

Implementing Regulation 1107/2009 State of Progress – An Industry Perspective

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Content

State of Progress:

Active substance
approval criteria

Zonal evaluations

Comparative assessment
& substitution

AIR

Other areas



Stage of Progress

Active Substance Approval



Active substance approval criteria

■ Endocrine Disruption:

- DE/UK joint approach in defining ED criteria is welcome
- Concerns related to Pr. Kortenkamp's 'State of the Art' report (part 1 – science)

■ Limited regulatory developments for CMR, POP, PBT, vPvB

- Need community guidance for POP/PBT/vPvB

■ ECPA position on 'negligible exposure'

Zonal Evaluations and Mutual Recognition



Implementing 1107 – Stage of progress

Zonal Evaluation – Mutual recognition(1)

Encouraging feedback from (majority of?) Member States to make zonal system a success, but...

- ... many report capacity problems, exacerbated by industry's pre-June submission peak
- A few Member States do not want to mutually recognize 91/414 authorizations
- Consistent approach?

- **Some MS require draft dRRs available during pre-submission meetings**
 - Not required by 1107 or guidance document
 - In most cases, dRRs not ready 6 months before application
- **Several MS refuse to be zonal Rapporteur and discourage applications**



Implementing 1107 – Stage of progress

Zonal Evaluation – Mutual recognition (3)

- **Guidance documents with sensible content and available on time**
- **Signs that zones consider generating their own data requirements**
- **No practical progress in addressing country-specific requirements**
- **Some MS review all national addenda to dRR**
- **Lack of trust across MS?**

Industry promotes:

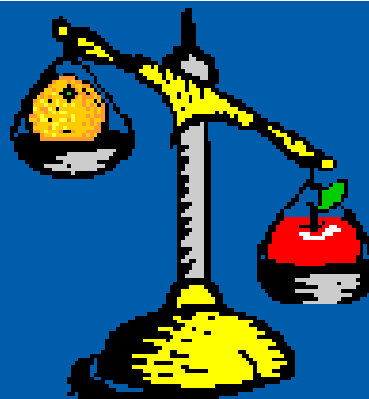
- Treat 91/414 authorizations as 1107 authorizations
- Mutually recognize them to decrease workload (art. 40-42)
- Review all national data requirements:
 - Remove or harmonize
 - Concrete proposals made by ECPA
 - Share efficacy data across agro-climatic zones
- No zonal specific requirements other than functioning processes
- No new requirements unless discussed at community level

DARE TRUST !



Comparative Assessment & Substitution





- Limited regulatory developments
- ECPA position under development
 - Position and guidance
 - Avoid unnecessary substitutions and limit workload
- ECPA invitation to discuss comparative assessment (and cut-offs) on 23 November in Brussels

AIR Program



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AIR3

- AIR3 regulation and guidance document late
- Risk that speed will be driving program

Industry supports:

- Quarterly submissions with ca 15 substances each (60/year)
- No grouping, waves populated by order of expiry
- AIR3 program covering all substances expiring in 2018 or before
- Need for administrative extensions to eventually cease
- All AIR3 submissions compliant with amended data



Miscellaneous Provisions



Implementing 1107 – Stage of progress Miscellaneous Provisions (1)

Residue data protection

- Residue data not always protected under 91/414
- Residue data to be protected when meeting 1107 Article 59 data protection conditions when:
 - New, necessary for first authorization (extension) and GLP
- Consistent interpretation required



Implementing 1107 – Stage of progress Miscellaneous Provisions (2)

Pursue harmonized classification & labelling:

- Not all active substances benefit from harmonized classifications
- Some are under ECHA review
- Harmonized classification of PPPs possibly achieved through:
 - Self-classification by the applicant (CLP rule)
 - And/or enforcement by the zonal Rapporteur Member State

Implementing 1107 – Stage of progress Miscellaneous Provisions (3)

Guidance needed soon in the following areas:

- **Vertebrate data sharing process**
- **Minor formulation changes**
- **Comparative assessment/substitution**



Conclusions



Implementing 1107 – Stage of progress

Conclusions

- **Very early feedback!**
- **Much is in place (guidance, processes)**
- **Zonal system impaired by capacity problems and lack of trust**
- **As ever... success will require collective willingness to extract the best of the new regulation...**

... and pragmatism

Thank you for your attention!

