2023

SURVEY 2022 COMPILED DATA & INFORMATION

ON MINOR USES WORK IN EU COUNTRIES + NORWAY, SWITZERLAND & THE UNITED KINGDOM

EUROPEAN MINOR USES COORDINATION FACILITY

MinorUses
MAJOR IMPORTANCE

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Minor Uses Survey 2022 summary and discussion points

As part of its work programme the European Minor Uses Coordination Facility (MUCF) conducted a survey in 2022 focusing on minor uses regulatory procedures regarding Plant Protection Products Regulation (EU) No. 1107/2009 and impediments to the implementation of these procedures.

The objectives of this survey were to update and extend the available information on minor uses work in European countries and to provide valid data for future discourse, analysis, synthesis and actions related to minor uses and associated issues.

The questionnaire for the Minor Uses Survey 2022 contained 60 questions and was forwarded to 30 countries (the EU countries also referred to as EU Member States, the United Kingdom, Norway, and Switzerland, hereafter referred to as "the European countries").

The survey 2022 response was good. In total, 22 out of 30 MUCF National Contact points participated in the survey 2022. Respondents included preliminary representatives from governmental bodies (i.e. competent authority).

The findings of the 2022 survey (hereafter referred to as "Minor Uses Survey 2022") provides an update of information collected in a survey conducted in 2017, with additional added information regarding the risk envelope and mutual recognition procedure, and the compilation of the draft Registration Report (dRR).

The compiled data and information from the Minor Uses Survey 2022 establishes a foundation, to explore the possibility to define criteria for a European-wide harmonised definition of a minor crop and to develop an abridged draft Registration Report Part A (dRR Part A) template, which is foreseen to be used on a voluntary basis by the applicant and/or the competent authority. These actions will be carried out by the MUCF expert working groups in the coming year(s).

<u>With the data & information collected during the survey, it was possible to ascertain that:</u>

- All the responding European countries engage in work regarding minor uses, in national working groups and/or are implicated in European working groups (i.e., MUCF expert groups). This highlights the significance of minor uses for European countries and emphasises the importance their participation in the work of the MUCF, as the MUCF makes national minor uses information available on one dedicated platform, to be accessible and useable by everyone.
- In 2022, the definition of a minor crop was not harmonised between European countries. All responding countries possessed a national list of minor and/or major crops and/or minor and/or major uses.
- Minor crops, though occupying a lower production acreage in Europe compared to major crops may be high value crops and are important for the environment, farmers/producers, and consumers. Continuing the cultivation of minor crops in Europe contributes directly to increasing food security, agricultural & dietary diversity and climate resilience.
- Art. 51 of Regulation (EC) 1107/2009, implemented to increase the number of authorisations of plant protection products (PPPs) for minor uses, is used less than

envisioned. Respondents to the Minor Uses Survey 2022 still perceive several hurdles to be overcome (e.g., trial data generation, national distinct administrative procedures, regulatory or data requirements) so that this provision is used as intended. It is encouraged by MUCF experts that the applicant applies for as many minor uses as possible via Art. 51.

- A full implementation of the mutual recognition (Art. 40 (1-2) and Art. 51 (7)) procedure, relying on the evaluation and assessment performed by the reference EU Member State[1] whenever possible is advocated by MUCF experts.
- Several European countries apply national requirements for extensions of authorisation for minor uses or mutual recognition, for example for risk assessment (6 respondents out of 20), or determination of public interest (15 respondents out of 21). These national requirements are cited as obstacles to the application for Art. 51 extensions of authorisation (Art. 51 (1-6)) or mutual recognition (Art. 51 (7)) and should only be considered if relevant, i.e., to demonstrate that a minor use is safe for human health and the environment.
- The lack of resources (time, human resources, finance, knowledge) needed to draft and assess a draft Registration Report (dRR) is cited as an obstacle to use the dRR format properly. An abridged dRR part A template document could ease the application and evaluation process according to the respondents and would provide a good basis to increase the number of applications by applicants such as growers' organisations. Allocating further funds to the competent authorities could help to improve the process of drafting and assessing the dRR.
- To increase the amount of information accessible to the competent authorities throughout Europe, it may be beneficial for additional countries to adopt the method of uploading their Registration Report (RR) and assessments, preferably in English, on CIRCABC.
- To mitigate the need for more resources being allocated to conduct residue and efficacy trials on minor crops, data sharing and access amongst European countries whilst observing data protection principles is encouraged by MUCF experts.
- New residue and efficacy extrapolation possibilities, as well as new trial data, would facilitate the authorisation of PPPs for minor uses.
  -Minor uses applied under Art. 33 have to be supported by appropriate efficacy data per EPPO climatic zone.
  -Extrapolation is possible for efficacy (EPPO extrapolation tables) and residues (according to SANCO 7525/VI/95 Rev. 10.3 or later) for applications according to Art. 33, Art. 40 (1) and Art. 40 (2).
  -No efficacy data and evaluation are required for minor uses applications under Art. 40 (1), 40 (2), 51 (1)-(6) and 51 (7) for the same use and under comparable agricultural practices, but extrapolation for residue is possible (according to SANCO 7525/VI/95 Rev. 10.3 or later).

[1] See Regulation (EC) 1107/2009, Article 40 (1.a)

Content

Definitions, abbreviations, terminology, and useful links

The **European Minor Uses Coordination Facility (MUCF)** supports European stakeholders in closing crop protection gaps in minor uses. It coordinates collaboration and information exchange to improve the availability of sustainable crop protection solutions within an IPM framework. The objective is to enable farmers to produce high-quality crops and contribute to sustainable European agriculture: https://minoruses.eu/.

The **MUCF Commodity Expert Groups (CEG)** work to close, as a joint effort, minor use gaps at the European level by finding chemical or non-chemical solutions within an Integrated Pest Management (IPM) framework.

CIRCABC (Communication and Information Resource Centre for Administration, Businesses and Citizens) 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.

Draft Registration Report (dRR): All applications (new product, amendment, and renewal) for PPPs should be made in the form of a draft Registration Report (dRR). The dRR is split into three sections:

- Part A – risk management
- Part B – data evaluation and risk assessment
- Part C – confidential information

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) 1107/2009, EU Member States shall establish and regularly update a list of minor uses.

GAP Table: 'Good Agricultural Practice' (GAP) table means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed.

Harmful organism: any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products (Art. 3 (7) of Regulation (EC) 1107/2009).

ISO codes: In this report, the European countries are identified via an ISO code (*Table 1*). The corresponding list of ISO codes for each European country is as follows:

Table 1: European countries' ISO codes.

ISO code	European country	ISO code	European country
AT	Austria	**GR**	Greece
BE	Belgium	**IE**	Ireland
BG	Bulgaria	**IT**	Italy
CH	Switzerland	**LT**	Lithuania
CY	Cyprus	**LU**	Luxembourg
CZ	Czech Republic	**LV**	Latvia
DE	Germany	**MT**	Malta
DK	Denmark	**NL**	The Netherlands
EE	Estonia	**NO**	Norway
ES	Spain	**PL**	Poland
FI	Finland	**PT**	Portugal
FR	France	**RO**	Romania
HR	Croatia	**SE**	Sweden
HU	Hungary	**SI**	Slovenia
GB	United Kingdom	**SK**	Slovakia

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

National Minor Uses Contact Points of the MUCF are appointed by country. At least two National Minor Uses Contact Points should be assigned per European country. MUCF Contact Points are usually representatives from governmental bodies (competent authorities, ministries). The responsibility of the National Minor Uses Contact Point is related to the following:

- The approval of experts to Commodity Expert Groups (CEG), Residue Expert Group (ReEG), and the Horizontal Expert Group (HEG).
- Adding information to the European Minor Uses Database (EUMUDA).
- Setting priorities in the 'table of needs'.
- The coordination of responses within their country and replying to requests from the European Minor Uses Coordination Facility (MUCF).

NLKUG: procedure for national extension of authorisation for minor uses in the Netherlands. The Netherlands developed a simplified application procedure as an interpretation of Article 51 section 3, the application for a national extension of an authorisation with minor uses (NLKUG). This procedure can be initiated to obtain an extension of uses only for the Netherlands (developed to facilitate the availability of plant protection products for minor uses). Conditions for NLKUG applications can be found at: https://english.ctgb.nl/plant-protection/applicationtypes-plant-protection-products/national-extension-minor-uses.

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' and 'Mutual Recognition':

(https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en).

Since the 27th of March 2021, the E-Submission Food Chain (ESFC) has been implemented for the submission of any new dossier relating to authorisation procedures in any area of the food chain, excluding plant protection products. In January 2023, the ESFC Platform replaced PPPAMS for the submission of emergency authorisations. The use of ESFC for other PPP application types will be considered in the future.

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

The **zonal Rapporteur Member State (zRMS)**: is selected in each zone where a PPP application is made, to carry out the assessment. Other EU Member States in the same zone comment on the zRMS evaluation.

1. Introduction

The objective of Plant Protection Products Regulation (EU) No. 1107/2009 is to ensure a high level of protection for human and animal health, the environment, improve the functioning of the internal market through harmonisation whilst at the same time maintaining the competitiveness of EU agriculture and improving agricultural production. The regulation aims to increase the free movement of plant protection products (PPPs) and availability of those products in the EU countries. There are numerous provisions within the regulation which aims to support these objectives, including an EU wide active substance approval procedure, zonal evaluation and mutual recognition systems and procedures for dealing with minor uses of PPPs. Whilst the regulation derives from the EU, authorisation of plant protection products is the responsibility of each European country.

Despite ongoing efforts towards harmonisation and mutual recognition procedures, certain European countries retain distinct administrative, regulatory, or data requirements. These demands, and their continual evolution, present a particular challenge specifically for minor uses.

Minor uses of pesticides refer to uses on or in minor, niche, respectively speciality crops, which hold a high economic value for farmers and producers, but usually are of minimal economic interest to the agri-pesticide industry. In the Regulation No 1107/2009, Article 3, paragraph 26, ‘minor uses’ are defined as the use of a plant protection product on a crop which is not widely grown in an EU Member State, or against pest problems which are not routinely encountered but may on occasion be very damaging in major crops.

Minor, niche, or speciality crops are considered minor in terms of production scale, when compared to the overall agricultural crop production per country. These crops include most fruits and vegetables, nurseries, mushrooms, tobacco, hops, rice, flowers, forest trees, seed production crops and some arable crops.

The agri-pesticide industries reluctance to authorize PPPs for “minor uses” is due to the extensive data packages (including residue and efficacy data) and distinct administrative, regulatory, or data requirements per country or regulatory zone obligatory. This is further interlinked with an economical impediment for the agri-pesticide industry of getting a financial return on their significant investment to gain an authorisation. This ultimately leads to a lack of authorized plant protection products on the market for farmers and growers to be used on these crops.

Although often overlooked, the production and continued cultivation of minor, niche, and specialty crops (hereafter referred to only as “minor crops”) holds a considerable significance that goes beyond their monetary value.

Growing a wide variety of crops, including minor ones, plays a vital role in preserving agrobiodiversity and improving ecological resilience and should therefore be considered as an ecosystem service, enforcing European food security and the sustainability of European agriculture in the long term.

Diversified crop production, especially incorporating minor crops, can result in habitat fragmentation of agricultural landscapes, which can benefit crop/pollination systems.

Diverse agricultural landscapes (e.g. greenscapes) and ornamental plants (e.g. cut flowers) can have positive effects on human health and mental well-being.

Cultivating a range of crops also promotes nutritional diversity. Minor crops (e.g., some fruits and vegetables, mushrooms, or herbs and spices etc.) can confer noteworthy nutritional advantages owing to their specific nutrient profiles. Introducing a variety of minor crops into the diet can improve overall dietary diversity and contribute to public health.

Some minor crops possess cultural and traditional importance, in varying significance per European country. Minor crops are cultivated due to cultural (e.g. saffron in Spain, or Damask rose in Bulgaria) or traditional reasons (e.g. apricot in Austria, or strawberry in Norway) and serve as an integral part of the local food culture and heritage. The preservation and promotion of these crops can aid in maintaining cultural legacy.

In terms of climate resilience, minor crops production can play a key role in building durable agriculture ecosystems that can better withstand the impacts of climate change. By diversifying crop rotations, incorporating crops with unique growing features countering therewith monocultural cropping systems, farmers can reduce the likelihood of crop failures and maintain productivity, even under changing environmental conditions.

In order to accomplish the mission of the Facility, which is ‘to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an integrated pest management (IPM) framework’, and due to many positive effects of a continued minor crop production, the MUCF expert working groups advised in 2021 to update and extend the information available on minor uses work in European countries.

Thus, the European Minor Uses Coordination Facility (MUCF) conducted a survey in 2022 focusing on minor uses regulatory procedures regarding Plant Protection Products Regulation (EU) No. 1107/2009 and impediments to the implementation of these procedures.

The Survey on Minor Uses work 2022 in the EU countries, plus Norway, Switzerland, and the United Kingdom (hereafter, Minor Uses Survey 2022) is a continuation of a work carried out in a survey conducted in 2017.

This document presents an overview of updated information and compiled data on minor uses work and procedures in several European countries.

It provides a foundation for future discourse and work actions related to minor uses and associated issues and raises discussion points for stakeholders (authorisation holders, scientific bodies involved in agricultural activities, agricultural organisations, competent authorities, European Commission, etc.), which should ultimately contribute to an increase in authorised PPPs for minor uses.

This document has been prepared and peer-reviewed in co-operation with the MUCF National Contact Points, who participated in the Minor Uses Survey 2022.

2. Material & Methods and supplementary survey information

The Minor Uses Survey 2022 was circulated to the National Contact Points of all MUCF European Member and Partner countries (*N*=30). These contact points are primarily based at competent authorities. The compiled data and information provided might therefore not be representative for all other bodies involved in minor uses work (e.g., growers associations, PPP companies etc.).

The term "**European countries**" used in the survey refers to:

- European Union Member States, the UK plus
- European States (EFTA states) which have implemented Regulation (EC) No 1107/20097, for example Norway. Switzerland is not a part 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.

The survey was open for completion by the European countries respondents from 2022-07-01 to 2022-09-30. An extension of the deadline was implemented to allow for additional countries to respond until 2022-10-31.

The 2017 survey comprised 16 questions (circulated to 30 European countries). In comparison, the 2022 survey comprised 60 questions, and was divided into 8 parts:

- Responsibility for minor uses in the European countries.
- Organisation of minor uses work, general questions on minor uses & minor crops.
- Trials.
- Extension of authorisation for minor uses.
- Risk assessment.
- Mutual recognition.
- Draft Registration Report.
- General topics.

A complete list of the Minor Uses Survey 2022 questions is available at the following link: Survey (minoruses.eu).

a. Structural presentation of the survey compiled data and information provided.

At the beginning of each question:

- a summary overview is given of the compiled data per individual question, in consultation with European MUCF Contact Point respondent, and/or
- In case of an open questions, the document contains all the individual responses given by the respondent (rewriting by the MUCF Secretariat was done for homogenisation purposes).

At the end of each main part, the MUCF Secretariat provides:

- a summary along with discussion points for further discourse in the MUCF expert groups, or with stakeholders.

When possible, the MUCF Secretariat includes a pre-synthesis and/or potential perspectives, which were elaborated after consultation with European MUCF Contact Point respondents and marked with the MUCF logo and written in *italics* for further discourse for in the MUCF expert groups or with stakeholders.

b. MUCF survey 2017 and 2022 participation map.

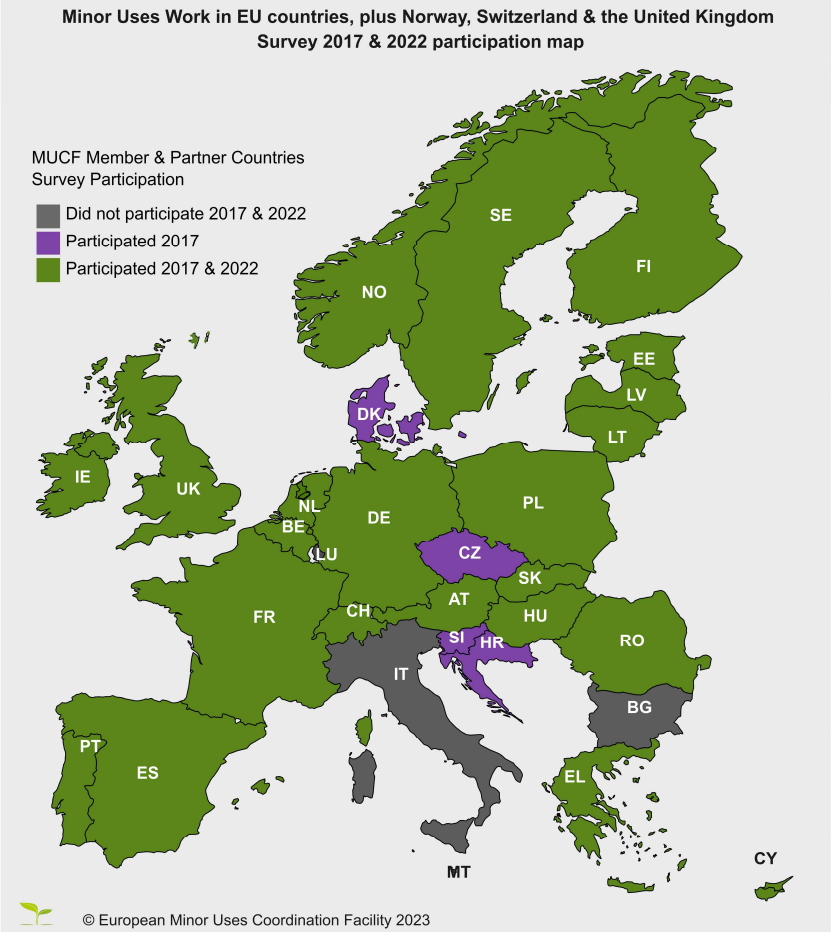

Figure 1: European countries survey 2017 and 2022 participation map.

c. Participation summary in MUCF surveys.

- 22/30 countries participated in the 2022 survey.
- 26/30 countries participated in the 2017 survey.
- The countries that participated in the 2022 survey are all former participants in the 2017 survey.

An absence of response to the Minor Uses Survey 2022 or 2017 does not mean a lack of regular and/or recent updates on information and data between that country and the MUCF.

The reduced number of responses to the Minor Uses Survey 2022 compared to 2017 may be because the 2022 survey was extended. The Minor Uses Survey 2022 contained more open-ended questions, which would have taken up more time for completion for the respondent.

