



REBECA



General proposals to improve current regulation practise of BCAs

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Aim

Gather information from REBECA meetings for the development of strategies to accelerate regulation of BCA



Activity

- Questionnaire on: *Main obstacles and proposals*
- Questionnaire on: *general improvements of the regulation and registration process of BCAs*
- Input received to questionnaires was discussed at several meetings



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5 thematic areas **with proposals that may be implemented** **within 2-3 years**

- **Improved communication between regulators and applicants**
- **Improved communication among regulators**
- **Lessons learned guidance doc from the 4th stage**
- **Fees / financial support**
- **More generic approach when possible**



4 thematic areas

with proposals that might be implemented on a longer term (or less likely to be implemented)

- **Strict timelines**
- **Specific data requirements for BCAs**
- **Efficacy evaluation**
- **Centralized authority**



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Improved communication between regulators and applicants

- A. Pre-submission meetings established as a routine in all EU member states
SUPPORTED
- B. Pre-submission information package
SUPPORTED
- C. Applicants given the opportunity of attending part time at evaluation/expert meetings
SUPPORTED

A. Pre-submission meetings established as a routine in all EU member states

Why?

- Applicant gain a better understanding of the regulatory process and data requirements
- Applicant and regulators agree on data waivers
- Applicants avoid producing unnecessary data
- Better dossiers, faster process, lower cost, faster authorisation and market access

Problems?

- Regulators may lack time for such meetings
- Further data requirements may arise after the meeting
- Waivers accepted by the RMS may not be accepted by other MS

Implementation

- Easy to implement
- Many MS have experience with pre-submission meetings

B. Pre-submission information package

Why?

- For regulators and applicants to agree on which studies are needed and which are likely to be waived
- Guidance to the applicants
- Applicants avoid producing unnecessary data
- Better dossiers, faster process, lower cost, faster authorisation and market access

Problems?

- Regulators may lack time for such meetings and lack time to go through the information package
- Further data requirements may arise after the meeting
- Waivers accepted by the RMS may not be accepted by other MS

Implementation

- Easy to implement

C. Applicants given the opportunity of attending part time at evaluation/expert meetings

Why?

- Applicants can be invited for clarification of specific questions, not for introducing new data nor for lobbying
- Minor issues/mistakes can be solved much faster
- Applicants will gain a better understanding of the procedure and the comments / reasoning made by MS/experts
- Faster process, may reduce cost, faster authorisation and market access

Problems?

- Regulators may feel that the presence of applicants would compromise the independence of the expert meetings and may fear pressure/lobbying from applicants
- Would cause additional cost for the applicant

Implementation

- Easy to implement



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Improved communication between regulators of BCAs

- A. Further and more regular expert-/evaluation meetings on the specific groups of BCAs
SUPPORTED
- B. 4th list lead RMS to have a role as lead RMS for new BCAs (microorganisms, semiochemicals and botanicals) **NOT SUPPORTED**
- C. Establish expert groups for BCAs
PARTICULARLY SUPPORTED

A. Further and more regular expert-/evaluation meetings on the specific groups of BCAs

Why?

- **BCAs should be discussed by experts/regulators with experience in the particular field**
- **Will speed up procedures for Annex I inclusion and market access to BCAs**
- **Regular meetings will contribute to building networks among MS and improve expertise and harmonization between MS**

Problems?

- **Further meetings will result in increased cost**

Implementation

- **Easy to implement if the Commission and/or MSs are willing to cover the additional costs**

B. 4th list lead RMS state to have a role as lead RMS for new BCAs

Why?

- Increase communication, harmonization and consistency in the risk assessment carried out by MSs
- Facilitate and speed up procedures for Annex I inclusion and market access to BCAs
- Make use of experiences gained in the 4th stage

Problems?

- Places additional burden on a few MS
- The process could become more complicated with a lead RMS

Implementation

- Easy to implement if the relevant RMSs are willing to take over this task

C. Establish expert groups for BCAs

- **One expert group for: Botanicals, Semiochemicals, Microbials**
- **Experts groups comprise a representative from: Commission, EFSA and national regulatory authorities**
- **One MS is appointed as chair**
- **Discuss risk assessment and risk management issues of both general and more specific character**
- **Develop draft guidance documents**
- **Is a network with several means of communication: a minimum of 2 annual meetings, e-mail discussions, conference calls, etc.**

C. Establish expert groups for BCAs

Why?

- Increases communication, harmonization and consistency in the risk assessment carried out by MSs
- Guidance to the RMS and the applicants
- Facilitates preparation of the DARs and the subsequent peer-review process
- reduces costs for dossier preparation and speeds up the registration process

Problems?

- Lack of time among regulators/experts
- High cost to cover the expenses for the meetings

Implementation

- Easy to implement



Lessons learned guidance documents from the 4th stage

- A. Used in pre-submission meeting to determine data requirements / waivers and generic safety profiles (QPS approach) **SUPPORTED**

A. Lessons learned guidance documents used in pre-submission meeting to determine requirements / waivers and generic safety profiles

Why?

