Key drivers in the decision making for active substances

Dr. Karin Nienstedt, DG Health and Food Safety, European Commission

Virtual Conference on Sustainable Solutions to Protect Crops, March 2021

Decisions made at active substance level

- Standing Committee on Plants, Animals, Food and Feed discusses and votes (qualified mayority needed)
- Commission has 6 months to present draft decision (review report and draft legal act) to Standing Committee

- Approved or non-approved (renewed / non-renewed)

… but also…

- Renewed / approved **with restrictions** (if representative use allows for it)
- Restrictions via **risk mitigation** set at EU level

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Decisions made at active substance level

2018 + 2019

- 8 approvals + 3 low risk approvals
- 11 renewals + 3 low risk renewals
- 4 renewals as CfS
- 20 non approvals/ non renewals

Basics: 3 approved; 2 non-approved

2020

- 4 low risk approvals
- 4 renewals + 5 low risk renewals
- 1 restricted renewal
- 1 renewal as CfS
- 8 non-approvals/non-renewals

Basics: 3 approved; 3 non-approved

So far 38 dossiers pending on ED stop the clock (> 3 months)

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Decisions made at active substance level

Critical factors so far

- Metabolites
- Genotoxicity
- Cut-off / unclear CLP classification
- ED
- Birds & Mammals (treated seeds)
- uses are claimed as important by the applicant which are not presented as representative uses in the dossier

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Sometimes we need to send mandates to EFSA on issues critical for decision making which are not resolved

- … when significant changes during peer review led to unresolved issues (*something was „safe“ at DAR but is no longer „safe“)*
  - Not all data (original dossier) are considered
  - Not all representative uses are explored (RA is based on worst case, less worst case RU are not assessed)

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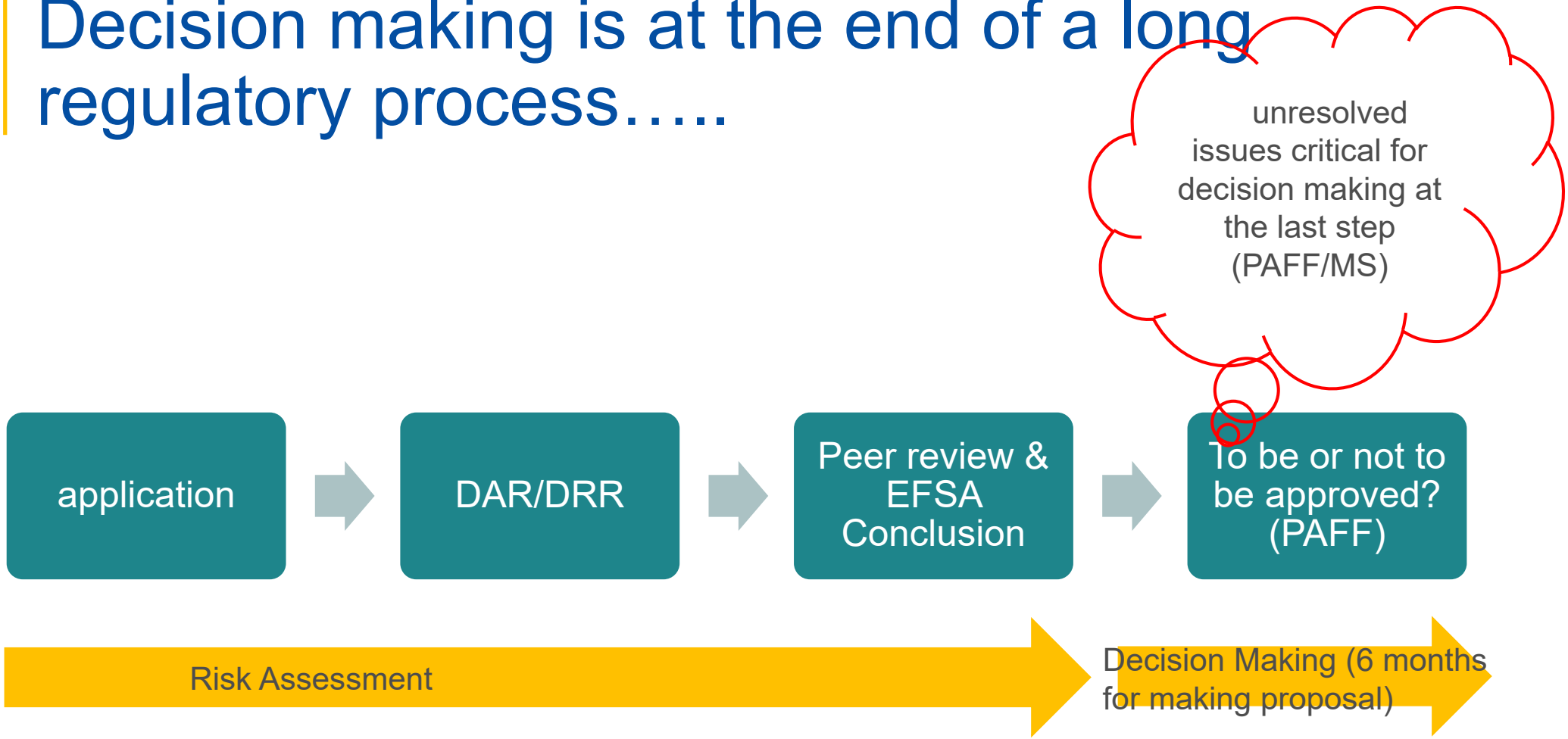
- … on particular substances which do not fit GD and which would merit „ad-hoc“ assessments (e.g. highly volatile)

