

EUROPEAN UNION MINOR USES COORDINATION FACILITY

Report on the Questionnaire on Minor Uses work in EU Member States, Norway and Switzerland



Final version rev. 1

EU Minor Uses Coordination Facility 21 bd Richard Lenoir, 75011 Paris, France

Phone: +33 (0)1 45 20 77 94 Email: contact@minoruses.eu

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1. Introduction

In order to better address minor uses problems in Europe the need to assess how Member States deal with minor uses was identified by experts. In January and February 2017, the Minor Uses Coordination Facility (MUCF) organised a survey of EU Member States, Norway and Switzerland. The aim of the survey was to collect information on who is dealing with Minor Uses issues in Member States, how Member States organise minor uses work and address minor uses, what is the capacity of Member States to carry out and fund trials and how Member States can contribute to the sharing of data. The survey was performed through a questionnaire distributed to contact points of Member States. An earlier version of the questionnaire had been used within the Commodity Expert Group Fruits and Vegetables. It was decided to update the questionnaire and extend the survey further as the information is important to all parties. An overview of the results from the questionnaires was presented by the MUCF in a plenary session of the Minor Uses Expert Group meetings on 28 March 2017. It was then agreed that a report on the results from the questionnaires should be prepared by the MUCF.

The term 'Member States' usually refers to the 28 Member States of the European Union. The questionnaire was addressed not only to the 28 EU Member States but also to Norway and Switzerland. For the purpose of clarity and simplicity, in this report the term 'Member States' covers the 28 EU Member States, as well as Norway and Switzerland.

2. Questionnaire and methodology

2.1 Preparation and distribution of the questionnaire

The questionnaire for the survey of Member States was prepared based on a questionnaire used within the Commodity Expert Group Fruits and Vegetables.

The questionnaire asked:

- Who is responsible for minor uses in your Member State?
- How is the minor uses work organised in your Member State?
- How does your Member State deal with article 51- extension of authorisations for minor uses?
- Do you have research facilities to carry out trials?

Are you able to finance trials to generate data for minor uses extensions? The questionnaire was circulated by the MUCF in January 2017, in preparation of the Commodity Expert Groups (CEG) and Horizontal Expert Group (HEG) meetings of March 2017.

It was sent to all 28 EU Member States, and to Norway and Switzerland. In September 2017, the MUCF sent a reminder to the Member States who had not replied to the first request.

The questionnaire is shown below:



EUROPEAN UNION MINOR USES COORDINATION FACILITY

Questionnaire

Member State:	
Who is responsible for minor uses in you	r Member State?
Who is/are the national contact point(s)?	
Who is/are your representative in the Commodity Expert Group(s)	
Who can/does apply for Art 51 extensions?	
Which organisation evaluates the applications?	
How is the minor uses work organised in	your Member State?
Do you have a list of minor uses available?	
What are the criteria for a minor use? Or what is the maximum area (ha) in your Member State to be classified as minor use culture?	
Which (working) groups or parties are involved in minor uses in your Member State and what is their role?	
How is the risk assessment for Minor Uses done? Do you have special national legislation or provisions?	
Do you have a list of minor uses available?	

Article 51: extension of authorisations fo	r minor uses:
How much do you charge for an Art 51 extension? (per crop, per application, different fees for zonal applications?)	
Do you require efficacy data for an Art 51 extension?	
Do you have research facilities to carry of	out trials (GEP, GLP,)?
If so, which organisation is carrying out trials (efficacy and residues) in minor uses?	
Are you able to finance trials to generate residue,):	e data for minor use extensions (efficacy,
If you have data, would you share them with other MS. What are the conditions to do so?	
If you do not have data, how can you still contribute to the sharing of and access to data?	

2.2. Analysis of the questionnaires

The approach taken to analyse the questionnaires was as follows:

- Questions were considered under the different subheadings
- Trends and categories were identified (e.g. minor uses criteria, national fees)
- Member States were grouped where relevant.

3. Results

3.1 Response rate

The response rate to the questionnaire was already high for the minor uses meetings in March 2017: 21 out of 28 EU Member States replied, plus Norway and Switzerland. This corresponds to a rate of 75% for EU Member States and a rate of 77% for all Member States contacted.

In addition, in September 2017, the MUCF sent a reminder to the Member States who had not yet replied. Three additional Member States completed the questionnaire, leading to 24 Member States within the EU and a total of 26 Member States when including Norway and Switzerland. The final response rate was very high with 86% responding within the EU (Figure 1) and 87% for all Member States contacted (Figure 2).