European countries are encouraged to actively participate in the work of the MUCF to make additional information and data on minor uses available.

3. Responsibilities, definitions, figures of minor uses and minor crops.

3.1 MUCF National Contact Point(s) responsible for minor uses.

The MUCF can provide a list of MUCF National Contact Points upon request.

3.2 Availability of national lists of minor/major crops or minor/major uses.

Detailed information on the national database of several European countries can be accessed on the MUCF website (https://www.eumuda.eu/), as well as additional useful PPP links.

Table 2 compiles lists published by the European countries, which either concern minor and/or major crops, and minor and/or major uses. Depending on the European country, different types of lists are available:

- If a European country has circulated a list of major crops, any crop grown in that European country that is not indicated on that list is considered a minor crop.
- If a European country has circulated a list of minor crops, it is considered that all uses on these indicated crops are minor. Moreover, all crops not included on that list are considered major crops.
- If a European country has circulated a list of major uses, each use in that European country that is not indicated on that list is considered a minor use.
- If a European country has circulated a list of minor uses, each use of this European country not indicated on that list is considered a major use.

If a European country does have a minor crop list in place, *Table 3* provides information on the update frequency.

Table 2: Lists of minor/major crops and minor/major uses available to MUCF for the European countries (2017 and 2022 surveys).

Country	Type of list	Links
AT	Minor crops	https://www.eumuda.eu/media/files/country_information/AT_Minor_Uses_Definition.pdf
	Minor uses	https://www.eumuda.eu/media/files/country_information/AT_Minor_Uses.xlsx
BE	Minor crops	https://www.eumuda.eu/media/files/country_information/BE_minor_crops_list_20230712.xls
	Minor uses	There is only one minor use in a major crop, *Erwinia amylovora,* in apple and pear trees.
CH	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/CH_minor_major_crops_2021-07-08.xlsx
CZ	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/CZ_minor_major_crops.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/CZ_minor_major_uses.xlsx
DE	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/DE_minor_major_crops_2021-07-01.xlsx

	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/DE_minor_major_uses_2021-07-01.xlsx
DK	Major crops	https://www.eumuda.eu/media/files/country_information/DK_major_crops_20210701.xlsx
EE	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/EE_minor_major_crops_2021-10-08.xlsx
ES	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/ES_minor_major_crops_2021-11-16.xlsx
FI	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/FI_minor_major_crops.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/FI_minor_major_uses.xlsx
FR	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/FR_minor_major_crops_2021-09-02.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/FR_Official_Catalogue_of_uses_2021-04-15.xlsx
GB	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/GB_minor_major_crops_2021-10-01.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/GB_minor_major_uses-2021-09-13.xlsx
HU	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/HU_minor_major_crops_2021_07_09.xlsx
	Major uses	https://www.eumuda.eu/media/files/country_information/HU_Major_uses_2021-08-16.xlsx
IE	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/IE_minor_and_major_crops_2021-07-15%20.xlsx
	Major uses	https://www.eumuda.eu/media/files/country_information/IE_major_uses_2021-07-15.xlsx
IT	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/IT_minor_major_crops_2021-09-30.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/IT_minor_major_uses_2021-10-04.xlsx
LT	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/LT_minor_major_crops_2021-10-01.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/LT_minor_major_uses_2021-09-15.xlsx
LV	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/LV_minor_major_crops_2021-07-16.xlsx
NL	Minor crops	https://www.eumuda.eu/media/files/country_information/NL_minor_major_crops_2021-07-16.xlsx
	Minor uses	https://www.eumuda.eu/media/files/country_information/NL_minor_major_uses_2021-08-07.xlsx

NO	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/NO_minor_major_crops_2021-09-06.xlsx
	Minor uses	https://www.eumuda.eu/media/files/country_information/NO_minor_uses_2021-08-27.xlsx
PL	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/PL_major_minor_crops_2021-10-01.xlsx
	Minor uses	https://www.eumuda.eu/media/files/country_information/PL_minor_uses_2021-07-08.xlsx
PT	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/PT_minor_major_crops_2021-10-01.xlsx
	Minor uses	https://www.eumuda.eu/media/files/country_information/PT_minor_major_uses_2021-09-14.xlsx
RO	Minor crops/ minor uses	https://www.eumuda.eu/media/files/country_information/RO_Minor_Uses_List_and_Minor_Crops.pdf
SI	Minor crops	https://www.eumuda.eu/media/files/country_information/SI_Minor_Crops_List.pdf
SK	Major/ minor crops	https://www.eumuda.eu/media/files/country_information/SK_minor_major_crops_2021-07-22.xlsx
	Major/ minor uses	https://www.eumuda.eu/media/files/country_information/SK_minor_major_uses_2021-07-06.xlsx

Table 3: Update frequency of minor crops' lists (N=19/22[2]).

Update frequency	**European countries**
Every 1-2 years	BE, DE, PT, SK (4)
Every 3-5 years	EE, FI, LT, NL, RO, PL (6)
Every 6-10 years	AT (1)
Not regularly	CH, ES, FR, GB, HU, IE, LV, NO (8)
No response provided	CY, GR, SE (3)

10 European countries out of 19 update their list of minor crops regularly, at two to five years intervals. It can be noted that it is uncommon that the status of a crop (minor versus major) changes within a short period of time.

[2] In this document, '(*N*={x})' refers to the number of European countries that provided information to the MUCF Secretariat.

3.3 Criteria for the definition of a minor crop.

A summary overview of the criteria to define a minor crop is provide in *Table 4*. Individual response for criteria to define a minor crop in the European countries are listed in *Table 5*. A European country may use several criteria to define a minor crop.

Table 4: A summary overview of the criteria to define a minor crop (N=24).

Criteria	No.	Details		European countries
Acreage	21	< 30 000 ha (Forestry)		ES
		< 20 000 ha		FR, **IT**[3] (2)
		< 10 000 ha		AT, **CZ,** DE, ES (excluding forestry), IE, LV, PT, SK (8)
		< 8 000 ha		FI
		< 6 000 ha		HU
		< 5 000 ha		LT
			Field crops	NL
		< 2 500 ha		NO
		< 1 000 ha	Field crops	CH
			Greenhouse crops	NL
		< 500 ha (Vegetables, fruits)		CH
		Percentage of total acreage:	< 1%	EE
			< 2%	**PL**
			< 0.0035% (very minor crop)	SK
		No threshold was provided.		BE, GR, SE (3)
Consumption	7	< 7.5 g/day/capita		EE, ES, PT (3)
		< 1.5 g/day/capita		**CZ**
		< 0.125 g/kg body weight (bw)/day		DE, FR (2)
		No threshold provided		BE
Volume of production	5	< 40 000 tonnes/year		DE, FR (2)
		Percentage of total plant production volume (< 1%)		EE
		No threshold provided		BE, GR (2)
Type of crop Which crops are considered minor depends on different categories as detailed here.	4	Greenhouse, horticulture, autumn-sown oilseed crops, winter cereals apart from winter wheat & winter rye		FI
		Fruits, vegetables, ornamentals.		SE
		Forestry, ornamentals.		**IT**
		All crops are minor apart grass, oats, barley, forage maize, wheat, sugar beet, dry harvest field beans, canola & potatoes other than seed potatoes.		GB
Deduction	3	Any crop not listed in the national major crop list is minor.		**DK**, NO, RO
None	4	No definition provided		CY, LU, MT, SI

[3]Countries in bold are those that did not participate in the Minor Uses Survey 2022, but for which data are available from previous exchanges with the National Contact Points (2017 survey, call for description of criteria to define a minor crop).

A listing of the different criteria used by the European countries to define a minor crop is available on the EUMUDA Homepage.

Table 5: Criteria to define a minor crop with details by country (N=24, MUCF in-house data for the countries that did not participate to the 2022 survey, and information update from the Minor Uses Survey 2022):

Criteria	**European country**
- Cultivation area: less than 10 000 ha. For more details please consider the 'Lückenerlass' ('GAP decree'), which is available for download at this URL.	AT
- Cultivation area (no precise number defined) and/or, - Production volume (no precise number defined) and/or, - Average consumption (no precise number defined). Whether or not a crop is considered as a minor crop is decided by the National Authorisation Board. The Board considers various criteria (acreage, production volume, dietary intake, number of applications submitted by the authorisation holder for the crop, etc.).	BE

- Cultivation area:
  - Less than 1 000 ha for field crops.
  - Less than 500 ha for vegetables.
  - Less than 500 ha for fruits.
- For small fruits:
  - Major crop: strawberry (which comprises 56% of the cultivated small fruits).
  - Minor crops: all other small fruit crops except strawberry.
	CH

No response was provided.	CY
- Cultivation area: less than 10 000 ha and/or, - Average consumption: less than 1.5 g/day/capita.	**CZ**
- Cultivation area: less than 10 000 ha and/or, - Production volume: less than 40 000 tonnes/year and/or, - Average consumption: less than 0.125 g/kg bw/day (roughly 8.85 g/day/capita based on an average weight of 70.8 kg in Europe). Status: A possible criteria change may be made, greatly increasing the cultivation area from less than 10 000 ha to less than 50 000 ha.	DE
Any crop which is not included in the list of major crops provided by Denmark is considered a minor crop.	**DK**
- Cultivation area: less or equal to 1% of the total utilised agricultural land and/or, - Production volume: less or equal to 1% of the total plant production volume and/or - Average consumption: less than 7.5 g/day/capita. The Estonian Agriculture and Food Board updates the list of major and minor crops for Estonia according to the methodology proposed in a study carried out by the Estonian Institute of Economic Research. According to this methodology major crops in Estonia are those: - Which are grown on more than 1% of the total utilised agricultural land and/or,	EE

- For which production volume is greater than 1% of the total plant production volume and/or, - For which average daily consumption rate is higher than 7.5 g/day/capita. Crops that are not on the major crop list are all listed as minor crops.	

- Cultivation area:
  - Less than 10 000 ha for agricultural production.
  - Less than 30 000 ha for forestry.
- Average consumption: less than 7.5 g/day/capita.
	ES

- Cultivation area: less than 8 000 ha.
- Crop type:
  - Greenhouse crops
  - Horticultural crops
  - Autumn-sown oilseed crops
  - Winter cereals, except for winter wheat & winter rye
Crops whose cultivation area is 8 000 ha or more are considered major.
All crops cultivated in greenhouses and horticultural crops are minor crops because of the minor growing area.
Precision: the basis for this definition is the total Finnish crop cultivation area of 2 300 000 ha. The grassland area is 800 000 ha, and the crop production area for cereals is 1 000 000 ha. The remaining 500 000 ha include all other crops and fallow fields.
Additionally, a list of major crops and uses and criteria to define a minor crop has been discussed in the Northern zone. Most Finnish major crops are the same as in other Northern zone countries. Winter wheat and winter rye are major crops sown in autumn in Finland, other cereals sown in autumn are minor crops, as well as oilseed crops sown in autumn.
	FI

- Cultivation area: less than 20 000 ha and/or, - Production volume: less than 40 000 tonnes/year and/or; - Average consumption: less than 0.125 g/kg bw/day (roughly 8.85 g/day/capita based on an average weight of 70.8 kg in Europe). Some crops are defined as major crops for residues, if the cultivation area is limited in France, it is considered as a minor crop. In this case, the crop remains major for residues, but all uses are considered minor. For example, kiwi (4 000 ha in France) is considered as a major crop for residues in the South zone, but all uses are minor in France. Therefore, the number of residue trials required is the same as for all other major crops, but the uses on kiwi are eligible for an Art. 51 authorisation.	FR

- Crop type: all crops which are not listed below are considered minor:
  - Grassland
  - Cereals: barley, forage maize, oats, wheat
  - Oilseed rape
  - Dry harvested field beans
	GB

- Sugar beet - Potato (other than seed potato)	
- Cultivation area (no precise number available). - Production volume (no precise number available).	GR
- Cultivation area: less than 6 000 ha. Crops that are (or are expected to be) cultivated on an area of less than 6 000 ha are considered minor. These crops are listed in the Hungarian decree No. 89/2004 FVM (under renewal).	HU
- Cultivation area: less than 10 000 ha. Ireland does not have a legal definition of what constitutes a major or minor crop. However, if a crop is grown for several years during which the area is more than 10 000 ha, the crop can be considered major. All other crops are considered minor.	IE
- Cultivation area: less than 20 000 ha or, - Crop type (regardless of the acreage): - Forestry - Ornamentals	**IT**
- Cultivation area: less than 10 000 ha.	LV
- Cultivation area: less than 5 000 ha. The minor crop definition may change in the future to increase the area from less than 5 000 ha to less than 10 000 ha.	LT
- Cultivation area: - Less than 5 000 ha for field crops - Less than 1 000 ha for greenhouse crops	NL
- Cultivation area: less than 2 500 ha or, - Crop not mentioned in the Norwegian list of major crops.	NO
- Cultivation area: less than 2% of total utilised agricultural land.	PL
- Cultivation area: less than 10 000 ha. - Average consumption: less than 7.5 g/day/capita.	PT
A minor crop consists of any crop which is not included in the list of major crops provided by Romania.	RO
- Cultivation area: less than 10 000 ha. A minor crop is a crop grown on an area equal to or less than 10 000 ha. A 'very minor' crop is a crop grown on an area of less than or equal to 0.0035% of the total area of agricultural land. The size of the crop area and the total agricultural land are obtained from the agricultural statistics of the previous calendar year. A major crop is a crop grown on an area of 10 000 ha or more, and hence is a priority for the country because of its economic and agronomic value.	SK
- Crop type: - Fruits - Vegetables - Ornamentals	SE

The criteria used by most European countries (21countries out of the 24, which provided criteria) to classify a crop as a minor crop is the crop cultivation area, either an absolute value in hectares or a percentage of the total national agricultural area.

Lithuania and Germany indicated that their national definition for a minor crop, based on the crop cultivation area (among other criteria), might change in the future (from 5 000 to 10 000 ha for LT, from 10 000 to 50 000 ha for DE).
The potential reclassification would result in an expansion of the national list of minor crops for those two countries, as more crops would be categorised as minor.

3.4 Approximate acreage (ha) of total cultivated crops (major and minor).

Table 6: Approximate acreage (ha) of cultivated crops per country (N=20/22).

Acreage (to the nearest thousand ha)	European country
26 800 000	FR
18 090 000	DE
16 644 000	ES
9 845 000	NO
8 538 000	RO
5 000 000	HU
4 010 000	GB
3 900 000	PT
3 217 000	GR
2 938 000	LT
2 559 000	SE
2 000 000	FI
1 969 000	LV
1 368 000	BE
1 346 000	SK
1 300 000	AT
1 042 000	CH
987 000	EE
837 000	NL
357 000	IE

Table 7: Approximate acreage (ha) of cultivated crops (major and minor crops) per country data collection year (N=20/22).

Year	European countries
2022	HU
2021	AT, BE, CH, EE, FI, GB, LT, NO, SE (9)
2020	DE, ES, FR, IE, LV, NL, RO, SK (8)
2019	GR, PT (2)
No response provided	CY, PL (2)

Responding countries stated that data were collected in 2019 at the latest and between 2020 and 2022 in most cases. Data can be considered recent.

Note: *Depending on the responding European country the total acreage of cultivated crops, acreage of minor crops, as well as the total production value and minor crop production value (Table 6, Table 8, Table 10, Table 13), can include different types of crop commodities. Respondents did not always consider the same commodities. Some countries, for example, incorporated grassland and forest trees in the presented values, and others did not.* ***Therefore it is emphasized that presented values should not be compared directly between countries but remain valid information on a country level.***

In order to evaluate this assumption the MUCF Secretariat conducted a comparison (Figure 2) between the approximate total cultivated crop acreage information collected in 2022 (map c) and data available on Eurostat (data set: apro_cpsh1 & 2) on total utilized agricultural area (map b) and utilized agricultural area (map a), after manually cleaning of nested data and averaging accessible data over the years 2018 to 2020 (σ=2018-2020).

The maps (map a, b, c) depict that countries used different crops in their presented values. Only for the countries AT, HU, IE, NL and SK (map a) it was possible for the MUCF Secretariat to recalculate the value given by the country respondent within ± 100 000 ha which was considered by the MUCF to be an acceptable difference*. All other countries had a larger difference between the presented value and the Secretariat calculated ones, which was more than ± 100 000 ha.*

Data intersection work on Eurostat's apro_cpsh1 & 2 datasets, as well as the development of a methodology for nested crop data cleaning, would be necessary to extract crop production values & cultivated crop acreage for all 30 European countries. This further analysis could allow a comparison of figures between all 30 European countries and aggregation of figures for these countries.

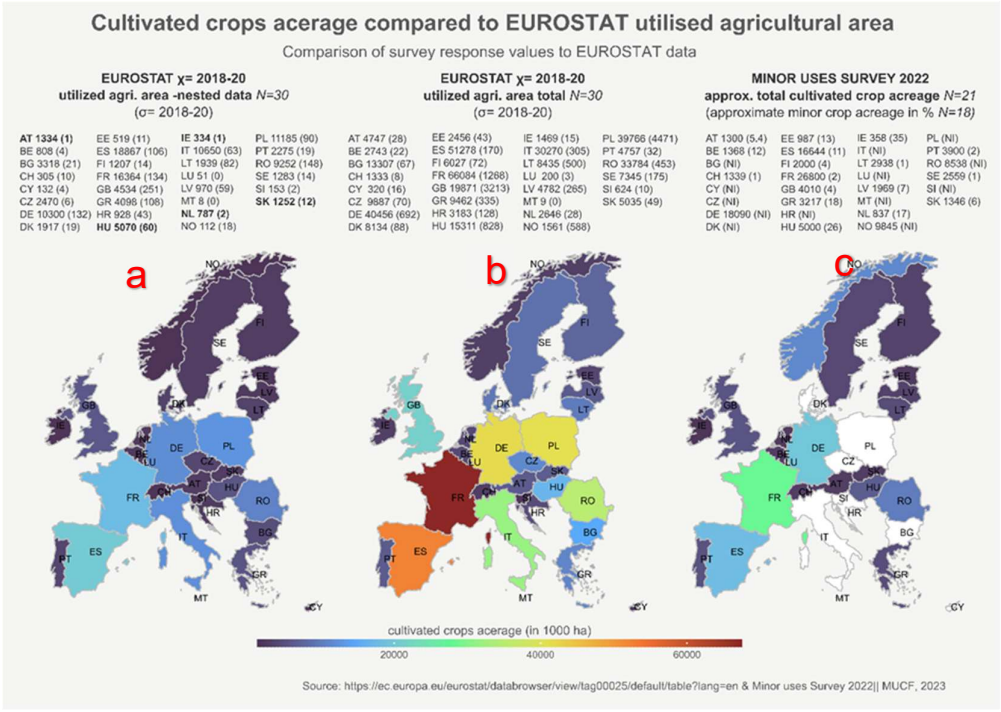

Figure 2 Comparison of European cultivated crop acreage values.

