



# AIR4 & low-risk substances

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# Contents

- Definitions and background
- Fine-tuning AIR4 program
- AIR4 dossiers
- Conclusion

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# Definitions

- Low-risk Substances
- Introduced by R(EC) 1107/2009
- LR-based PPP are of low risk: no spec. RMM
- Criteria (Annex II)
- End of the routine evaluation

# Definitions

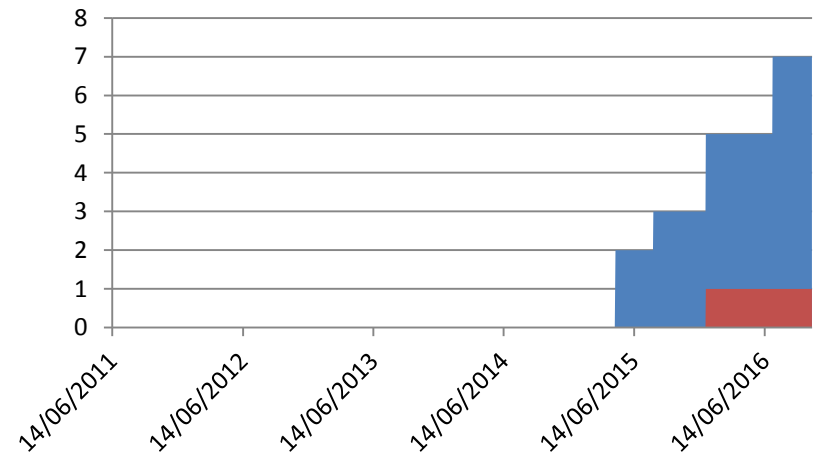
- **Low-risk** Substances
- Introduced by R(EC) 1107/2009
- LR-based PPP are of low risk: no spec. R
- Criteria

## **Low-Risk:**

- **First approval for 15y**
- **Fast-track PPP authorisations (120d)**

# Overview of LR substances

- New process
- 7 substances approved as LR
  - 5 new ones
  - 2 renewed AS



# Updating the LR criteria

- Criteria relevant for chemicals
- Update clause in R(EC)1107/2009
- Dedicated WG: draft proposal
  - Different sets of criteria
  - Specific criteria for different origins
- Internal consultation on-going

# AIR

- Annex Inclusion Renewal
- After the 10y approval
- Described in Reg (EU) 844/2012:





## Renewal Timelines (Reg. 844/2012)

### Activity

- Dossier submission:
- **Admissibility check:**
- Renewal Assessment Report (RAR):
- **RAR circulated to MS and applicant:**
- **Public Commenting** (incl. MS & applicant):
- EFSA peer-review:
- **Stop the clock:**
- COM draft decision:

### Time

0  
**1 month**  
11 months  
**1.5 months**  
**2 months**  
**5 months**  
**3 months**  
6 months

**Max Total**

**29.5 months**

## The AIR programmes

- ❑ *AIR-1* – 7 substances – 14 MS
- ❑ *AIR-2* – 31 substances – 21 MS
- ❑ *AIR-3* – 150 substances – 28 MS
- ❑ *AIR-4* – 214 substances – 28 MS



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# Workload



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# AIR4 contains

- Former 4th batch of EAS:
  - approved in 1 go in 2009
  - several strains of biopesticides or semiochemicals
- 214 AS (**118** in 2019)



# Reshuffling AIR4



- Work program (D(COM) 2016/C 357/5)
- Allocation RMS/co-RMS (R(EU)2016/183)
- Renewal program (updated regularly)



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**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation  
**Pesticides and biocides**

**SANTE-2016-10616–rev 4**

**October 2016**

**DRAFT WORKING DOCUMENT**

**AIR IV RENEWAL PROGRAMME**

[http://ec.europa.eu/food/plant/docs/pesticides\\_ppp\\_app-proc\\_air-4\\_renewal-program.pdf](http://ec.europa.eu/food/plant/docs/pesticides_ppp_app-proc_air-4_renewal-program.pdf)

# Reshuffling AIR4

- 4 batches
  - Renewal process launched
  - Potential low-risk substances (+1y)
  - Potential failing substances (+1y)
  - Other substances (+2-3y)
- Need to prolong current approvals