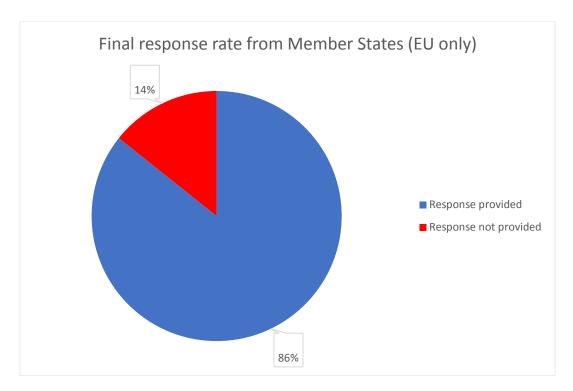


Figure 1: Final response rate from EU Member States on the questionnaire on minor uses work

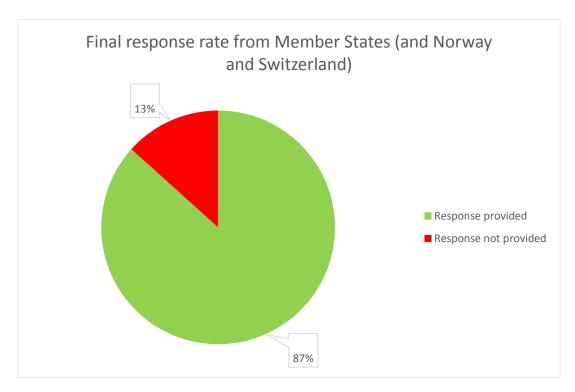


Figure 2: Final response rate from EU Member States (and Norway and Switzerland) on the questionnaire on minor uses work

3.2 Who is responsible for Minor Uses?

3.2.1 National contact point(s) responsible for minor uses

All responding Member States answered this question.

In general, one to three persons per Member State were indicated as contact points for minor uses.

A majority (73%) of the national contact points responsible for minor uses are exclusively from the national competent authority dealing with authorisation of plant protection products (PPPs). In other cases, contact points (15%) are from another authority, e.g. the Ministry of Agriculture or the National Plant Protection Organisation (NPPO). For one Member State (4%) contact points are from the national competent PPP authority and another authority i.e. Ministry of Agriculture, and for another Member State (4%) from the competent PPP authority and a professional organisation. For one Member State (4%), the contact persons work for an official scientific organisation and professional organisations. See Figure 3.

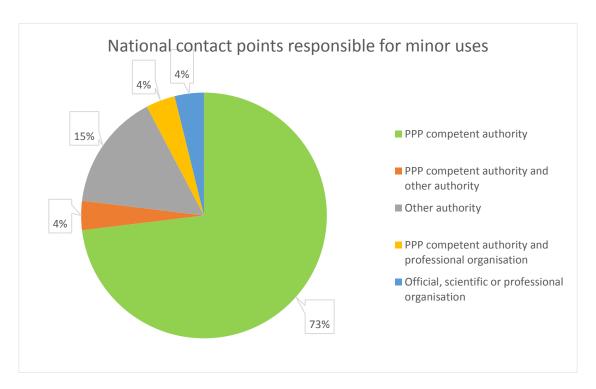


Figure 3: Type of organisation to which national contact points responsible for minor uses belong in EU Member States, Norway and Switzerland

3.2.2 Participation of countries in Commodity Expert Groups

All Member States who responded to the questionnaire addressed this question. Two Member States joined the Commodity Expert Groups (CEGs) in the meetings organised in March by the MUCF after the survey was organised, so this information was also taken into account in the final results.

Information on the participation of Member States in this section is also sourced from the MUCF. For four Member States who had not replied to the questionnaire, the information on their participation was available to the MUCF so information on these Member States was also considered. In addition, information on the participation of two countries, who were not part of the survey, Macedonia and the United States, was taken into account.

A high participation of Member States in Commodity Expert Groups is noted (Figure 4). 78% of Member States have appointed one representative (or more) in the CEGs.

The United States attends the CEG Hops as this country is a major hops producer, and Macedonia the CEG Tobacco. However they did not participate in this survey.

It should be noted that some CEGs are dealing with crops that are not grown in all Member States (e.g. hops, rice, tobacco, mushrooms). Nine Member States are not currently participating in the CEGs. They are from the Northern (Finland, Estonia, Norway), Southern (Cyprus and Malta), Central (Luxembourg) and Eastern (Bulgaria, Croatia, Romania) Europe.

