Issues for Product Authorization: The Industry Experience

Jack Poppleton
Director, Head Global Regulatory Affairs
Arch Timber protection

Content

- Historical Background
- Suppliers and formulators – partnership or competition?
- Technical issues and opportunities
- Procedural issues
- Costs & Timing
- Summary

arch TIMBER PROTECTION

Historical Background

- **15 years and counting**
  - BPD programme started in 2000
  - Anticipated 10 year programme
  - BPR now looking to a programme to 2025

- **Major changes**
  - Over this timeline significant fundamental changes have occurred
  - Technical and Procedural changes
  - Complexity unravelling

- **How does the formulator keep pace with the change and remain competitive?**

arch TIMBER PROTECTION

Suppliers and formulators – partnership or competition?

- **BPD/BPR is a two phase system**
  - Phase 1 – Active substances
  - Phase 2 – Biocidal products

- **Active substances**
  - Prime objective to gain entry onto the Union List
  - One single use to be demonstrated for listing
  - May be based on "dummy product"
  - Some cases where no supplier would support the AI

- **Biocidal Products**
  - Authorisation for every product
  - Authorisation primarily in every country in the Union
  - Limitations to Union Authorisation
  - Link to active substance (Letter of Access)
  - Product Family approach

arch TIMBER PROTECTION

Suppliers and formulators – partnership or competition?

- The Inclusion decision
  - Sets an initial envelope for authorisation of Products
- By no means an exhaustive evaluation of the active AND its use in products
  - Certainly not an evaluation of combinations of actives
- Likely to include a set of restrictions which could significantly impact your existing market
  - E.g. Professional or non-professional use
  - May include the need for significant mitigation measures

arch TIMBER PROTECTION

Suppliers and formulators – partnership or competition?

- How useful is the Inclusion decision?

- Data gaps
  - In the rush to meet the timetable for completion of the active substance review programme, many decisions are left to Product Authorisation phase

  - Who will provide the data?
  - Who will own the data?
  - How will the data be presented and evaluated?
  - If there are multiple suppliers, does every supplier have a full data set
  - Do they have access to data not yet used that could be useful?

- How useful is the Article 95 List?

arch TIMBER PROTECTION

Suppliers and formulators – partnership or competition?

- The AI supporters intent may not fit with your requirements
  - Is their supported use for Inclusion the same as your needs?
  - How did the evaluation process compare with the original intent?
  - Even where data has been examined under national schemes previously, the new interpretation is likely to much more conservative and therefore restrictive to your uses

- **Decision Time**
  - Do you partner with an AI supplier or simply buy on the market?

arch TIMBER PROTECTION

Technical issues and opportunities

- Long evaluation time has had significant implications
- Adaptation to technical progress has changed the guidance documents
- ….. and Regulators interpretation of the guidance
- This has also potentially changed interpretation of existing data, exposures etc. or
- …. Set new data requirements at product authorisation phase for both the product and the active substance
- Increasing importance of hazard profiles / classification

arch TIMBER PROTECTION

Technical issues and opportunities

- Products are the result of a significant product development programme

- Typically 5 years of development PLUS registration time
  - Efficacy and use pattern
  - Product Stability
  - Specific tox / ecotox data

- Many formulated product are a combination of actives and uncertainty on any active is multiplied at the product phase.
  - The AI supplier will have only considered their substance, not the combinations
  - PEC/PNEC for product = Summation of PEC/PNEC of all substances in the product

arch TIMBER PROTECTION

Procedural issues

- New technology
  - Increasing drive towards electronic systems for applications and data submission
  - How many SME's will have the ability to use such systems?
- IUCLID
- SPC Editor
- R4BP3
  - Many teething problems.
  - Caused numerous issues.
  - Prevented applications in some cases.
  - IT updates issued without sufficient testing.
  - Fix a problem but create others.
  - Compatibility/upload issues.
  - MS have similar problems.

arch TIMBER PROTECTION

Procedural issues

- Mutual recognition
  - One primary application to the Reference Member State
  - MR in other states

- Experience with RefMS and MR
  - Not a simple system
  - Very common for MS to reject MR
  - In some cases even data evaluated at AI stage is re-evaluated at MR stage
  - Experience and Legal developments are improving this

- However…..