Decision making is at the end of a long regulatory process…..



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Decision making builds on work of others under challenging conditions

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"Day to Day" of decision makers / risk managers

EFSA Conclusions
+ DAR + peer review tables

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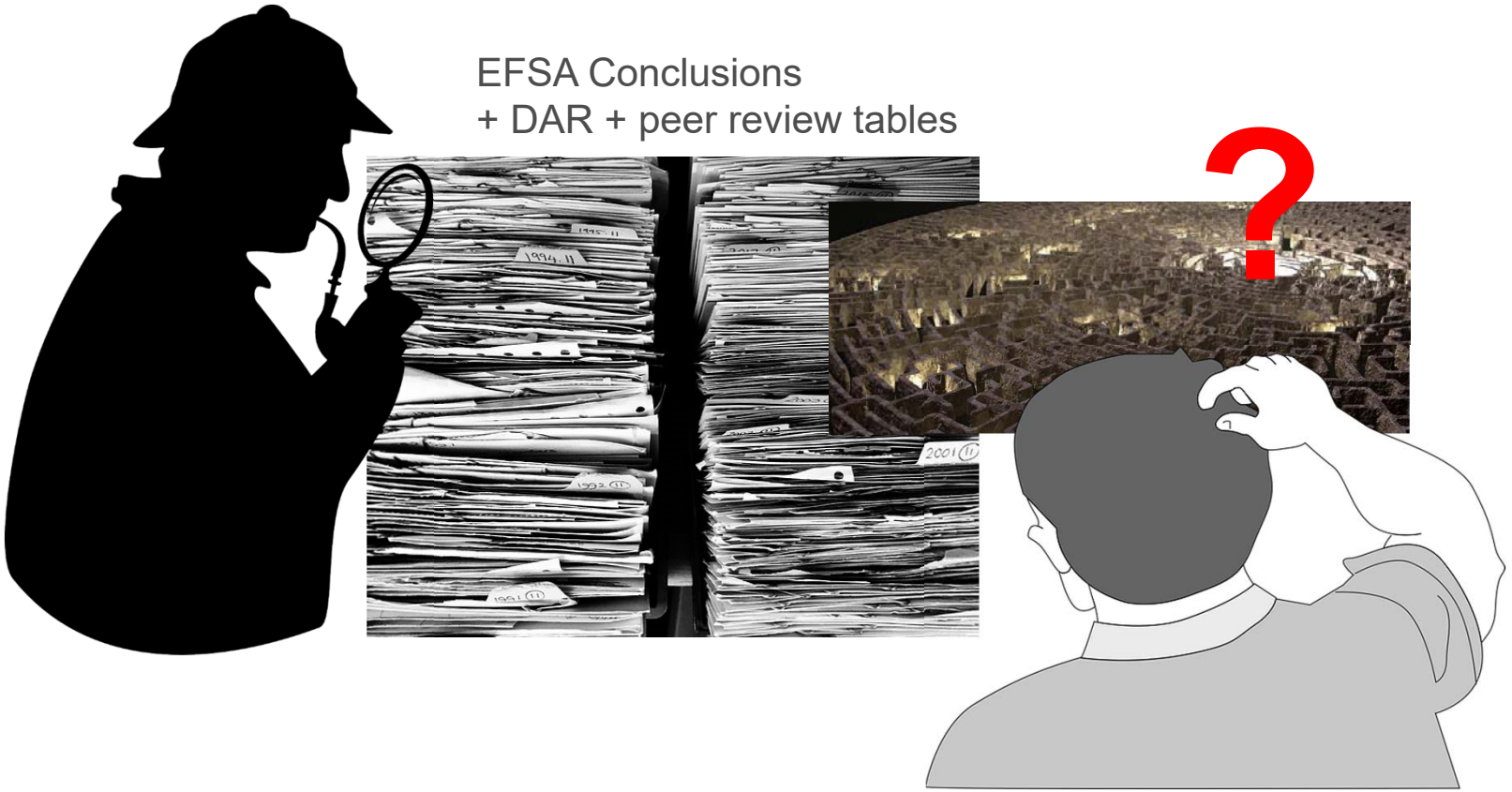