3.5 Approximate crop production value (EUR) of total cultivated crops.

Table 8: Approximate crop production value (EUR) of total cultivated crops (major and minor; N=12/22).

Crop Production value (to the nearest million EUR)	European country
49 500	FR
14 000	NL
12 200	BE
10 950	GB
6 700	PT
3 284	CH
3 200	SE
3 073	LT
2 400	FI
2 241	IE
1 279	NO
602	SK
556	EE
No answer provided	AT, CY, DE, ES, GR, LV, HU, PL, RO (9)

Table 9: Year of crop (major and minor) production value (EUR) data collection (N=12/22).

Year of data collection	European countries
2022	BE (1)
2021	EE, FR, GB, IE, LT (5)
2020	CH, FI, NO, SE, SK (5)
2019	NL, PT (2)
No response provided	AT, CY, DE, ES, GR, LV, HU, PL, RO (9)

All the information was gathered between 2019 and 2022. Data can be considered recent.

3.6 Approximate acreage of minor crops (ha).

Table 10: Approximate acreage (ha) of cultivated minor crops (N=17/22).

Acreage of cultivated minor crops (ha)	European country
1 913 654	ES
1 300 000	HU
569 772	GR
470 000	FR
166 900	BE
158 000	GB
145 000	LV
140 000	NL
125 401	EE
125 000	IE
84 923	SK
80 000	FI
72 000	PT
70 000	AT
42 698	LT
30 234	SE
18 818	CH
No answer provided	CY, DE, NO, PL, RO (5)

Some European countries that could provide the acreage of total cultivated crops did not provide the acreage of cultivated minor crops (20 European countries provided data on total cultivated crops, while 17 provided acreage of minor crops).

Table 11: Year of minor crops acreage (ha) data collection (N=17/22).

Year of data collection	European countries
2021	AT, BE, EE, GB, HU, LT, SK (7)
2020	CH, FI, FR, IE, LV, NL, PT, SE, NO (9)
2019	GR (1)
No response provided	CY, DE, ES, PL, RO (5)

All the information was gathered between 2019 and 2021. Data can be considered recent.

3.7 Comparison of the acreage (ha) of minor crops to the total acreage (ha) of cultivated crops (major and minor).

MUCF pre-analysis Table 12.

Table 12: Comparison of the acreage of minor crops to the total acreage of cultivated crops (major and minor) in hectares (N=20/22).

Acreage of cultivated crops (1 000 ha)	Acreage of minor crops (1 000 ha)	Percentage of minor crop acreage compared to total cultivated crop acreage	European country
26 800	470	2%	FR
18 090	NA	NA	DE
16 644	1914	11%	ES
9 845	NA	NA	NO
8 538	NA	NA	RO
5 000	1300	26%	HU
4 010	158	4%	GB
3 900	72	2%	PT
3 217	570	18%	GR
2 938	43	1%	LT
2 559	30	1%	SE
2 000	80	4%	FI
1 969	145	7%	LV
1 368	167	12%	BE
1 346	85	6%	SK
1 300	70	5%	AT
1 042	19	2%	CH
987	125	13%	EE
837	140	17%	NL
358	125	35%	IE

The percentage of minor crops compared to the total acreage of cultivated crops (major and minor) are highly variable between the European countries, ranging from 1 to 35%.

3.8 Approximate crop production value (EUR) of minor crops.

Table 13: Crop production value of minor crops (EUR) per European country (N=8/22).

Production value of minor crops (to the nearest million EUR)	European country
13 300	FR
4 754	GB
1 172	FI
669	SE
498	CH
224	LT
168	EE
72	SK
No response provided	AT, BE, CY, DE, ES, GR, HU, IE, LV, NL, NO, PT, PL, RO (14)

Compared to the responses for production acreage of minor crops (*N=17*), a lower number of respondents could indicate the production value of minor crops (*N=8*).

Table 14: Year of minor crops production value (EUR) data collection (N=8/22).

Year of data collection	European countries
2021	EE, FR, GB, LT (4)
2020	CH, FI, SK, SE (4)
No response provided	AT, BE, CY, DE, ES, GR, HU, IE, LV, NL, NO, PT, PL, RO (14)

All the information was gathered between 2020 and 2021. Data can be considered recent.

3.9 Comparison of the of minor crops production value (% of the total crop production value) to the minor crop acreage (% of the total crop acreage).

MUCF pre-analysis Table 15.

Table 15: Comparison of the minor crop production value (% of the total crop production value) to the minor crop acreage (% of the total crop acreage; N=8/22).

Percentage of acreage of minor crops (% of the total crop acreage)	Percentage of production value of minor crops (% of the total crop production value)	European country
13%	30.3%	EE
6%	12.0%	SK
4%	43.4%	GB
4%	48.8%	FI
2%	26.9%	FR
2%	15.2%	CH
1%	7.3%	LT
1%	20.9%	SE

Although comprising less than 4 % of the totally produced crops acreage, minor crops production contributes more than 40% to the countries total crop production value in the case of Finland and the United Kingdom.

Table 16: Information source used by the respondent to provide acreage and production value numbers.

European country	Information source	Acreage	Production value
AT	https://gruenerbericht.at	X	
BE	https://statbel.fgov.be/fr	X	X
CH	https://www.bfs.admin.ch	X	X
	https://www.sbv-usp.ch/en/services/agristat-swiss-agriculture-in-figures		X
DE	https://www.destatis.de	X	
EE	https://andmed.stat.ee/en/stat	X	X

GR	https://www.statistics.gr/en/home/	X	
ES	https://www.mapa.gob.es	X	
FI	https://www.luke.fi/en	X	
	https://portal.mtt.fi/portal/page/portal/taloustohtori/kokonaislaskenta/aikasarja/Tuottoerittely/		X
FR	https://agreste.agriculture.gouv.fr	X	
	https://www.insee.fr/fr/accueil		X
GB	https://www.gov.uk/government/statistics/latest-horticulture-statistics	X	X
	https://www.gov.uk/government/statistical-data-sets/agriculture-in-the-united-kingdom	X	X
HU	https://www.ksh.hu/?lang=en	X	
IE	https://www.cso.ie/en/	X	X
LV	https://ec.europa.eu/eurostat	X	
LT	https://osp.stat.gov.lt	X	X
NL	https://www.agrimatie.nl	X	
	https://www.cbs.nl		X
NO	www.ssb.no	X	
	https://www.nibio.no/en		X
PT	https://www.ine.pt	X	X
RO	https://stat.gov.pl/en/	X	
SK	https://slovak.statistics.sk/	X	X
SE	https://jordbruksverket.se	X	X

The number of European countries for which the production value of minor crops is available is limited. Production data might not always be available to MUCF national Contact Points, especially for crops cultivated on a very small scale.

Improving the communication regarding the importance of minor crops production is notable, as minor crops, although grown on less acreage than major crops, make a high economic contribution to a country's total crop production value.

In some cases, minor crops are only grown on 4% of the total cultivated area but contribute to more than 40% of the total production value of a country (Finland and the United Kingdom).

3.10 Criteria for the definition of a minor use.

Regulation (EC) 1107/2009 defines a minor use in Art. 3 (26) as follows:
'*Minor use means the use of a plant protection product in a particular MS on plants or plants products which are:*

(a) Not widely grown in that Member State; or
(b) Widely grown, to meet an exceptional plant protection need'.

This definition serves as a basis for setting up a national definition of minor uses in several European countries. The definition leaves room for interpretation of what may be considered a minor use in/on a major crop. Following this definition, all uses on or in a minor crop are usually considered as minor uses. A summary overview of criteria to define a minor use is given in *Table 17*. One European country may use several criteria to define a minor use (*Table 17* & *Table 18*).

Table 17: A summary overview of criteria to define a minor use (N=21).

Criteria	No.	Details	European countries*
Uses on minor crops are considered minor uses	18		AT, BE, CH, **CZ,** DE, EE, FI, FR, GB, GR, **IT**, LT, LV, NO, NL, **PL**, PT, RO
Occurrence of the harmful organism on a major crop (sporadically and low acreage)	17	< 10 000 ha	DE, LV
		< 5 000 ha	LT
		No precise threshold was provided.	AT, BE, CH, **CZ,** FR, GB, GR, **IT**, LT, LV, NO, PL, RO
		< 5% of the acreage of the major crop total cultivation area.	PT
The use is considered of public interest (Public interest criteria are defined nationally)	3	The crop is important in AT, or application is carried out within the framework of regionally adapted cultivation methods.	AT
		Economic argument, minor uses gap, availability of solutions, resistance mitigation measure, etc.	DE
		Low availability of PPP solutions for the use.	PT
Case by case	2	"Exceptional need" criterion.	NL
		No criteria were defined.	SE
Deduction from the list of major uses	2	All uses not listed in the major uses list are considered minor uses.	HU, IE
The product is authorised for organic farming	1		**CZ**
Control of quarantine pests	1	According to. Regulation. (EU) 2019/2072	**IT**

*Countries marked in **bold** are countries that did not provide the information in the Minor Uses Survey 2022 but for which data are available from previous exchanges with the National Contact Points (2017 survey, call for description of criteria to define a minor use).

Table 18: Criteria to define a minor use (Information source: in-house data from previous exchanges and updated information from the Minor Uses 2022 survey; N=21):

Criteria to define minor use	European country
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in or on a major crop. - The authorisation applied for is considered of public interest. Public interest means the intended application is in a crop that is important for Austria or can be carried out within the framework of regionally adapted cultivation methods.	AT
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	BE
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	CH
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop. The occurrence of a harmful organism is considered sporadic if a treatment is required less than once every three years. - The product is authorised for organic farming.	CZ
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop (area of application for the product: less than 10 000 ha per year). - The authorisation applied for is of public interest. Public Interest (Art. 51 (2) c) of Regulation (EU) 1107/2009: - The pest must be worthy of control in the crop. - There must be a minor use gap (no sufficient practicable non-chemical or chemical alternatives), considering the implementation of appropriate resistance mitigation measures, i.e., usually the presence of 2 - 4 (in general at least 3) non-cross-resistant active substances for closing the gap. - There is no profit expected for the manufacturing company. The public interest is denied if sufficient or equivalent agents are available for use and/or the pest is not economically significant. An application with the same active ingredient in the same indication (the active ingredient is already approved in the indication applied for) is not of public interest. Calculating an economic benefit does not necessarily lead to the failure of the public interest but to levying charges. If the urgency of the availability of the PPP for practice is demonstrated, the public interest criterion is met even if there is an expectation of profit. Ongoing work is noted on a possible criterion change from less than 10 000 ha to less than 50 000 ha.	DE
- All uses in minor crops. The Estonian Agriculture and Food Board updates the list of major and minor crops for Estonia according to the methodology proposed in a	EE

study carried out by the Estonian Institute of Economic Research. By this methodology major crops in Estonia are those: - Which are grown on more than 1% of the total utilised agricultural land. - Which production volume is greater than 1% of the total plant production volume. - Which average daily consumption rate per capita is higher than 7.5 grams. Crops that are not on the major crop list are all listed as minor crops.	
All uses in minor crops.	FI
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop. On major crops, some uses are major, some uses are minor. The uses are considered minor when they are of occur on a limited surface compared to the surface area of the crop or have an erratic character (frequency of appearance and importance). No precise threshold is defined.	FR
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop. According to the Chemical Regulation Division (CRD) efficacy guidelines, all uses not listed in the Major GB Pests spreadsheet could be considered minor: https://www.hse.gov.uk/pesticides/pesticides-registration/efficacy-guides/index.htm.	GB
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	GR
All uses not listed in the list of major uses provided by Hungary.	HU
- All uses not listed in the list of major uses provided by Ireland. Ireland does not have a legal definition of major and minor uses. There is only a list of pests which would typically be considered a major use in major crops.	IE
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop. - Union quarantine pest according to Regulation (UE) 2019/2072.	IT
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop (area of application for the product: less than 10 000 ha).	LV
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	LT
- All uses in minor crops. - Exceptional need criterion (evaluated case by case). The 'exceptional need' criterion is assessed if the crop production area is larger (more than 5 000 ha for field crops and more than 1 000 ha for greenhouse crops). These are uses in widely grown crops which	NL

are needed only under exceptional circumstances. The applicant must provide verifiable information about the nature and scope of the use. Based on the information provided, advice is given by the competent authority about whether the application is a minor use.	
- All uses in minor crops. The Norwegian regulation on plant protection products of May 6th, 2015, nr. 455 section 3 refers to Art. 3 (26) of Regulation (EC) 1107/2009 to define a minor crop. The Norwegian Food Safety Authority further defines minor use by giving an overview of major crops. Crops not mentioned in this list are considered as minor.	NO
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	PL
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop: o The harmful organism is localised (less than 5% of this crop's total cultivated area) or occurring sporadically (1 or 2 times in 5 years). o There is no PPP available for the use, or the available solution is not sustainable.	PT
- All uses in minor crops. - Control of a harmful organism that only occurs sporadically in a major crop.	RO
No criteria defined, case by case decision.	SE

Nineteen European countries out of the 21 respondents use the criteria to define a minor use according to Regulation (EC) 1107/2009. The criteria that a use on or in a minor crop is automatically considered a minor use is not given by all responding European countries as a possibility to define a minor use. Several countries have implemented additional criteria to define a minor use on or in a major crop. For example, if a use on a major crop concerns a small crop production acreage (e.g., a pest that only occurs on a small scale), the use is of public interest, or there is a limited or non-existent number of plant protection solutions available to control the harmful organism. These uses on a major crop can be considered minor uses in these countries.

Table 19: Update frequency of the minor uses list (N=16/22).

Update frequency	**European countries**
Every 1-2 years	BE, DE, FR, PT, SK (5)
Every 3-5 years	EE, FI, LT, NL, PL, RO (6)
Every 6-10 years	/
Not regularly	AT, CH, GB, HU, IE, LV (5)
No response provided	CY, ES, GR, PL, SE (6)

11 European countries update their minor uses list on regular basis (1 to 5 years).

3.11 Review of the links displayed on the EUMUDA website.

The relevant changes, which have been communicated to the MUCF, are implemented on the EUMUDA homepage. The national MUCF Contact Points are encouraged to communicate any further change that might occur regarding the nationally provided information. Please refer to the EUMUDA front page for detailed information on a country level: https://www.eumuda.eu/.

3.12 Overview of national working groups involved in minor uses work at a country level and specification of their role.

Table 20: Summary overview of the participants origins to the national working groups on minor uses (multiple responses possible; N=22).

European country	Competent authorities	Growers' associations	National minor uses working groups/ helpdesk	Technical Institutes & Universities	PPP Companies' Associations & PPP industry	Others	No national working group, but participation in the MUCF work
AT	X		X				
BE	X	X	X		X		
CH	X	X	X				
CY	X						
DE	X		X				
EE	X	X		X	X	X	
ES	X			X			
FI	X	X			X		
FR	X	X	X	X	X	X	
GB		X	X				
GR	X			X			
HU	X	X		X			
IE	X			X		X	
LT			X				
LV							X
NL	X	X	X			X	
NO							X
PL		X			X	X	
PT		X		X			
RO	X			X			
SE	X	X	X				
SK	X						
Total	**16**	**11**	**9**	**8**	**5**	**5**	**2**

Competent authorities (16) and/or growers' associations (11) are mainly involved in national working groups regarding minor uses.

Nine countries have one (or several) dedicated national working groups on minor uses in place.

Table 21: National working groups involved in minor uses work at a country level and specification of their role, individual response (N=22).

National working groups involved in minor uses work	European country
The 'Steuerungsgruppe Lückenindikationen' (Minor Uses Steering Group): are, e.g., organising meetings, discussing, and providing information about the present situation in Austria. Furthermore, they support applications for PPP authorisations and trials, coordinate various activities, and are contact points to the German 'BLAG-Lückenindikationen' and EU Committees (e.g., CEG working groups). http://www.oeaip.at/fachinformation/lueckenindikationen/ Members of the groups are comprised of representatives from: - Austrian Federal Office for Food Safety (BAES). - Austrian Agency for Health and Food Safety (AGES). - Federal Ministry for Agriculture, Forestry, Regions, and Water Management (BML). - Chambers of Agriculture.	AT
Several working groups in Belgium are involved in work on minor uses. These are on: - Horticulture. - Fruit growing. - Indoor vegetable growing. - Outdoor vegetable growing. - Organic fruits and vegetables.	BE
Commodity groups conduct annual surveys regarding registration gaps among technical advisers and growers.	CH
Two different sections in the Department of Agriculture: - The Plant Protection and Apiculture Section. - The Agrochemical and Feed Section.	CY
The BLAG-LÜCK (federal organisation). This organisation comprises representatives from: - Federal Ministry of Food and Agriculture. - Länder Ministry of Agriculture. - Registration Authorities. - Plant Protection Service of the Länder. The implication in MUCF Commodity Expert Groups working on: - Arable crops. - Vegetables. - Fresh herbs. - Medical plants. - Spices and tobacco. - Ornamental plants. - Hops.	DE

These experts are representatives from the plant protection service of the Länder, registration authorities, and the growers' association.	
The Estonian Agriculture and Food Board evaluates applications for PPP authorisations and research data regarding extensions of uses. Moreover, the following entities can give input on the needs of the growers, as well as insights on potential products for authorisation: - The Estonian Horticultural Association. - Estonian University of Life Science. - Estonian Crop Protection Organisation. - Plant growth advisors. - Professional growers.	EE
The following bodies are involved in work on minor uses: - Ministerio de Agricultura, Pesca y Alimentacion (Ministry of Agriculture, Fishing and Alimentation). - Instituto Nacional de Investigacon y Technologia Agraria y Alimentaria (INIA-CSIC); Unidad de Productos Fitosanitarios (PPP Unit of the National Agricultural and Food Research and Technology Institute).	ES
No specific group is dedicated to minor uses. However, growers' associations of minor crops are involved in national cooperation with the authorities and the PPP industry for research and advising.	FI
The French Organisation for Orphan Uses, coordinated by the Ministry of Agriculture, comprised of the following sub-groups: - CUO (Commission of the Orphan Uses) drives the organisation as political instance. - CTOP (Operational Technical Committee on Orphan Uses) implements the actions. Technical authority with technical experts. - GTF (Working group by sectors: Fruits, Vegetables, etc.) All the stakeholders are involved in this organisation: Ministry of Agriculture (DGAL), ANSES (evaluation authority), PPP Companies (e.g., Phyteis, IBMA), Technical Institutes, and Professional organisations.	FR
The following bodies are involved in work on minor uses: - HCP Ltd (Horticulture Crop Protection Ltd): works with growers' associations across multiple crops to establish PPP needs, commission residue trials, and apply for extensions of authorisations for minor uses. - Specific growers' groups not represented by HCP submit their own applications for extension of authorisation for minor uses.	GB
The following entities are tasked with defining minor crops and uses and issuing the relevant ministerial decrees: - Hellenic Ministry of Rural Development and Food.	GR

