official or scientific bodies involved in agricultural activities, professional agricultural organisations, professional users and competent authorities, as well as for the MUCF Commodity Expert Groups (Chapter 8) and Horizontal Expert Groups (HEG).

Issues related to safeners and synergists (according to Article 25(3) of Regulation (EC) No 1107/2009) are not considered in this Note.

3 EU approval of active substances, authorisation of plant protection products and legal framework

The approval process for active substances and the authorisation process for plant protection products are summarised below.

3.1 General description of the approval process

Active substances have to be approved under Regulation (EC) No 1107/2009, and a dossier has to be compiled according to the data requirements as laid down in Part A and Part B of Regulation (EU) No 283/2013 (active substance) and Part A and Part B of Regulation (EU) No 284/2013 (plant protection product). The legal framework is also the basis for the peer review and decision-making process, and therefore the data requirements and the protection goals as laid down in the Uniform Principles, Part I and Part II (Regulation (EU) No 546/2011), have to be respected.

In general, data requirements can be fulfilled by submitting studies, a reasoned approach and relevant literature. If applicants submit relevant literature, they should explicitly reference the specific data requirements addressed

[19] https://www.eppo.int/ACTIVITIES/plant_protection_products/extrapolation_tables

[20] https://ec.europa.eu/food/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf

by this literature. Where scientific literature is provided, it should have been searched for and selected without bias and determined to be 'reliable'. In this respect, the EFSA guidance on the submission of scientific peer-reviewed open literature applies (EFSA 2011; see also Article 8(5) of Regulation (EC) No 1107/2009)[21].

When providing technical reports/studies on the properties or safety on the active substance concerning human or animal health, the environment or efficacy, the tests and analyses should be conducted under the principles of Good Laboratory Practice (GLP) and Good Experimental Practice (GEP) according to the provisions in Article 3(19)(20) of Regulation (EC) No 1107/2009 and Regulation (EU) N0 283/2013, Introduction Point 3 and Regulation (EU) No 284/2013, Introduction Point 3 with the underlying practical arrangements. Residue data must be provided according to good experimental practice (GEP) and good laboratory practice (GLP). However, the GLP- and GEP-requirement is accepted as not applying to studies reported in a journal with a published robust peer-review policy.

It should be noted that the test methods should be those specified in Commission Communications 2013/C 95/01 and 2013/C 95/02. Any other methods used or deviations from the methods should be justified. Where the identity of the test substance or material has not been adequately specified, or its stability in dosing vehicles or solvents used is questionable, the impact on the validity/reliability and usefulness of the test or study has to be assessed.

More detailed information on the EU approval process for active substances is given at:
https://ec.europa.eu/food/plants/pesticides/approval-active-substances_en

3.2 General description of the authorisation process of plant protection products

Plant protection products (PPPs) contain at least one approved active substance; these include compounds from different origins, e.g., 'conventional' chemicals and biologicals such as micro-organisms, pheromones, semiochemicals or botanicals.

Before any PPP can be placed on the market or used, it must be authorised in the Member State(s) concerned. A zonal system operates in the EU to enable a harmonised and efficient system.

The EU is divided into three regulatory zones for authorising plant protection products: North, Central and South. The implementation of the zonal system is laid down in SANCO/13169/2010 rev. 11 - 25 Jan 2021 'Guidance Document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009'[22].

A Member State assesses applications on behalf of other countries in their zone or on behalf of all zones. Regulation (EC) No 1107/2009 sets out the requirements, procedure and timeframes for authorisation of PPPs. Further details about authorisation for minor uses are provided in Chapter 4 of this Note.

More detailed information on the EU authorisation process is given in:
https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products_en

[21] https://www.efsa.europa.eu/en/efsajournal/pub/2092

[22] https://ec.europa.eu/food/system/files/2021-01/pesticides_aas_guidance_mut_rec_en.pdf

4 Authorisations for minor uses

This Chapter has been compiled to describe the legal requirements and procedures for authorisations for minor uses as laid down in Regulation (EC) No 1107/2009 and associated legislation. An overview of the general principles of the zonal system, mutual recognition, and applications for minor uses and are intended to encourage harmonisation of authorisation procedures for minor uses in accordance with Regulation (EC) No 1107/2009 is presented.

An applicant can apply for an authorisation for a minor use according to Article 33, Article 40 (1, 2) or Article 51 (1, 7). The general principles of the zonal system, mutual recognition, and applications for extension of authorisations for minor uses are described in **Table 1**.

The implementation of the zonal system and the principle of mutual recognition is laid down in SANCO/13169/2010 rev. 11 - 25 Jan 2021 'Guidance Document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009'.

