CONFERENCE SMS Steering Committee / Industry associations
18 November 2022
9 hours to 14 hours (CET)
Venue: Real Jardín Botánico (CSIC) - Salón de actos
Calle Claudio Moyano, 1

8:30 – 8:55	Reception of attendees
9:00 – 9:30	Welcome **Ms. Esther Esteban Rodrigo** (Directora INIA – CSIC) **Mr. Valentín Almansa** (Director General de Sanidad de la Producción Agraria – MAPA)
9:30 – 9:45	Update of the SMS SC (*Mr José Luis Alonso Prados (ES) INIA-CSIC*)
HOW TO ACCELERATE PROCEDURES FOR AUTHORIZATION OF LOW RISK PPP ***Chair of the session: Mr José Luis Alonso Prados (ES)***	
9:45 – 9:55	**CLE** point of view (*Ms. Cristina Adalid (chair of the regulatory group AEPLA)*
9:55 – 10:05	**ECCA** point of view (*Mr.Manuel Duarte, ECCA)*
10:05 – 10:15	**IBMA** point of view (*Ms. Flora Limache – IBMA France*)
10:15 – 10:25	**SMS SC** (*Mr. José Luis Alonso Prados (ES)*)
10:25 – 10:40	Debate
10:40 – 11:00	Coffee Break (offered by AEPLA)
HOW TO IMPROVE THE QUALITY OF THE PPP ZONAL DOSSIERS ***Chair of the session: Ms Natalia Nogueira, (ES) MAPA***	
11:00 – 11:10	**CLE** point of view (*Ms. Cristina Adalid (chair of the regulatory group AEPLA)*
11:10 – 11:20	**ECCA** point of view (*Mr. Manuel Duarte, ECCA)*
11:20 – 11:30	**IBMA** point of view (*Mr Jeremy Belzunces – IBMA Global*)
11:30 – 11:40	**SMS SC** (*Ms Natalia Nogueira (ES))*
11:40 – 11:55	Debate
AGREEMENTS ACHIEVED FOR APPLICATIONS OF PPP TO BE USED IN GREENHOUSES ***Chair of the session: Mr José Luis Alonso Prados (ES)***	
11:55 – 12:05	**CLE** point of view (*Ms. Cristina Adalid (chair of the regulatory group AEPLA)*
12:05 – 12:15	**ECCA** point of view (*Mr.Manuel Duarte, ECCA)*
12:15 – 12:20	**IBMA** point of view (*Ms Adriana Guerra – IBMA Spain*)
12:20 – 12:30	**SMS SC** (*Mr José Luis Alonso Prados (ES)*)
12:30 – 12:45	Debate
12:45 – 13:00	Final remarks and close of the meeting **Mr. Guy Vancanneyt** (Vice-Director Técnico INIA-CSIC)
13:00 – 14:00	Appetizer (offered by AEPLA)

UPDATE OF THE ACTIVITIES OF THE SOUTHERN MEMBER STATES STEERING COMMITTEE IN THE YEAR 2022

JOSE LUIS ALONSO PRADOS

INVESTIGADOR (DEP PROTECCION VEGETAL (INIA-CSIC)
DIRECTOR CIENTÍFICO/TECNICO DE LA UNIDAD DE PRODUCTOS FITOSANITARIOS
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Art 43 – SMS Agreements”

- **ALLOCATION OF ZRMS is made by the SMS SC**
  1. Proposal of the applicant
  2. ZRMS shall be cMS
  3. Capacities of the MS
  4. Risk envelope between applications

✓ For Cat. 4 studies the opinion of the zRMS will be accepted .

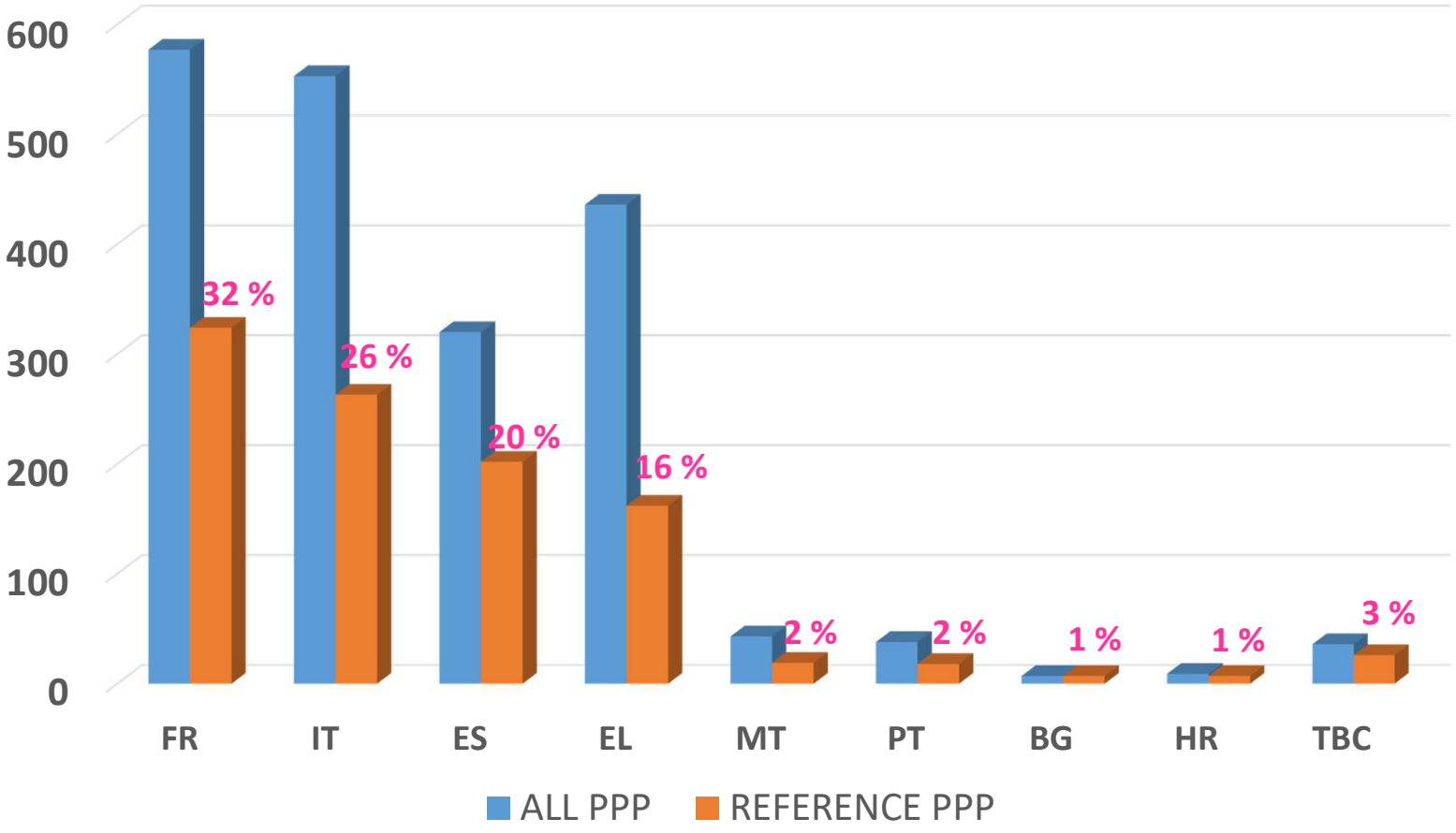
✓ Date of DRR submission should be based upon the date the latest study available +3m.

✓ The zRMS will inform the zone through the CoCh. If the cat. 4 studies are not accepted the applicant can be given an extra 3 months to react.

✓ If no dossier is submitted for the PPP withdrawal of the authorisation of the PPP one year after the entry into force of the renewal regulation of the a.s. In some occasions this deadline is covered by the grace period granted under Article 46 of Regulation 1107/2009.

✓ There is no “stop the clock” under Art. 43 but zRMS may request information or clarification but should not request or accept new studies.

