ZAPID workshop

5-7 December, Braunschweig, DE

IBMA Feedback

BPWG, 10-11 June 2024

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

ZAPID WORKSHOP – IBMA General Remarks

General remarks:

- Discussion at the ZAPID Workshop took place in 5 different Breakout Groups (BOGs). IBMA was represented in all BOGs.
- ZAPID was important for IBMA to see how IBMA´s policy asks (*see next slide*) fit within the regulatory developments.

IBMA´s recommendations:

- Identify clearly progress made since the EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorization (Dublin, June 2015).
- Develop detailed action plan (timing and actors) based on summary tables in the report.

IBMA´s three steps to speeding up authorisation

1. EU Definition of biocontrol

2. Short-term procedural measures (within Reg. 1107/2009):
   - Priority lane
   - Provisional authorisation
   - Label extension facilitated
   - No re-registration procedure for biocontrol (unless a need has been identified)

3. New Regulation for Biocontrol by 2030

Limit Complexity and Tackling Delays (I)

Limit complexity by:

- ZAPID Report: Priority setting for the evaluations of active substances and PPPs is needed at EU level.
- IBMA: Introducing a definition of biocontrol would facilitate priority setting of a well-defined group of substances and products and as such would safe Member States resources.
- IBMA: A definition of biocontrol is the preferred option as ´low-risk´ or ´low-concern´ can only be attributed after an evaluation and/or risk assessment and not upfront.
- IBMA: In addition, regarding ´low risk´ manufactures benefit in practice only from an approval period of 15 years (e.g. not 120 days).

Limit Complexity and Tackling Delays (II)

Limit complexity by:

- ZAPID Report: Set up a pilot “excellence network” with experts from the MS. The experts should have specialized knowledge/expertise in a specific area. They can then be consulted on their areas of expertise by experts in the other MS. The outcomes could then be catalogued so that all experts can learn the agreed approach to the various issues. This could be developed in combination with the EFSA training platform.
- IBMA: This approach of an “excellence network” is strongly supported by IBMA as it would increase consistency and harmonization in decision-making. It would speed up procedures and encourage a similar way of using and interpreting Guidance Documents (e.g. by training of experts). Eventually, such a network could become part of a new regulatory framework for biocontrol.

Provisional authorisations for biopesticides

- ZAPID Report: Participants of the ZAPID Workshop took different attitudes on provisional authorisations for biopesticides. Some alternative fast-tracking options were discussed.
- IBMA: The provisional authorisation is a way to promote the faster availability of biopesticides. To reinstate the provisional authorization does not imply more work and can be used to reduce timelines considerably.
- IBMA: In addition, reinstating the provisional authorization would reduce or limit the number of emergency authorisations.
- IBMA: This is considered one of the short-term solutions to speed up the process within the current regulatory framework of Regulation 1107/2009 (Art. 30).

Mutual Recognition (I)

- ZAPID Report: With the introduction of Regulation (EC) No 1107/2009, the zonal system of authorisation was introduced with the intention of ensuring co-operation between MSs with comparable climatic conditions. …… Despite the regulatory avenues and guidance available, it is obvious that there are difficulties for MSs and applicants alike in achieving an efficient and pragmatic approach to the implementation of mutual recognition.
- IBMA: National Specific Data Requirements, national legal aspects and citizen's scrutiny of PPP authorisations remain blocking factors for straightforward Mutual Recognition.
- IBMA: Although IBMA strongly favours a reduction of national specific requirements, an overview of national specific requirements per zone is the least that should be prepared.

Mutual Recognition (II)

- IBMA: Re-opening of the dossier is seen as a major obstacle in the disfuntioning of Mutual Recognition. A change of mindset within Member States is needed to make the system operate as it was intended.
- IBMA: IBMA strongly recommends to conduct a study to investigate the effects of asking additional assessments based on national specific requirements (i.c. do they lead to different decisions/RMM in MSs) as these results can be used to convince Member States to make better use of their resources without impacting the safety for humans, animals or the environment.

Facilitate label extensions

- ZAPID Report: During the renewal process, industry loses the opportunity for label extensions as Member States would not do a label extension until the end of the renewal.
- IBMA: Allow label extensions for biocontrol products during the renewal period by using the current endpoints for immediate availability of new uses of existing products to the farmers.
- IBMA: Facilitate label extensions and extrapolation possibilities for biocontrol products (crop grouping, risk envelope approach, similar pest-target combinations to different crops)
- IBMA: Renewal process for biocontrol will only be initiated when there is a need or concern identified. This is to make best use of available recourses.
- IBMA: IBMA supports considering an easier use of non-EU residue data and rethinking the zonal concept for residues.
- IBMA: These are considered part of the short-term solutions to speed up the process within the current regulatory framework of Regulation 1107/2009.

Implementation of new scientific and technical knowledge

IBMA supports the revision of SANCO/10328/2004 – rev 9 and the suggestions provided in the summary table on how to handle new data post-approval/renewal of an a.s.