4.1 Principle of the risk envelope approach

The risk envelope is a concept that exploits the idea that in each area of assessment, the supported uses of a product can be grouped taking into account specific criteria (e.g., crop, application rate, number of applications, timing, etc. and the assessment can cover a group of uses rather than individual uses. Beyond that, it may be possible to identify a 'worst-case group' for a specific field of assessment, which can be assessed as representative for all other groups, i.e., the assessment of this worst-case use or group will cover all other situations where the Good Agricultural Practice (GAP) is less critical or the same (see Guidance Document SANCO/11244/2011 rev. 5[23]). Whenever possible, the risk envelope approach should be used. This should be substantiated within the assessment when the risk envelope is used. Aspects that are covered by the risk envelope should not be reassessed. Application of the risk-envelope approach is a risk management decision and utilises risk assessment where necessary.

4.2 Draft Registration Report for an extension of authorisation for minor uses according to Article 51

To optimise and facilitate a harmonised process for minor uses applications, the use of the draft Registration Report (dRR) may be considered. The current templates of dRR (all sections: https://ec.europa.eu/food/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en) already include minor uses. However, a simplified format of the dRR for Article 51 applications for minor uses can be used. It should be agreed between the applicant and regulatory authority who should complete the dRR for minor uses. The competent authority may assist as they perform an evaluation and assessment in all cases. If this is done, there should be a clear division between those who help or complete the dRR and those who assess it for regulatory purposes. For an Article 51 application, at least part A (risk management) and relevant sections of part B should be completed. Within this dRR, reference should always be made to the final Registration Report (RR) prepared by the zonal Rapporteur Member State (zRMS) to grant the original authorisation for the product. If reference is made to the final Registration Report, it should be ensured that the final Registration Report is prepared in English and is available for all EU Member States on CIRCABC. Access for a grower or a growers' association to the final Registration Report should be facilitated. Reference to the final Registration Report is essential for areas of the risk assessment that do not need to be updated due to the extension of authorisation for minor uses applications. The dRR sections on the minor use assessment will be uploaded on CIRCABC.

[23] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf

Table 1: Overview of the general principles of the zonal system for minor uses, mutual recognition and applications for extension of authorisations for minor uses.

Aspect: Applicant	
Article 33 Application for authorisation	Applicant (*not defined*).
Article 40(1) General mutual recognition of authorisations	Authorisation holder.
Article 40(2) General mutual recognition of authorisations	The holder of an authorisation, or official or scientific bodies involved in agricultural activities or professional agricultural organisations.
Article 51(1)-(6) Extension of authorisations for minor uses	The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations, or professional users.
Article 51(7) Specific mutual recognition for minor uses	The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations, or professional users.

Aspect: Requirements, consent, and procedure	
Article 33	See Articles 28-39 of Regulation (EC) No 1107/2009. Applications are evaluated on a zonal basis. For use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, the zone means all zones defined in Annex 1 of Regulation (EC) No 1107/2009. Also, other indoor uses, e.g., mushrooms or witloof, fall under the single EU zone concept.
Article 40(1)	The authorisation was granted by a reference Member State (MS) which either belongs to the same zone, or by a reference MS which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another MS within the same zone. Article 41 and 42 apply. Please note that as the product is already authorised in an MS before the minor use is applied for, it may be more expedient to apply for minor use in accordance with Article 51. It is advisable to consult the relevant MS regarding which Article would be most expedient to apply under.
Article 40(2)	The **consent of the authorisation holder** is necessary. However, if the authorisation holder refuses its consent, the competent authority of the MS concerned may accept the application **on public interest** grounds. In such case, the applicant under Article 40 (2) 'must demonstrate that the use of such a plant protection product is of **general interest** for the MS of introduction'. Applications for mutual recognition can only be made if there is an existing authorisation in the reference MS granted in accordance with Article 29. Mutual recognition may be applied for 'the same use', meaning the same crop-pest combination. Mutual recognition is possible from one minor use to another minor use and from a major use to a minor use.
Article 51(1)-(6)	The applicant may ask for the authorisation of a plant protection product **already authorised in the MS concerned** to be extended to minor uses not yet covered by that authorisation. An application can be made **without the consent of the authorisation holder.**