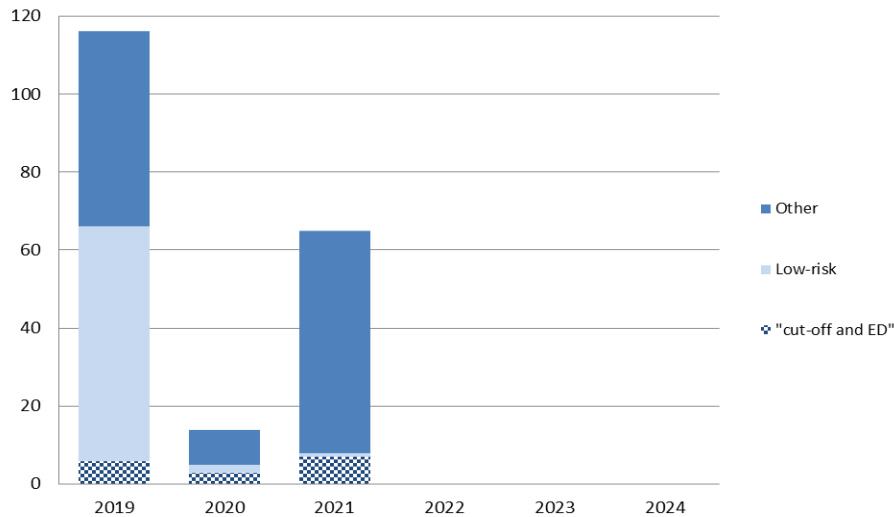




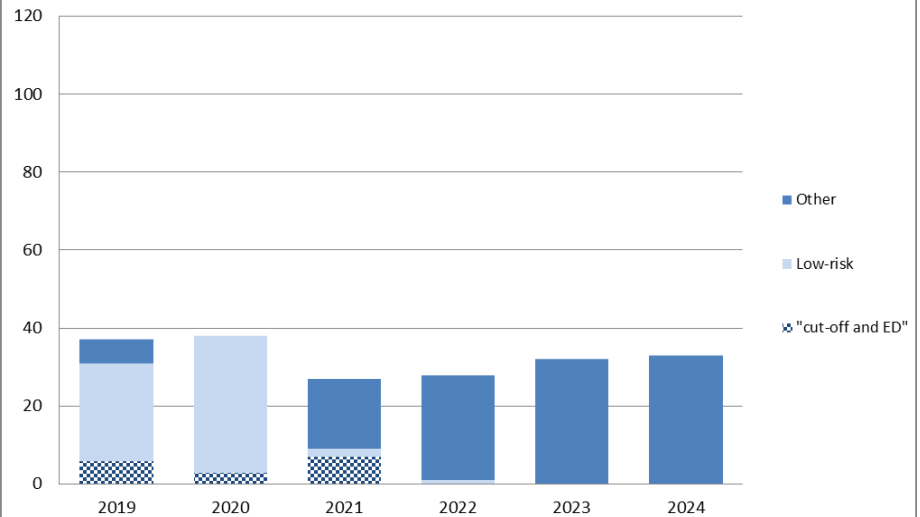
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# Reshuffling AIR4

Dossiers per year with current expiry dates



Dossiers per year with new proposed expiry dates



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- **AIR4 dossiers**
- Conclusion

# Preparing AIR4 dossiers

- Fruitful pre-submission meetings
- Exhaustive dossier
- Specific issues
  - Secondary metabolites
  - Genotoxicity
  - Antibiotic resistance
  - ...

# Preparing AIR4 dossiers

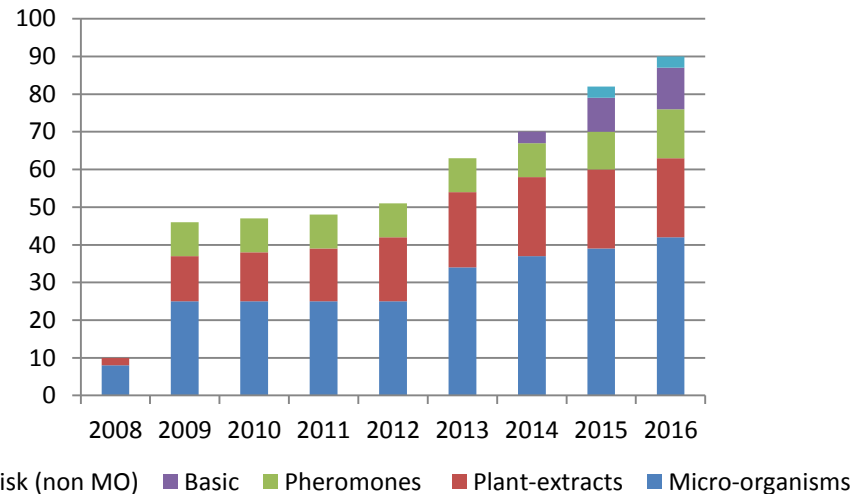
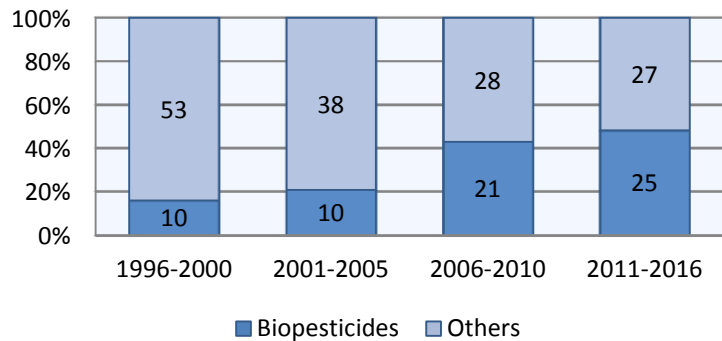
- Addressing the new data requirements
- Exhaustive literature search
- Using all the available guidance or information
  - EU guidance (as noted), working documents
  - OECD guidance, reports (BPSG seminar)
  - Proceedings (NL Workshop 2015, EPPO 2016...)
  - ...

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# Biopesticides – where now?

**Applications for new active substances since 1996**



# Low-risk and AIR program

- ❑ *AIR-1* – 7 substances – 14 MS –
- ❑ *AIR-2* – 31 substances – 21 MS – 2 LR
- ❑ *AIR-3* – 150 substances – 28 MS – **7? LR**
- ❑ *AIR-4* – 214 substances – 28 MS – **63? LR**

# Accelerating sustainable plant protection

- Expert group on Sustainable Plant Protection (19 MS, COM, EFSA)
- Implementation plan endorsed by agriculture ministers in Council (June 2016)
- 40 short term and long term actions identified to:
  - Increase availability of low-risk products
  - Accelerate implementation of IPM in MS
- Scope: 2016-2017 and beyond



## Actions focused on measures to...

- Expedite approval and authorisation procedures (within limits of Regulation 1107/2009)
  - Support businesses to apply for low-risk approval and authorisation
  - Clarify regulatory requirements
  - Cooperate and share experience between MS
  - Provide input for REFIT of 1107/2009 to increase regulatory incentives for low-risk products.
- > *Implementation plan available @ [Council website](#)*

Thank you very much  
for your attention

<http://ec.europa.eu/food/plant/pesticides/>

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