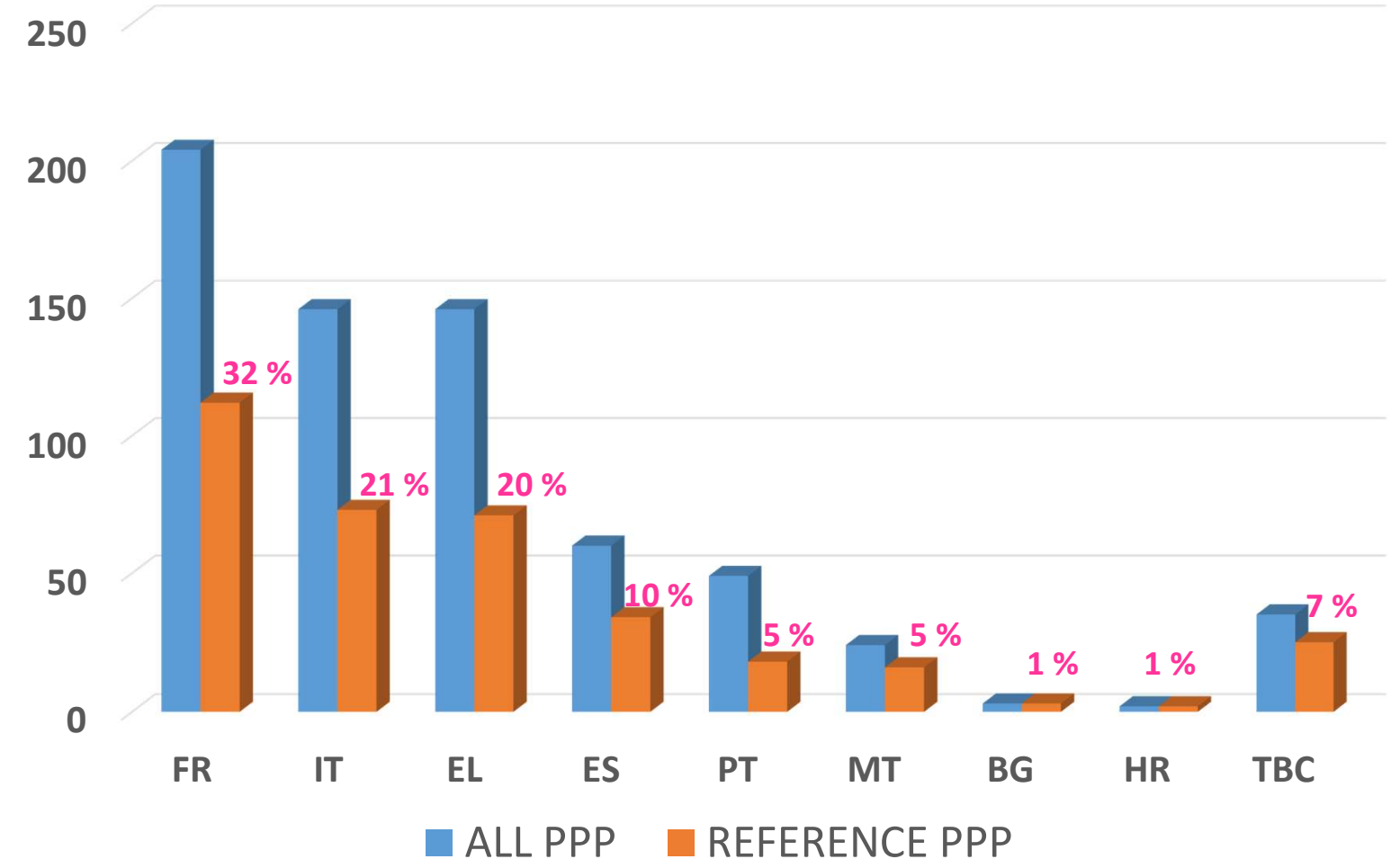
ALLOCATION OF PPP ART 43 AIR IV



FR COORDINATE

2054 PPP

ALLOCATION OF PPP ART 43 AIR V - DRAFT



ES COORDINATE

669 PPP

UNACCEPTABLE COFORMULANTS

COMMISSION REGULATION (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products

Member States which have granted authorisations for plant protection products containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation, **shall amend or withdraw those authorisations as soon as possible but no later than 24 March 2023**.

In Southern zone the approach is that independently on whether the original authorisation has been given is under the art. 40 or art. 33, if the applicant informs that an application has been submitted to the reference MS according a zonal procedure, they wait for the RMS conclusions; if this is not the case, they assess on their own.

NATIONAL DATA REQUIREMENTS - REFIT Action for MS

DCG asked MS thorough IZSC to assess the possibility to revise their national legal requirements and give feedback to the IZSC. With reference to national requirements it is requested the following:

1) What is the basis for the national requirements (political decisions, different risk assessment approaches, agronomical necessaries, national law, …)

2) Identification of those requirements which are based on risk assessment approaches. All MS should also identify requirements which could easily be lifted.

SMS are updating of the Appendix 4 (national data requirements) of the SMS Guidance document. Afterwards, where necessary, the overall document will be revised.

New appendix 4 – February 2023

PROCEDURE FOR AUTORIZATION OF LR PPP

DCG asked MS thorough IZSC to improve and accelerate the process for authorization of Biopesticides and low risk PPPs (REFIT Action Point)

SMS SC – survey to know the national procedure for the authorization of LR PPP

HOW TO IMPROVE THE QUALITY OF DOSSIER

DCG asked MS, thorough IZSC, to collect MSs Practices Procedure to identify and handle with low quality, inadmissible dossiers

SMS-SC have to agree on a common position of what is taken on board on each MS regarding the admissibility of the dossiers

Survey was coordinate by ES to collect the procedures for admissibility of the dossiers in each SMS

PROCEDURE FOR ART 33 + ART 34

EL prepared a document with a procedure identifying different situations

Different approaches are followed by SMS – Common position is not possible to achieve

Document with the different approaches by each MS will be prepared

THANK YOU FOR YOUR ATTENTION

CLE presentation

Southern Zone Steering Committee.

Southern Zone meeting November 18th 2022

HOW TO ACCELERATE PROCEDURES FOR AUTHORIZATION OF LOW RISK PPP

- Reference to SZSC answer from 2021 SZSC meeting
- Legal timeline - 120 days

- Industry sugestions & questions
  - A potential faster process could include authorising the Low Risk PPP already for the representative use (and representative formulation), while the other uses are still being assessed (same submission in 2 parts – 1 fee)
  - One izRMS (center of expertise)
  - Alignment on common interpretation of Low Risk between zRMS and cMS
  - Specific section in SCoPAFF agenda on “potential” Low Risk actives

  - Publication of clear guidance for submission
  - Wasn’t there a IZSC survey to MS to collect best practices to fast-track LR PPPs?

ADDITIONAL TOPICS

- New application technologies (drones, trunk injection, paint brush, spot applications, precision agriculture) are being developed very fast. It is necessary to start trials to demonstrate enhanced safety
  - Protocols, clear definition of Risk Assessment approach and clear criteria (e.g. on how to define in the GAP) agreed at EU level are necessary to continue in the right direction
  - Industry is ready to start working with authorities to generate data and focus on common agreed priorities
- FR Microplastics 2027 ban – effect on SZ workload
- Mutual recognitions: We are calling upon SZ authorities to take advantage of the opportunities of the new guidance to increase MR among MS and optimise resources.
- SZSC 2021 Follow-up
- Harmonized approach to the notification of non-significant composition changes (e.g. same CAS No, different supplier of co-formulants). Currently there are different approaches from different MS: from notification to evaluation

Southern Zone Steering Committee meeting with the Industry

Madrid, 18th November 2022

Southern Zone SC meeting with the Industry

How to accelerate low risk PPP

- The shorter timelines set for low risk PPPs is a political decision, translated then to Reg 1107/2009.
- ECCA members, have in their portfolio both low risk PPPs and other PPPs. We assume that the shorter timelines for evaluation of low risk PPPs, will not slow down the timelines for evaluation of the other PPPs.
- The main “advantage” that low risk PPPs may have when considering the evaluation, is that for some sections, the risk assessment can be simplified or even waived out considering the characteristics of the active substance.
  - *Set up and publish clear guidance of when applicants can simplify or waive out risk assessment*
- Re-allocate staff doing unnecessary full re-evaluations of MR applications, to the evaluation of low risk PPPs.