	According to Article 51, applications of authorisations for minor uses could follow the zonal system, if appropriate[24]. According to Article 51(3), MS may take measures to facilitate or encourage submitting applications for minor use extensions. Different options are listed in Chapter 7. According to Article 51(4), the extension may take the form of an amendment to the existing authorisation (independently of the legal basis of the authorisation, e.g., under Article 33, 40 or 51) or maybe a separate authorisation in accordance with the administrative procedures of that MS. Article 51(5): When MS grant an extension of authorisation for a minor use, they shall inform the authorisation holder of the product, who may change the labelling accordingly in accordance with the national procedure in the relevant MS. The MS shall ensure that users are entirely and explicitly informed of the new instructions for use. If the authorisation holder does not change the labelling, the MS shall inform the users by means of an official publication or an official website. MS may make this information publicly available for all authorised minor uses. It is possible to apply for amendments, e.g., change to the period of application, a change in the preharvest interval (PHI), a crop grown in a different season (e.g., summer and winter grown lettuce), additional pests (e.g., *T. absoluta*, *D. suzukii*), or crops (e.g., quinoa, Miscanthus) to the authorisation. Such amendments need to be supported by suitable risk assessments and data (if necessary). This may help to avoid Article 53 applications.
Article 51(7)	Mutual recognition in accordance with Article 40(1) could be requested provided that those uses are **also considered minor in the MS of application** and in the **reference MS**. An application can be made **without the consent of the authorisation holder**. The provisions of Article 41 shall be followed. The conditions of **Article 40(2) are not applicable** to mutual recognition under Article 51(7) (no need to demonstrate general interest).

Aspect: Efficacy	
Article 33	Appropriate efficacy data per EPPO zone to support authorisation for a PPP. Minor uses may also be applied for under Article 33[25]. EPPO Standard PP 1/226(3) provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose and per EPPO zone.
Article 40(1)	For mutual recognition, **no additional efficacy data** and evaluation is required for the same use and under comparable agricultural practices.
Article 40(2)	For mutual recognition, **no additional efficacy data** and evaluation is required for the same use and under comparable agricultural practices.
Article 51(1)-(6)	An extension of authorisation for minor use **does not need to be supported by efficacy data**.
Article 51(7)	For mutual recognition, **no additional efficacy data** and evaluation is required for the same use and under comparable agricultural practices.

Aspect: Assessment if the use is a minor use in the given MS	
Article 33	Not assessed.
Article 40(1)	Not assessed.
Article 40(2)	Not assessed.
Article 51(1)-(6)	The legal definition of a minor uses is in Article 3 (26) of Regulation 1107, but it is a national matter to assess whether the use is minor in the MS of application.
Article 51(7)	As far there is no international harmonised definition of a minor use, it is a national requirement to assess whether the use is minor in the MS of application.

[24] The Member States are strongly encouraged to share their assessment reports under Article 51 on CIRCABC.

[25] An application under Article 33 could be applied simultaneously with a minor use extension under Article 51(1)-(6).

Aspect: Assessment of the public interest	
Article 33	Not assessed.
Article 40(1)	Not assessed.
Article 40(2)	Yes, the text of Article 40(2) refers to the general interest, but it is considered to be the same as the public interest under Article 51.
Article 51(1)-(6)	Yes, Article 51(2)(c). Because of the different situations (availability of PPP authorisations, resistance situation, etc.) in the countries, the public interest has to be evaluated on national level.
Article 51(7)	There is no direct reference to the public interest in Article 51(7). However, some MS apply 'per analogy' Article 51(2) and assess the public interest even for application under Article 51(7).

Aspect: Extrapolation regarding efficacy and residue	
Article 33	Extrapolation is possible for efficacy (EPPO extrapolation tables) and residues (according to SANCO 7525/VI/95 Rev. 10.3 or later).
Article 40(1)	Extrapolation is possible for efficacy (EPPO extrapolation tables) and residues (according to SANCO 7525/VI/95 Rev. 10.3 or later).
Article 40(2)	Extrapolation is possible for efficacy (EPPO extrapolation tables) and residues (according to SANCO 7525/VI/95 Rev. 10.3 or later).
Article 51(1)-(6)	No efficacy data and evaluation are required for minor uses applications under Article 51. Extrapolation is possible for residues (according to SANCO 7525/VI/95 Rev. 10.3 or later).
Article 51(7)	No efficacy data and evaluation are required for minor uses applications under Article 51. Extrapolation is possible for residues (according to SANCO 7525/VI/95 Rev. 10.3 or later).

Aspect: Risk assessment: residue, environmental fate, ecotoxicology, and toxicology	
Article 33	The risk assessment should reflect guidance applicable at the date that the zRMS received the application. The risk envelope should be used whenever possible. Aspects that are covered by the risk envelope should not be reassessed.
Article 40(1)	Application of new guidance documents should be limited to aspects that are justified by national circumstances. **A complete** reassessment of the PPP should be avoided.
Article 40(2)	Application of new guidance documents should be limited to aspects that are justified by national circumstances. **A complete** reassessment of the PPP should be avoided.
Article 51(1)-(6)	Application of new guidance documents should be avoided as far as possible for minor use extensions as the already authorised uses are already evaluated. The risk envelope should be used whenever possible. For aspects that are not covered by the risk envelope, the risk assessment should reflect guidance applicable at the date that the MS received the application. **A complete** reassessment of the PPP should not be performed.
Article 51(7)	Application of new guidance documents should be limited to aspects that are justified by national circumstances. **A complete** reassessment of the PPP should not be performed.