- Benaki Phytopathological Institute.	
The following organisations are tasked with proposals for extensions of authorisation, discussions to find solutions, and consultation in minor uses plans and actions: - Hungarian Chamber of Agriculture. - Hungarian Chamber of Crop Protection Specialists and Plant Doctors. - Producer organisations. - Scientific bodies. - Interprofessional organisations.	HU
The following bodies are involved in work on minor uses: - Teagasc: advisory, research service. - Bord Bia: Irish food board. - Department of Agriculture of the Irish Ministry.	IE
National working groups on fruits, vegetables, and ornamentals.	LT
Growers' associations submit minor uses extensions; no national working group is involved.	LV
The following bodies are involved in work on minor uses: - Helpdesk Minor Uses: provides advice on minor uses to industry, agricultural sector representatives and the government. - Minor Uses Fund: financial support for the authorisation of plant protection products and biological control agents. - Expert Centre for Specialty Crops: knowledge network. - Coordinators for effective PPPs and non-chemical methods: the interface between government, industry, and agricultural sector.	NL
No national working group on minor uses. Participation in the MUCF CEGs and HEG.	NO
The following entities can apply for the extension of authorisation of an authorised PPP to a minor use: - The authorisation holder. - Professional agricultural organisations. - Professional users.	PL
The following bodies are involved in work on minor uses: - Professional organisations: meetings to discuss minor uses issues and possible solutions, applications for minor uses extensions of authorisation. - Universities, Research Facilities: projects, breeding programs in partnership with professional organisations and innovation to develop innovative and effective solutions for crop protection.	PT
Research & Development Institute for Plant Protection (Ministry of Agriculture).	RO

- Swedish Board of Agriculture: coordinates and finances minor use work. - Swedish Minor Use project: prioritises and plans trials and applications and looks for possible solutions. Comprised of: o Federation of Swedish Farmers: minor uses trials, applies for Art. 51, contact with PPP industry representative o Svenskt Växtskydd (Swedish association of PPP industry). o Swedish Chemical Agency: evaluates Art. 51 applications.	SE
Ms Iveta Jakabovicoca is the national contact point for minor uses in the country, dealing with the authorisation of PPPs. The role within minor uses is to search for possibilities to conduct residue trials in some cases and to make decisions for extension of authorisation for minor uses.	SK

3.13 Summary and discussion points

Responsibilities, definitions and figures of minor uses and minor crops.

Minor crops:

In most cases, the criteria chosen to define a minor crop are acreage, production volume and dietary intake.

The percentage of minor crops cultivated area varies between in the responding European countries from 1% to 35%.

Although minor crops are grown on less acreage compared to major crops (mostly below 10% of the total cultivation acreage), the generated production value is high (7 to 48% of the total agricultural production value).
This illustrates the economic importance of minor crop production for the farmers' incomes and for the European agricultural production.

Minor uses:

The definition of minor uses for each European country is, in most cases, based on Regulation (EC) 1107/2009, sometimes in combination with national adaptations to consider different issues (e.g., public interest, uses on major crops).

Lists of major/minor crops and/or uses are available for 22 European countries. The information is not always presented in the same manner (e.g., some countries present only a list of major crops, stating that every use on crops not listed is a minor use, or only a list major crops with minor uses on major crops).

Working groups with focus on minor uses gaps and issues:

Nine countries have national working groups dedicated to minor use issues.

Different stakeholders (e.g., competent authorities, technical institutes, PPP companies, or growers' associations) work on topics regarding minor uses issues at national level.

If a country does not have a national working group covering minor use issues, respondents indicated that experts participate in the relevant MUCF working groups.

4 Trials

4.1. Availability of research facilities to conduct trials (Good Experimental Practice (GEP), Good Laboratory Practice (GLP), monitoring trials, etc.).

Table 22: Research facilities availability in the responding country to conduct trials summary overview (2022; N=22).

Research facilities availability 2022	European countries
Yes	AT, BE, CH, DE, EE, ES, FI, FR, HU, IE, LV, PL, RO, SK (14)
No	CY, GB, GR, LT, NL, NO, PT, SE (8)

For those countries that stated they lack facilities to conduct trials, it does not necessarily imply that they cannot generate trial data if needed. The survey question specifically pertains to public trial facilities. Private trial contractors can be engaged as an alternative.

In the 2017 survey, in comparison, more countries stated that research facilities were available at a national level (*Table 23*).

Table 23: Research facilities availability in the responding country to conduct trials summary overview (2017; N=26).

Research facilities availability 2017	European countries
Yes	AT, BE, CH, CZ, DE, DK[4], ES, FI, FR, GB, GR, HR, HU, IE, LT, LV, NL, NO, PT, RO, SE, SI (22)
No	EE, SK (2)
No answer provided.	CY, PL (2)

Differences in the trail facilities considered (public versus private) could explain variances between the 2017 and 2022 responses. Some countries may have included private trial contractors in the 2017 survey response. Reducing available funds or political decisions may have led to facility closing in some countries.

4.2. Facilities conducting trials on minor uses (efficacy and residues).

Table 24: Facilities conducting trials on minor uses, individual response (multiple answers possible; N=14/22).

Facilities	European country
No response was provided.	AT
Several research stations. Universities.	BE
Agroscope.	CH
No organisation is carrying out trials in Cyprus.	CY

[4] GEP – Good Experimental Practice units in DK: https://eng.mst.dk/media/229797/gep-recognized-research-units-in-dk-2021.pdf.

Plant Protection Service of the Länder. PPP companies.	DE
No response was provided.	EE
No response was provided.	ES
Natural Resources Institute Finland (Luke). Research centres and laboratories can conduct trials for growers' associations. Residue trials cannot be conducted in Finland anymore.	FI
Ministry of Agriculture. Professional Institutes.	FR
Contract Research Organisations.	GB
No governmental organisation is carrying out trials in Greece	GR
No response was provided.	HU
National organisations. Private companies. No facility is available to conduct residue trials.	IE
UAB Agrolab Baltic. Lithuanian Research Centre for Agriculture and Forestry. Syngenta Polska. UAB 'Agrokoncernas'.	LT
No response was provided.	LV
PPP companies. GEP research institutes.	NL
Norwegian Institute of Bioeconomy Research.	NO
No response was provided.	PL
National organisations. Private organisations: - Ascenza. - Bayer. - Syntech Research. No organisations are doing efficacy or residue trials for minor uses under Art. 51.	PT
No response was provided.	RO
UAB Agrolab Baltic. Husec.	SE
No response was provided.	SK

For additional information on GEP research facilities, please refer to: https://gepeu.wordpress.com/

For additional information on GLP, please refer to the OECD page on Good Laboratory Practice:
https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm#:~:text=The%20OECD%20Principles%20of%20Good,Acceptance%20of%20Data%20(MAD)

4.3 Ability of the National Contact Points organisation to finance and generate trial data for minor uses extension (efficacy or residue).

Table 25: National Contact Points' organisation ability to finance trials response summary overview (2022; N=22).

Ability to finance trials, Response to the 2022 survey	European countries
Yes	BE, CH, DE, ES, FR, GB, HU, IE, NL, PL, SE (11)
No	AT, CY, EE, FI, GR, LT, LV, NO, PT, RO, SK (11)

11 European countries out of 22 stated that their organisation lacks the financial means to produce either efficacy or residue trials for minor use extensions.

It has to be noted that in question 4.1, 13 European countries answered (*Table 22*) that they had research facilities to carry out trials. Among these 13 countries, six stated that they cannot finance trials to generate data for minor uses extensions (AT, EE, FI, LV, RO, SK).
Most of the available budget is used to generate data on major crops rather than on minor crops. A publication by *Meynard et all. (2018)* highlight that the development of minor crops production is hindered by a socio-technical lock-in in favour of the dominant species (wheat, rapeseed, maize, etc.). They showed that this lock-in is characterized by strongly interconnected impediments, occurring at every link of the value chains, such as lack of availability of improved varieties and methods of plant protection, scarcity of quantified references on crop successions, complexity of the knowledge to be acquired by farmers, logistical constraints to harvest collection, and difficulties of coordination within the emerging value chains.

In the 2017 survey, in comparison, the responses from the European countries were as follows:

Table 26: National Contact Points' organisation ability to finance trials response summary overview (2017; N=26).

Ability to finance trials, Response to the 2017 survey	European countries
Yes	BE, CH, DE, DK, ES, FR, GB, GR, HU, NL, SE (11)
No	CZ, EE, FI, IE, LV, NO, PT, RO (8)
No answer was provided.	AT, CY, HR, LT, PL, SI, SK (7)

Regarding the countries that answered both surveys, Ireland, which stated in 2017 that no funding was available for trials on minor uses, now has finances allocated to this type of trial. This might be explained by the percentage of minor crop acreage compared to the total agricultural surface in Ireland (~35%), showing the importance of minor crops in the country.

Greece, which stated in 2017 that they were able to finance trials, is no longer able to do so in 2022.

4.4 Willingness to share trial data.

Table 27: Willingness to share trial data response summary overview (N=22).

Willingness to share trial data	European countries
Yes	AT, BE, CH, ES, DE, FI, FR, GB, GR, HU, IE, LV, NL, PT, SE, SK (16)
No	EE, LT, RO (3)
I don't know.	CY, NO, PL (3)

16 European countries out of 22 stated that they would be willing to exchange data with other countries.
For three European countries, sharing the trial data would not be possible. The reason is not detailed in the answer. However, these are all countries for which the National Contact Point stated that their organisation did not have the financial means to conduct trials. The answer might hence be that it is impossible to share data because of a non-availability rather than an unwillingness to do so.
Data sharing may be possible on a case-by-case basis, dependent on the needs of individual countries, as orally communicated (after the survey, in meetings) by experts to the MUCF.

Table 28: Summary overview of the national requirements foreseen for data exchange between European countries (multiple responses possible; N=16/22).

Requirements for data exchange	European countries
Data exchange without fee	BE, DE, ES, FR, HU, IE, NL, SE (8)
Data exchange with a fee	DE, GB, NL (3)
Data exchange, pending approval from stakeholders	ES, GB, PT (3)
Case by case	AT, FI (2)
Not specified	CH, GR (2)
No data available for sharing	LV, SK (2)
No response provided	CY, GR, LT, PL, RO (5)

16 out of 22 responding European countries would be willing to exchange data. The application of a fee is often seen as an alternative to the data exchange rather than the primary request (all the countries that stated they could require a fee for data also indicated that data exchange would be considered). This illustrates, that data sharing is the preferred option over charging a fee.

4.5 Data generation (efficacy or residue) foreseen in the near future.

Table 29: Data generation foreseen in the near future response summary overview (N=22).

Response to the 2022 survey	European countries
Yes	BE, CH, DE, ES, GB, HU, SE (7)
No	AT, CY, EE, GR, IE, LV, LT, NL, NO, PT, RO (11)
I don't know.	FI, FR, PL, SK (4)

BE, CH, DE, ES, GB, HU, SE stated that their organisations intend to produce trial data in the near future. In 11 European countries data generation is not foreseen soon. This illustrates that quickly, data gaps will become more prominent, which is more related to the inadequate funding than to the unwillingness of the countries to produce data.

4.6 Summary and discussion points

Trials

Facilities (governmental or private) to conduct trials (efficacy (GEP) and/or residue (GLP)) are in place in most European countries.

The given findings underpin the willingness to produce and share data among the European countries (16 out of 22 respondents stated that they are willing to share data), preferably in exchange for trial data rather than a fee.

It is encouraged that all the European countries to support data sharing amongst European countries and access whilst observing data protection principles.

There is a lack of resources allocated by different stakeholders to conduct residue and efficacy trials on and in minor crops (according to article 51, 2b of Regulation (EC) 1107/2009, efficacy data are not required for minor uses).

Major crops have more resources allocated for data generation.

A publication by *Meynard et all. (2018)* highlight that the development of minor crops production is hindered by a socio-technical lock-in in favour of the dominant species aka major crop (wheat, rapeseed, maize, etc.). They showed that this lock-in is characterized by strongly interconnected impediments, occurring at every link of the value chains, such as lack of availability of improved varieties and methods of plant protection, scarcity of quantified references on crop successions, complexity of the knowledge to be acquired by farmers, logistical constraints to harvest collection, and difficulties of coordination within the emerging value chains.

It is important to grant and provide funding for trials related to minor uses. A possible solution could be a European minor uses mutual fund for efficacy and residue trial data generation.

As such a fund is not currently established, further extrapolation possibilities for residues (MRLs) and efficacy can be explored to provide a good basis to increase the number of registered PPPs for minor uses.

The agri-pesticide industry is encouraged to collaborate with official or public bodies to generate residue trial data that support new residue extrapolations from major crops to minor crops.

5 Article 51 (extension of authorisation for minor uses).

5.1 Fees applied for an Art. 51 extension of authorisation.

Table 30: Summary overview of the fees applied for an extension of authorisation for minor uses (rounded to the nearest EUR, multiple responses possible; N=26).

Fee for Art. 51 extension	Specification (No of countries)	Condition/ amount	European countries
Free	No fee required (6)	No condition.	CH, EE
		The applicant is a third party.	BE, IE
		The applicant is from the authority.	DE
		In certain cases.	HU
Variable	(2)	Fee schedule/table of charges: https://www.baes.gv.at/fileadmin/baes/Amtliche_Nachrichten/in_Kraft/04-2023_PST-Pflanzenschutzgebuehrentarif.pdf	AT
		Different fees for zonal applications.	HU
Not specified	(4)	Fee amount is not specified.	**CZ*, DK, SI,** RO
≤ 1 000 EUR	Per application (11)	20 EUR acc. Art. 51 (7) 10 EUR for low-risk substance.	CY
		300 - 1 000 EUR if the applicant is the authorisation holder.	IE
		180 EUR.	LT
		142 EUR if the applicant is a third party. If the applicant is the authorisation holder: - 356 EUR for a mutual recognition - 711 EUR if the country is concerned Member State (cMS).	LV
		250 EUR for one application (crop x pest) at national level.	PT
		150 000 HUF, equivalent to roughly 375 EUR.	HU

		9 815 NOK, equivalent to roughly 980 EUR for a national evaluation.	NO
		1 900 PLN, equivalent to roughly 405 EUR.	PL
		Depending on the time needed to assess the application.	**HR**
		373 EUR administrative fee (additional assessment fee may apply). 149 EUR if the extension is of public interest.	ES
		246 EUR if SK is zRMS. 88 EUR if SK is cMS. Additional charges are possible for expert remuneration.	SK
	Per crop (1)	300 – 500 EUR depending on the amount of evaluation work needed.	GR
1 000 – 14 000 EUR		6 000 EUR if the applicant is the authorisation holder.	BE
		2 000 EUR.	FR
		1 250 – 5 200 EUR depending on the amount of work needed.	FI
		1 722 EUR if the country is zRMS and the applicant is the authorisation holder.	LV
	Per application (9)	~14 000 EUR for national application (6 000 EUR application + ~8 000 EUR assessment) depending on the amount of assessment work needed.	NL
		7 700 EUR for an application acc. 51 (7) at a zonal level.	PT
		1 499 - 1 723 EUR if an assessment is needed.	ES
		1 250 EUR.	SE
	Per crop x application	1 768 GBP, equivalent to roughly 2 000 EUR.	GB

*Countries marked in **bold** did not respond to the 2022 survey, but information is available to the MUCF from previous exchanges (2017 survey).

Table 31: Fees applied for an Art. 51 extension of authorisation application, individual response (N=22).

Individual responses to the 2022 survey	European country
- 3272.80 EUR for a zonal Art. 33 application if AT is the zRMS. - 3666.60 EUR for an interzonal Art. 33 application if AT is the international zRMS. - 2392.20 EUR for a zonal Art. 33 application in which AT is the only cMS. - 655.20 EUR for an extension of the authorisation according to Art. 40. - 1327.70 EUR for an application following Art. 45 (Withdrawal or amendment of an authorisation at the request of the authorisation holder), as an extrapolation of an existing Austrian authorisation. Additional fees may be applied depending on the amount of assessment work needed. The applicable fees can be found in the current fee schedule of the Federal Office for Food Safety: https://www.baes.gv.at/fileadmin/baes/Amtliche_Nachrichten/in_Kraft/04-2023_PST-Pflanzenschutzgebuehrentarif.pdf These fees are calculated for each additional working hour.	AT
Art. 51 applications submitted by third parties are free of charge.	BE
No fee is required.	CH
For all registrations, the mutual recognition procedure is followed. - 20 EUR per application. - 10 EUR per application if the active substance is low-risk.	CY
No fee is required.	EE
- No fee is required if the applicant is a competent authority. - A low fee is required if the profit expectation exceeds a certain limit. In this case, if the applicant is a competent authority, it is recommended to hand over the application to the authorisation holder	DE
- 373.18 EUR: standard administrative fee. - 149.29 EUR: administrative fee if the extension of use is of public interest). - 1 349.35 EUR: assessment fee, if needed.	ES
- 1 250 EUR per application for an extension of use application according to Art. 51. - Maximum price of 5 200 EUR depending on the amount of assessment work needed (e.g., number of uses applied for).	FI
- 2 000 EUR per application.	FR
1 768 GBP (~2 000 EUR) per application. One application per basic crop as per the 'Crop Definitions List'. For products requiring no residues/consumer risk evaluation, covering multiple basic crops within the same parent crop group is possible. Additional risk assessments required are charged (e.g., field or orchard uses, outdoor or protected).	GB
- 300 EUR per crop if no additional evaluation is required. - 500 EUR per crop if evaluation is needed.	GR
- Standard fee: 150 000 HUF (~375 EUR)	HU

- Different fees for the zonal application and national application according to the national legislation (Ministerial Decree of Rural Development about the rate of administrative service fees). - In certain cases, a 40% reduction or no fee is required. - Total cost depends on necessary inputs, the amount of assessment work needed, and the sections to be evaluated.	
- No fee is required for non-authorisation holders. - Typical fee charged: 300 EUR per application. - Up to 1 000 EUR for applications where comprehensive evaluation is needed.	IE
If the applicant is the state, scientific bodies, or professional agricultural organisations: - 142.29 EUR per PPP for state, scientific bodies, or professional agricultural organisations. If the applicant is the authorisation holder: - 355.71 EUR per PPP for a mutual recognition. - 711.43 EUR per PPP if LV is cMS. - 1722.29 EUR per PPP if LV is zRMS.	LV
180 EUR per application (all claimed uses).	LT
On average 14 000 EUR for national applications (NLKUG): - 6 000 EUR application costs (always applied). - ~8 000 EUR assessment cost depending on the amount of assessment work needed (parts which do not fall under the risk envelope approach and must be assessed).	NL
9 815 NOK (~980 EUR) per application. The rates are slightly adjusted each year.	NO
Art. 51 extension of authorisation: - 250 EUR for a national evaluation (crop x pest). - 7 600 EUR per PPP for a zonal evaluation (including all uses). - 7 700 EUR for a mutual recognition (including all uses). If the minor use requested by the applicant is not included in the RR and is not authorised in other Member States, the fee applied is the one for national applications (250 EUR).	PT
A single fee for extension of authorisation to all minor uses.	RO
1 250 EUR per application.	SE
- 245.72 EUR per PPP if SK is the zRMS. - 87.76 EUR per PPP if SK is a cMS. - Additional charges for experts involved in the assessment.	SK

No significant changes could be identified in the fees required by the European countries for an Article 51 extension of authorisation from 2017 to 2022.