ECCA

Southern Zone Steering Committee Meeting

Flora Limache, IBMA France

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Southern Zone Steering Committee - Questions

- **How to accelerate procedures for the authorization of low risk PPPs and biocontrol products?**
- **How to improve the quality of the PPP zonal dossiers?**
- **Agreements achieved for application of PPPs to be used in greenhouses**

How to accelerate procedures for the authorization of low risk PPPs and BC products?

In general, we recommend to:

- **identify low risk and biocontrol products at the start of the application** for example: France - Form with special box to tick
- **prioritize these dossiers** and proceed with a **fast track** at all levels of the procedures: administrative – admissibility and decision, and evaluation
- employ **dedicated and specialized coordination agents for low risk and biocontrol PPPs** in each competent authority
- set up a **network of evaluation experts for low-risk and biocontrol in Southern zone** and in the other zones
- exchanges (emails and letters) **should be possible in English** in addition to the national language
- organise **pre-submission meetings earlier before submission e.g. 12 months rather than 6 months**.
- **simplify the regulations** wherever possible

How to accelerate procedures for the authorization of low risk PPPs and BC products?

ADMINISTRATIVE PART - RECEIVABILITY

- Allow product application process to **start prior to completion of active substance approval**
- Application forms should be **in both national and English languages** and **easily accessible**
- A **help desk (e.g. CTGB) should be implemented in each competent authority, which provide fast replies** (within 15 days for example)
- **Fees should not be too high for low-risk PPPs and biocontrol PPPs and the proceeding of fees should not delay the start of the procedure**

ADMINISTRATIVE PART – COMMENTING PHASE

- The coordination between MS for the commenting should be done efficiently within the timeframe

ADMINISTRATIVE PART – DECISION MAKING

- This part of the process should not be delayed. The maximum duration should be 30 days

How to accelerate procedures for the authorization of low risk PPPs and BC products?

TECHNICAL EVALUATION

- **Member States should be encouraged not to "reopen the box".** This is a particular problem in safety evaluations in Spain
- **Guidance documents on evaluation and procedures including work-sharing, should be updated to include biocontrol products**. This will help to ensure consistency and provide confidence between MS
- **Specific requirements or restrictions should not be added for these products.** E.g. classification as sensitizer for micro-organisms
- **We recommend the creation of "ad hoc" working groups, which deal exclusively with biocontrol active substances, to ensure the evaluation of product dossiers in the shortest possible time.** Potentially also the applicant should be contacted for further information or clarification

How to accelerate procedures for the authorization of low risk PPPs and BC products?

TECHNICAL EVALUATION

- Member States have certain latitude in **allowing extrapolation to other crops** and IBMA advocates that this possibility should be used more proactively, so that MS could grant automatic extension of the authorization on all uses wherever possible
- Regular **training could be organised for the evaluation experts** dedicated to low-risk and biocontrol PPPs in all Member States

Thank you

IBMA
International Biocontrol Manufacturers Association AISBL

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HOW TO ACCELERATE PROCEDURES FOR AUTHORIZATION OF LOW RISK PPP

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PROCEDURE FOR AUTORIZATION OF LR PPP

DCG asked MS thorough IZSC to improve and accelerate the process for authorization of Biopesticides and low risk PPPs (REFIT Action Point)

SMS SC – survey to know the national procedure for the authorization of LR PPP

LEGAL FRAMEWORK - REGULATION 1107/2009

Article 47: Placing on the market of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product **provided no specific risk mitigation measures are needed following a risk assessment**. This plant protection product shall also meet the following requirements:

(a) the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;
(b) it does not contain a substance of concern;
(c) it is sufficiently effective;
(d) it does not cause unnecessary pain and suffering to vertebrates to be controlled;
(e) it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as **'low-risk plant protection products'**

LEGAL FRAMEWORK - REGULATION 1107/2009

Article 47: Placing on the market of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are low-risk active s

The Member State shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product

(b)
(c) it is sufficiently effective;
(d) it does not cause unnecessary pain and suffering to vertebrates to be controlled;
(e) it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as **'low-risk plant protection products'**

GUIDANCE ZONAL EVALUATION & MUTUAL RECOGNITION

- Procedure remains the same as for the conventional products but the timeframe is reduced (120 days + max 6 months if additional data are requested)
- Applicants shall state in their notification form that they intend to seek authorisation for a low-risk product.
- Especially important to use, where appropriate, the risk envelope approach
- All intended uses for the product meet all the requirements for low-risk PPPs set in Article 47.1
- CoCh in 3 weeks if it becomes apparent that the product applied for cannot be a low-risk product in the zone the zRMS should not accept the application.
- cMS shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application.

GUIDANCE ZONAL EVALUATION & MUTUAL RECOGNITION

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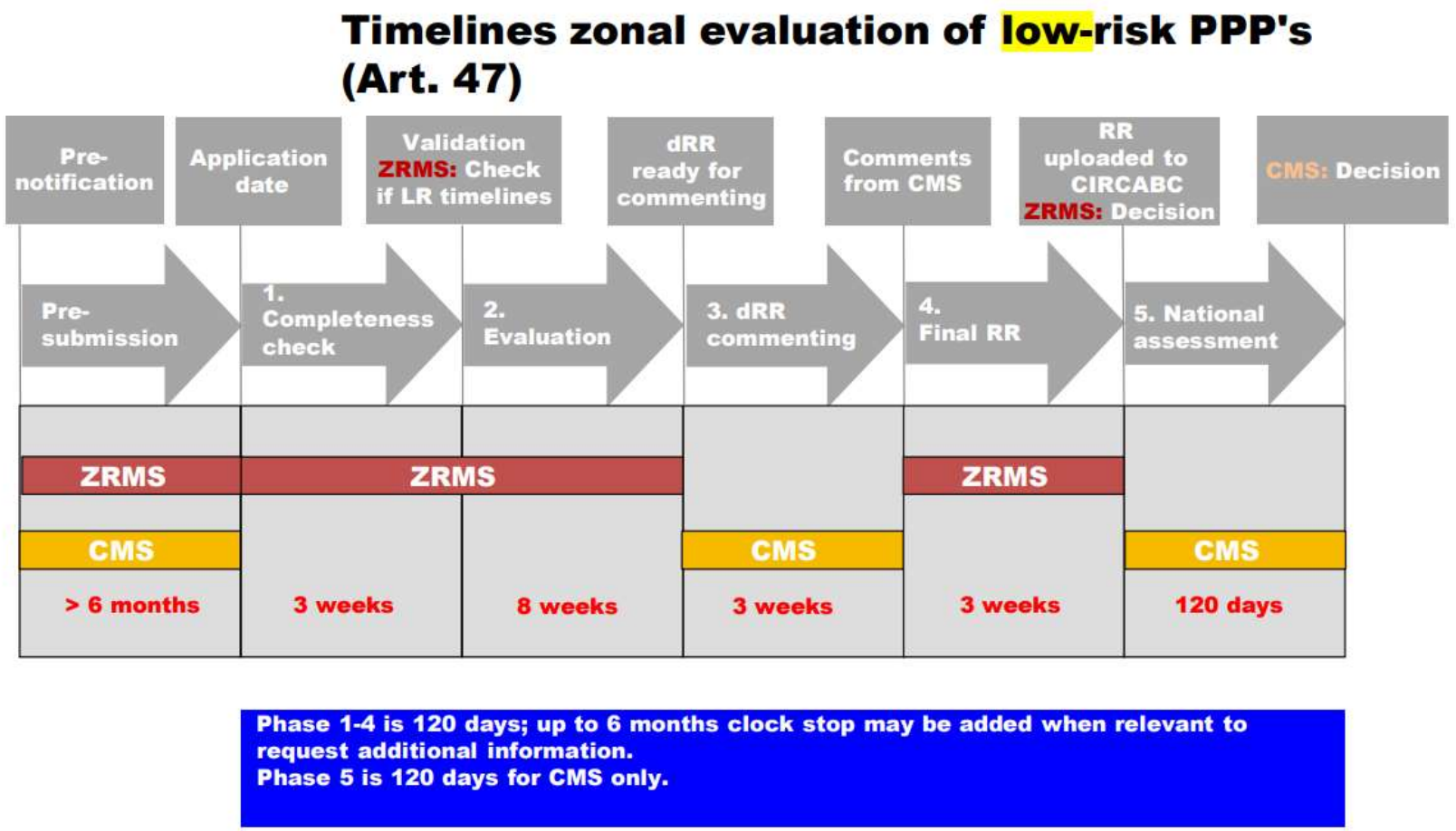

