Pitanja i učinak: Evaluacija aktivnih tvari:

- Hitne situacije
- AIR program
- Kašnjenje evaluacije novih aktivnih tvari
- Endokrini disruptori i ostali cut-off kriteriji

Euros Jones, ECPA

Issues & impact: Review of active substances:

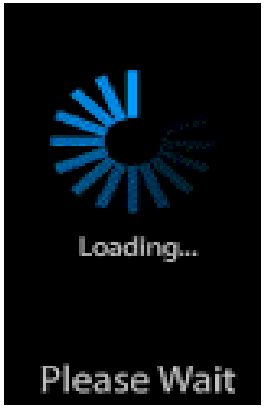
- Emergency situations
- AIR programme
- New active substance evaluation delays
- ED and other cut-off criteria

Euros Jones, ECPA

AIR programme

Status Renewal program

- **AIR 1 complete, post approval ongoing**
- **AIR 2 all 29 RAR, but few voted on**
  - Extension until June 2016 voted…
- **AIR 3 on-going**
  - New data requirements apply…
- **Next renewals - expiry after Jan 2019**
  - Planning difficult, no RMS/co-RMS identified
- **2016 workload**
  - AIR 2 post-renewal
  - AIR 3



Phasing needed to ensure manageable workloads!

AIR-2 challenges – Metabolites & classification

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- **Current practice**
  - EFSA suggests hazard classification **>>**
  - Commission propose **APPROVE** plus ***confirmatory data***
    - ECHA decide classification - additional data when required

      Predictable process!

- **New challenges in decision making?**
  - EFSA suggests hazard classification **>>**
    - Member State view?
    - Commission proposal?
    - Possible loss of ASs & products from the market

      ➢ ***Unpredictable impact on many important products!***

A policy shift could impact 1 in 3 active substances

Keep the current process!

AIR-2 challenges – Interim ED criteria

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- Interim criteria apply until final criteria are agreed
- Some ASs trigger interim criteria even though they have no endocrine related effects
- **EFSA** suggesting many additional classifications
  - But not discussed by **ECHA** (**THE** competent authority)

Way forward:

- Decisions should be based on **ECHA** classification

ASs suggested as C-2 + R-2 should **only** trigger the interim criteria **when based on an endocrine effect**

AIR-2 challenges – Managing the derogations…

- **Defining negligible exposure**
  - Guidance document under development
  - To be discussed in December Standing Committee
  - Commission decision (internal procedure)

- **Application of Article 4.7 (derogation to cut-off)**
  - Important element but no clear process
  - Flexibility to be managed by the Commission…

Conservatism in evaluations

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- **Growing concerns about conservatism**
  - E.g. many evaluations only based on lower tier data
  - Higher tier data rejected
  - Lack of expertise in EFSA to deal with complexity of higher tiers?

- **ECPA focus**
  - Workshop with EFSA in January 2016
    - Understand the blockers to higher tier data
    - Need for expert judgement

- ***Cumulating conservatism does not improve outputs!***
  - Unrealistic conclusions (assumptions of risks that cannot occur)
  - Unreliable for risk management decisions >> loss of safe solutions

Active substances review (AIR-2)

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What delayed the process?

- Initial AIR-2 programme was unrealistic (timelines/ process)
- Delays in Member State evaluations
- Complexity of Regulation 1107/2009
- Political attention in the process…

What needs to be done?

- Extension of approval of active substances voted
  - ***Member States to extend product authorisations!***

Products authorisations should be extended !

Realistic timelines for the future…!

Active substanc

Products authorisations should be extended !

Realistic timelines for the future…!

New data requirements and waivers

- Challenges in dealing with new data requirements where no test method currently exists
- Clarification in guidance doc. SANCO/10181/2013-rev 2.1, which states that in cases where:
  - "…*test methods or guidance documents are not yet available […] waiving of these particular data requirement points is considered acceptable as long as no test methods or guidance documents are published in form of an update of the Commission Communications 2013/C 95/01 and 2013/C 95/02.*"
  - ***Provision needs to be applied by RMSs & EFSA!!***

New active substance evaluation delays

New active substances delays

- **ASs approval: expected in 30-42 months in 1107/2009**
  - Reality is much slower
- **MRL approvals: COMM refuse MRLs until AS approval**
  - Additional delays of 6-8 month
  - Not in line with the legislation: ECPA to challenge
- **ECPA view**
  - MRLs must be set prior to substance approval
    - COM should progress MRL setting once EFSA opinion is completed

Market entry should not be delayed

Endocrine disruption and other cut-off criteria

ED update

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Public consultation

- Finished January 2015 >> report published 24 July
- Limited EU Member State authority input

Impact assessment

- **Substance by substance evaluation**: March 2016
- **Socio-economic impact**: 3rd quarter 2016
- **Proposals for criteria**: late 2016
- **Criteria adoption**: 1Q 2017 - entry into force 2Q 2017

ECPA focus

- Communication on AS evaluation (no blacklist!!)
- Pragmatic application of interim criteria

Roadmap – what are the options?

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Option	Options for criteria to identify EDs
1	No criteria specified; the interim criteria for pesticides and biocides apply
2	A single category based on the WHO/IPCS definition
3	A multiple category approach based on the WHO/IPCS definition. • Category 1: endocrine disruptors • Category 2: suspected endocrine disruptors • Category 3: endocrine active substances
4	WHO/IPCS definition and inclusion of potency as an element of hazard characterization

Option	Approaches for regulatory decision making
A	No policy change required
B	Introduction of elements of risk assessment into sectorial legislation as opposed to basing on hazard alone. Introduction of negligible risk to replace negligible exposure.
C	Introduction of further socio-economic considerations, including risk-benefit analysis, into sectorial legislation. Exemption from the ban for cases where not approving the substance would have a disproportionate negative impact on society.

Emergency situations

Emergency situations

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- **Large number of 'emergency authorisations'**
  - 140+ in October Standing Committee
  - ~1000 in 2015??
- **Why?**
  - Delays in national PPP registrations
  - Ineffective minor use systems
  - Impact of AS decision making
- **Is this the result of Regulation 1107/2009?**
  - Emergencies replace real authorisations?
  - ***Review of Regulation 107/2009 needs to evaluate and find solutions!!***

Conclusions

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Legislation getting more difficult

- Political challenges at EU level in **AS review**
- Major delays and unexpected ‘blockers’
- Knock on effects on PPP re-evaluation planning…
- **New active substances**: Delays in substance approval and MRL setting – Improvements possible!
- **Endocrine disruption**: Criteria under development >> to be implemented in 2017?
- **Emergency situations**: Used due to impact of inefficiency and delays in 1107/2009….
- ***Review of Regulation 1107/2009 is needed***
- ***But we still need to better implement what we have!!!***

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Thank you for your attention