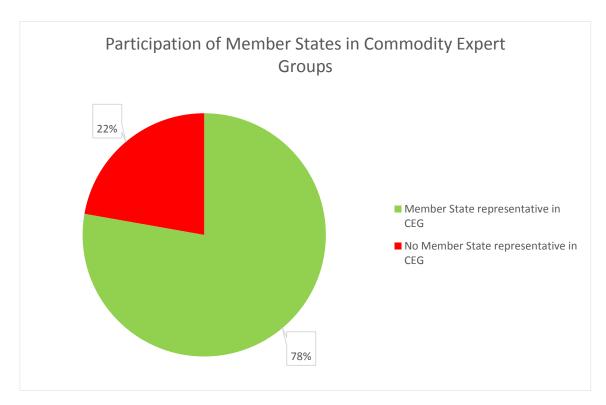


Figure 4: Participation of Member States in Commodity Expert Groups

Information on the participation of Member States in individual CEGs was sometimes provided in the questionnaire although it was not specifically asked. This information was also available to the MUCF so is provided hereafter. Figure 6 displays the number of countries in each CEG and Table 1 details on which countries are participating in CEGs.

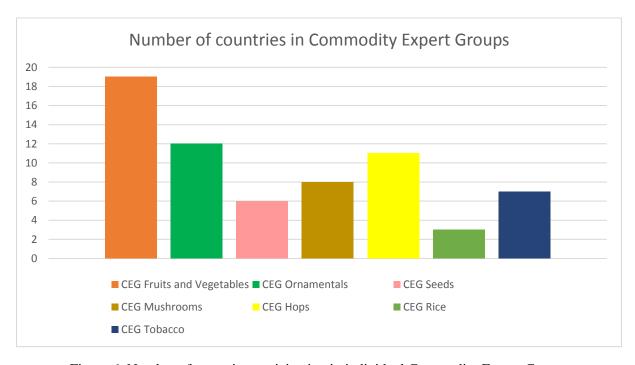


Figure 6: Number of countries participating in individual Commodity Expert Groups

Table 1: Number and name of countries participating in individual Commodity Expert Groups

Commodity Expert Group	Number of	Name of country
	Countries	
Fruits and Vegetables	19	DK, SE, LT, LV, AT, BE, CZ, DE,
		HU, IE, NL, PL, SK, UK, EL, ES, FR,
		PT, CH
Ornamentals	12	DK, SE, BE, DE, IE, NL, UK, EL, ES,
		FR, IT, CH
Seeds	6	NL, DE, UK, EL, ES, FR
Mushrooms	8	BE, IE, NL, PL, EL, ES, FR, IT
Hops	11	AT, BE, CZ, DE, PL, SI, UK, EL, ES,
		FR, US
Rice	3	EL, FR, IT
Tobacco	7	DE, PL, EL, ES, FR, IT, MK

3.2.3 Who can or does apply for article 51 minor uses extensions?

According to Regulation (EC) No. 1107/2009, article 51, paragraph 1, several categories of applicants may apply for a minor use extension:

'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'.

All responding Member States addressed the question on who can or does apply for a minor use extension.

For more than half of the Member States (54%) all the applicant categories that are mentioned in article 51 can or do apply for a minor use extension (Figure 6). The other Member States indicated a limited range of these categories, with most of the times two categories combined such as authorisation holders and professional organisations (15% of the Member States) or official or scientific bodies and professional organisation (11% of the Member States). In the other Member States, authorisation holders, and/or professionals and/or scientific organisation can or do apply. One Member State (non-EU) mentioned that only the authorisation holder can apply.

The results for this question show that not all the possible categories of applicants are used in all Member States, while in principle as according to article 51 all the categories listed may apply for a minor use extension.

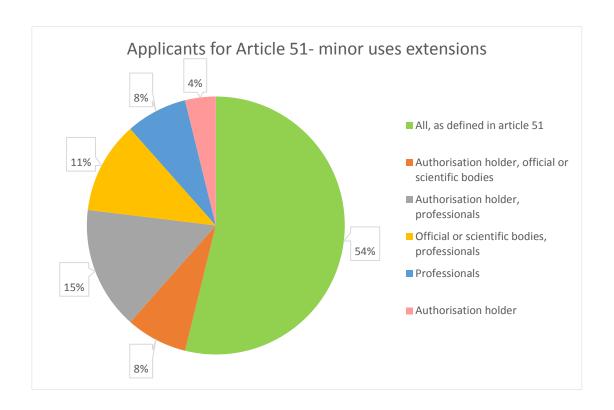


Figure 6: Categories of applicants that can/do apply for minor uses extension under article 51 in Member States

3.2.3 Organisations evaluating the applications

All contacted Member States responded to the question: 'Which organisation evaluates minor uses applications?'

As shown in Figure 7, for a majority of Member States (88%) the PPP competent authority is the only organisation evaluating minor uses applications. For two Member States, the PPP competent authority used advice from another organisation to validate if the uses claimed by the applicant are actually minor and if the minor use is of public interest. One Member State indicated that another competent authority, the Ministry of Agriculture, in principle evaluates minor uses dossiers, but if it is needed the PPP competent authority can do this work.