REFIT

- The European Green Deal and the Farm to Fork Strategy make the reduction of dependency on pesticides and the move towards low-risk substances a priority.

- Accelerate the availability of low-risk substances and products. The Commission calls on Member States for reinforced commitment to implement the actions assigned to them in the light of the progress report presented to the Council in July 2019

- DCG asked MS thorough IZSC to improve and accelerate the process for authorization of Biopesticides and low risk PPPs (REFIT Action Point)

SURVEY – SMS

61 active substances approved as LOW RISK: 21 Pheromones; 25 Microorganisms; 8 chemicals; 8 natural compounds

Timelines imposed by the regulation do not completely take into account the need for assessments by MSs and that such timelines are demanding resources.

Survey was prepared in the SMS SC and adopted for the three zones

Review the state of the procedure for LR PPP in the MS

SURVEY – SMS

61 active substances approved as LOW RISK: 21 Pheromones; 25 Microorganisms; 8 chemicals; 8 natural compounds

- **RISK ASSESSMENT : Specific national ASSESSMENT PROCEDURE for proposed LRPPP**
- **RISK MANAGEMENT: Specific national ADMINISTRATIVE or LEGAL PROVISIONS for LRPPP**
- **FAST TRACK PROCEDURE IN PLACE**
- **LOWER FEES**

Review the state of the procedure for LR PPP in the MS

SURVEY – Results SZ

- No specific National assessment procedure for LR PPP.
- No specific National administrative or legal provision for LR PPP – BG has specific legal provision
- Fast track procedure as foreseen in the GD is possible in some MS: FR; BG(MR); MT (no specific for LRPPP); EL. SMS try to comply with the deadline of the Reg 1107/2009
- Lower Fees: YES. However how the lower fees is applied is different in the MS.

SOME IDEAS FOR IMPROVING THE PROCEDURE FOR LR PPP

- Applicants shall prepare the DRR indicating the LR PPP status
- All uses shall comply with the LR PPP provisions (Art 47) – specially those refered to RMM
- Use the risk envelope approach when possible
- Fast track
- Reduce commenting period
- MS to implement a fast track procedure for LR PPP applications
- MS have identified the necessity of specific experience in RA of LR PPP, specially for MO and should explore the actions required

HE PROJECT FUNDED BY EU COMMISSION

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RATION

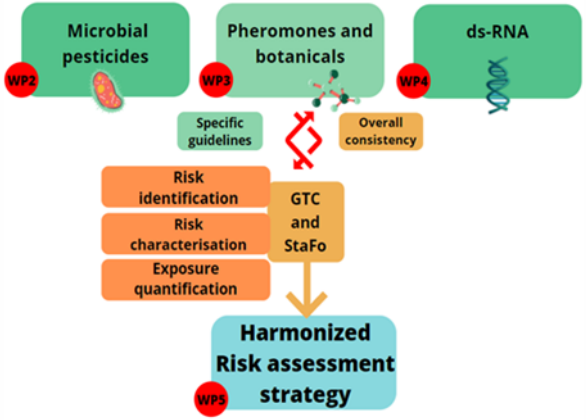
Project funded by the European Commission

Risk AssessmenT InnOvatioN for Low-Risk Pesticides

- Grant Agreement No. 101084163, **Duration 1.11.2022-31.10.2026**

Main Goal: ***to develop a novel risk assessment scheme for LRP, supported by the necessary guidance, methods, and tools for its implementation. This scheme will consider the specific characteristics of currently available LRPs (microbials, plant extracts, pheromones, semiochemicals) and emerging LRPs (e.g., ds-RNA)***

- **Partners: 21**
  - 9 Industrial
  - 11 Academic
  - 1 Regulatory (risk assessor) body
- **Countries: 13**
- **Coordinator:** University of Thessaly



How is it going to be done?

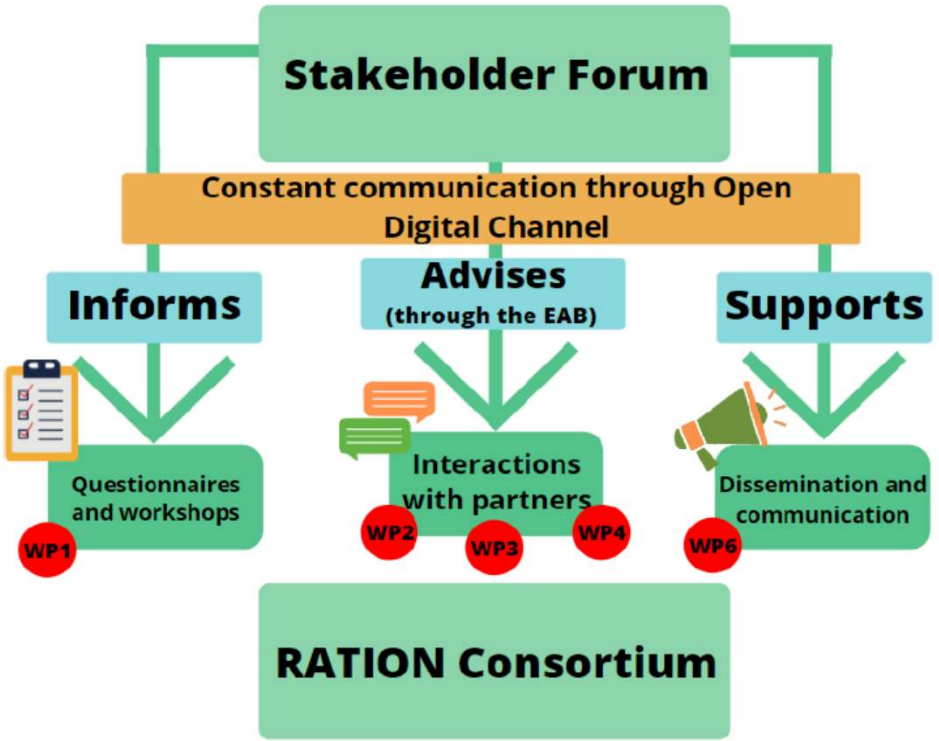
Invitation to participate in the Stakeholders Forum of RATION

Who is going to participate?

Stakeholders from industry, academia, regulatory bodies, users and consumers representatives

What is the commitment required?

Meet with partners every six months (online) and through workshops and other communication activities (ad-hoc)



How could you participate?