- Make use of experiences gained in the 4th stage
- Will result in better and more focused dossiers
- Improves consistency among MS
- May reduce need for studies, lower the cost for applicants and result in a faster procedure for Annex I inclusion and market access to BCAs

Problems?

- Data protection must be insured
- Applicants should be aware that new uses and other kinds of exposure may trigger further data requirements

Implementation

- Easy to implement by those MSs that are open to this approach



Fees and financial support

- A. Fees for microbials and semiochemicals to be lowered substantially **SUPPORTED**
- B. Financial support and guidance for registration of new microbials, botanicals and semiochemicals **SUPPORTED**

Fees and financial support

- **Registration fees are high in some MS**
- **SMEs producing products for niche markets can not afford Annex I inclusion and national registration if fees are high**
- **Some member states have no fees and may even have specific programmes in order to support and guide the applicants in the process of submission of dossiers for alternative plant protection products (GENOEG in NL and Biopesticides scheme in UK)**

A. Registration fees for microbials and semiochemicals to be lowered substantially

Why?

- Products should be supported since they are used mainly for niche markets, they have low risk profiles and are in line with EU policies
- Reduced cost of product development, faster procedure for Annex I inclusion and market access to BCAs

Problems?

- National governments have to finance the evaluation
- Unequal treatment compared to low risk chemical pesticides

Implementation

- Likelihood and degree of implementation varies greatly between member states

B. Financial support and guidance for registration of new microbials, botanicals and semiochemicals

Why?

- **Guidance will help SMEs in generating good dossiers that will be easy for regulators to evaluate**
- **Lower cost of product development and thus increased market access for BCAs**

Problems?

- **Problems of financing such programmes**
- **Define which product types can be subsidized and why**
- **Not in line with free market economy**

Implementation

- **Likelihood and degree of implementation varies greatly between member states**



Generic approach in risk assessment

- A. Establish risk management strategies taking a generic approach wherever possible - evaluating certain active substances as a group

SUPPORTED

A. Establish risk management strategies taking a generic approach

Why?

- In some cases species might be included in Annex I rather than strains, groups of semiochemicals rather than each active substance, etc. This could reduce cost for producing studies, and speed up the evaluation and registration procedure.

Problems?

- Data protection must be ensured
- Such approach can only be taken if there exists enough experience and scientific evidence about a certain group

Implementation

- Requires considerable discussion



Strict and short timelines

- A. **Strict and short timelines for the EU risk assessment as well as for national registrations should be included in the EU regulation**
SUPPORTED, however exact deadlines and procedures need to be developed

A. Strict and short timelines

Why?

- Most applicants of BCAs are SMEs with limited resources and thus need to place their products on the market as fast as possible
- Strict timelines would provide better predictability on the length of the evaluation/registration process

Problems?

- MS have difficulties in respecting short timelines due workload/lack of resources
- If data is missing applications may be rejected

Implementation

- Requires considerable discussion regarding procedural issues
- Lack of resources in MS and EFSA

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Specific data requirements for BCAs

- A. Generate new guidance documents with new specific data requirements for microbials and semiochemicals**
SUPPORTED

A. Generate specific data requirements

Why?

- Dir. 91/414 is not adequately adapted to microbials and semiochemicals
- Experience with 4th list substances could be used in the preparation of new data requirements
- Facilitates preparation of dossier
- Increases predictability of the process

Problems?

- Requires resources and adequate time for discussion among MS

Implementation

- Would take some time, but implementation is possible
- Depends on the outcome of the revision of Dir. 91/414

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Efficacy evaluation

- A. Authorities should accept modified trial protocols, provided that the applicant can justify the modification **SUPPORTED**
- B. Introduction of efficacy into EU evaluation needs to be accompanied by guidance on evaluation criteria **SUPPORTED**
- C. Products with minor beneficial effect should be acceptable **SUPPORTED**
- D. No efficacy evaluation prior to registration **NOT SUPPORTED**
- E. No efficacy evaluation prior to a 5 year registration period, however data should be collected over the first five years of market use **SUPPORTED**



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Centralized registration authority

- A. Establishment of a new and centralized authority (similar to U.S. EPA) for the evaluation of the active substances: microbials, botanicals and semiochemicals **NOT SUPPORTED** due to **difficulties in implementation**

A. Establishment of a new and centralized authority

Why?

- Few products based on BCAs compared to chemicals and thus not much experience in many MSs
- A centralized authority could build up expertise
- Speeds up evaluation process, reduces the cost of dossier preparation, improves the quality and consistency of the risk assessment

A. Establishment of a new and centralized authority

Problems?