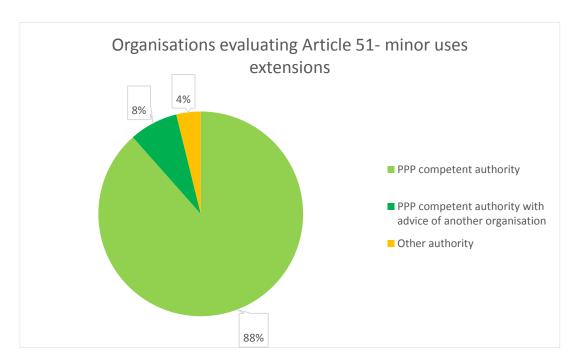


Figure 7: Types of organisations evaluating minor uses extensions in Member States

3.3 How is Minor Uses work organised in Member States?

3.3.1 List of minor uses

All contacted Member States provided a response to the question on whether they have a list of minor uses available.

More than half of the Member States (54%) indicated that they have national list on minor uses available (Figure 8). The other Member States have a list available, but of another type, and three Member States mentioned they have no list available, however one is under preparation in one (non-EU) Member State.

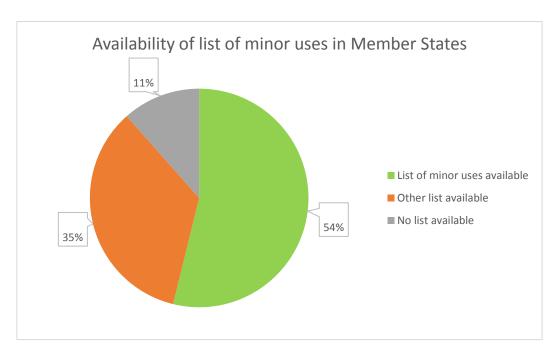


Figure 8: Availability of list of minor uses in Member States

The other types of list are detailed in Figure 9. Five Member States have a list of plant protection products authorised for minor uses. A few other Member States provide a list of minor crops, a list of major uses or a list of pest problems.

It is noted that two Member States have two types of list: (i) list of minor uses and of minor crops, and (ii) list of PPP authorisations and list of pest problems.

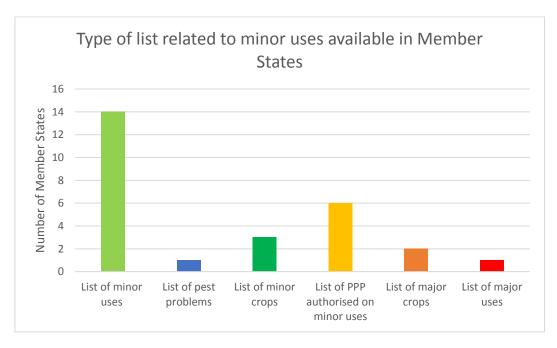


Figure 9: List of minor uses and other types of list available in Member States

3.3.2 Criteria for minor uses

Regulation (EC) No 1107/2009, article 3, paragraph 26 (b) provides a definition for a minor use:

Two Member States refer to the above definition for a minor use but actually use more detailed criteria. Thus, the definition of Regulation (EC) No 1107/2009 is not kept as criteria in the results.

Three Member States did not provide information on the criteria they use to define a minor use. Overall the criteria given by the Member States are very diverse, and of quantitative and/ or qualitative nature (Figure 10). To qualify a use as minor, Member States use primarily criteria linked to the crop: surface, production volume, type of crop (speciality) or dietary intake. Some Member States also consider the pest occurrence. One Member State referred to the type of agriculture (organic/ecological farming). It should be noted that various Member States use more than one criterion.

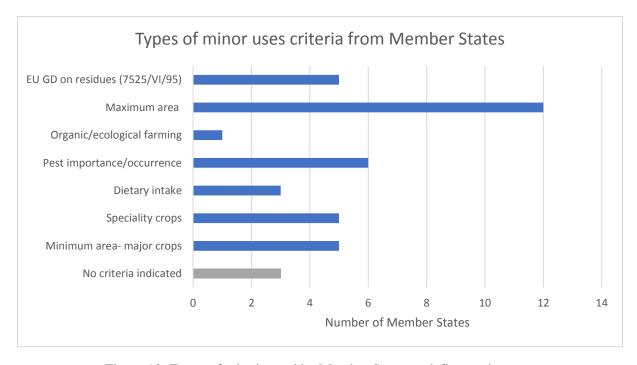


Figure 10: Types of criteria used by Member States to define a minor use

• Criteria from EU Guidance Document on residues

Five Member States (France, Spain, Greece, Cyprus, Austria) refer to EU criteria provided by the EU guidance document on residues (7525/VI/95) for major crops or dietary intake:

'Daily intake contribution > 0.125 g/kg bw/day and/or production (> 400 000 tonnes per year) in the zone

OR

Cultivation area > 20 000 ha and Production > 400 000 tonnes per year'.