Express your interest via email to dkarpouzas@uth.gr

CLE QUESTIONS

A potential faster process could include authorising the Low Risk PPP already for the representative use (and representative formulation), while the other uses are still being assessed (same submission in 2 parts – 1 fee)

- **Proposal is welcome. 2 applications and 2 fees are necessary.**
- **It is in line with the application of the risk envelope approach when possible.**
- **To be considered also by IZSC**

One izRMS (center of expertise)

- **Leagally speaking iZRMS only for Greenhouse/seed treatment/post harvest**
- **Explain more….**

Alignment on common interpretation of Low Risk between zRMS and cMS

- **Biopesticide WG in connection with PAI will consider it**

Specific section in SCoPAFF agenda on "potential" Low Risk actives

- **EU Commission to consider this possibility and to decide on the procedure for decision**
- **Explain more ¿what is the advantage?**

CLE PROPOSALS

Publication of clear guidance for submission

- **Zonal and MR Guidance includes guidance for LR PPP applications.**
- **SMS SC will update the SMS Guidance document and will be aligned with the Zonal and MR guidance**
- **Biopesticide WG / PAI WG will consider**

Wasn't there a IZSC survey to MS to collect best practices to fast-track LR PPPs?

- **Yes a IZSC survey has been done to collect the practices in different zones and to collect proposals for improvement**

IBMA PROPOSALS

- **Proposals are welcome.**
  - **identify low risk and biocontrol products at the start of the application for example**: France - Form with special box to tick – **Applicant shall include the LR status (Art 47) in the application and in the DRR and justify it; to be confirmed by the assessment of ZRMS. Already implemented.**
  - **prioritize these dossiers and proceed with a fast track** at all levels of the procedures: administrative – admissibility and decision, and evaluation – **Fast track procedure as foreseen in the GD is possible in some MS, difficult to implement in other MS due to the national administrative procedures and laws**
  - **employ dedicated and specialized coordination agents for low risk and biocontrol PPPs** in each competent authority – **Specific procedures are more relevant**
  - **set up a network of evaluation experts for low-risk and biocontrol in Southern zone and in the other zones** – **Biopesticide WG. A net work for efficacy experts is already established; for the other sections experts can contact and collaborate.**
  - **exchanges (emails and letters) should be possible in English in addition to the national language.**
  - **organise pre-submission meetings earlier before submission e.g. 12 months rather than 6 months. For all type of PPP and applicant has to apply for it**
  - **simplify the regulations wherever possible**

IBMA PROPOSALS

- **ADMINISTRATIVE PART - RECEIVABILITY**

- **Allow product application process to start prior to completion of active substance approval** – **Art 37.3 allows it**
- **Application forms should be in both national and English languages and easily accessible – National laws do not oblige to use English**
- A help desk (e.g. CTGB) should be implemented in each competent authority, which provide fast replies (within 15 days for example) – **Resources are needed for this**
- Fees should not be too high for low-risk PPPs and biocontrol PPPs and the proceeding of fees should not delay the start of the procedure – **All SMS have lower fees for LR PPP**

- **ADMINISTRATIVE PART – COMMENTING PHASE**

- The coordination between MS for the commenting should be done efficiently within the timeframe approval – **This is made by SMS for Art 33 application not only for the LR PPP**

- **ADMINISTRATIVE PART – DECISION MAKING**

- This part of the process should not be delayed. The maximum duration should be 30 days – **SMS when acts as ZRMS try to comply with the timeline established in the "*Zonal assessment and MR guidance document*" (30 days) and 120 days for cMS**

IBMA PROPOSALS

- **TECHNICAL EVALUATION**

- Member States have certain latitude in **allowing extrapolation** to other crops and IBMA advocates that this possibility should be used more proactively, so that MS could grant automatic extension of the authorization on all uses wherever possible – **This can not be made automatically, case by case and well justified by the applicant**

- **Regular training** could be organised for the evaluation experts dedicated to low-risk and biocontrol PPPs in all Member States – **Agree (BTSF course is ongoing)**

ECCA PROPOSALS

- Set up and publish **clear guidance** of when applicants can simplify or waive out risk assessment

- **Zonal and MR Guidance includes guidance for LR PPP applications.**
- **SMS SC will update the SMS Guidance document and will be aligned with the Zonal and MR guidance**
- **Biopesticide WG / PAI WG will consider**

- **Re-allocate staff** doing unnecessary full re-evaluations of MR applications, to the evaluation of low risk PPPs.

- **Available resources in MS are allocated in the more efficient way to perform all the obligations of the Regulation 1107/2009 for active substances; plant protection products & MRL applications.**
  - **Art 38; Art 33; Art 43; Art 40; Art 51; Art 34; Art53 etc…**
  - **Zonal and IZ coordination**
  - **Guidance documents**
  - **Working groups**
  - **Peer review**
  - **IUCLID……..**

THANK YOU FOR YOUR ATTENTION

CLE presentation

Southern Zone Steering Committee.

Southern Zone meeting November 18th 2022

HOW TO IMPROVE THE QUALITY OF THE PPP ZONAL DOSSIERS

Current situation: Longer evaluation times surpassing the legal timelines, high workload in evaluating agencies/authorities, increasing administrative and technical complexity

- Status SZ guidance document, including National requirements : Even if incomplete, at least publish a **live document** of SZ MS criteria in CIRCA and include any additional agreed positions over time. A minimum of 6 months transition period for implementing any new guidance or criteria should be respected

- Presubmission meeting (with follow-up) 1 year before submission is key to agree with applicants on the correct submission details (data/requirements)

- Harmonise the different risk mitigation measures. Share with Industry the RMM accepted by COM and publish the implementation ways in the MS.

- What are the key quality issues you see as authorities in the dossier you get ? – Link to 2023 zonal workshop

Southern Zone Steering Committee meeting with the Industry

Madrid, 18th November 2022

Southern Zone SC meeting with the Industry

How to improve the quality of PPP zonal dossiers?

- Publish clear and detailed guidance and rules
  - *Bullet points published at CIRCABC.*
  - *Indicate MS specific requirements, when relevant, and keep them updated.*
  - *Changes in guidance should be announced, and enough time to enter into force granted.*

- Hold open and transparent Pre-Submission Meetings
  - *Very useful and significant on MSs that accepts.*
  - *A significant source of technical issues on dossiers, in MSs that don't organize PSMs. This leads to delays on the procedure.*
  - *Pre-Submission Forms – do not replace dialogue.*
  - *Advisable to allocate the evaluation to the experts providing the pre-submission advice.*

ECCA

Southern Zone SC meeting with the Industry

How to improve the quality of PPP zonal dossiers?

- Run a detailed technical completeness check, before starting the evaluation of the dossier
  - *Good experience when zRMS implements such procedure.*

- Endpoints used for the evaluation of dossiers
  - *Lack of consistency was reported.*
  - *The assessment must be made with the EU agreed endpoints. Any deviations needs to be properly justified.*

ECCA

Southern Zone SC meeting with the Industry

How to improve the quality of PPP zonal dossiers?

- When generic applicants refers to data out of protection, they are being asked to provide full study summaries/study reports and evaluate unprotected data to new guidance
  - *But generics have no access to these study summary/reports. We are being asked to do the impossible.*
  - *Can MS's commit to publish RR and study reports or make them available upon request?*

- Release of proper Art 60 lists
  - *Clearly indicating if the study was considered as necessary and start/end of data protecion.*

ECCA

Southern Zone Steering Committee Meeting

Jérémy Belzunces, IBMA Global

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Southern Zone Steering Committee - Questions

- How to accelerate procedures for the authorization of low risk PPPs and biocontrol products?
- How to improve the quality of the PPP zonal dossiers?
- Agreements achieved for application of PPPs to be used in greenhouses

General statement

- The **majority of low risk substances are biocontrol**
- Biocontrol is **essential to achieve the objectives of the Farm to Fork strategy**
- IBMA **welcomes the inclusion of the definition of biocontrol** as reflected in its comments on the draft Regulation on the sustainable use of pesticides.
- We need a **straightforward common set of rules** on the production of dossiers and their assessment
- IBMA asks for the **EU timelines to be respected (Regulation N°1107/2009**). We propose timelines should be reduced further for biocontrol products. Furthermore, It is indispensable **to take immediate measures under Regulation 1107/2009 to accelerate the evaluation and marketing of both low-risk and biocontrol PPPs**
- We advocate for a **smart use of derogations** under article 53 (temporary "emergency" authorisations). This procedure should be more often used for biocontrol products to respond to urgent plant protection needs and accelerate the use of biocontrol products
- If we would like to speed up the use of biocontrol, we should **make sure that biocontrol products are not penalised with the HRI calculation (SUR)**. A fair weighting system should be applied to biocontrol products. Therefore, biological control **should be treated similarly to low-risk products and be included in 'group 1' or, alternatively, both groups should be excluded from this calculation**

How to improve the quality of the PPP zonal dossiers

- Organise **pre-submission meetings** earlier before submission e.g. 12 months rather than 6 months. The more you anticipate the better the dossiers and the competent authorities are prepared.
- Applicant should be supported and a dialogue with **agents specialized and dedicated to low-risk and biocontrol PPPs** with each competent authority should be possible (expertise for each type of PPP)
- Applicants should be helped by **support and funding schemes** set up by MS
- **Training** could be organised for applicants
- **IBMA works constantly to provide training to members on the latest guidance for dossier application**. This is done at our annual biocontrol industry meeting (ABIM) where we invite regulators to share their experiences and advices with our members.