Aspect: Comparative Assessment	
Article 33	Article 50(1)(d): The consequences on minor use authorisations should be considered when performing a comparative assessment. More information can be found in the 'Guidance Document on Comparative Assessment, SANCO/11507/2013 rev. 12' and EPPO Standard PP 1/271 (3).
Article 40(1)	Not obligatory; it is up to the MS. The MS can also refuse mutual recognition based on Article 41(2)b) where the plant protection product contains a candidate for substitution.
Article 40(2)	Not obligatory; it is up to the MS The MS can also refuse mutual recognition based on Article 41(2)b) where the plant protection product contains a candidate for substitution.
Article 51(1)-(6)	No Comparative Assessment should be conducted.
Article 51(7)	No Comparative Assessment should be conducted.

Aspect: Liability	
Article 33	Authorisation holder.
Article 40(1)	Authorisation holder.
Article 40(2)	/
Article 51(1)-(6)	Article 51(5): Authorisation holder of the plant protection product already authorised in the MS concerned. When the authorisation holder refuses its consent under Article 51(5), the liability is assumed by the person using the product for which the minor use is granted. Where the authorisation holder declines, the MS shall ensure that users are entirely and explicitly informed as to instructions for use by means of an official publication or an official website. The official publication or, where applicable, the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.
Article 51(7)	Article 51(5) 'per analogy'.

Aspect: Data Protection	
More information about Data protection can be found in the Commission Notice 2019/C 229/01(Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009), published in the OJ C 229/1.	
Article 33	The general provisions of Article 59-62 apply.
Article 40(1)	The general provisions of Article 59-62 apply.
Article 40(2)	Data protection could be granted only for data supporting the mutual recognition application. In this case, Article 59(1) applies, and the data protection is ten years [26].
Article 51(1)-(6)	According to Article 59(1), the period of data protection shall be extended by three months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, and if the authorisation holder makes the applications for such authorisations at the latest five years after the date of the first authorisation in that MS. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 (low-risk plant protection products), the total period of data protection may in no case exceed 15 years. According to Article 59(1), the same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for authorisation extension for minor uses as referred to in Article 51(1).
Article 51(7)	Data protection could be granted only for data supporting the mutual recognition application and only if requested by the concerned MS. In this case, Article 59(1) applies, and the data protection is ten years.[27]

[26] See point 22 of the Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009), published in the OJ C 229/1.

[27] Idem.

4.3 Renewal

After the renewal of the approval of an active substance, an authorisation shall be renewed, in accordance with Article 43, by the authorisation holder. The applicant should provide a list of all the intended uses in the zone (or interzonal if applicable). In this list, minor uses authorised according to Article 51 should be mentioned in the GAP-table separately.
Particular when products contain more than one active substance (with subsequent evaluations/assessments of the PPP), and category 4 studies (see definition on page 3) are needed, a possible extension for a minor use may be delayed considerably, and this is a disadvantage for minor uses. If the extension for the minor uses can be based on extrapolation and the use is already covered by the original risk envelope assessment, it will be possible to extend the authorisation. In this respect, the 'original risk envelope' is the risk envelope used for the (first) authorisation.

More information can be found in the 'Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170 rev. 14)[28].

5 Residues and MRLs in or on treated products, food and feed

Residue data should be provided for all edible (food and feed) crops and crops grown in rotation with edible crops to demonstrate compliance with established MRLs, or to propose new MRLs, and to enable a consumer dietary intake risk assessment. The applicant should ensure that its minor use application is accompanied by an MRL application if required. This means that sufficient data on storage stability, plant metabolism data, processing, rotational crops and livestock are available. The most common problem is the lack of plant metabolism data.

To evaluate residue behaviour and the setting of maximum residue levels (MRLs) according to Regulation (EC) No 396/2005, the European Union has been divided into two zones, a Northern European and a Southern European zone. For use in greenhouses, as post-harvest treatment and for treatment of empty storage rooms, one residue zone applies. The number of crops residue trials to provide should be specified according to Regulation (EU) No 283/2013 (active substance) or the Technical Guideline on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin [Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 REV. 10.3].

As a general rule, the minimum number of trials varies between 4 independent trials per residue zone for a minor crop and eight independent trials per zone for a major crop. In certain specific circumstances, reducing the number of trials is acceptable. According to Regulation (EU) No 283/2013, if the GAP is the same in both residue zones, six trials equally distributed in the representative growing zones are generally sufficient for a minor crop. Under Regulation (EU) No 544/2011, at least four trials per zone are required, even if the GAP is the same in both zones.

