European Food Safety Authority

EFSA's role in the EU evaluation process

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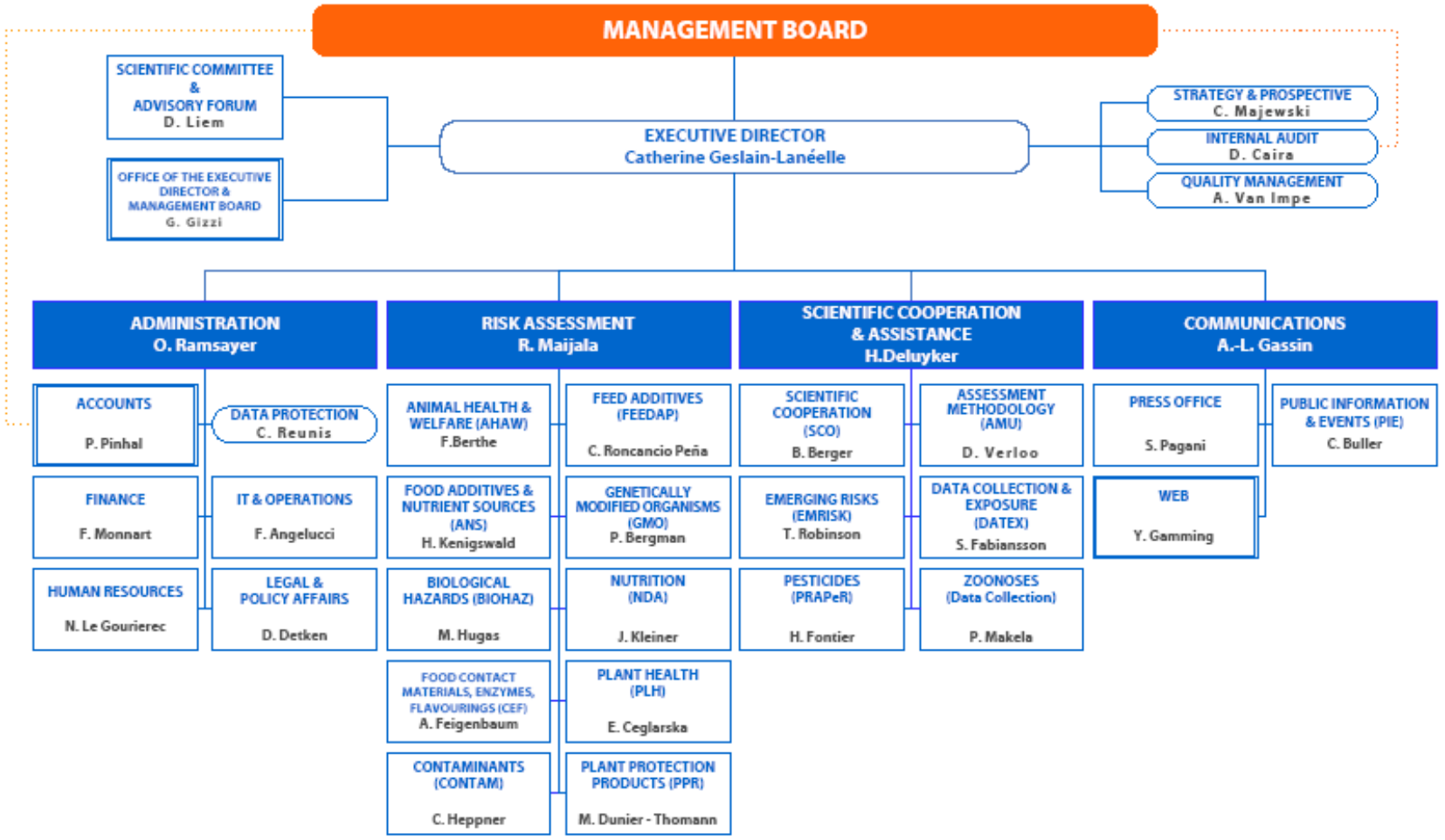
Content

- EFSA and its pesticide Units
- Peer review and mutual recognition
- MRL setting and mutual recognition

EFSA's structure



Organisational chart 2010

EFSA's Pesticide Units

- Two EFSA Units are involved in the work on pesticides
  - PPR (Plant Protection products and their Residues) Unit
  - PRAPeR (Pesticide Risk Assessment Peer Review) Unit