  We extend our invitation to the Spanish authorities for next year's meeting!

Thank you

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GOBIERNO DE ESPAÑA
MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

SMS SC
Southern Member States Steering Committee

HOW TO IMPROVE THE QUALITY OF THE PPP ZPNAL DOSSIERS?

Natalia Nogueira de Diego
Consejera Técnica
Registro de productos fitosanitarios
SG Sanidad e higiene Vegetal y Forestal

GOBIERNO DE ESPAÑA
MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

ORIGIN OF THE SURVEY

"How to improve the quality of the PPP zonal dossiers"

REFIT REPORT EU COM

Analysis with the objective of simplify procedures and shorten approval times for a.s. and PPPs

IZSC MARCH 2022

The zonal steering committees are asked to further discuss this action, to collect MSs practices and feed back to IZSC for discussion on best practices.

SZSC JUNE 2022

SZSC launches the survey with the aim of:

- Collect MSs practices
- Feed back to IZSC for discussion

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Southern Member States Steering Committee

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6 QUESTIONS TO IDENTIFY MS´S PRACTICES

2022-181-1

1.- SCOPE OF THE INITIAL CHECK OF A PPP DOSSIER IN YOUR MS?

Define the scope of the initial check: administrative, technically, regarding the content of the dossier.

2.- DO YOU ALLOW THE APPLICANT TO UPDATE THE DOSSIER AFTER THE INITIAL CHECK?

Describe and if yes, what are the guidelines and/or timelines for this.

3.- ARE THERE DIFFERENCES DEPENDING ON THE ROLE OF YOUR MS IN THE PROCEDURE?

Depending on the procedure of zRMS, cMS, MR.

4.- HAVE YOU EVER REJECTED DOSSIERS BECAUSE THEY WERE INADMISSIBLE?

If yes, please explain the reasoning.

5.- WHAT DOCUMENTATION IS AVAILABLE TO APPLICANTS IN YOUR MS FOR INFORMATION ON HOW TO PREPARE HIGH-QUALITY DOSSIERS

If posible, please provide for information.

6.- COULD YOU DESCRIBE EXAMPLES OF WHAT MAKE A DOSSIER INADMISSIBLE?

e.g. if…is lacking, we cannot accept the application.

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1.- SCOPE OF THE INITIAL CHECK OF A PPP DOSSIER IN YOUR MS?

SUMMARY:

THE SCOPE OF THE INITIAL CHECK IS ONLY ADMINISTRATIVE AND COMPLIANCE WITH THE DATA REQUIREMENTS.

AT THIS STAGE, THE TECHNICAL/SCIENTIFIC INFORMATION OR JUSTIFICATIONS AND THE QUALITY OF THE DATA IS NOT EVALUATED.

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2.- DO YOU ALLOW THE APPLICANT TO UPDATE THE DOSSIER AFTER THE INITIAL CHECK?

SUMMARY:

UPDATE IS POSSIBLE AFTER THE INITIAL CHECK IN ALL MS.

THE APPLICANTS ARE GIVEN 10 DAYS TO 2 MONTHS TO PROVIDE ANY FURTHER INFORMATION.

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3.- ARE THERE DIFFERENCES DEPENDING ON THE ROLE OF YOUR MS IN THE PROCEDURE?

SUMMARY:

YES, THERE ARE DIFFERENCES DEPENDING ON THE ROLE OF THE MS IN THE PROCEDURE:

- ADMINISTRATIVE CHECK IS PERFORMED FOR ALL PROCEDURES

- THE TECHNICAL COMPLETENESS CHECK IS ONLY FOR BEING ZRMS (ART. 33/43) IN MOST OF MS

- FOR CMS, TECHNICAL EVALUATION IS LIMITED TO DRR COMMENTING PHASE.

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4.- HAVE YOU EVER REJECTED DOSSIERS BECAUSE THEY WERE INADMISSIBLE?

SUMMARY:

DIFFERENT EXPERIENCES FROM MS

2 MS DID NOT REJECT DOSSIERS

6 MS REJECTED DOSSIERS, SOME EXAMPLES

- MAINLY DUE TO ONGOING STUDIES.
- THE DOSSIER DOES NOT CONTAIN ALL THE REQUIRED STUDIES OR STUDIES ARE ON GOING AND THE DOSSIER IS NOT IN COMPLIANCE WITH THE LATEST TOX REFERENCE VALUES / END POINTS
- DOSSIER NOT REVISED ACCORDING TO ACTIVE SUBSTANCE RENEWAL ENDPOINTS OR LACK OF DOCUMENTS.
- FOR DIFFERENT REASONS; LACK OF DOCUMENTS, DATA PROTECTION, FROZEN PERIOD, UNAVAILABILITY OF RRS.
- INCOMPLETE DOSSIERS MOSTLY DUE TO RELYING ON PROTECTED DATA.
- DUE TO DIFFERENCES ON FORMULATION.
- …. / …..

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5.- WHAT DOCUMENTATION IS AVAILABLE TO APPLICANTS IN YOUR MS FOR INFORMATION ON HOW TO PREPARE HIGH-QUALITY DOSSIERS

SUMMARY:

5 MS DO NOT HAVE NATIONAL ADMINISTRATIVE GD

3 MS HAVE NATIONAL ADMINISTRATIVE GUIDANCE DOCUMENT ON HOW TO PREPARE HIGH-QUALITY DOSSIERS:

- FR:

- ARRÊTÉ DU 30 JUIN 2017 FIXANT LA COMPOSITION DES DOSSIERS
- NOTE_FORMULAIRES_NOTICES_DOSSIER_PPP.PDF (ANSES.FR)
- HTTPS://WWW.ANSES.FR/FR/SYSTEM/FILES/ADVICES_TO_APPLICANTS_10_01_2022_FINALE.PDF
- HTTPS://WWW.ANSES.FR/FR/CONTENT/DOCUMENTS-RELATIFS-AUX-AUTORISATIONS-DE-MISE-SUR-LE-MARCH%C3%A9-AMM-DES-PRODUITS

- ES:

-MICROSOFT WORD - NOTA INFORMATIVA REFERENTE A LOS PROCEDIMIENTOS DE REGISTRO DE PRODUCTOS FITOSANITARIOS.V.2.DOCX (MAPA.GOB.ES)

- MT:

HTTPS://MCCAA.ORG.MT/MEDIA/7326/GUIDANCE-DOCUMENT-APPLICANTS-FINAL.PDF

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6.- COULD YOU DESCRIBE EXAMPLES OF WHAT MAKE A DOSSIER INADMISSIBLE?

LACK OF DOCUMENTS:

- ✓ Lack of documents K – all the data requirements must be fulfilled or a justification for waiving must be included in the DRR
- ✓ Lack of a complete DRR (Part A ; B and C)
- ✓ The translation of Part A to national reques
- ✓ Lack of a declaration that the technical material has been considered equivalent.
- ✓ Lack of a material Safety Data Sheets of the co-formulants and plant protection products
- ✓ Lack of list of test and studies (sanitized version)
- ✓ Lack of list of test and studies for which data protection is claimed
- ✓ They do not provide the composition of the final product, or they provide it without the corresponding signature.