Extrapolation possibilities (for residues) can be found in the Technical Guideline on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin [Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 REV. 10.3]). Extrapolations can also provide solutions for minor crops, for which the available residue trials would often not be sufficient to derive MRL proposals: Extrapolation, however, is not limited to minor crops but can apply for major crops where insufficient residue data for the specific crop are available or for deriving MRLs for crop groups.

[28] https://ec.europa.eu/food/system/files/2016-11/pesticides_aas_guidance_renewal_1107-2009.pdf

As laid down in the introduction of the Annex to Commission Regulation (EU) No 283/2013 and No 284/2013, both the field phase and the analytical part of residue trials should be conducted in accordance with the GLP principles. However, for minor crops the field phase may be conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements as laid down in point 3.2 and 3.3 of the introduction of the Annex to Regulation (EU) No 284/2013. The analytical phase, if not done in accordance with the GLP requirements, shall be conducted by laboratories accredited for the relevant method in accordance with the European standard EN ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories'.

Residue data obtained from trials respecting the principles of GLP and GEP generated outside the EU or from another EU residue zone should be considered in granting minor uses extensions (see OECD Test Guideline 509: Crop Field Trial[29]).

It is acceptable that part of the trials have been conducted outside the Union for minor uses. In Regulation (EC) No 283/2013, it is stated under Part A Section 6.3: *Part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable*.

In all crops, including speciality crops, residue data are not required for some groups of (bio)pesticides if it has been determined that quantifiable residues (limit of quantification according to Regulation (EC) No 396/2005) on the consumable commodity are unlikely to occur or that residue levels are unlikely to exceed natural exposure levels during outbreaks of the pest (see Guidance Document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005; SANCO 11188/2013, rev. 2)[30].

6 Efficacy

According to Article 51(2), **no efficacy data and evaluations** are required for an extension of authorisation for a minor use.

When an authorisation for a PPP, including minor uses, has been granted according to Article 33, efficacy for the minor uses has been addressed by trials and extrapolations. For the efficacy evaluation of plant protection products, Europe has been divided by the European and Mediterranean Plant Protection Organization (EPPO) into EPPO zones: These EPPO zones consider different agro-climatic subareas for the purpose of efficacy evaluation trials on PPPs. These zones are the Mediterranean zone, the Maritime zone, the North-East zone and the South-East zone (https://pp1.eppo.int/standards/PP1-241-2).

Efficacy trials should be conducted in accordance with relevant EPPO Standards. More detailed information about EPPO standards is given at: https://pp1.eppo.int/.

[29] https://www.oecd.org/env/test-no-509-crop-field-trial-9789264076457-en.htm

[30] https://ec.europa.eu/food/system/files/2016-10/pesticides_mrl_guidelines_sanco-2013-11188.pdf

7 Possible measures for EU Member States and MUCF Member Countries to explore and facilitate the submission of applications for minor use extensions

According to Article 51(3), Member States (MS) can take measures to facilitate or encourage the submission of applications for minor use extensions. This could be done by applying one or more of the following options:

Options
a) To apply a system of reduced fees or no fees.
b) To promote and assist applicants in applying for Article 51(3) extension, a particular 'minor uses' contact point ('helpdesk') and specific information on websites through a simplified application form.
c) If practical, the zonal RMS should evaluate all uses applied across the zone, not just the uses within their Member State.
d) MS are encouraged to perform evaluations of minor uses in English and upload the evaluations on CIRCABC for other MS (in the same zone) to see and use as they see fit. Thus, the applicants of minor uses (e.g., farmers' organisations and growers' groups) are not burdened with the expenses to submit a draft risk assessment, if required in a given Member State etc.
e) To display all authorised minor uses in a MS on a webpage/database for all to see.
f) To set priority (while still respecting the legal deadlines) in evaluating applications containing minor uses.
g) To work closely with farmers' organisations and growers' groups.
h) To participate in and contribute to the European Minor Use Coordination Facility.
i) To encourage applicants to apply for as many relevant minor uses as possible *via* Article 33.
j) To encourage applicants to include all relevant Member States in a zone in a minor use application, if applied together with Article 33 or other articles than 51.
k) To encourage a harmonised crop commodity grouping system, justified extrapolations, and maximise the use of extrapolation possibilities taking into account Toxicological Reference Values (TRV), Acceptable daily intake (ADI), acute reference dose (ARfD) and acceptable operator exposure levels (AOEL).
l) To perform a minor use extension/authorisation according to Uniform Principles, using EU agreed on endpoints to clearly indicate this. However, minor uses should be demonstrated safe for human health and the environment the same as major uses. Therefore, national requirements should be considered when relevant.
m) To accept authorisations granted under Directive 91/414/EEC according to Uniform Principles[31] as these products can be considered as authorised under Regulation (EC) No 1107/2009.
n) To fully implement mutual recognition relying on the evaluation and assessment performed by the reference Member State wherever possible.
o) To support data sharing amongst Member States and access whilst observing data protection principles.
p) To encourage industry to collaborate with official or public bodies to generate residue trials data that support MRL extrapolations from major crops to minor crops.