^{&#}x27;minor use' means use of a plant protection product in a particular Member State on plants or plant products which are:

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

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

• Criteria for minor crops

For a majority of Member States, criteria used to define minor crops are related to the maximum area. These criteria are detailed in table 2.

For one Member State minor crops are not very minor crops and not major crops.

One Member State did not indicate a limit for the maximum area.

<u>Table 2</u>: Maximum cultivated and/or treated areas to define minor crops in Europe

Type of criteria	Maximum area	Number of Member States	Name of Member States	Condition
Cultivated area	1000 ha	1	NL	Protected crops
	5000 ha	4	FI, LT, IE, NL	Field crops (NL)
				In 3 subsequent years (LT)
	10 000 ha	5	LV, CZ, DE, SK, PT	In the year of minor use application (CZ)
	1%	1	PL	and against pests in specific areas
	<0.0035%	1	EE	For very minor crops. % of total utilised agricultural land of agricultural households
Production volume	<0.0035%	1	EE	For very minor crops. % of total plant production volume of agricultural households
Treated area	10 000 ha	2	CZ, DE	In the last 3 years before minor use application (CZ)

• Criteria for major crops

Four Member States define major crops and use the principle that all crops that are not major are minor. For major crops the criteria used are related to cultivation area and/or dietary intake and/or production volume. See table 3.

Dietary intake is also used as criteria to define minor uses (see page 16).

<u>Table 3</u>: Minimum cultivated area, production volume and/or dietary intake to define major crops in Europe

Type of	Minimum	Number of	Name of Member	Condition
criteria			States	
Cultivated area	>2500 ha	1	NO	Non- crop areas and
				lawns excluded
	>10 000 ha	1	PT	and dietary intake
	>1%	1	EE	% of total utilised
				agricultural land of
				agricultural households

Production	>1%	1	EE	% of total plant
volume				production volume of
				agricultural households
Dietary intake	>7.5 g/day	2	EE, PT	And/or cultivated area
				and production
				volume>1% (EE)
				and cultivated
				area>10 000 ha (PT)

• Speciality crops

Five Member States consider that when a crop is a speciality crop, that the related use is minor. The speciality crops concerned are fruits and vegetables, ornamentals, mushrooms and crops other than field crops (Table 4).

Table 4: Speciality crops used to define minor uses in Europe

Speciality crop	Number of Member States	Name of Member State	Condition
All fruits and vegetables	2	DK, IE	except potatoes (DK)
Onion and tomato	1	HR	in greenhouse
Berries	2	DK, CH	around 500 ha (CH)
Outdoor vegetables	1	СН	around 1000 ha
Ornamentals	2	DK, IE	
Mushrooms	1	IE	
All crops other than	1	UK	
wheat, barley, oats,			
oilseed rape, potatoes and sugar beets			

• Dietary intake

The criteria of dietary intake is used by two Member States to define a minor use. For one Member State, it concerns very minor crops (other criteria are also considered). See Table 5. Dietary intake is also used as a criterion to define major crops, see section on criteria for major crops.

<u>Table 5</u>: Dietary intakes used to define minor uses in Europe

Dietary intake	Number of	Name of	Condition
	Member	Member State	
	States		
0.75 g/day/60 kg bw	1	SI	
<1.5 g/day	1	EE	For very minor crops.
			Consider as well cultivated
			area and/or production
			volume

• Pest occurrence

Pest occurrence is part of the definition of a minor use under Regulation (EC) No 1107/2009:

Five Member States indicated a description related to occurrence of the pest (frequency and distribution) and occurrence of the pest in major crops (Table 6).

<u>Table 6</u>: Description of pest occurrence to define minor uses in Europe

Criteria	Description	Number of Member States	Name of Member State
Occurrence	Frequency irregular,	1	CZ
(frequency)	maximum one		
	treatment in 3 years		
Occurrence	Losses only in	1	PL
(distribution)	specific areas		
Occurrence in	currence in Rarely endangers		LV
major crops large cultivated areas			
Pest not significant		1	HR
	in a major crop		
Treatments not		1	NO
	common against a		
	pest in a major crop		

• Organic/ ecological farming

The type of agriculture is used as a criterion by one Member State (Czech Republic). This Member State indicated that uses for organic/ecological farming are qualified as minor uses.

3.3.3 National groups on minor uses

All responding Member States except one addressed the question on which (working) groups or parties are involved in minor uses.

• Organisation of minor uses groups

Overall 34% of Member States have set up a group specific to minor uses (Figure 11). Almost 60% of the Member States do not have a specific group but stakeholders have activities on minor uses and meetings are held. One Member State indicated they have not set up a group specific to minor uses.