Mandate of the PPR Panel

- **To produce scientific opinions** answering questions on risk assessment for specific pesticides *(e.g. Q from Commission on deltamethrin)* or related generic issues with regard to users, consumers and the environment *(e.g. Q from Commission on the revision of the Annexes II and III of Directive 91/414/EEC)*
- **Responsible of EU Guidance Documents** on pesticide Risk Assessment *(previously DG SANCO)*
  - **Revision** of existing GDs
  - **Development** of new GDs

  ➔Aim: promotion of new and harmonized scientific approaches and methodologies in the EU

PPR panel and WGs

Supported by the EFSA Secretariat =PPR Unit

PRAPeR Unit (peer review)

- The **PRAPeR Unit** is in charge of the peer review of new and existing **active substances** and produces EFSA **conclusions** on Draft Assessment Reports prepared by the Rapporteur Member States
- The Commission bases its decision making (**inclusion or not** on the Annex I of Directive 91/414/EEC) on the EFSA conclusion

PRAPeR Unit (MRLs)

- The PRAPeR Unit evaluates the safety of new maximum residue limits (MRLs), of MRLs of concern and of existing MRLs after a decision on inclusion or non-inclusion of an a.s. (reasoned opinions)
- The PRAPeR Unit is in charge of the drafting of the Annual Report on Pesticide Residues

Peer review and mutual recognition

- In attachment to the EFSA conclusion on the active substance, a list of endpoints is provided (ADI, AOEL, ARfD, LC50,…)
- These endpoints must mandatorily be used in the national assessments for plant protection products (PPP)
- The EFSA conclusions and Guidance Documents are key elements in the harmonisation of the PPP evaluation and are therefore essential for mutual recognition (MR)

MR and MRL setting: time lines

- Time lines for MRL setting (Regulation 396/2005)
  - Art. 8-9: MS evaluation of the application for MRL setting (no time line)
  - Art. 11: reasoned opinion by EFSA, normally within 3 months; 6 months where more detailed evaluations are needed; stop the clock where extra info is needed
  - Art. 14: Commission to prepare proposal to SCoFCAH within 3 months
- Conclusion: in best case ± 1 year needed for the MRL setting

MR and MRL setting: time lines

- Time lines for PPP authorisation and MR (Regulation 1107/2009)
  - Art. 37(1): within 12 months evaluation of the application (including for MRLs) by an evaluating MS (assessment report drafted) in each zone (+ ≤ 6 months for additional information) and decision on authorisation by these MSs
  - Art. 37(2): within 120 days of the receipt of the assessment report and of copy of the authorisation of the evaluating MS, decision on the authorisation in the other MSs

MR and MRL setting: problems

- Several potential problems can be identified
  - If the evaluation of the MRL application is only submitted with the assessment report drafted under Regulation 1107/2009, the authorisation process will be delayed with about 9 months
  - If EFSA needs to perform more detailed evaluations, another 3 months will be added
  - There is a potential for repetition of the same MRL evaluations in the 3 zones,
  - MRL proposals for the same crop may be different for the different zones

MR and MRL setting: recommendations

- Where possible, MRLs should be applied for together with the active substance application under Regulation 1107/2009 (even for other than the representative uses)
  - Art. 8(1)(g): the application for approval should contain MRL applications
  - Art. 11(2): these applications must be evaluated by the RMS in the draft assessment report
  - Art. 12: EFSA's conclusion contains the reasoned opinions on these MRL applications

MR and MRL setting: recommendations

- Where there is a need to set new MRLs, the evaluation report to be drafted in accordance with Art. 8-9 of Regulation 396/2005 should be finalised within 3 months
- The following 9 months will be needed for the following steps, up to the entry into force of the Regulation setting the new MRLs
- This will enable granting of the PPP authorisation within 1 year

MR and MRL setting: recommendations

- Where possible, it should be avoided that EFSA needs to perform detailed evaluations, leading to 6 instead of 3 months for drafting a reasoned opinion; such evaluations are for instance needed for new metabolism studies, new methods of analysis,…
- Where available, such studies should be submitted with the dossier for approval of the a.s., even if they are not relevant for the representative uses

MR and MRL setting: recommendations

- In each zone, a MS is performing the evaluation; however:
  - The central zone includes part of the southern MRL zone
  - The southern zone includes part of the northern MRL zone
- There is thus a potential repetition of the assessment of the same MRL applications

MR and MRL setting: recommendations

- It is therefore recommended that a single MS evaluates all MRL applications
- This could be the MS evaluating the data not related to environmental and agricultural conditions, in accordance with Art. 35, last paragraph, of Regulation 1107/2009
- This MS would have an overview of all GAPs and MRL applications and would be able to select the most critical GAP/MRL combination

Thank you for your attention!