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[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31997L0057

8 MUCF description of the process from identification of a crop-pest need to minor use application

The process steps the MUCF intends to undertake, from identifying a crop-pest need to a minor use application, are described and outlined below. The steps are taken by the EU Member States, the United Kingdom, Norway, Switzerland, members of the MUCF.

The MUCF is in the process of exploring the possibility of developing a feature in EUMUDA to work on non-chemical methods or additional IPM-solutions.

Detailed information about the MUCF and EUMUDA is given at: www.minoruses.eu

Process Steps
a) A minor use need has been identified and entered in EUMUDA[32]. This can be done by MUCF national contact points (see definition on page 4), the Chair/co-Chair of a CEG, or the MUCF team. In entering a minor use need, the minimum data provided are the name of the crop and the pest and the respective EPPO Codes. The MUCF will check these data for completeness. A compiled list of minor uses needs is publicly accessible in EUMUDA.
b) The MUCF will check databases such as PPPAMS, Homologa, the IR-4, PMC and C-IPM (Coordinated Integrated Pest Management in Europe) for possible solutions (chemical and non-chemical). The sustainability of possible solutions will be checked (e.g., renewal status of an active substance).
c) If the consulted databases provide a solution, the MUCF will bring the declarant of the minor use need into contact with the relevant national contact point to advise on further actions (e.g. the possibility of exchange of efficacy or MRL data, clarification if mutual recognition is a possibility, establishing contact with the registration holder etc.). If an ongoing application can provide for a (possible) solution, the MUCF will contact the applicant while respecting the rules on confidentiality.
d) If the consulted databases do not provide viable solutions, the MUCF and the relevant CEG(s) will investigate possible solutions. Projects will be established based on the priorities specified in the list of minor uses needs and according to the work plans of the CEG(s).
e) When a project has been established, the CEG determines which data has to be generated and which information is already available. The CEG will nominate a project leader (see definition on page 5).
f) When all project parameters have been set, this information will be entered in EUMUDA by the project leader with the help and supervision of the MUCF team. The project leader will deliver project details and results within a set timeframe. The MUCF will assist whenever necessary and follow the project to keep it on track. A list of minor uses projects is publicly available in EUMUDA. Confidential information (i.e., active substance, product names, registration holder, and data owner) is available only for registered users (CEG members).
g) The data generated in a minor use project might eventually become part of a minor use application. When all relevant data are available, a minor use application/minor use application for an authorisation or extension of use should be submitted by the nominated applicant, considering the requirements of all participating/interested EU Member States, the United Kingdom, Norway and Switzerland.

[32] More detailed information can be found in the 'Guide for users of EUMUDA' (www.eumuda.eu).

9 References

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (2013/C 95/01)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013XC0403%2802%29

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (2013/C 95/02)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013XC0403%2803%29

Commission Notice 2019/C 229/01(Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009), published in the OJ C 229/1
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019XC0708%2801%29

Commission Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32005R0396

Commission Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0546&from=en

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013)
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0283

Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0284

Commission Regulation (EU) 2017/1432 of 7 August 2017 amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1432&from=ES

DIRECTIVE 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0128

EPPO extrapolation tables:
https://www.eppo.int/ACTIVITIES/plant_protection_products/extrapolation_tables

EPPO Standards (PP1): https://pp1.eppo.int/standards/

MUCF Commodity Expert Group Terms of Reference, Rev. 1, May 2021:
https://www.minoruses.eu/media/files/CEG_Minor_uses_final_terms_of_reference.pdf

MUCF Horizontal Expert Group Terms of Reference, Rev.1, May 2021:
https://www.minoruses.eu/media/files/HEG_Minor_uses_final_terms_of_reference.pdf

MUCF Rules for confidentiality and access rights, Rev. 1, December 2017:
http://www.eumuda.eu/media/files/Rules_confidentiality_and_access_rights_EUMUDA.pdf

MUCF Guide for users of EUMUDA, Rev. 0, December 2017:
http://www.eumuda.eu/media/files/Users_guide_EUMUDA_rev_0.pdf