^{&#}x27;minor use' means use of a plant protection product in a particular Member State on plants or plant products which are:

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

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

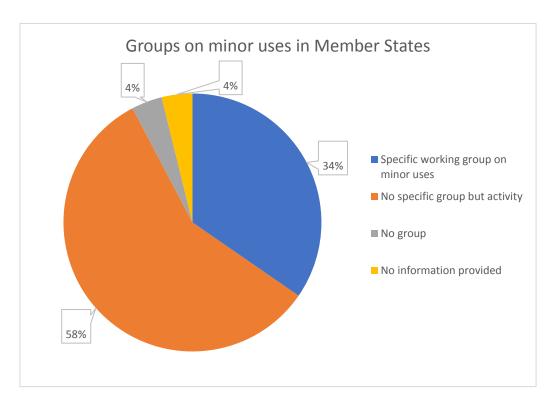


Figure 11: Groups involved in minor uses in Member States

The groups are considered specific to minor uses when the name of the group indicates this, e.g. 'orphan uses committee' in France or 'Minor uses Working group' in Germany, or when it is coordinated by the organisation specific to minor uses, e.g. the Expert Centre for Speciality Crops in the Netherlands.

Most of the Member States do not have a specific group but organise cooperation between stakeholders (e.g. authorisation holders, professional organisations and users, research organisations). Often the competent authority organises the meetings, such as in the United Kingdom and Estonia.

• Role of minor uses groups

The national minor uses groups cover a variety of activities, as shown below:

- Identification of minor uses needs and priorities
- o Identification of possible solutions
- o Application for funding
- o Application for minor uses
- o Carrying out of trials
- o Measure of the impact of Annex I renewal (AIR) programmes
- o Integrated Pest Management (IPM) guidance for minor crops

3.3.4 Risk assessment for minor uses

Four Member States did not respond to the question on how the risk assessment for minor uses is done and if there is national legislation or if there are provisions in place.

Many Member States (10) indicated that for minor uses they conduct a risk assessment following the risk envelope approach (Figure 12). One Member State uses this approach for all assessment areas except for residues.

A few Member States use the mutual recognition procedure, in principle without performing an additional national risk assessment.

Five other Member States simply mentioned that for the risk assessment they follow Regulation (EC) No 1107/2009.

Four Member States indicated they have national legislation or provisions. In the Netherlands, timelines are shorter for national minor uses extensions. Denmark has requirements linked to the soil, ground water and public interest:

- Groundwater: No leaching of active substances and metabolites (even harmless) is accepted
- Persistence in soil: Degradation of 50% of the active substance and relevant metabolites must not exceed 180 days
- Minor use applications (public interest): If there is an existing authorization for the minor use purpose the Danish Environmental Protection Agency (EPA) will reject the application unless they can verify that the product can solve special problems such as resistance management etc.

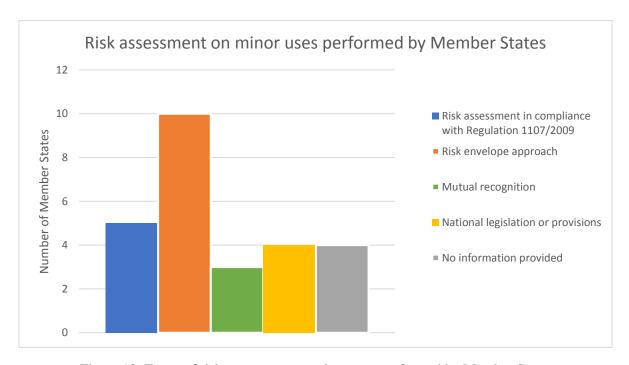


Figure 12: Types of risk assessment on minor uses performed by Member States

3.4 Article 51-Extension of authorisation for Minor Uses

3.4.1 National fees for minor uses

All contacted Member States responded to the question on how much they charge for an article 51 minor use extension.

It should be noted that although the question was related to minor uses extension under article 51, the responses cover not only applications for minor uses extensions, but more generally applications on minor uses (zonal, mutual recognition).

From the survey results it can be concluded that quite some different levels of fees are charged by Member States (Figure 13). A majority of Member States does not charge a fee or charge a low fee, between 10 to 800 euros. Many Member States (13) required a medium to high fee, from 1000 up to 50 000 euros. One Member State has no fee established for minor uses. It should be noted that some Member States have various levels of fees.

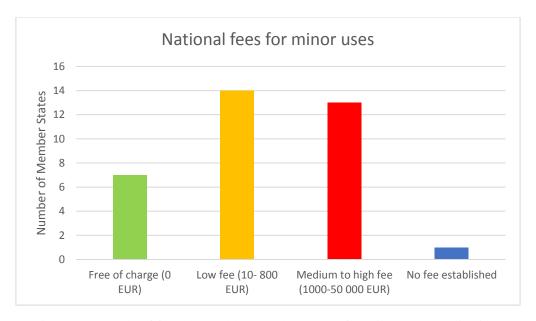


Figure 13: Levels of fees charged by Member States for minor uses applications

Table 7 shows more details on the fees charged by Member States for minor uses. Some Member States indicated that some conditions need be fulfilled to be charged for a specific level of fees.