The highest stated fee is approximately 14 000 EUR in the Netherlands for a national application if the minor uses application of extension involves a significant amount of assessment work.

The financial aspect (e.g., application fees and additional data generation requirements) is frequently cited as a hurdle by the applicant (as indicated by MUCF experts) when it comes to applying for a PPP extension for minor uses.

5.2 Article 51 (extension of authorisation for minor uses).

For the full definition of Art. 51. of Reg. (EC) 1107/2009, please refer to App. A (p. 86).

Table 32: Entities able to apply for Art. 51 extension of authorisation responses summary overview (multiple responses possible; N=22).

Entity	European countries
The authorisation holder	All 22 responding European countries.
Professional agricultural organisations	AT, BE, CY, DE, EE, ES, FI, FR, GB, GR, HU, IE, LT, LV, NO, PL, PT, SE, SK (19)
Official bodies involved in agricultural activities	AT, BE, CY, DE, ES, FI, FR, GB, GR, HU, IE, LV, NL, NO, PL, PT, RO, SK (18)
Scientific bodies involved in agricultural activities	AT, BE, CY, DE, EE, ES, FI, FR, HU, IE, LV, NO, PL, PT, RO, SK, SE (17)
Professional users	AT, BE, CY, EE, FI, GB, GR, IE, LV, NO, PL, PT, SE (13)

The authorisation holder can apply for an Art. 51 extension of authorisation in all the responding European countries. The eligible entity which can apply in the fewest number of countries (13) are the professional users.

Spain reported on a national procedure for minor uses extension applications. More information about '*Ampliación de uso de un product fitosanitario a un cultivo menor*'[5] can be accessed in Spanish under:

- https://sede.mapa.gob.es/portal/site/seMAPA/ficha-procedimiento?procedure_suborg_responsable=93&procedure_etiqueta_pdu=null&procedure_id=377&by=type

5.3 Entities that apply for Art. 51 extension of authorisation.

Table 33: Entities that apply for Art. 51 extension of authorisation response summary overview (multiple responses possible; N=22).

Entity	European countries
The authorisation holder	AT, CH, CY, DE, ES, FR, GB, GR, HU, LT, LV, NL, NO, PL, PT, RO, SK (17)
Professional agricultural organisations	BE, FI, GB, IE, LV, LT, NO, PT, SK, SE (10)
Professional users	AT, EE, IE, LV, PT (5)
Official bodies involved in agricultural activities	DE, IE, LV (3)
Scientific bodies involved in agricultural activities	EE, LV (2)

In 17 European countries out of 22, the applicant for a minor uses extension of authorisation is primarily the authorisation holder.

[5] https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/procumdiciembre2014_tcm30-618107.pdf

Professional users, official and or scientific bodies do not seem to apply for extensions for minor uses in many countries, even if they are eligible.

Greater involvement of official or scientific bodies, in collaboration with professional organisations, might increase the number of minor use extensions.

For France, it is specified that the application for an extension of use, when made by the authorisation holder, is often done with the support (e.g., support letters) of professional growers' organisations.

5.4 Organisation evaluating extension of authorisation for minor uses.

Table 34: Organisation evaluating the extension of authorisation for minor uses (multiple responses possible; N=21/22).

Organisations	Link	European country
Austrian Agency for Health and Food Safety (AGES).	https://www.ages.at/en/	AT
Department for Plant Protection Products Authorisation Institute for Plant Protection Products Division for Food Security	https://www.baes.gv.at/en/admission/plant-protection-products	
Federal Public Service Health, Food Chain Safety and Environment	https://www.health.belgium.be/en	BE
Federal Food Safety and Veterinary Office	https://www.blv.admin.ch/blv/en/home.html	CH
Federal Office for Agriculture	https://www.blw.admin.ch/blw/en/home.html	
Plant Protection and Biocides Board	http://www.moa.gov.cy/moa/da/da.nsf	CY
Federal Office of Consumer Protection and Food Safety (management authority) in cooperation with Julius Kühn-Institute (efficacy and bees).	https://www.bvl.bund.de/EN/Home/home_node.html	DE
Federal Institute for Risk Assessment (residues, MRL, worker and bystander)	https://www.bfr.bund.de/en/home.html	
Federal Environmental Agency (environment)	https://www.umweltbundesamt.de/en	
Estonian Agriculture and Food Board	https://pta.agri.ee/en/establishment-agriculture-and-food-board	EE
Ministry of Agriculture, Fisheries and Food	https://www.mapa.gob.es/en/ministerio/default.aspx	ES
Ministry of Ecological Transition	https://energia.gob.es/en-US/Paginas/index.aspx https://www.sanidad.gob.es/en/home.htm	
Ministry of Health	https://www.sanidad.gob.es/en/directoa/home.htm	

Ministry of Health Spanish Agency for Food Safety and Nutrition	https://www.aesan.gob.es/en/AECOSAN/web/home/aecosan_inicio.htm	
Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA-CSIC)	https://www.inia.es/en-en/Pages/Home.aspx	
Safety and Chemicals Agency (Tukes)	https://tukes.fi/en/frontpage	FI
Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES)	https://www.anses.fr/fr	FR
National Food Chain Safety Office	https://maradeknelkul.hu/en/about-us/about-nebih/	HU
Health and Safety Executive (HSE) - Chemicals Regulation Division (CRD)	https://www.hse.gov.uk/pesticides/	GB
No response provided		GR
Pesticide Registration and Controls Divisions of the Department of Agriculture, Food, and the Marine	https://www.pcs.agriculture.gov.ie/	IE
State Plant Service	https://www.vatzum.lt/en	LT
State Plant Protection Service	https://www.vaad.gov.lv/en	LV
Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)	https://english.ctgb.nl/	NL
Norwegian Food Safety Authority, National Approvals Department	https://www.mattilsynet.no/language/english/	NO
Ministry of Agriculture and Rural Development – Department of Plant Breeding and Protection	https://www.gov.pl/web/agriculture/plant-breeding-and-protection-department	PL
Directorate General for Food and Veterinary (DGAV)	https://www.dgav.pt/	PT
Research Development Institute for Plant Protection	http://www.ipsw.gr/en/departments/plant-protection-patra	RO
National Institute of Public Health	https://eody.gov.gr/en/npho/	
Swedish Chemicals Agency	https://www.kemi.se/en/about-the-swedish-chemicals-agency	SE
Central controlling and testing institute of agriculture	https://www.uksup.sk/o-nas-historia	SK

5.5 Efficacy data requirements for Art. 51 extensions of authorisation.

Table 35: Efficacy data requirements for an extension of authorisation for minor uses response summary overview (N=22).

Efficacy data requirements Art. 51	European countries
No	All 22 responding European countries.

According to Art. 51 of Regulation (EC) 1107/2009, no efficacy data for minor uses are required.

Table 36: Specific requirements on efficacy data for Art. 51 extension of authorisation, individual response (N=7/22).

Specific requirements on efficacy data for Art. 51 extension.	European country
- If the use is applied according to Art. 51 and covered by the 'Lückenindikationserlass[6]', then no efficacy assessment is necessary. - If the use is NOT applied according to Art. 51 but covered by the 'Lückenindikationserlass', the EPPO data packages according to EPPO Standard PP 1/224 *Principles of efficacy evaluation for minor uses* and PP 1/257 *Efficacy and crop safety extrapolations for minor uses* are necessary.	AT
As part of the mutual recognition procedure (efficacy data are required by the reference Member State).	CY
No efficacy data are required for the application and the authorisation. However, efficacy trials are conducted by the extension services to ensure that only effective PPPs are put on the market, and to generate data for the Plant Protection Advice Service.	DE
No efficacy data are required, but some knowledge of the product's mode of action and use is needed (use rates, sensitivity, etc.).	FI
The following text appears on all United Kingdom's extensions of authorisations for minor uses: '*This extension of the authorised use provides for the use of the [product name] regarding crops and situations other than those included on the product label [above].* *No effectiveness or phytotoxicity data have been assessed, and as such, the 'extension of use' is at all times done at the user's choosing, and the commercial risk is entirely theirs.'*	GB
No efficacy data are required in general (in case of similarities with authorised uses in other crops or possibilities for extrapolation) but might be required in specific cases.	HU
For the extension of authorisation for minor crops, extrapolation is made from a major crop. In some situations, the applicant submits efficacy data for minor uses.	RO

Belgium, Finland, and Hungary stated in the 2017 survey that they anticipated some form of efficacy data for Art. 51 evaluation. These countries now affirm that efficacy data is unnecessary.

Hungary and Finland emphasize that some information regarding the products efficacy is beneficial for the assessment.

5.6 Experience with data protection claims for minor uses (according to Art. 51 extension of authorisation).

Table 37: Experience with data protection claims response summary overview (N=22).

Data protection claims	European countries

[6] https://lueckenindikationen.julius-kuehn.de/was-sind-lueckenindikationen.html (in German language).

Yes	BE, DE, ES, GR, IE, LV, NL, PT, SE (9)
No	CY, EE, FI, FR, GB, HU, LT, NO, PL, RO (10)
I don't know.	AT, CH, SK (3)

Table 38: Handling of data protection claims response summary overview (N=10/22).

Procedure for data protection	**European countries**
Handled as foreseen in Regulation (EC) 1107/2009.	AT, BE, DE, ES, GR, IE, LV, NL (8)
A letter of access to the data is always required.	PT (1)
National regulation	GB (1)

Table 39: Handling of data protection claims, individual response (N=11/22).

Handling of data protection claims	**European country**
Data protection (according to Art. 51) is handled according to the "Technical guideline on data protection" (according to the official journal of the EU, C 229, from 8th July 2019). *'The document provides Member States and applicants with guidance on the procedures and policies surrounding various elements of data protection, as related to plant protection products legislation. It considers the practical application of the legal provisions of Art. 59 – 62 and 80 of Regulation (EC) 1107/2009 of the EU Parliament and the Council*.	AT
Data protection rules are applied as foreseen in Regulation (EC) 1107/2009.	BE
Companies require data protection for a first product application and new product developments.	DE
The data protection claims for applications, according to Art. 51 are handled in the same way as Art. 33.	ES
Any new data submitted will be protected for ten years from the date of issue of the first authorisation of the product. The covering letter will detail the data submitted, whether it was used, and a data protection period applied. Where the authorisation holder applies for an Extension of Authorisation for Minor Uses (EAMU) and submits new data in support of the application, these data will be protected for ten years from the date of issue of the first product authorisation. The data protection period for the original data package for the product will be extended by three months if the extension of use is issued within five years of the first authorisation of the product.	GB
An application, according to Art. 51 with new residue trials can prolong the data protection period for three months.	GR
All data used in the evaluation of Art. 51 authorisations must be accompanied by a letter of access from the data owner or have an expired data protection period unless the applicant owns the data.	IE
Data protection rules are applied as foreseen in Regulation (EC) 1107/2009, Art. 59 (1).	LV

Ctgb has produced a decision tree to explain how it handles the granting of additional data protection for minor uses applied with Art. 51 of Regulation (EC) 1107/2009. Several examples are provided below the decision tree for illustration purposes. See: https://english.ctgb.nl/plant-protection/types-of-application/minor-uses/extra-data-protection	NL
An access letter from the authorisation holder is always requested. In the minor use evaluation, the owner of residue data is verified.	PT
Data protection claims have been made on residue trials belonging to growers' associations.	SE

5.7 Possible obstacles in minor uses authorisation (according to Art. 51 extension of authorisation).

Table 40: Obstacles perceived in Art. 51 extension of authorisation response summary overview (N=22).

Obstacles perceived in Art. 51 extension	European countries
Yes	AT, DE, EE, ES, FI, HU, IE, NO, PT, SE (10)
No	BE, CH, CY, FR, GR, LT, LV, NL, PL, RO, SK (11)
I don't know.	GB (1)

The obstacles perceived may vary from one country to another. Eleven countries did not perceive any obstacle regarding the authorisation of Art. 51 extension of authorisation applications.

Table 41: Obstacles perceived in the evaluation of Art. 51 extension of authorisation response summary overview (multiple answers possible; N=11/22).

Obstacles perceived in Art. 51 extension evaluation	European countries
Lack of data	AT, EE, ES, FI, IE, NO, SE (6)
Conflict with companies due to national requirements	DE (assessment of public interest) (1)
Provided data are not relevant	HU (1)
Differences in national assessment requirements	NO (1)
Number of applications to assess	PT (1)
Financing trials and applications	AT (1)
No response provided	GB (1)

In most cases, when a respondent perceives an obstacle, it is linked to the lack of data to grant the authorisation.

Table 42: Obstacles perceived in the application for Art. 51. extension of authorisation, individual response (N=11/22).

Obstacles perceived in Art. 51 extension application	European country
Difficulty in financing trials and applications for authorisation.	AT

Some PPP companies opinionated that the public interest must not be reevaluated (cMS or in the framework of mutual recognition) when it was already done in the country of origin. The EC confirmed that a country can reevaluate the public interest based on its national criteria and conditions.	DE
- No data available for the regulatory zone. - Difficulty to find a suitable product for the intended minor use.	EE
Extrapolations of environmental fate, behaviour and ecotox. from the major crop to the minor crop is demanding and requires additional data.	ES
- Low number of residue trials available. - Difficulty to meet the set MRL for the respective crop. - Several data gaps when the product is authorised for use in greenhouses, and the extension of use is claimed for a use on the field (or the other way around).	FI
Applications are unsuitable and not supported by acceptable documentation (i.e. efficacy is not expected based on the application).	HU
It is not possible to gain access to data generated by growers' organisations in other European countries.	IE
- Difficulty to meet the requirements of the regulation and at the same time to achieve the purpose of the Art. 51. - The agricultural extension service finds it demanding to retrieve documentation on residues.	NO
- To many minor uses are applied for by the PPP authorisation holder. - A higher number of biological products are being authorised for a larger number of minor crops and minor uses.	PT
- Several data gaps when the product is authorised for use in greenhouses, and the extension of use is claimed for field use (inversely). - No risk assessment or risk mitigation possibility with the spraying system (e.g., fan sprayer in tall crops) applied for. - The packaging of the product is not adapted to the minor use (e.g., product packaged as 1000 litre doses are not suitable for a minor use requiring a smaller dosage). - The use applied for is on crops that have no scenarios for environmental fate (e.g., nurseries, forest nurseries). - Risk envelope approach[7] is impossible due to different crop sizes, different means of application, smaller application intervals than evaluated, higher doses than evaluated, and different application timing, lack of information regarding groundwater or environmental fate.	SE

[7] SANCO/11244/2011 rev.5: '*The risk envelope is a concept which exploits the idea that in each area of assessment the supported uses of a product can be grouped taking into account certain criteria (e.g., crop, application rate, number of applications, timing, etc.) and the assessment can be targeted at the group rather than at 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 GAP is less critical or the same.'*

5.8 Zonal application procedure for minor uses (according to Art. 51 extension of authorisation).

In most cases, the zonal application is evaluated following Regulation (EC) 1107/2009. Three countries stated that national guidelines have been implemented (2 responding countries are not part of the European Union; Switzerland, and the United Kingdom).

Table 43: Handling of zonal application according to Art. 51 extension of authorisation, individual response (N=20/22).