- Are Reference MS now being much more conservative in their approach to primary authorisation so as to avoid challenges at the MR stage?

arch TIMBER PROTECTION

Procedural issues

- New data
  - Under the AI evaluation programme, new data has not been considered
  - Where data has been developed either to answer existing requirements or to further elaborate on the substance or product profiles, how is it to be submitted?
  - What will be considered relevant ?
  - Will there be an open approach to accepting new data or will the pressure on time reject such new approaches?
  - How will the Assessment report for the Active Substance be updated
  - What are the timelines for all of this

arch TIMBER PROTECTION

Costs & Timing

- Companies have to face the commercial reality
  - Suppliers have the costs of active substance investment and commercial operability
  - Formulators have to face the supplier cost, the development costs of their products, and the market acceptability.
  - Authorisation costs are very significant – affordable?

- The charging regimes are onerous and differ State to State and according to the type of application

- Timing is not always as given in the Regulation, issues may arise that change the timescales

arch
TIMBER PROTECTION

Costs & Timing

- Products are the result of a significant product development programme
  - Typically 5 years of development PLUS registration time
- AI Listings are for a maximum of 10 years
  - Review starts 550 days before actual renewal date
- If experience of the BPD is any pointer to future developments, then what confidence can formulators have to undergo a development programme which may be undermined by the renewal phase?

arch TIMBER PROTECTION

Some experiences

Some thoughts on experiences-

- Critical to Understand the IT tools
  - When they don't work, how do you work with your MS?

- Mutual recognition – will it ever work properly?
  - Apparent lack of trust between some MS
  - Too many differences of opinion.
  - Process takes far too long
  - Costs in some MS are unacceptable
    - paying for re-evaluation?

arch TIMBER PROTECTION

Some experiences

Some thoughts on experiences-

- Communication with MS.
  - Some are very good.
  - Some do not respond.
  - One way communication in some cases.
  - Applicant should be kept up to date but this is not always the case.

- Timelines not always observed.
  - Can take much longer than those set in BPD or the Regulation.

arch TIMBER PROTECTION

So what to do?

- Plan your application well in advance.
  - The whole process is very complicated.
- Read any guidance documents carefully
- Then read them again!
  - Some of it is still not clear and open to different interpretations even between Member States.
- Choose your member state carefully.
  - Is your application for a single MS or multiple MS?
  - If the latter, then which will provide the greatest assurance of Mutual recognition

arch TIMBER PROTECTION

So what to do?

- Understand exactly how your product will be used and ensure you cover what you want.
  - Make sure that you explain both the product and its uses clearly in your application
  - The regulator may not know your uses well. He will know your product even less.

- Understand the active reviews.
  - Ensure you fit within active substance approvals or that you cover data gaps/uses etc. in full.
  - Consider your relationship with the AI supplier
  - How much help can they give?
  - How do you protect your Intellectual Property?
  - Insist upon Confidentiality Agreements

arch TIMBER PROTECTION

So what to do?

- Explain your product and its use clearly.

- Run risk assessments early to identify areas of concern.
  - Understand your risk assessment and models.
  - Do they really work?
  - Do the answers make sense?

- Would you benefit from a Product Family approach?
  - More complex
  - More expensive
  - Potentially more flexible.

- Anticipate questions.
  - Avoids delays and potential costs.

Talk to the regulator before submission if necessary.

arch TIMBER PROTECTION

Summary

- The route to product authorisation is NOT paved with gold
- There are many rocks strewn across the path
- Critical to form good relationships:
  - Supplier to formulator
  - Formulator to regulator
  - Formulator to customer
- Critical to understand the process and be able to work within the limitations set
- Some companies will not survive the onslaught

arch TIMBER PROTECTION