<u>Table 7</u>: Fees charged by Member States for minor uses applications

Level of fee	Per application/use	Number of Member States	Member State	Condition
Free of charge 0 EUR	-	6	BE, DE, IE EL EE HU CH	-If public interest or third party (BE, DE) -If minor use applied before main registration granted (IE) -If zonal Rapporteur Member State (zRMS) (EL) -Depends on the type of application and assessment (HU) - If minor use extension (CH)
Low 10 to 800 EUR	Per use Per crop Per application	14	DE, PT EL CZ, HR, PT, PL, SI, IE, AT LV, LT ES HU CY	-If authorisation holder (DE) -If public interest or third party (LV, ES) -Depends on the type of application (LT, HR, HU) and assessment (HU) - If concerned Member State (cMS) (LV) -10 EUR if the product contains a low risk active substance (CY)
Medium to high 1000 to 50 000 EUR	Per application Per crop group	13	FR, BE, LV, PT, FI, LT SE, NO AT, DK, NL SK UK	- If authorisation holder (LV, BE, FR) -Depends on applicant (growers or authorisation holder) (UK) -If zonal application (LT, PT) -If zonal Rapporteur Member State (zRMS) for all zones (AT) -For national application (FI) -Depends on the type of extension, zonal or national, and assessment required (NL) - Depends if crops edible or non-edible (DK) -Advance payment required (NL)
No fee established	-	1	RO	

3.4.2 Efficacy data for an article 51 minor uses extension

According to Article 51(2)(b) with reference to Article 4(3)(a) and (c) for an extension of authorisations for minor uses it is not required to meet the conditions that 'it shall be sufficiently effective' and that 'it shall not have any unacceptable effects on plants or plant products'.

All Member States except one indicated whether efficacy data is required for an article 51 minor use extension.

Overall, as shown in Figure 14, a high proportion of Member States (81%) do not require efficacy data for minor uses extensions (article 51).

Three Member States sometimes require data and one Member State requires it. When required, the latter and one of the three countries indicated they accept a reduced data package.

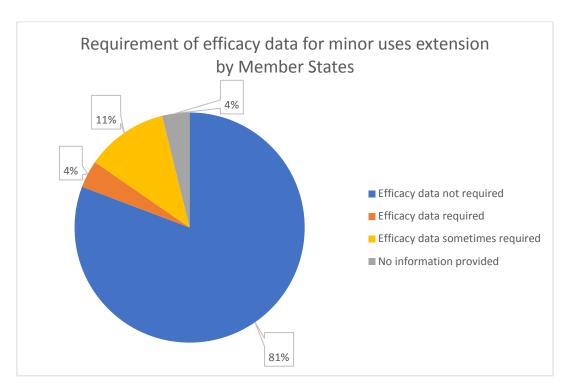


Figure 14: Requirement of efficacy data by Member States for a minor use extension (article 51)

3.5 Capacity of Member States to carry out trials

All contacted Member States except two responded to the question if they have research facilities to carry out trials. Results show that a large majority of Member States have the capacity to carry out trials (84%), see Figure 15.

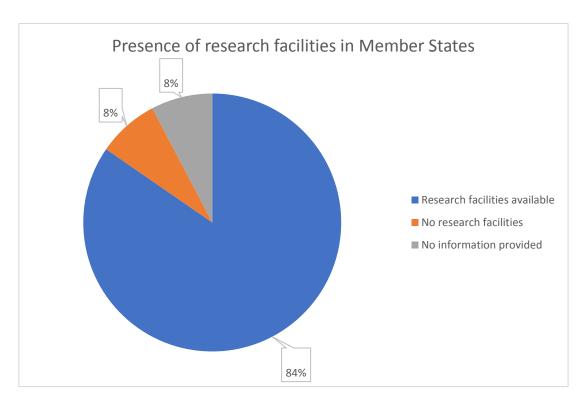


Figure 15: Capacity of Member States to perform trials for minor uses

When Member States have research facilities, these facilities are often Good Laboratory Practice/Good Experimental Practice (GLP/GEP) certified or accredited. There are a variety of type of facilities among Member States: public institutes/research stations, private or professional research stations. A majority of Member States has both public and private research facilities, as shown in Figure 16. A smaller proportion (27%) of Member States has solely public facilities in place.