Zonal application procedure for minor uses handling	European country
Zonal applications, in general, are dealt with according to Art. 33. For extensions of authorisations for minor uses, additionally, the conditions according to Art. 51 apply.	AT
Art. 51 applications submitted by third parties are treated as zonal applications without cMS.	BE
Switzerland applies its own national procedure for the extension of authorisation for minor uses. According to Art. 35 of the Swiss Ordonnance on PPP, Switzerland applies a simplified 'Mutual recognition' procedure for minor uses if these minor uses are authorised in a European country climatically and ecologically comparable to Switzerland.	CH
No response was provided.	CY
All applications, according to Art. 51 are zonal applications. All applications undergo a commenting phase, all EU countries can comment, and these comments are considered in the decision-making scheme.	DE
If a minor use is applied for in a zonal application, it will be assessed according to Art. 51.	EE
A national procedure has been implemented in Spain, available at this link (in Spanish): https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/procumdiciembre2014_tcm30-618107.pdf	ES
No zonal application for minor uses has been received in Finland yet. Currently, part of the re-authorisation of the PPPs includes the possibility to apply for extension of authorisation on minor uses.	FI
No specific procedure. The evaluation is carried out simultaneously with the other extensions of authorisation applied for.	FR
- The HSE assess zonal applications for Northern Ireland only. The zonal application for extension of authorisations on minor uses is carried out in the process of the product renewal. - Applicants can request a new extension of authorisations on minor uses for use in Northern Ireland only, based on a zonal application with Northern Ireland as cMS or a mutual recognition under Art. 40.	GB

- The authorisation holder must support the extension of authorisations on minor uses. - Application for an extension of authorisation on minor uses is done either by the authorisation holder or by HCP Ltd (on behalf of the growers). - For the minor use applied for to be added on the product label, efficacy data is required. Otherwise, the uses remain as an extension of authorisations on minor uses and will be issued as such at the end of the assessment. - As the United Kingdom is not an EU Member State, it cannot undertake any zonal assessments, even for Northern Ireland.	
A dRR is provided by the applicant. The competent authorities evaluate the dRR, and a commenting period is launched. After the commenting period, a Registration Report is finalised and the extension of uses according to Art. 51 is granted.	GR
As cMS in a zonal application, if no issues with data protection are identified, Ireland always tries to grant as many minor uses as possible.	IE
For label extensions, the following information is required: - dRR Part A. - Updates/addenda for relevant sections of dRR Part B, depending on the amendments (e.g., efficacy, toxicology, fate, residues, ecotoxicology, analytical methods for residues if not addressed at EU level). - Only the necessary assessment relevant for the amendment should be inserted in the respective sections of dRR Part B. An amendment should not include studies under evaluation for the active substance renewal and/or product studies according to the new data requirements (Regulation 284/2013). - For further information, see Appendix 4 of the guidance document SANCO/13169/2010.	LT
No zonal applications for minor uses have been received in Latvia yet.	LV
Minor uses (Art. 51, Regulation (EC) 1107/2009) can be part of a zonal application. This can be done immediately with the first application for authorisation of the product (at the same time as a major use application) or later by means of a zonal extension application. Minor uses applications are indicated separately on the GAP under the heading ‘Art. 51’. The risk envelope approach is applied (are the minor uses comparable to a major use applied for within the same application, or is a separate assessment required). When minor uses are applied under Art. 51 within a zonal application, no efficacy assessment is performed.	NL

The authorisation holder can submit the zonal application together with the application for the new product (Art. 33) or during the renewal of the product (Art. 43). The authorisation needs to include the minor uses applied for in the dRR. The zRMS will then evaluate the minor uses included in the GAP table. The decision is made nationally.	NO
A dRR is requested for minor uses in major crops for national applications. For zonal applications (Portugal is a concerned Member State): all the minor uses existing (crop x pest) in Portugal are authorised.	PT
No response was provided.	PL
Extension of authorisation on minor uses are accepted if the available data (on which the extrapolation is based) come from the Central zone.	RO
The zonal application for extension of authorisation on minor uses is carried out in the process of product renewal. The evaluation follows the risk envelope approach (except for residues) based on the assessment carried out in the first registration process.	SE
Slovakia has evaluated only one zonal application for extension of authorisation on minor uses. The process is similar to the registration of application according to Art. 33.	SK

5.9 Use of 'public interest' as a criterion to assess a registration according to Art. 51 extension of authorisation.

Table 44: Use of the 'public interest' as a criterion for evaluation of Art. 51 extension of authorisation response summary overview (N=21/22).

Public interest criterion	European countries
Yes	AT, BE, CY, EE, ES, FI, FR, GB, DE, HU, IE, NO, PT, SE, SK (15)
No	CH, GR, LT, LV, NL, RO (6)
No response provided	PL (1)

Depending on the European country, 'public interest' is assessed according to different criteria.

5.10 Criteria to assess 'public interest'.

Table 45: Criteria to assess 'public interest' response summary overview (multiple criteria possible, N=15/22).

Public interest criteria	European countries
The use applied for is intended for a crop on which no/insufficient PPP solutions are available.	BE, DE, FR, IE, PT, SK (6)
Official bodies and/or Growers' associations support the necessity of the use.	CY, EE, FI, GB, HU, SE (6)
The use applied for is considered minor.	AT, DE, FR, NO (4)
The product would provide a resistance mitigation measure.	FR, PT (2)

A rationale from the applicant is required.	FI, HU (2)
The PPP product is low-risk.	FR (1)

Table 46: Assessment of the 'public interest' criteria, individual response (N=15/22).

Assessment of the 'public interest' criteria individual response.	**European country**
The crop, or the use, is considered as minor.	AT
Most third-party extensions of authorisations are requested for fruits and vegetables, being an important part of the Belgian diet. Due to the cost of generating data and administrative fees, the lack of economic return for the authorisation holder greatly limits the number of authorisations in these crops. It could increase the risk of illegal use, which could threaten human health. This justifies the public interest.	BE
The Department of Agriculture identifies public interest issues. It then notifies the issue of public interest to the authorisation holders to search for a possible solution through applications, acc. to Art. 51.	CY
An Art. 51 application is of public interest if the intended use is a minor use, and the minor use gap is not closed (available tools to solve the plant protection problem are insufficient). The public interest status of an Art. 51 application is evaluated by the Julius-Kühn Institute.	DE
The following entities can forward issues considered of public interest to the competent authorities: - Growers' associations. - The Estonian Horticultural Association. - Estonian University of Life Science. - Estonian Crop Protection Organisation. - Plant growth advisors. - Professional growers.	EE
The competent authority assesses the public interest based on a rational provided by the applicant.	ES
The competent authority assesses the public interest based on a rationale provided by the applicant. The rational must also include the necessity of the minor use application.	FI
The use applied for must be minor and an orphan use (no PPP solution available). Other criteria that can be considered: - Resistance mitigation measure. - The substance is low-risk or on the biocontrol list. - Applications with substances CMR1 (cut-off criteria) cannot be considered of public interest. - Other criteria can be considered.	FR
The following entities can forward issues considered of public interest to the competent authorities: - Growers' association. - Official bodies. - Authorisation holders. A need with applications of multiple emergency authorisations can also be considered of public interest.	HU

Applications must be submitted with a reasoned case to demonstrate the public interest status for the proposed use, including: - Details of the nature of the problem, which must include reference to named harmful organism(s). - Details of the scale of the problem. - Explanation as to why alternative means of control (both existing authorisations and cultural methods) cannot be used. - Support letter(s) from grower's associations for the use applied for.	GB
It is deemed to be in the public interest for Irish consumers to have access to Irish-grown produce as much as possible. If the production of these crops in Ireland requires the authorisation of certain PPPs to control pests, then authorisations under Art. 51 are possible.	IE
The use applied for is considered minor.	NO
The use is considered of public interest if the combination of crop and pest is found in the country, and there is a lack of solutions (PPP or other solutions) available for this use.	PT
If professionals (e.g., growers association, professional user) state an interest in an Art. 51 authorisation, it is considered of public interest.	SE
The use is considered of public interest if: - Less than five plant protection products with different active substances (mode of action) are authorised for this use. - It is proven that authorised plant protection products are not sufficiently effective due to the occurrence of resistance. - Due to specific requirements to protect the health of people, animals, or the environment, it is no longer possible to use an authorised plant protection product.	SK

5.11 Summary and discussion points

Article 51 (extension of authorisation for minor uses)

Authorisation holders are the main applicants for extension of authorisation for minor uses following Art. 51, even though this procedure is open to various stakeholders (growers' associations, official and scientific bodies).

As indicated by MUCF experts, the requested fee to apply for an authorisation following Art. 51 is often lower than for an Art. 33 application.

Efficacy data are not required for an Art. 51 application, as foreseen in Regulation (EC) 1107/2009.

MUCF experts indicated that the absence of efficacy/phytotoxicity data requirements for Art. 51 poses challenges to the agri-pesticide industry. While such data is not mandatory for the application, its absence could harm the companies reputation upon authorisation.

Half of the respondents indicated that they experienced some hurdles in the process of Art. 51 authorisation. These hurdles were often linked to a lack of trial data (6 respondents out of 11).

Fifteen countries out of 21 respondents consider the public interest in the assessment of Art. 51 applications.

The criteria used to define and assess a public interest may vary between countries. The most frequently cited criteria are:

- There is a lack of authorised PPPs for the applied for use.
- The use is supported by official bodies and/or Growers' associations.
- That an applied for use is considered minor.

Applicants are encouraged to apply for as many minor uses as possible via Art. 51 & to include all relevant Member States in a regulatory zone in a minor use application if applied together with Art. 33 or other articles than 51.

6 Risk assessment

6.1 Carrying out of the risk assessment for minor uses.

For a description of the key parameters to be considered in developing an appropriate risk envelope, please refer to Appendix B (p. 87).

Table 47: Risk assessment procedure for minor uses, individual response (N=21/22).

Risk assessment procedure	European country
- The risk envelope approach is used for minor use applications. If the minor use applied for falls within the risk envelope approach as regards the registered uses (in terms of GAP), residues only are to be considered, and the residue dRR only is to be provided. A simple statement in Part A indicating that the new use falls within the risk envelope is sufficient for the remaining sections. - If the minor use applied for is different in terms of GAP (e.g., dose, application timing, etc.), other sections must be addressed accordingly (and the respective dRR needs to be provided). - If the minor use applied for falls within the risk envelope approach regarding registered uses (in terms of GAP), and residues may be simply handled via extrapolation (no new data	AT

needs to be evaluated), it is possible to use Art. 45 (Withdrawal or amendment of an authorisation at the request of the authorisation holder). - The same procedure might be applied if a use on the crop is already registered, but a new use only is to be listed in the GAP (under the precondition that the GAP will not be changed compared to the registered crop).	
The risk envelope approach is used for minor use applications.	BE
- The risk assessment is not required for mutual recognition for minor uses. - If the use is not claimed under a mutual recognition procedure, the risk assessment is extrapolated from authorised uses (risk envelope approach).	CH
Minor uses are only granted under mutual recognition in Cyprus. No additional risk assessment is required, as it is evaluated by the reference Member State.	CY
- The risk envelope approach is used for minor use applications. Usually, minor use applications are covered by the risk assessment of an already authorised use. - Residues are under evaluation in all applications. The compliance with existing MRLs is verified, and new MRLs are requested where necessary. - If the risk envelope approach does not cover the environmental risk assessment for the use applied for, a full risk assessment has to be conducted. - Regarding effects on groundwater and the environment, the criteria for the extension of authorisations for minor use are the same as for regular authorisations (Article 51 (2) point (b) in conjunction with Article 4 (3) points (b) and (e) of Regulation (EC) 1107/2009).	DE
- The risk envelope approach is used for minor use applications. - Only residues are under evaluation in all minor uses' applications. The compliance with existing MRLs has to be verified. - If no MRLs are set (extrapolation is impossible), additional residue trials are requested where necessary. Based on experts' judgement, other assessments can be conducted.	EE
- The risk envelope approach is used for minor use applications. The minor use extension will be covered under the risk assessment carried out for the major uses, which is already authorised. - The risk envelope approach has to be justified, but no additional data is required. - For a minor use authorisation, the most important point is that an MRL has already been set for the active substance applied for. If no MRL has been set, the authorisation will not be granted.	ES
- The risk envelope approach is used for minor use applications. - Residue trial data have to be available.	FI

- A new assessment may be carried out if the authorised uses don't cover the minor uses applied for.	
- The risk envelope approach is used for minor use applications. - Usually, minor uses applications are covered by the risk assessment of an already authorised major use. - New assessments are needed if a major crop does not cover the specific GAP of the minor use applied for.	FR
All points of the safety aspects of the risk assessment for the proposed use must be addressed using data and/or reasoned scientific cases: - Risk to non-dietary human exposure (operators, workers, bystanders). - Risk to consumers (residues) - Ecotoxicology - Environmental fate The reasoned case may include extrapolation from relevant authorised crops (for example, where the authorised on-label use(s) reflect those proposed for the extension of authorisation for minor uses).	GB
- The risk assessment for minor uses is identical to the risk assessment for major uses, except for the efficacy section (not required for minor uses under Art. 51).	GR
No response was provided.	HU
- The risk envelope approach is used for minor use applications. - If the risk envelope approach does not cover the use applied for, an assessment is conducted for the relevant sections. - In the case of Art. 51, this mostly regards the evaluation of residue and metabolism data.	IE
All assessments are carried out according to the Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products.	LT
- The risk envelope approach is used for minor use applications. - If the risk envelope approach does not cover the use applied for, similar data requirements are applied for Art. 51 applications as for label extension after Art. 33.	LV
- The risk envelope approach is used for minor use applications. The risk envelope approach means that the assessment of a particular 'most critical use' also applies to other situations in which the GAP is equally critical or less critical. The assessment of the most critical GAP is then considered to be representative of all other less critical or similar GAPs. - More detailed information on Ctbg policy on how the risk envelope approach is used in assessments can be accessed under: https://english.ctgb.nl/plant-protection/types-of-application/national-extension-minor-uses/risk-envelop-approach.	NL
- The risk envelope approach is used for minor use applications. - A national assessment is usually carried out for sections regarding the environmental part, such as residues, which is not covered by the risk envelope.	NO
- The risk envelope approach is used for minor use applications.	PL

- Extension of authorisation for a minor use is done according to Art. 51 on the base of submitted documentation about residues and toxicology.	
- The risk envelope approach is used for minor use applications. - Use of extrapolations when possible. - If new data are provided, an assessment is conducted.	PT
- The risk envelope approach is used for minor use applications. - Use of extrapolations is done when possible. The risk assessment is presented in a dRR format suitable for minor uses. The dRR is limited to Part A, which includes, in particular, the extrapolation elements of the risk assessments available for major uses already authorised in Romania if no additional risk assessment is needed, especially for the section on metabolism in plants and residues. The elements (e.g., conclusions, extrapolation arguments, precise references to existing authorisations, etc.) are integrated in the dRR, together with the table of good agricultural practices (GAP) in English (reference uses and claimed minor uses).	RO
- The risk envelope approach is used for minor use applications. - The risk assessment is conducted as for Art. 33 applications, except that no efficacy trials are required. - Justification of the risk envelope approach has to be provided. - Residues are under evaluation in all applications. The compliance with existing MRLs is verified. - If no MRLs are set (extrapolation is impossible), additional residue trials are requested where necessary.	SE
Five institutes conduct the risk assessments regarding minor uses: - Central control and testing institute of agriculture. - Water management institute. - Slovak Hydrometeorological Institute. - National Agricultural and Food Centre. - Public health institute.	SK

17 countries out of 22 responded that they conduct the risk assessment following the risk envelope approach whenever possible: AT, BE, CH, CY, DE, ES, FI, FR, IE, LT, LV, NL, NO, PL, PT, RO, SE.

If the risk envelope does not cover the uses applied for, 14 countries stated that they have similar requirements for Art. 51 as they have for Art. 33.

6.2 Special legislation or provisions for the risk assessment.

Table 48: Presence of national legislation or provisions for the risk assessment response summary overview (N=20/22).

National legislation for the risk assessment in place	European countries
Yes	AT, CH, GB, LT, NL, NO (6)
No	BE, CY, DE, ES, EE, GR, FI, FR, HU, IE, LV, PT, RO, SE (14)
No response provided	SK, PL (2)

6 European countries out of 20 stated that they have special national legislation or provision regarding the risk assessment in place.

Table 49: National legislation or provisions for the risk assessment, individual response (N=6/22).

National legislation or provisions for the risk assessment	European country
Special national requirements are in place for the following sections of the Registration Report: - Environmental fate. - Ecotoxicology. These requirements are available online at the following BAES website: https://www.baes.gv.at/zulassung/pflanzenschutzmittel/bewertung	AT
For minor uses, mutual recognition or extrapolation from approved uses are possible.	CH
- Residues: The United Kingdom operates different consumer exposure models and MRL requirements compared to the other European countries. Additionally, residue trial extrapolations guidance is different between Great Britain (England, Wales, Scotland) and Northern Ireland and European countries. - Environmental Fate: the surface water requirements are different in the United Kingdom. Some of the groundwater requirements are also different. - Ecotoxicology: differences exist, such as choosing focal species in certain situations. Additionally, different spray drift models are used, such as for the aquatic buffer zones using drift reduction technology. For details of requirements from the United Kingdom, please see: Data Requirements Introduction and Index (https://www.hse.gov.uk/).	GB
Some national requirements are in place. They can all be found in the 'Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products'.	LT
The Netherlands developed a simplified application procedure as an interpretation of Art. 51 (3), the 'application for a national extension of an authorisation with minor uses' (NLKUG). If an extension of authorisation for minor use is applied for in the Netherlands only, it can be assessed in a non-zonal national procedure, based on Regulation (EC) 1107/2009, Art. 51, with this simplified application procedure. This procedure can be initiated to obtain an extension of uses only for the Netherlands and is developed to facilitate the availability of plant protection products for minor uses.	NL
Some national requirements are in place. They can all be found in the 'Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products'.	NO

6.3 Data requirements when the risk envelope approach does not cover the uses applied for.

Table 50: Similar requirements for Art. 51 as for Art. 33 label extension if the risk envelope approach is impossible response summary overview (N=22).

Data requirements	European countries
Yes	AT, FI, FR, DE, GB, GR, HU, IE, NL, LV, LT, PT, ES, SE (14)
No	BE, CH, EE, NO, RO (5)
I don't know.	CY, PL, SK (3)

Table 51: Data requirements if the risk envelope approach does not cover uses applied for, individual response (N=14/22).