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6.- COULD YOU DESCRIBE EXAMPLES OF WHAT MAKE A DOSSIER INADMISSIBLE?

OTHER REASONS REPORTED BY MS:

- ✓ It is not shown that the representative is authorized by the applicant to carry out the application procedures.
- ✓ Non-payment of the fees.
- ✓ The authorization document of the country for which mutual recognition is requested is for other crops or has expired, or the translation of the document and its label is not provided.
- ✓ lack of a supplier of the active substance authorized in the MS,
- ✓ lack of a product manufacturing agreement
- ✓ ongoing studies (Doc K)
- ✓ lack of the minimum number of trials for efficacy or residue assessment
- ✓ In the case of MR or cMS, RMM not applicable in specific National situation or insufficient information to demonstrate, by national addenda, the applicability of RMM at national level.
- ✓ art.43 dossier not revised according to active substance renewal endpoints
- ✓ application concerns a product whose authorization is under renewal (“frozen period”) or will be in the next months.

SOME PROPOSALS FOR IMPROVEMENT

GUIDANCE DOCUMENTS AND RULES

- ✓ CIRCABC: bullet points
- ✓ GD: Live, updated
- ✓ CHANGES: Enough time for enter into force

TRAINING

- ✓ For applicants

PRESUBMISSION PROCEDURE

- ✓ In place in all MS
- ✓ 1 year before submission

NATIONAL LEVEL

- ✓ RMM accepted.
- ✓ ENPOINTS used
- ✓ SPECIFIC REQUIREMENTS
- ✓ Art 60 list justified

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Southern Member States Steering Committee

THANK YOU FOR YOUR ATTENTION

Natalia Nogueira de Diego

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CLE presentation

Southern Zone Steering Committee.

Southern Zone meeting November 18th 2022

AGREEMENTS ACHIEVED FOR APPLICATIONS OF PPP TO BE USED IN GREENHOUSES

- Great example of collaboration between industry and MS authorities to tackle a difficult problem
- Excel file agreed by the SZSC for “Assessment of plant protection products under protected conditions” is applicable from **01/06/2022.**
  - Only for new applications
  - Former criteria should be applied for previously submitted dossiers and ongoing evaluations
- The approach to evaluate uses under protected structures should be harmonized between the zones and an interzonal alignment is required.
- Industry questions
  - What is the status of the discussions in the IZSC in this regards?
  - How to apply this guidance if izRMS is outside the southern zone and is not familiar with or does not accept this guidance ?

Southern Zone Steering Committee meeting with the Industry

Madrid, 18th November 2022

Southern Zone SC meeting with the Industry

Agreements achieved for applications of PPP to be used in greenhouses

- Good example of a clear guidance/rules provided by authorities, made available at CIRCABC with enough time for entry into force

- We understand this is being discussed at inter zonal Steering Committee. Can you update on the status of such discussions? Can we expect to have a similar guidance adopted at EU level?

ECCA

Southern Zone Steering Committee Meeting

Adriana Guerra, IBMA Spain

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

Southern Zone Steering Committee - Questions

- How to accelerate procedures for the authorization of low risk PPPs and biocontrol products?
- How to improve the quality of the PPP zonal dossiers?
- **Agreements achieved for application of PPPs to be used in greenhouses**

Agreements achieved for application of PPPs to be used in greenhouses

- IBMA national associations (FR, SP, IT) see benefits in the application of the agreed greenhouse definitions. **The harmonisation of the definitions could speed up biocontrol product applications** as biocontrol is widely used in greenhouses
- The **new agreement** confirms that for **high/low technology and Mediterranean greenhouses, the evaluation will be performed by one interzonal rapporteur MS**
- **For walk-in tunnels and open protective structures, a zonal evaluation applies**
- **Before the agreement**, it was possible to include the protected structures in an open field application (zonal) or in a greenhouse application (interzonal, 1 dossier). **If one wanted to cover all zones with one dossier, a greenhouse submission including open protective structures was an option**
- However, **now** it is obligatory to have zonal applications for walk-in tunnels/open protective structures (3, if whole EU to be covered) and the interzonal greenhouse application to get the same result, **so all together 4 registration procedures instead of one**

Agreements achieved for application of PPPs to be used in greenhouses

- **This might make sense for products with a potential environmental impact, but not for low risk products**
- IBMA fears that the new interzonal/zonal agreement could generate **extra costs** and **longer delays in approval** of biocontrol products when applying in different zones. We believe that this is not justified regarding the low risk level of biocontrol products
- This is especially of concern, as **IBMA has over 230 members of which 85% are SMEs**
- For walking tunnels and open protective structures for which a zonal evaluation applies, IBMA asks that **a zone would accept trials done in another zone if the applicant demonstrates that the agro-climatic conditions are the same**
- Finally, as the **two agreements** are recent, IBMA would be eager to better understand the current status of their application in the SZ Member States

Thank you

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AGREEMENTS ACHIEVED FOR APPLICATIONS OF PPP TO BE USED IN GREENHOUSES

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LEGAL FRAMEWORK - REGULATION 1107/2009

Article 3 point 27:
A 'greenhouse' means a walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products (PPPs) into the environment.

- Applications for greenhouse uses: One EU Zone; One ZRMS
- Interzonal evaluation

Types of protected structures



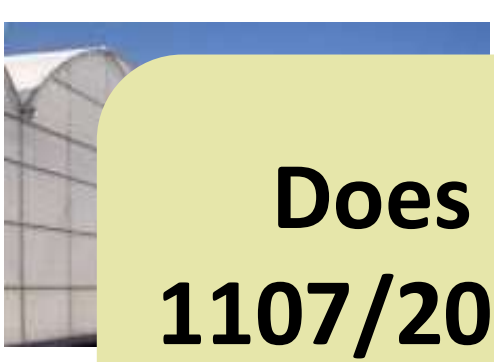
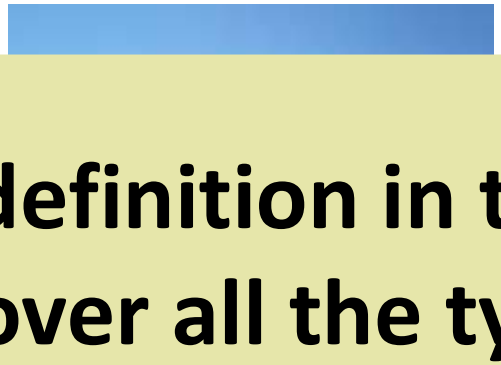






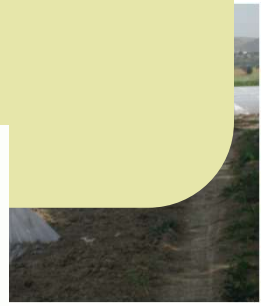
Types of protected structures

Does the definition in the Regulation 1107/2009 cover all the types of protected structures?