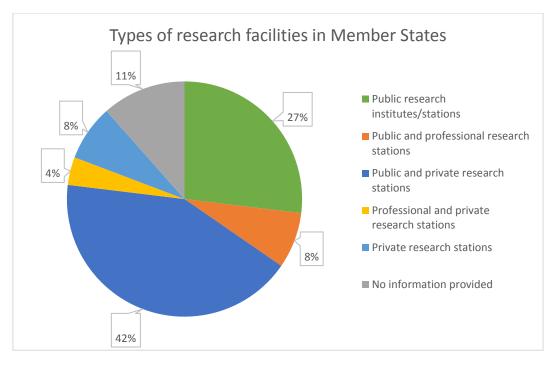


Figure 16: Types of research facilities in Member States for minor uses trials

3.6 Trial funding

To the question: 'Are you able to finance trials to generate data for minor uses extensions?', seven Member States did not respond. This is probably due to the fact that in the form the question was maybe not visible enough in the questionnaire.

42% of Member States responding to this question are able to finance trials, and 31% do not (currently) have this capacity. See Figure 17.

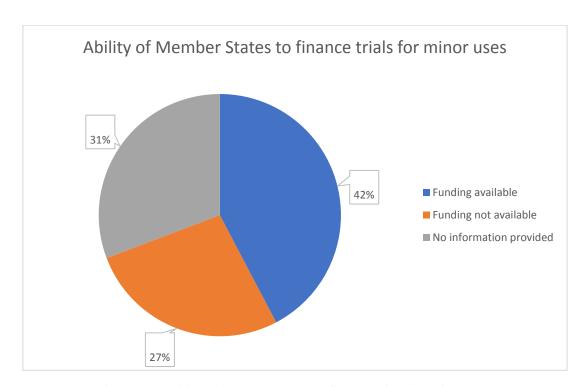


Figure 17: Ability of Member States to finance trials for minor uses

3.7 Data sharing

Almost all Member States (21 out of 26) responded to one or both questions related to data sharing: 'If you have data, would you share them with other MS. What are the conditions to do so?' and 'If you do not have data, how can you still contribute to the sharing of and access to data?'

When Member States own data, most of them are willing to share data and indicated some conditions:

- other Member States should also be willing to share data
- the sharing should be to solve common problems (at zonal or European level) and thus work on common projects (and not only on national projects)
- an agreement is sometimes needed.

One Member State mentioned that it is not willing to share data with other Member States when the corresponding trials have been financed by agricultural organisations.

When Member States do not own data, support from authorisation holders and authorities is needed. From authorisation holders support is needed to:

- provide the authorities with data from different Member States in the same zone for minor uses extensions
- agree on sharing of data (no longer protected). The data sharing should of course follow data protection rules according to Regulation (EC) No 1107/2009.

From authorities, support is needed to:

- keep record of data used for authorisations
- finance trials.

4. Conclusion and recommendations

Overall from this survey on minor uses work in EU Member States, Norway and Switzerland, the following can be concluded:

- There was a high response rate to the questionnaire (87%)
- A majority of national contact points for minor uses are from the national authority competent for plant protection products
- Most of the Member States are represented in Commodity Expert Groups. Some Member States not yet participating are mainly from the Northern, Southern and Eastern Europe
- The CEG Fruits and Vegetables, as well as the CEG Ornamentals, have the highest number of Member States participating
- Not all possible categories of stakeholders actually apply for minor uses extensions
- For a majority of Member States, the competent authority for plant protection products is the only organisation evaluating minor uses applications
- Only 54% of Member States have an available national list for minor uses
- The criteria used by Member States to define minor uses are mainly linked to the crop: surface, production volume, type of crop (speciality crop), dietary intake
- Many Member States do not have a group specific minor uses
- Ten Member States conduct a risk assessment following the risk envelope approach
- Four Member States have national legislation or provisions
- Various levels of fees are charged by Member States for minor uses applications. Some charge no fees, other low or medium fees, and other high fees.
- A majority of Member States do not require efficacy data for minor uses extensions
- A majority of Member States have research facilities to perform trials for minor uses
- 31% of Member States do not have the capacity to fund trials
- Most of Member States owning data are willing to share data under certain conditions
- When Member Stats do not own data, support is needed from authorisation holders and authorities.

The MUCF can provide the following recommendations based on this survey:

- All Member States are encouraged to participate in Commodity Expert Groups (and in the Horizontal Expert Group)
- Member States should encourage all relevant categories of stakeholders to apply for minor uses
- All Member States should establish a reference list of minor uses and make it available
- An agreement for a harmonized EU definition for minor uses is needed

- The risk envelope approach should preferably be used by all Member States
- Member States should not apply national requirements to minor uses
- All Member States should have an appropriate fee system (with no or lower fees) for minor uses
- Member States should improve their organisation as regards minor uses work for optimal national and zonal coordination
- Member States are encouraged to build up capacity for carrying out and financing trials
- All relevant stakeholders should support data sharing and access.