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The situation of decision makers

- Legal deadline → 6 months for proposing drafts of RR and legal act to PAFF
- Increased scrutiny
  - resolutions of EP against extensions (Art 17)
  - Ombudsman → limited use of “confirmatory data”
- Increased transparency
  - documents for discussion & vote at PAFF meetings are published in the Comitology Register (Sections B & C)
  - Access to Documents
  - notification and publication of studies (amendment General Food Law)

Horizontal actions to improve decision making

- Legislative acts
  - Amendment Regulation (EU) No 844/2012 for alignment with CLP
  - Amendment to GFL and Implementing Regulation (EU) 2020/1740 (repealing Regulation (EU) No 844/2012)
- Discussions
  - general discussion at PAFF (standing point on agenda)
  - Bilateral with EFSA (e.g. how to improve EFSA Conclusions, presentational, data gaps)
  - at Pesticide Steering Network (PSN)
  - on reduction of exposure to PPPs and risk mitigation (workshop 17 January 2020)

Decision maker's wish list…

- No unresolved issues (data gaps) in EFSA Conclusions
  - new EFSA format of Conclusion will quality data gaps, providing more qualified information
- No unresolved issues after the peer review
  - CLP classification (amendment to Regulation 844/2012!)
  - use weight of evidence and expert knowledge if needed (GDs are not legally binding)

Take home message for risk assessors (MS):

- Deliver risk assessments with no “open issues”
- Complete risk assessment on ALL representative uses in the dossier – not only for the worst case use (this allows better risk management decisions)
- Consider potential risk mitigation measures
- Consider ad-hoc risk assessment with weight of evidence and expert knowledge if needed
- Good documentation of the peer review

Take home message for applicants

- make use of pre-submission meetings (RMS & EFSA)
- Select well the representative uses, consider several kind of uses if needed
- Better definition of representative uses / GAP table(s)
- Consider risk mitigation measures, if needed, and provide relevant data and good justifications to demonstrate these measures work
- Provide all the data needed
- Provide dossiers with no “open issues”, there is limited possibility for supply data afterwards.

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… let‘s all contribute to move to better conditions…

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Thank you

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