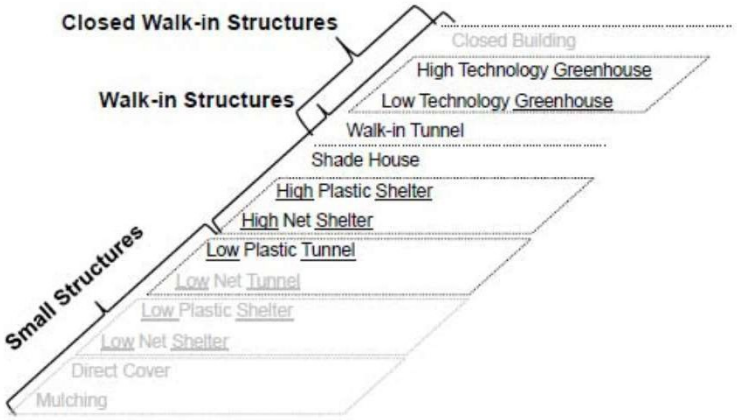




GUIDANCE ON RANKING EMMISIONS GREENHOUSES

EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (EFSA Journal 2014; 12(3): 3615)



- **Soil Receptor**
- **Surface Water Receptor**
- **Ground Water Receptor**
- **Air Receptor**

August 2018

"Classification of scenarios of use and their correlation with the clustering and classification of emmissions of the EFSA guidance document (2014)"

1. Categories for registration: Open Field/Greenhouse
2. Applications for use in GREENHOUSE: Shall cover all categories described in EFSA Guidance Document
3. Agreement how to perform the assessment for the different categories

2021: Southern Zone Proposal

1. Closed building and warehouse
2. Greenhouse
2.1 High technology
2.2 Low technology
3. Walk-in tunnel
4. Field and open protective structures
4.1 Plastic/net cover, anti-hail shelter and shade house
4.2 Micro-tunnel (plastic/net) and thermal blanket
4.3 Field

Accesibility
Temporary
Permeable Cover
Soil Permeable
Growing Media
Soil bound
Soil Less

A methodology for the risk assessment in each type of structure and for each area (efficacy/Residues/OPEX/fate/ecotox) has been agreed among SMS

AVAILABLE AT CIRCABC: https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/6af24efd-6b01-4d8d-a89a-b7b76ce9f16a/details

Date of application for zonal applications in the Southern Zone: 1 June 2022

Structure type	Accessible Y/N	Temporary Y/N	Permeable cover Y/N	Soil Permeable Y/N	Growing media	Cycle close/open nutrient solution	OPERATOR	WORKER	BYSTANDER & RESIDENT	Efficacy and Residues [i]	Environmental fate assessments				Need for ecotoxicology risk assessments Y/N[ii]				
											Ground-water	Surface water	Soil	Air	Birds & mammals	Bees & NTAs	Soil organisms	NTPs	Aquatic organism
1. Closed building and warehouse	Y	N	N	N			BfR GH	EFSA	Y [xv]	I	Not relevant	Relevant[v]	Not relevant	FOCUS AIR	N	N	N	N	N
2. Professional greenhouse																			
2.1 High technology	Y	N	N	Y	Soil-bound		BfR GH	EFSA	Y [xvi]	G	FOCUS GW [xiv]	FOCUS D[iii]	Only for persistent substances	FOCUS AIR	N[iv]	N	Only for persistent substances [xiii]	N	Y
				N	Soil-less	Close	BfR GH	EFSA	Y [xvi]	G	Not relevant	Not relevant	Not relevant	FOCUS AIR	N	N	Not relevant	N	N
				N	Soil-less	Open	BfR GH	EFSA	Y [xvi]	G	Not relevant	Scenario to be developed[vi]	Not relevant	FOCUS AIR	N	N	Not relevant	N	Y
2.2 Low technology	Y	N	N	Y	Soil-bound		BfR GH	EFSA	Y [xvii]	G	FOCUS GW [xiv]	FOCUS D[iii]	Only for persistent substances	FOCUS AIR	N[iv]	N	Only for persistent substances [xiii]	N	Y
				N	Soil-less	Close	BfR GH	EFSA	Y [xvii]	G	Not relevant	Not relevant	Not relevant	FOCUS AIR	N	N	Not relevant	N	N
				N	Soil-less	Open	BfR GH	EFSA	Y [xvii]	G	Not relevant	Scenario to be developed[vi]	Not relevant	FOCUS AIR	N	N	Not relevant	N	Y
3. Walk-in tunnel	Y	Y/N	N	Y	Soil-bound		BfR GH	EFSA	Y [xvii]	G[viii]	FOCUS GW [xiv]	(FOCUS D)[ix]	FOCUS	FOCUS AIR	Y[x]	Y[xi]	Y	Y[xii]	Y
				N	Soil-less	Close	BfR GH	EFSA	Y [xvii]	G[viii]	Not relevant	(Drift)[vii]	Not relevant	FOCUS AIR	Y[x]	Y[xi]	Not relevant	Y[xii]	Y
				N	Soil-less	Open	BfR GH	EFSA	Y [xvii]	G[viii]	Not relevant	(FOCUS D)[ix]	Not relevant	FOCUS AIR	Y[x]	Y[xi]	Not relevant	Y[xii]	Y
4. Field and open protective structures																			
4.1 Plastic/net cover, anti-hail shelter and shade house	Y	Y	Y	Y/N	Soil-bound		EFSA	EFSA	EFSA	F	FOCUS	FOCUS	FOCUS	FOCUS AIR	Y	Y	Y	Y	Y
4.2 Micro-tunnel (plastic/net) and thermal blanket	N	Y	Y/N	Y/N	Soil-bound		EFSA	EFSA	EFSA	F	FOCUS	FOCUS	FOCUS	FOCUS AIR	Y	Y	Y	Y	Y
4.3 Field	-	-	-	-	Soil-bound		EFSA	EFSA	EFSA	F	FOCUS	FOCUS	FOCUS	FOCUS AIR	Y	Y	Y	Y	Y

AGREEMENT ACHIEVED AT IZ LEVEL

Applicants that submit applications for the registration of PPP to be used under protected conditions should submit the following:

- **1 DRR** with the information and risk assessment for the protected structures for which the risk assessment does not include the consideration of the agronomic and environmental conditions of the different zones. This DRR shall be evaluated at interzonal level and will include the **high technology and the low technology (including the Mediterranean) greenhouses**. These types of structures include soil bound and soil less growing media. **This DRR will be evaluated by the izRMS.**

- **1 DRR** with the information and risk assessment for the protected structures for which the risk assessment does include the consideration of the agro-nomic and environmental conditions of the different zones. This DRR shall be evaluated at zonal level and will include the **walk in tunnels, open protective structures and the field uses. This DRR will be evaluated by the zRMS.**

This agreement is applicable since June the 1st of 2022.

INTERZONAL WG – FATE SECTION

3 Meetings in 2022

NZ: DK; SE; NO
CZ: DE; AT; BE
SZ: ES; FR, EL; PT

Only focus on the PEC calculation for High and Low Technology Greenhouses (IZ)

Agreement on PECsoil; PECsw; PECgw calculation

A Draft IZ guidance document will be distributed by the end of the year

CLE QUESTIONS

What is the status of the discussions in the IZSC in this regards?

- Commenting period for high and low technology greenhouse for the CZ and NZ has been initiated by IZSC. Comments will be collated and aswered by ES

- Environmental fate and behaviour IZ WG has been established for agreement on high and low technology greenhouse risk assessment

How to apply this guidance if izRMS is outside the southern zone and is not familiar with or does not accept this guidance ?

- Fate section an agreement will be reached at IZ level by the end of the year

- For the other sections and agreement will be reached by the next months

IBMA QUESTIONS

For walking tunnels and open protective structures for which a zonal evaluation applies, IBMA asks that a zone would accept trials done in another zone if the applicant demonstrates that the agro-climatic conditions are the same

- **Efficacy trials : EPPO standards are applicable. Trials performed in other zone can be accepted if justified and case by case**

- **Residue trials: SANTE Guidance is applicable. Trials performed in other zone can be accepted if justified and case by case**

IBMA would be eager to better understand the current status of their application in the SZ Member States

- **Agreement applicable for applications submitted from 1 June 2022**

ECCA QUESTIONS

We understand this is being discussed at inter zonal Steering Committee. Can you update on the status of such discussions? Can we expect to have a similar guidance adopted at EU level?

- **Commenting period for high and low technology greenhouse for the CZ and NZ has been initiated by IZSC. Comments will be collated and answered by ES**

- **Environmental fate and behaviour IZ WG has been stablished for agreement on high and low technology greenhouse risk assessment**

- **Excel table will be separated for the Inter Zonal Assessment (high and low tech greenhouses) and the Zonal Assessment (walk in tunnels/open structures/field)**

THANK YOU FOR YOUR ATTENTION