In IBMA opinion, an important issue was identified during the discussion as summarised in the ZAPID report:

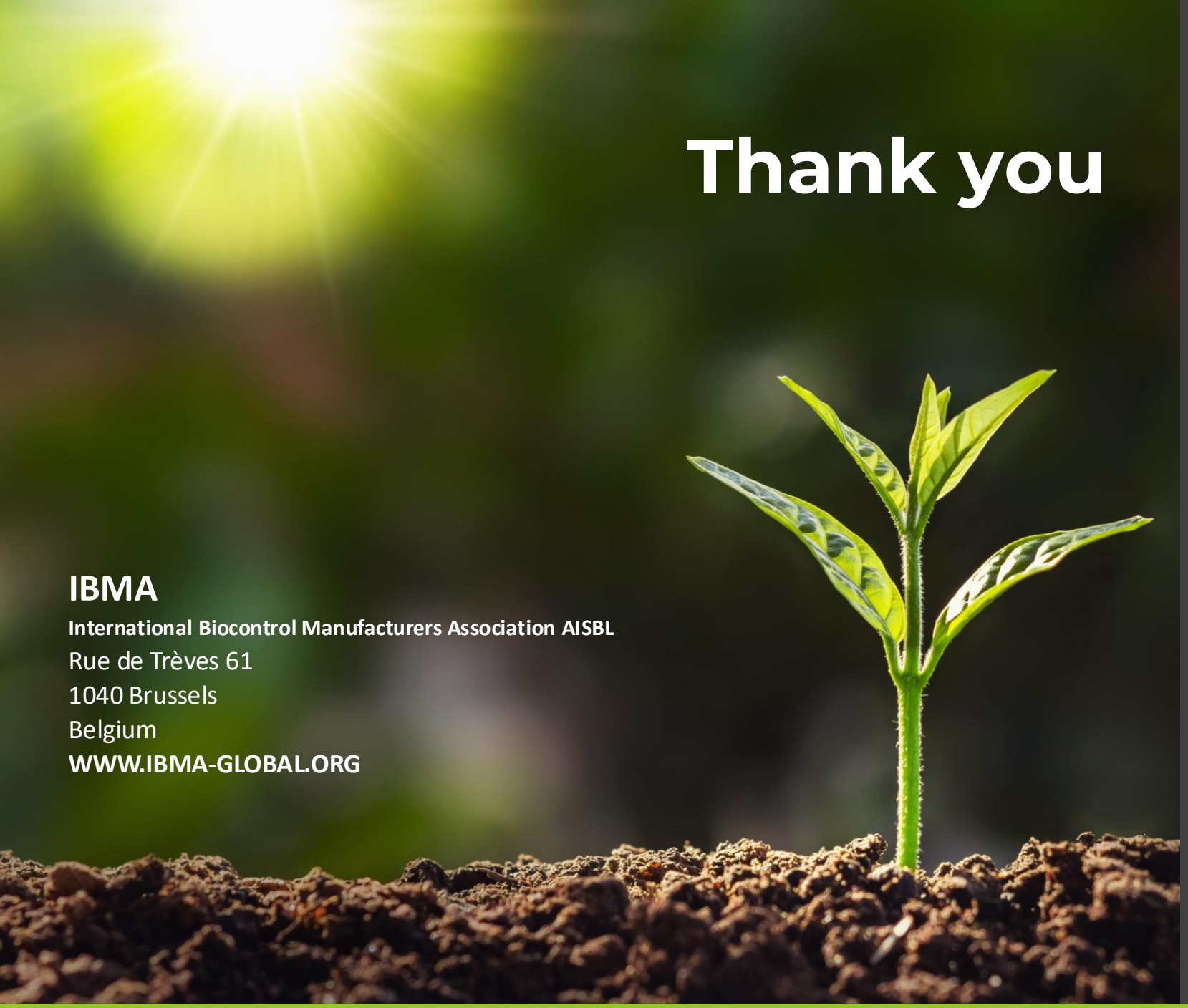
"It was obvious from the discussions in the BOG that MS have different views on which guidance document (GD) should be followed and what data to be used in a PPP application. It is also unclear if there is a common understanding of what "new" scientific knowledge means. This results in unpredictable requirements for the applicants and disharmony in approaches between MS in the zonal evaluation.:

IBMA: The different views on when a new GD should be used (at draft stage, when publicly available to applicants, when noted but not yet implemented, at implementation date) and a common understanding of what constitute "new scientific knowledge" is leading to inconsistence Zonal assessments and delays in authorisations. A harmonised approach would overcome these issues.

Authorisation of ppp in the light of the Green Deal

- ZAPID Report: Pilot project: Identify one example of LR AS with field uses to perform an interzonal assessment by one RMS, one co-zonal RMS (applicant should prepare dossier accordingly – efficacy in different zones etc.)
- ZAPID Report: Pilot project: Stakeholders to select one example and propose one zonal RMS and one co-ZRMS and to propose it to be agreed in the interzonal Steering Committee.
- IBMA: Supports the initiative of an interzonal pilot project and wants to closely follow this (contribute/participate?).

Thank you



IBMA

International Biocontrol Manufacturers Association AISBL

Rue de Trèves 61

1040 Brussels

Belgium

WWW.IBMA-GLOBAL.ORG

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

EXECUTIVE DIRECTOR

Jennifer Lewis

jennifer.lewis@ibma-global.org

SENIOR ADVOCACY AND OUTREACH MANAGER

Isabelle Pinzauti Babrzyński

isabelle.pinzauti@ibma-global.org

TECHNICAL PROJECT MANAGER

Jérémy Belzunces

jeremy.belzunces@ibma-global.org

REGULATORY ADVISER

Jeroen Meeussen

jeroen.meeussen@ibma-global.org

COMMUNICATIONS MANAGER

Niamh Holland-Essoh

niamh.holland@ibma-global.org

PROJECT MANAGER

Britta Schnittger

britta.schnittger@ibma-global.org

OFFICE MANAGER

Soizick Menais

soizick.menais@ibma-global.org