Data requirements if the risk envelope approach does not cover uses applied for	European country
- Zonal applications, in general, are dealt with according to Art. 33 label extension. - For extensions of authorisations for minor uses, additionally the conditions acc. to Art. 51 apply. If the minor use falls within the risk envelope approach for some sections, these sections can simply be addressed in Part A (stating that extrapolation is sufficient). Other sections are to be addressed accordingly, and the respective dRRs are to be provided. - If the minor uses are covered by the risk envelope approach (all sections) as regards the registered uses, the application can be dealt with accordingly to an Art. 45 application. For the sections for which an assessment is to be carried out, the relevant documents and draft assessment report must be submitted with the application. Efficacy data requirements for minor uses: EPPO Standard PP 1/224 *Principals of efficacy evaluation for minor uses* and PP 1/257 *Efficacy and crop safety extrapolations for minor uses*.	AT
A label extension for minor uses can be applied for, if the concerned PPP is authorised for the use applied for in another country (with similar agronomical conditions). If that is not the case, a regular application (Art. 33) has to be made. A risk envelope approach can always be applied, if the risk is covered. This is also the case for major uses.	CH
- Data requirements of Regulations (EU) No 283/2013 and 284/2013 are used. - The evaluation of Art. 51 application is based on the data submitted for the basic product's authorisation (worst-case scenario) if possible. National legislation explicitly allows the authority to refer to the data submitted for the product authorisation, where necessary (§ 3 (4) of national regulation PflSchMV (https://www.gesetze-im-internet.de/pflschmv_2013/).	DE

- Additional data can be required regarding environmental risk assessment if needed. The data requirements are identical to major uses authorisations (e.g., according to Regulation (EU) No 284/213).	
The data requirements are included in the EU legislation.	ES
National requirements are in place regarding: - Ecotoxicology. - Environmental fate. If the risk envelope approach does not cover the uses applied for, data and evaluation are required of the following sections: - Toxicology. - Consumer exposure.	FI
If the risk envelope approach does not cover the uses applied for, the data requirements are the same as for Art. 33 extensions.	FR
The data requirements are the same as for Art. 33 label extensions, except that efficacy and crop safety data are not required. Supporting information may come from: - Field trials. - Laboratory trials. - Grower information. - Independent consultants (for example, ADAS, AICC, Vegetable Consultancy Ltd). - The public domain. - United Kingdom research laboratories where appropriate.	GB
If the risk envelope approach does not cover the uses applied for, the data requirements are the same as for Art. 33 extensions.	GR
The data requirements depend on the areas that are not covered under the risk envelope. All European agreed-on/legally binding data requirements are necessary, and all data is assessed following the Uniform Principles (see Regulation (EC) 1107/2009, Art. 29 (6)).	IE
All requirements are available in the 'Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products'.	LT
The risk assessment is carried out in the following sections: - Environmental fate. - Toxicology (operator, worker, bystander safety). - Ecotoxicology - Residue.	LV
If the risk envelope approach does not cover the use applied for: - In the case of a national application for minor uses (NLKUG): the assessment will be done in accordance with the assessment framework used for the original authorisation or last renewal.	NL

If the original assessment is completed before the first version of the Pesticide Evaluation Manual[8] (HTB) comes into effect, the assessment will be done in accordance with HTB 0.2. - In exceptional cases, if a major, unacceptable risk can be expected, it is possible to deviate from the previous assessment framework and use the current assessment framework. - In case of a zonal application for extension of authorisation for minor uses (ZWTG) or a national application to amend the current authorisation (NLW(T)G), the assessment will be done in accordance with the assessment framework of the date the application is received.	
Additional risk assessment is carried out on the following sections if the risk envelope approach does not cover the new application: - Environmental fate. - Toxicology (operator, worker, bystander safety). - Ecotoxicology. Residues: additional data required from the European Food Safety Agency (EFSA) evaluation reports, Registration Report, or additional trials.	PT
The risk envelope approach is considered case by case. The following steps can be taken to make it possible to use the risk envelope approach: - Changing the application timing. - Changing the BBCH stage(s) on which application occurs. - Changing the number of applications. - Changing the intervals of application. - Changing the doses of application. Growers' organisations can rarely provide extra data except for residue trials.	SE

[8] https://english.ctgb.nl/biocidal-products/assessment-framework/evaluation-manual

6.4 Summary and discussion points

Risk assessment

17 out of 22 European countries use the risk envelope approach for risk assessment. The use of the risk envelope approach is a risk management decision, and areas covered by the risk envelope should not be reassessed.

When the risk assessment is not covered by the risk envelope approach, additional data are required by the competent authority of the assessing European country.
The required data, aim to fill the gaps in the different sections of the dRR (toxicology, ecotoxicology, environmental fate, etc.) in order to achieve the same standard expected for the risk assessment of an application for a label extension under Article 33.

Six European countries have implemented additional national requirements, provisions and legislation to conduct the risk assessment.

Risk envelope approach definition proposal: The risk envelope approach means that the assessment of a particular "most critical use" (worst-case scenario) also applies to other situations in which the GAP is equally critical or less critical. The assessment of the most critical GAP is then considered to be representative of all other less critical or similar GAPs.

It is recommended using the risk envelope approach whenever possible. However, in the assessment it has to be justified if the risk envelope approach was used.

7 Mutual recognition

Mutual recognition is defined. in Regulation (EC) 1107/2009, for the description of the definition please refer to **Appendix C** (p. 87).

7.1 Procedure followed for mutual recognition.

Table 52: Procedure followed for mutual recognition response summary overview (N=20/22).

Procedure followed for mutual recognition	European countries
Reg 1107/09 (Art. 51 (7) and Art. 40 (1 and 2))	AT, BE, DE, EE, ES, FR, GR, HU, IE, LT, LV, NL, PT, RO, SK (15)
No mutual recognition has been received so far for NO, only one in the past for SE.	NO, SE (2)
Art. 35 of Swiss ordonnance on PPP: mutual recognition procedure for minor uses if authorised in a European country climatically and agronomically comparable to Switzerland.	CH (1)
No further applications accepted for mutual recognition, except for Northern Ireland.	GB (1)
Same zone, same GAPs in accordance with national requirements. Applications from other zones can be accepted on a case-by-case basis. However, no mutual recognition application for minor uses have been received yet by Finland.	FI (1)
No response provided	CY, PL (2)

Most countries follow Regulation (EC) 1107/2009 or the guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010.rev11[9]) for mutual recognition.

Table 53: Procedure followed for mutual recognition, individual response (N=20/22).

Procedure followed for mutual recognition, individual responses to the 2022 survey.	European country
Mutual recognition is handled following Regulation (EC) 1107/2009, Art. 40 - 42 and Art. 51 (7).	AT
Mutual recognition is handled following Regulation (EC) 1107/2009, Art. 40 (1-2) - 42 and Art. 51 (7).	BE
According to Art. 35 of the Swiss Ordonnance on PPP, Switzerland applies a simplified 'Mutual recognition' procedure for minor uses if these minor uses are authorised in a European country climatically and agronomically comparable to Switzerland.	CH
No response was provided.	CY
- Mutual recognition is handled according to Regulation (EC) 1107/2009 following Art. 51 (7). - The authorisation of the country of origin must be from the same regulatory zone (field uses) or be interzonal (e.g., seed treatments).	DE

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

- The evaluation if the uses are minor and of public interest is done nationally. - Registration Report, Part A, is not currently provided until now (it is planned that this will be used in the future). - Applicants can be a company (registration holder) or third parties (mainly extension services).	
Mutual recognition is handled following Regulation (EC)1107/2009.	EE
Mutual recognition is handled following Regulation (EC) 1107/2009, Art. 40 (1-2).	ES
The following requirements apply: - Application and data come from the same regulatory zone as Finland. - The uses applied for should not differ from the uses authorised in the reference Member State. National requirements must be fulfilled.	FI
No data assessment is conducted. The competent authority (ANSES) only checks the admissibility of the dossier (following the guidance document SANCO/13169/2010) to verify if it is in line with the guidance documents in force at the time it is submitted.	FR
No further mutual recognition applications can be accepted under the Great Britain (England, Wales, Scotland) PPP regime. Any ongoing evaluation will be continued to a Great-Britain-only decision. Where there is no divergence with European conditions of authorisations, a Great Britain and Northern Ireland authorisation may be issued. European mutual recognition applications can continue to be considered for Northern Ireland.	GB
- Mutual recognition is handled following Regulation (EC) 1107/2009. - National requirements are taken into account.	GR
Mutual recognition is handled following Regulation (EC) 1107/2009 and the guidance document SANCO/13169/2010/rev11.	HU
- Mutual recognition is handled following Regulation (EC) 1107/2009. - Having access to the necessary data for the minor uses applied for is mandatory. - Ireland also considers mutual recognition from all three regulatory zones.	IE
The procedure of mutual recognition is described in Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products: (https://www.kemi.se/download/18.663e01517a129aa97f20/1623826662866/Northern-Zone-Guidance-Document-2021.pdf).	LT
Efficacy data are not required. Additional assessment, if necessary, is carried out in: - Environmental fate section. - Ecotoxicology section.	LV
- Mutual recognition is handled following Regulation (EC) 1107/2009. - To place a product on the market in several countries, the authorisation holder can apply for national authorisation in one	NL

Member State and for mutual recognition in the other Member States. - Applications for mutual recognition can be made parallel to the application in the reference Member State (European country in which the product is authorised) or in sequence with the authorisation in the reference Member State.	
No mutual recognition applications, according to Art. 51 (7) have been received by Norway so far.	NO
Portugal requires the following documentation to evaluate a mutual recognition: - Confirmation that the PPP formulation is identical to the formulation of the reference product. - Copy of approval in the reference Member State. - Registration Report.	PT
No response was provided.	PL
Mutual recognition is handled following Regulation (EC) 1107/2009. The national Romanian procedure for mutual recognition can be found at the following link (in Romanian): https://www.anfdf.ro/central/omologare/proceduri/procedura_recunoastere_reciproca.pdf.	RO
On sole mutual recognition, application for minor uses was received in Sweden in the past. There is a reluctance from the growers' associations to apply for mutual recognition. Placing a product on the market is the responsibility of the applicant. Growers' associations do not have the means to handle the necessary logistics (product storage, product distribution, etc.).	SE
- The mutual recognition procedure for a minor use is the same as the procedure for a major use. - Mutual recognition is handled following Regulation (EC) 1107/2009, Art. 40 and 41, provided that: o The plant protection product is authorised in the reference Member State. o The use applied for is considered minor in the reference Member State.	SK

Ireland stated that they consider mutual recognition applications from all three regulatory zones.

Sweden stated one issue with the possible reluctance to apply for mutual recognition when the applicant is a growers' association. Placing a product on the market is the responsibility of the applicant. Growers' associations do not have the means to handle the necessary logistics (product storage, product distribution, etc.).

7.2 Obstacles perceived with the procedure of mutual recognition according to Art. 51 (7).

Table 54: Summary overview of the obstacles perceived with the procedure of mutual recognition according to Art. 51 (7) (multiple responses possible; N=18/22).

Obstacles perceived	European countries
Lack of, or outdated data.	AT, EE, ES, DE, FR, LT, PT, RO (8)
Differences in national assessments requirements (e.g., not following the uniform principles).	AT, CH, ES, FR, GB, HU (6)
Different classification of crops and uses (minor/major) from one country to another.	FI, LV, PT (3)
No obstacles perceived.	BE, NL (2)
The reluctance of some European countries to consider mutual recognition.	IE, SE (2)
The data provided are from the wrong zone.	EE (1)
Provided data are not relevant.	AT (1)
The applicants lack the means for the launch of the product on the market.	SE (1)
No application has been submitted.	NO, FI (2)
No response provided.	CY, GR, PL, SK (4)

The procedure of mutual recognition is intended to increase the number of registered PPPs by avoiding duplication of work (regulatory) and reducing costs (data generation) in European countries.

The main obstacles European countries perceive are the lack of trial data and the varying national requirements from one country to another.

2 countries, Belgium and the Netherlands did not encounter any obstacles with the procedure of mutual recognition according to Art. 51 (7) yet.

Table 55: Obstacles perceived in the procedure of mutual recognition according to Art. 51 (7), individual response (N=18/22).

Obstacles perceived, individual responses to the 2022 survey.	European country
- Crops or uses applied for are not relevant in Austria. - Differences in crops and uses status (major or minor) from one country to another (data requirements are incompatible from one country to another). - Pests applied for are not relevant in Austria. - Pests applied for are protected in Austria according to national legal basis. - Resistance issues. - National requirements or agricultural practices are not comparable to the reference Member State, thus not covered by the assessment of the reference Member State. - Assessment was not carried out according to uniform principles in the reference Member State.	AT
No obstacles are encountered.	BE

Switzerland applies its own national procedure for mutual recognition.	CH
No response was provided.	CY
The information on the authorisations in the country of origin is often very limited, as the uses are not published in detail (e.g., unclarity about crops, pests, or area of use).	DE
- No trial data was provided. - The trial data are from a different regulatory zone.	EE
- The Registration Report is not available in the reference Member State. - The extension of use was granted under national provisions in the reference Member State that are not valid in Spain. - The risk envelope approach used for the extension of minor use in the reference Member State is not applicable under the national conditions.	ES
- Differences in crops and uses status (major or minor) from one country to another. - The product has to be on the market in both countries, as stated in Art. 51. - Needs for pest control and dose rates differ from country to country.	FI
The main reasons for the refusal of mutual recognition in France are regarding the sections: - Environment / Ecotoxicology. - Residues.	FR
Mutual Recognition in the United Kingdom applies to Northern Ireland only. Northern Ireland cannot act as a reference Member State. If a mutual recognition application for an extension of authorisation for minor uses for Northern Ireland only is submitted, it will be considered.	GB
No response was provided.	GR
- MRL threshold might change during the mutual recognition procedure. - Practical experience with phytotoxicity issues.	HU
Some European countries competent authorities are reluctant or refuse to consider these types of applications.	IE
Data is considered outdated or insufficient to conduct the risk assessment.	LT
Differences in crops and uses status (major or minor) from one country to another.	LV
No obstacles are encountered.	NL
- No mutual recognition application has been submitted yet in Norway. - The uses are not evaluated zonally.	NO
No response was provided.	PL
- Differences in crops and uses status (major or minor) from one country to another. - Crops or uses applied for are not relevant in Portugal. - GAPs authorised in the reference Member State (e.g., number of applications, crop stage of application, water volume, etc.) must be adapted to national conditions.	PT

- Lack of possible extrapolations from a major crop. - No trial data or few trial data provided for the extension to the minor crop.	RO
Reluctance to apply for mutual recognition when the applicant is a growers' association. Placing a product on the market is the responsibility of the applicant. Growers' associations do not have the means to handle the necessary logistics (product storage, product distribution, etc.)	SE
No response was provided.	SK

7.3 Assessment and/or approval of mutual recognition for minor use, according to Art. 51 (7).

Table 56: Art. 51 (7) procedure experience response summary overview (N=22).

Art. 51 (7) procedure experience	European countries
Yes	AT, BE, CH, CY, DE, EE, FR, GB, GR, HU, IE, LT, LV, NL, PL, PT, RO (17)
No	FI, NO, SE, SK (4)
I don't know.	ES (1)

17 countries out of 22 have received at least one application for mutual recognition following Art. 51 (7).

Table 57: Entities applying for mutual recognition according to Art. 51 (7) response summary overview (multiple answers possible; N=16/22).

Applicant	European countries
Authorisation holder	AT, BE, CH, CY, DE, EE, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO (16)
Grower's associations	BE, GB (prior to Brexit: AHDB on behalf of the growers' associations), IE (3)
Extension services comprised of working groups on minor crops and minor uses.	DE (1)
No response provided	ES, FI, NO, SE, SK (5)

7.4 Experience with mutual recognition application following Art. 51 (7) by a third party where the authorisation holder refused its consent.

Table 58: Experience with an application following Art. 51 (7) by a third party where the authorisation holder refused its consent (N=22).

Experience with the refusal of consent for application	European countries
No	AT, BE, CH, CY, DE, EE, FI, GB, GR, HU, IE, LT, LV, NL, NO, PT, RO, SE (18)
I don't know.	ES, FR, PL, SK (4)

None of the respondents recalled encountering a case where an authorisation holder refused its consent for a mutual recognition applied for by a third party.

7.5 Summary and discussion points

Mutual recognition

The procedure of mutual recognition in the responding European countries is mostly carried out following Regulation (EC) 1107/2009, Art. 40-42 and Art. 51 (7) or/and the SANCO/13169/2010.rev11 document.

Applicants for the mutual recognition procedure are mostly authorisation holders.

17 respondents out of 22 have experiences with minor use applications, according to Art. 51 (7).

The procedure of mutual recognition is intended to increase the number of registered PPPs by avoiding duplication of work (regulatory) and reducing costs (data generation) in different European countries.

The lack of residue data, as well as the varying national requirements from one country to another, are the main obstacles perceived by the European countries.

Ireland (central zone) considers mutual recognition from all three regulatory zones. Other European countries could consider this approach as a pragmatic way of increasing the number of registered PPPs.

It is advocated to fully implement mutual recognition, relying on the evaluation and assessment performed by the reference Member State whenever possible.

8 Draft Registration Report

8.1 Compilation of the draft Registration Report by the applicant.

Table 59: Compilation of the dRR by the applicant response summary overview (N=22).

Compilation of the dRR by the applicant	European countries
Yes	AT, BE, CH, CY, EE, ES, FR, GB, GR, IE, LT, LV, PL, RO (14)
No	DE, FI, HU, NL, NO, PT, SE, SK (8)

8.2 Obstacles perceived in using the dRR (according to Art. 51).

Table 60: Obstacles perceived using the dRR response summary overview (multiple responses possible; N=16/22).

Obstacles perceived	European countries
Amount of resources (time, human resources, finance, knowledge) needed to draft and assess a dRR.	ES, FI, GB, HU, IE, NL, NO, PT, SE (9)
No obstacles perceived.	AT, BE, DE (3)
Non-relevant data presented.	EE, LT, LV (3)
Applicant is not the authorisation holder.	NO, PT, SE (3)
Lack of data presented.	LT, RO (2)
Lack of extrapolation possibilities.	LT, RO (2)
No answer was provided.	CH, CY, FR, GR, PL, SK (6)

The lack of resources is the most highlighted obstacle using the dRR (9 out of 16 European countries). These resources are related to drafting or assessing the dRR (e.g., finance, time, knowledge, human resources).

Table 61: Obstacles perceived in using the dRR, individual response (N=16/22).

Obstacles perceived, individual responses to the 2022 survey.	European country
No specific obstacle encountered.	AT
No specific obstacle encountered.	BE
No specific obstacle encountered. The Registration Report, Part A, is completed by the competent authority. It is a reduced Part A with some basic information on the authorised PPP, provisions of uses, and GAP table.	DE
Non-relevant data presented by the applicant, making the data collection to draft the dRR longer (only the residue chapter is required).	EE
Only the dRR Part A is required. It might sometimes be necessary to evaluate additional data.	ES
- The applicants (growers' organisations) don't have access to data and don't have the expertise to produce a dRR. - Time and resources needed to draft and assess a dRR.	FI

- Differences in crops and uses status (major or minor) from one country to another. - Differences in national requirements from one country to another.	
Applicants who are authorisation holders are expected to submit a full risk assessment to support their extension of authorisation for minor use applications in the form of a detailed application overview and/or dRR.	GB
Lack of human resources in the competent authority.	HU
The applicants (e.g., growers' organisations, advisory bodies), particularly infrequent applicants, don't have the expertise to produce a dRR.	IE
- Outdated data provided. - Insufficient data provided. - Lack of extrapolation possibilities.	LT
- If the applicant is the registration holder, the dRR must be submitted. - If the applicants are growers or growers' organisations, the dRR is not required to be drafted by them.	LV
- For "application for a national extension of an authorisation with minor uses" (NLKUG) for which the dRR format applies, the competent authority compiles an abridged dRR Part A following a template drafted by the German competent authority. The applicant does not have to provide a dRR. - For zonal applications, the applicant compiles a standard dRR.	NL
- If the applicant is the authorisation holder and the Art. 51 is submitted together with an Art. 33/Art. 43, a dRR is required. Minor uses are included in the GAP table in the dRR and has to be evaluated by the zRMS. - If the applicant is a third party (e.g., growers' association) and they don't have the expertise to produce a dRR, the competent authority will prepare the RR on behalf of the applicant. - Lack of resources in the competent authority.	NO
- Most minor uses applications are either zonal or mutual recognitions, but some national applications are still received. - Difficulties when the applicants are not the authorisation holder. - Time and resources needed to draft and assess a dRR.	PT
- Insufficient data provided (for a major crop in the dRR). - Lack of extrapolation possibilities.	RO
Most applications, according to Art. 51 are done by growers' organisations. They don't have the expertise to produce a dRR (especially Part B).	SE

8.3 Basic information about the authorisation to be provided if it is impossible to prepare a draft Registration Report Part A acc. to Art. 51.