Technical Guideline on data requirements for setting MRLs comparability of residue trials and extrapolation of residue data on products from plant and animal origin. [Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 REV. 10.3]).
https://ec.europa.eu/food/system/files/2020-11/pesticides_mrl_guidelines_app-d.pdf

Guidance Document on criteria for inclusion of active substances in Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013), Rev. 2, 14 September 2015).
https://ec.europa.eu/food/system/files/2016-10/pesticides_mrl_guidelines_sanco-2013-11188.pdf

Guidance Document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 SANCO/11507/2013 rev. 12, 10 October 2014.
https://ec.europa.eu/food/system/files/2016-10/pesticides_aas_guidance_comparative_assessment_substitution_rev_1107-2009.pdf

Guidance Document on the preparation and submission of dossiers for plant protection products according to the 'risk envelope approach'; SANCO/11244/2011 rev. 5 14 March 2011.
https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf

Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 SANCO/2010/13170 rev. 14, 7 October 2016.
https://ec.europa.eu/food/system/files/2016-11/pesticides_aas_guidance_renewal_1107-2009.pdf

Guidance Document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009; SANCO/13169/2010 rev. 9; 11 July 2014.
https://ec.europa.eu/food/system/files/2021-01/pesticides_aas_guidance_mut_rec_en.pdf

GUIDANCE OF EFSA Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009; EFSA Journal 2011;9(2):2092;
http://www.efsa.europa.eu/en/efsajournal/doc/2092.pdf

OECD Guideline for the Testing of Chemicals Nr 509: Crop Field Trial
https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-5-other-test-guidelines_20745796

All references in this section of the Minor Use Explanatory Note were last accessed and checked for validity in November 2021.

Appendix I - Article 51 of Regulation (EC) No 1107/2009[33]

1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

2. Member States shall extend the authorisation provided that:
(a) the intended use is minor in nature;
(b) the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;
(c) the extension is in the public interest; and
(d) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3. Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4. The extension may take the form of an amendment to the existing authorisation or maybe a separate authorisation, in accordance with the administrative procedures of the Member State concerned.

5. When Member States grant an extension of authorisation for a minor use, they shall inform if necessary the authorisation holder and request him to change the labelling accordingly. Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website. The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6. Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7. The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1) provided that a plant protection product concerned is authorised in that Member State. Member States shall authorise such uses in accordance with the provisions of Article 41 provided that those uses are also considered minor in the Member States of application.

8. Member States shall establish and regularly update a list of minor uses.

9. By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

10. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

[33] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Appendix II - General principles of IPM

Integrated pest management (IPM) involves careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. 'Integrated pest management' emphasises the growth of a healthy crop with the least possible disruption to the agroecosystems and encourages natural pest control mechanisms.

General principles of IPM, as laid down in the Sustainable Use of Pesticide Directive 2009/128/EC are schematically illustrated:

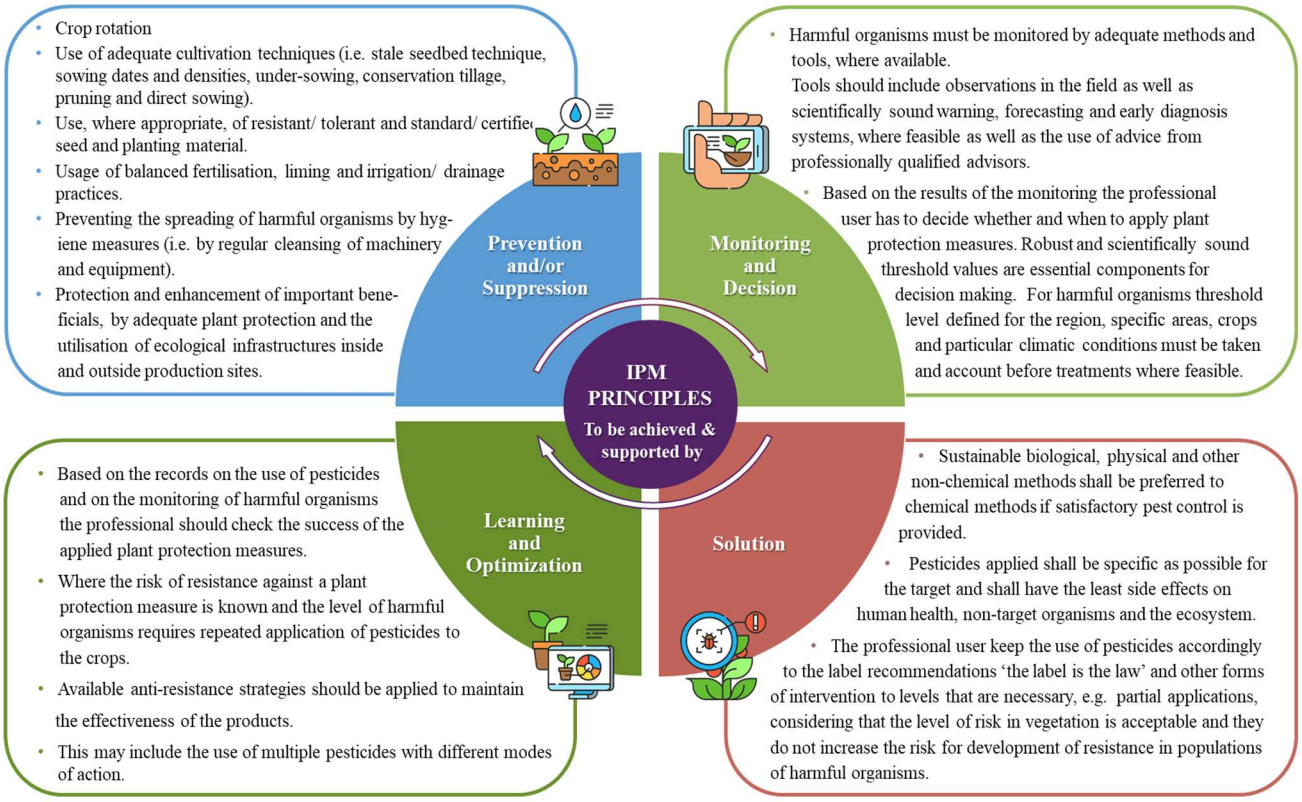

Figure 1: Schematically illustrated general principles of IPM, adapted from Annex III of Directive 2009/128/EC[34].

According to the mission of the MUCF, and to be in line with the general requirements of Directive 2009/128/EC, minor uses needs should be solved within an integrated pest management (IPM) framework. A possible solution for a minor use need can be chemical and non-chemical and can include basic substances or products based on low-risk substances. Several solutions should be combined to fill minor uses gaps. Authorisations and solutions with different modes of action are to be combined with all available IPM-tools to minimise reliance on specific plant protection products/active substances and subsequently counteract resistance development.

Chemical solutions refer to conventional chemical plant protection products or chemical pesticides.

'**Non-chemical methods**' are alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques or physical, mechanical or biological pest control methods. Biocontrol

[34] https://ec.europa.eu/food/plants/pesticides/sustainable-use-pesticides/integrated-pest-management-ipm_en

can be regulated by Regulation (EC) No 1107/2009 (e.g., micro-organisms, pheromones, semiochemicals, botanicals), or outside Regulation (EC) No 1107/2009 (e.g., macro-organisms, mainly invertebrates including nematodes).

Basic substances are not predominantly used for plant protection purposes but may be helpful in plant protection. They are substances that do not have an inherent capacity to cause effects on humans, animals, etc. and can support plant protection as far as their risks are acceptable. Some of these substances have been traditionally used by farmers and may include foodstuffs. Examples are vinegar, sucrose or calcium hydroxide. Their approval by the Commission allows the use for plant protection purposes, but they cannot be explicitly sold as a plant protection product. Applications concerning basic substances must be submitted using the IUCLID[35] format via the EFSA submission portal. The rules governing the procedure of approval apply as set out in the following document[36]: Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009; SANCO/10363/2012 rev.10.

An active substance can be approved as a **low-risk substance**[37] if regular approval criteria are met. Specific criteria for chemical substances and micro-organisms do exist. In addition, low-risk criteria as specified in Annex II, point 5 of Regulation (EC)1107/2009 apply. Products containing only low-risk substances can be authorised as low-risk plant protection products, and this low-risk status can be used to advertise the product. Due to their properties, farmers and other users should prefer low-risk products to manage the pest issue if pest control efficiency is given. The development and placing on the market of low-risk substances and products is encouraged by several regulatory incentives. For example, low-risk substances are approved for 15 years instead of 10 years and data protection on the studies submitted for the authorisation. Furthermore, subsequent authorisation is prolonged from 10 to 13 years. Moreover, a fast-track authorisation procedure with reduced timelines (120 days instead of one year) ensures that low-risk products are quickly placed on the market.

Detailed information about IPM is provided on the European Commission site:

https://ec.europa.eu/food/plants/pesticides/sustainable-use-pesticides/integrated-pest-management-ipm_en

[35] https://iuclid6.echa.europa.eu/

[36] https://ec.europa.eu/food/system/files/2021-06/pesticides_ppp_app-proc_guide_doss_swd-10363-2012.pdf

[37] https://ec.europa.eu/food/system/files/2017-09/pesticides_sup_low-risk-ppps.pdf