- **Politically it will be very difficult for MS to give up national evaluation of BCAs**
- **MS will lack experience for the national authorisation of products**
- **Not evident that such an authority would require less studies/accept further waivers than in the present system**
- **Resources needed to create and run such a new authority**
- **Applications may be submitted in irregular intervals**

A. Establishment of a new and centralized authority

Implementation

- This proposal conflict with the sovereignty of MS and meet strong opposition
- Would require considerable discussions and would still be very difficult to implement

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Proposals in the revision of Dir. 91/414 which REBECA highly supports

- A. **Compulsory mutual recognition of PPP within 3 climatic zones**
- B. **Low risk substances and basic substances**

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REBECA proposals which
are relatively easy to implement
at member state level

1. Pre-submission meetings
2. Pre-submission information package
3. Use of lessons learned documents from the 4th stage in pre-submission meetings
4. Flexible efficacy trial protocols
5. Acceptance of products with minor beneficial effects

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REBECA proposals which
are more difficult to implement
at member state level

1. Reduced registration fees
2. Financial support and guidance to applicants
3. Strict and short timelines for registration



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**REBECA proposals which
are relatively easy to implement
at EU level**

- 1. Applicants to attend evaluation/expert meetings**
- 2. Establishment of expert groups of BCAs (a microbial expert group already exists) as well as further and more regular expert-/evaluation-meetings on BCAs**

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REBECA proposals which are more difficult to implement at EU level

1. EU Efficacy evaluation criteria
2. New specific data requirements for microbials and semiochemicals
3. Generic approach in risk assessment
4. Strict and short timelines for EU risk assessment
5. No efficacy evaluation prior to a 5 year registration period

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REBECA proposals which
are very difficult to implement
at EU level

1. Centralized registration authority
2. No efficacy evaluation prior to registration



Main obstacles identified in questionnaire

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge on regulatory affairs in SMEs
- Regulators unwilling to accept waivers
- Poor dossiers
- High fees
- Long, unpredictable process
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial capacity
- Lack of guidance documents
- Lack of appropriate test guidelines



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge on regulatory affairs in SMEs
- Regulators unwilling to accept waivers
- Poor dossiers
- **High fees**
- **Long, unpredictable process**
- **Efficacy requirements**
- **Lack of mutual recognition**
- **Limited market – SME has low financial capacity**
- **Lack of guidance documents**
- **Lack of appropriate test guidelines**

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Pre-subm.
Meetings
Expert groups



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge in regulatory affairs in SME
- Regulators do not accept waivers
- Poor dossier
- High fees
- Long, unpredictable process
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial capacity
- Lack of guidance documents
- Lack of appropriate test guidelines

**National
political
issue**

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Pre-subm.
Meetings
Expert groups**



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge on regulatory affairs in SME
- Regulatory procedures too complex
- Poor dossier quality
- High fees
- Long, unpredictable process
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial capacity
- Lack of guidance documents
- Lack of appropriate test guidelines

National political issue

Strict and short timelines

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Pre-subm.
Meetings
Expert groups



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge on regulatory affairs in SME
- Regulator's strict and short timelines
- Poor dossier
- High fees
- Long, unpredictable procedures
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial capacity
- Lack of guidance documents
- Lack of appropriate test guidelines

National political issue

Strict and short timelines

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Pre-subm.
Meetings
Expert groups

Modified trial protocols, harmonization, minor beneficial effect accepted



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge in regulatory affairs in SME
- Regulatory barriers
- Poor dossier quality
- High fees
- Long, unpredictable procedures
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial capacity
- Lack of guidance documents
- Lack of appropriate test guidelines

National political issue

Strict and short timelines

Modified trial protocols, harmonization, ...
Only few BCA in Annex I yet
Revision of Dir. 91/414

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Pre-subm.
Meetings
Expert groups



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge in regulatory affairs in SME
- Regulatory barriers
- Poor dossier quality
- High fees
- Long, unpredictable procedures
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial resources
- Lack of guidance documents
- Lack of appropriate test guidelines

National political issue

Strict and short timelines

Modified trial protocols, harmonization, On

REBECA drafts EU Expert groups OECD-BPSG Research

REBECA Pre-subm. Meetings Expert groups



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Main obstacles identified

- Lack of information exchange among stakeholders
- Lack of expertise among regulators
- Lack of knowledge in regulatory affairs in SME
- Regulatory procedures
- Poor dossier quality
- High fees
- Long, unpredictable procedures
- Efficacy requirements
- Lack of mutual recognition
- Limited market – SME has low financial resources
- Lack of guidance documents
- Lack of appropriate test guidelines

National political issue

Strict and short timelines

REBECA Pre-subm. Meetings Expert groups

Modified trial protocols, harmonization, Only few BCA in Annex I yet

REBECA drafts EU Expert groups OECD-BPSG

Further research OECD-BPSG



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Thank you for your attention

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