Table 62: Basic information provided regarding authorisation acc. to Art. 51 if it is impossible to prepare a dRR Part A response summary overview (multiple responses possible; N=17/22).

European country	GAP Table	dRR Part A (Abridged and/or mandatory)	Draft Label	Supplementary details
AT		X		For a zonal application.
BE		X		
CH	X			According to the Art. 35 Swiss ordinance on PPP.
DE	X	X		
EE		X		
FI	X		X	Competent authority prepares an internal document which is not publicly accessible.
GB	X			For applications from or on behalf of Grower Associations, it is recommended to provide a table comparing the use rate, timings (time or year of application), situation of use (in- or outdoor), method of application and any other relevant information for the proposed extension of use and the authorised on-label use.
GR	X			
HU	X		X	
IE	X	X		GAP information is made available on the website.
LT		X		
LV	X			
NL		X		Information is provided on the Ctgb database.
NO	X			
PT	X			
SE	X			
SK	X			
Total	**12**	**7**	**2**	

If it is impossible to provide a dRR Part A, the GAP table is highlighted as the basic information required by 12 European countries out of 17. Only 7 European countries out of 17 stated that a dRR Part A is mandatory to apply for an Art. 51.

8.4 Summary and discussion points

dRR

A lack of resources (e.g., time, human resources, finance, knowledge) to draft and assess a dRR acc. to Art. 51 is highlighted as one of the main obstacles.

It is advocated to establish a European fund to allocate more resources to draft and assess the dRR.

9 General topics

9.1 Information produced after a minor use authorisation (Art. 33, 40 (1-2), 51 (1-6), 51 (7)).

Table 63: Information to be produced following a minor use authorisation, individual response (N=19/22).

Information to be produced following a minor use authorisation, individual responses to the 2022 survey.	European country
- For zonal applications, all relevant Registration Reports are prepared. - For mutual recognition, no Registration Reports are prepared.	AT
- Registration Report. - Authorisation deed.	BE
No response was provided.	CY
Authorisation deed.	CH
For Art. 33 and Art. 40ff: - Registration Report. - The Registration Report is uploaded to CIRCABC. For Art. 51ff (except for the Art. 51 (7) procedure): - Simplified Registration Report Part A: basic information of the authorised PPP, provisions of uses, GAP table. - The Registration Report is uploaded to CIRCABC. For Art. 51 (7): - A Registration Report format, Part A, for mutual recognition, according to Art. 51 (7) is under development.	DE
- An authorisation deed id provided to the applicant. - Approved PPP label. - Update of the Estonian PPP registry.	EE
- Draft Registration Report Part A. - GAP table. - Justification of the risk envelope approach and the major crops that were used as a reference for the extension of minor use.	ES
- Registration Report - In case of a minor use: memorandum/ internal documents of applied minor uses including assessment needed, GAP table, user instruction (in charge for label text of the product), decision paper.	FI
- Authorisation deed. - Update of the French PPP database. - GAP table.	FR
- Extension of authorisation for minor uses (EAMUS) may or may not appear on the product label. The label has to be consulted by the user and is a legal requirement. - A notice of authorisation is issued, shared with the authorisation holder, and published on the national HSE database. - The minor use can appear on the product label but in an area separate from the main label headed with the liability clause. The text in the covering letter to EAMUs which is copied to the authorisation holder when issued is as follows:	GB

Optional text for a product label for the Authorisation holder: '*This extension of the authorised use provides for the use of 'X' in respect of crops and situations other than those included on the product label (above). Neither the efficacy nor the phytotoxicity of the product for which this Extension of Authorisation for minor use has been granted has been assessed and, as such, the user bears the risk in respect of failures concerning its efficacy and phytotoxicity.'* The use must not appear in the biological use statement or important information area.	
For Art. 33 - Registration Report (Part A, B). - GAP table. For Art. 40: - GAP table. For Art. 51 with evaluation needed: - Registration Report (Part A, B). - GAP table. For Art. 51 with no evaluation needed (administrative procedure): - GAP table.	GR
Minor use extensions are listed separately in the authorisation document with the indication of the procedure (Art. 51).	HU
- Authorisation deed. - Approved PPP label. - 'Instruction for use document' in case of Art. 51. - Registration Report Part A. - Registration Reports Bart Bs if relevant.	IE
- Registration Report Part A. - Approved PPP label. - Update of the Lithuanian PPP database.	LT
For Art. 33, 40 (1), 51 (1-6), 51 (7), if the applicant is the authorisation holder: - Registration Report Part A. - Approved PPP label. For Art. 51 (1-6), if the applicant is an official or scientific body, professional organisation, or professional user: - Registration Report Part A. - Permit on minor use.	LV
For an 'application for a national extension of an authorisation with minor uses' (NLKUG): - National decision paper (C-paper) or draft Registration Report (depending on current admission format). - GAP table. - Approved PPP label. - Documents are uploaded on the Ctgb website (national database) but not on CIRCABC. For Art. 33: - Draft Registration Report. - GAP table. - Approved PPP label. - Documents are uploaded on the Ctgb website and CIRCABC.	NL

For Art. 40: - Draft Registration Report. - GAP table. - Approved PPP label. - Documents are uploaded on the Ctgb website. Availability on CIRCABC is uncertain.	
Updated or new additional label, which has to be prepared by the authorisation holder.	NO
For Art. 33: - Registration Report Part A. - GAP table. For Art. 40: - Registration Report Part A. - GAP table. - National report might be provided. For Art. 51: - GAP table.	PT
No response was provided.	PL
- Registration Report Part A. - GAP table.	RO
Competent authority: - Registration Report Part A (abridged Part A, without chemistry, CLP[10] or efficacy sections). Applicant: - GAP table. - User instruction (description of the intended uses).	SE
- GAP table.	SK

9.2 Communication of the information from the authorised GAP.

Table 64: Summary overview of the tools used to communicate information on the authorised GAP (multiple responses possible; N=18/22).

Mean of communication	**European countries**
National PPP database/registry	BE, CH, EE, FI, FR, GB, GR, HU, LV, LT, NL, NO, PT, SK, SE (15)
CIRCABC	AT, BE, DE, NL (4)
Information available upon request	IE (1)
Responsibility of the authorisation holder	RO (1)
No answer provided	CY, ES PL (3)

15 out of 18 European countries update the information on authorised GAPs on their national PPP database.

4 European countries stated that they use the CIRCABC platform to share the authorised GAP information.

[10] CLP : Classification, Labelling, Packaging.

Table 65: Communication of the information on the authorised GAP, individual response (N=18/22).

Individual responses to the 2022 survey.	**European country**
The Registration Reports are uploaded to CIRCABC for zonal applications (Austria is zRMS).	AT
The Registration Report is uploaded to CIRCABC.	BE
The Registration Report Part A (extension of uses) with a detailed GAP table is uploaded to CIRCABC.	DE
- Product information is updated on the Estonian PPP database https://portaal.agri.ee/avalik/#/taimekaitse/taimekaitsevahendid-otsing/en. - Updated label.	EE
Finish PPP database (KEMIDIGI) (https://www.kemidigi.fi/) is updated with: - Authorised minor uses. - Updated label. - Use instructions.	FI
French PPP database (EPHY) (https://ephy.anses.fr/) is updated with: - Authorisation documents. - Authorised uses. - GAP table. French decision register (https://www.anses.fr/fr/decisions): - Official decision documents. Upload of the documents on PPPAMS might be considered in the future.	FR
Extension of Authorisation Database: https://secure.pesticides.gov.uk/offlabels/search.asp.	GB
The ministerial decision is made available under: https://1click.minagric.gr/oneClickUI/frmFytoPro.zul?lang=en	GR
Registration documents are made available on the Hungarian national PPP database (Nébih, in Hungarian, https://novenyvedoszer.nebih.gov.hu/Engedelykereso/kereso).	HU
The relevant Registration Reports can be provided upon request to the applicants and to other Member States.	IE
All authorised PPPs and their uses are made available on the Lithuanian PPP database (http://www.vatzum.lt/en/activity/fields-of-activity/plant-protection-products-authorisation/).	LT
Details of minor use authorisations are made available (if the applicant is the authorisation holder) on the Latvian PPP database (in Latvian, http://registri.vaad.gov.lv/reg/aal_saraksts.aspx). The information on minor use permits issued to official or scientific bodies, professional organisations or professional users are not made available to other users and other countries.	LV
The national Dutch PPP database (Ctgb, https://pesticidesdatabase.ctgb.nl/en/authorisations) is updated with: - Authorisation documents, including dRR. - National decision paper (C-paper), including GAP table. CIRCABC:	NL

- Draft Registration Report in case of a zonal application.	
Norwegian PPP database (Mattilsynet, in Norwegian, https://www.mattilsynet.no/plantevernmidler/godk.asp?sortering=preparat&preparat=Alle&sprak=In+English): - Authorisation documents. - Approved PPP label.	NO
All PPP approvals are made available on the Portuguese PPP database (SIFITO) (www.sifito.pt).	PT
Making the information available is the responsibility of the authorisation holder.	RO
Extension of authorisation acc. Art. 51 (UPMA) and the decision are made available on the national Swedish PPP database: (https://www.kemi.se/en/pesticides-and-biocides/pesticides-register, also available in Swedish) For the newer authorisations, the user instruction might be included (in Swedish).	SE
Authorised uses are made available on the Slovakian PPP database (UKSUP, in Slovakian, http://pripravky.uksup.sk/pripravok/search).	SK

9.3 Specific procedure in place for minor uses applications for low-risk PPP.

Table 66: Specific procedure for minor uses on low-risk PPPs in place response summary overview (N=22).

Specific procedure	European countries
Yes	BE, CY, FI, FR, LT, NL, PL (7)
No	AT, CH, DE, EE, ES, GB, GR, HU, IE, LV, NO, PT, RO, SE, SK (15)

15 European countries out of 22 do not currently apply a specific minor uses application procedure for low-risk PPPs.

7 European countries stated that some specific procedure is nationally implemented for minor uses applications for low-risk PPPs.

Table 67: Summary overview of the type of specific procedure in place for low-risk PPPs (multiple responses possible; N=7/22).

Procedure for low-risk PPPs	European countries
Reduced application fees	CY, FI, LT, PL (4)
Shorter evaluation timeline	BE, NL (2)
Reduced data requirements	LT, NL (2)
Prioritisation of the dossier for evaluation	FR (1)

4 European countries out of 7 that implemented a specific procedure for the low-risk PPPs have set a lowered application fee. Moreover, the evaluation for low-risk PPPs is conducted on a quicker evaluation timeline in 2 countries and, in one country, prioritised over non-low-risk products.

Table 68: Specific procedure in place for minor uses applications for low-risk PPPs, individual response (N=9/22).

Specific procedure in place for minor uses applications for low-risk PPPs, individual responses to the 2022 survey.	**European country**
A separate pipeline with shorter evaluation timelines is foreseen.	BE
Reduced application fees are applied.	CY
The evaluation procedure, according to Art. 51 is already a shortened procedure compared to Art. 33.	DE
Reduced application fees are applied.	FI
If the PPP is low risk, it enters the criteria of 'public interest'. No reduced application fees are applied compared to non-low-risk PPPs (2 000 EUR/application).	FR
Reduced application fees are applied for: - Authorisation and the renewal of authorisation. - Mutual recognition procedure. - Label extension. - Issuing a duplicate of the registration certificate. - Issuing a permit for scientific trials with unauthorised PPPs. - Issuing a permit to use PPPs exceptionally for a period < 120 days. Reduced data requirements are applied for: - Residues. - Efficacy/crop safety.	LT
Shorter evaluation timeline and reduced evaluator workload. The approach is to handle the extension of low-risk PPPs with minor uses administratively, with no assessment. Implementation of this specific procedure is in progress. An assessment is still necessary if a maximum residue limit (MRL) applies to the active substance. Other exceptional situations in which an assessment is necessary are determined per active substance.	NL
Reduced application fees are applied.	PL
Standard procedure and timeline from Regulation (EC) 1107/2009 are followed. The evaluation of a low-risk PPP is often faster.	SE

9.4 Summary and discussion points

General topics

After the authorisation of a PPP for minor uses, several documents are made available to the public, depending on the European country: Registration Report (only Part A for some countries), GAP table, authorisation deed/permit and/or approved product label.

Most European countries make this information publicly available on their national PPP database/registry. A few countries also share this information on CIRCABC.

Regarding the authorisation of low-risk PPPs, 7 European countries out of 22 take specific measures to facilitate the authorisation of low-risk PPPs. They implemented a system of reduced fees and/or set priorities (whilst still respecting the legal deadlines) for the evaluation of the low-risk products.

However, Germany indicated that the Art. 51, which is dedicated to minor uses, is intended to simplify the evaluation procedure compared to Art. 33.

It is advocated to perform evaluations of minor uses applications in English and to upload the evaluation report to CIRCABC, that it can be accessed if needed by other European countries.

10 Perspective

Given the current global challenges, such as food security, increasing food prices, climate change, and geopolitical conflicts, pan-European collaboration to find PPP solutions for minor uses is of increasing importance. The collected and compiled data and information from the Minor Uses Survey 2022 provides a solid foundation for further actions on minor use issues, which in turn enhances minor crop production in Europe.

The Minor Uses Survey 2022 findings reveal several obstacles encountered by competent authorities and authorisation holders regarding regulatory issues in minor uses procedures.
Some findings highlight fragmentation and heterogeneity in the approach to minor uses and minor crops, specifically concerning existing regulatory procedures and their interpretation and national application in European countries under Reg. 1107/2009.

The data and information obtained from the Minor Uses Survey 2022 will undergo further analysis and discussion within the MUCF expert working groups.

For example in the following year(s), MUCF experts will explore the possibility to utilise some of the compiled data and information from the Minor Uses Survey 2022 to define criteria for a European-wide harmonised definition of a minor crop, or to develop an abridged draft Registration Report Part A (dRR Part A) template, which is foreseen to be used on a voluntary basis by the applicant and/or the competent authority.

The MUCF plans to establish additional objectives in their work programme in the upcoming years, based on specific findings of the Minor Uses Survey 2022.

This document compiles information from 24 European countries regarding the topic of minor uses. Leading to one MUCF future work objective, which is to have the same level of information available for the remaining 6 countries.

There will be additional information exchange among different stakeholders to raise awareness on minor uses and associated issues. For example in 2024, representatives from the agri-pesticide sector will be approached to address minor uses issues highlighted in the Minor Uses Survey 2022. The MUCF aims to strengthen networking and information sharing with the relevant industry through this initiative.

References Minor Uses Survey 2022

-Basic Rules for the Minor Uses Coordination Facility (MUCF)
https://www.minoruses.eu/media/files/about_mucf/MUCF_Basic_Rules_rev_5_2022.pdf

-Comprehensive list of the Minor Uses 2022 survey's questions
Survey (minoruses.eu)

-Explanatory Note on Minor Uses
https://minoruses.eu/media/files/documents/Explanatory_Note_on_Minor_Uses_V1_202204.pdf

-Guidance document on work-sharing in the Northern Zone in the Authorisation of PPP
https://www.kemi.se/download/18.663e01517a129aa97f20/1623826662866/Northern-Zone-Guidance-Document-2021.pdf

-Meynard, JM., Charrier, F., Fares, M. et al. Socio-technical lock-in hinders crop diversification in France. Agron. Sustain. Dev. 38, 54 (2018).

-Regulating Pesticide in the United Kingdom after Brexit
https://www.hse.gov.uk/pesticides/brexit.htm

-Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market
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 (europa.eu)

-Regulation (EU) 2019/2072
https://faolex.fao.org/docs/pdf/eur192043.pdf

-Report of the MUCF Survey 2017
https://minoruses.eu/media/files/resources/Report_Minor_Uses_work_MS.pdf

-Sanco Document /13169/2010
https://food.ec.europa.eu/system/files/2021-01/pesticides_aas_guidance_mut_rec_en.pdf

-Swiss Ordinance on PPP
Fedlex (admin.ch)

-Technical guideline on data protection" (according to the official journal of the EU, C 229, from 8th July 2019)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2019:229:FULL&from=EN

Appendices

Appendix A: Regulation (EC) 1107/2009, Article 51, Extension of authorisation for minor uses.

Article 51 of Regulation (EC) 1107/2009 defines extension of authorisation for minor uses as follows:

'*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 may be 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'.

Appendix B: Key parameter in each area of risk assessment that need to be considered in developing an appropriate risk envelope.

- Chemistry section and analytical methods (The risk envelope approach does not apply to these sections)
- Toxicology:
    - Operator exposure
    - Worker exposure
    - Bystander exposure
    - Resident exposure
- Residues and dietary risk assessment
- Environmental fate & behaviour:
    - Soil
    - Groundwater
    - Surface water
- Ecotoxicology:
    - Birds and mammals
    - Aquatic organisms
    - Honeybees
    - Non-target arthropods
    - Soil organisms
    - Non-target plants
    - Biological sewage treatment
- Efficacy

Appendix C: Mutual recognition according to Regulation (EC) 1107/2009.

General mutual recognition procedure

Article 40: Mutual recognition

'1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure provided for in this subsection, in the following cases:

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone; EN L 309/22 Official Journal of the European Union 24.11.2009

(b) the authorisation was granted by a Member State (reference Member State) 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 Member State within the same zone;

(c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

2. Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction. Where the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.'

Article 41: Authorisation

'1. The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies. 2. By way of derogation from paragraph 1, the Member State may authorise the plant protection product where: (a) an authorisation under point (b) of Article 40(1) was applied for; (b) it contains a candidate of substitution; (c) Article 30 has been applied; or (d) it contains a substance approved in accordance with Article 4(7).'

Article 42: Procedure

'1. The application shall be accompanied by the following: (a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application; (b) a formal statement that the plant protection product is identical to that authorised by the reference Member State; (c) a complete or summary dossier as required in Article 33(3) when requested by the Member State; (d) an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product. 2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days. 3. Where requested by the Member State, the applicant shall submit the application in the national or official languages of that Member State or one of those languages.'

Specific mutual recognition procedure for minor uses: Article 51(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.'