



Opinions of consultants on risk assessment procedures

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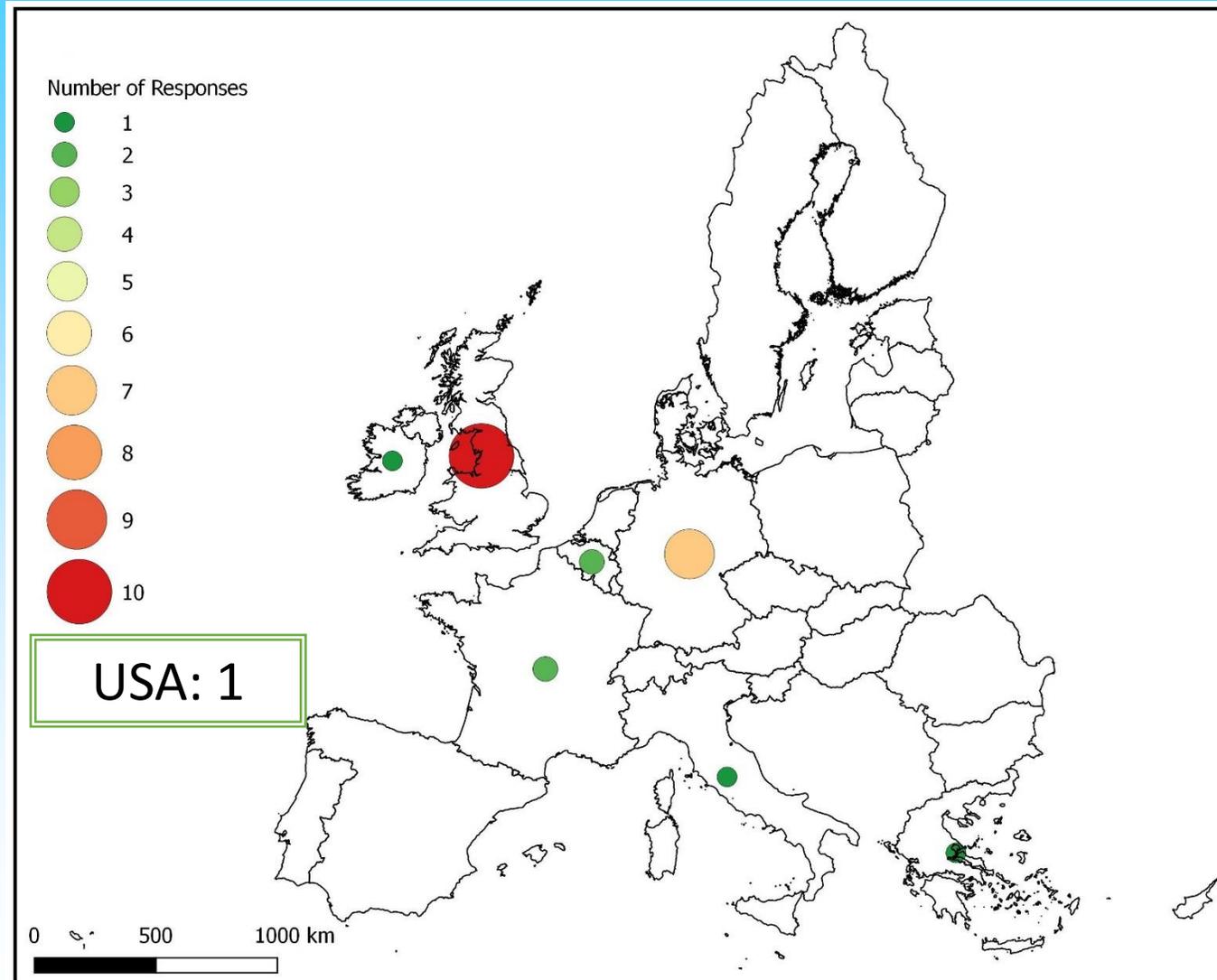
The brief

- Describe consultants' view on the changes to risk assessment procedures over the last 25 years
- Not limited to my own experience

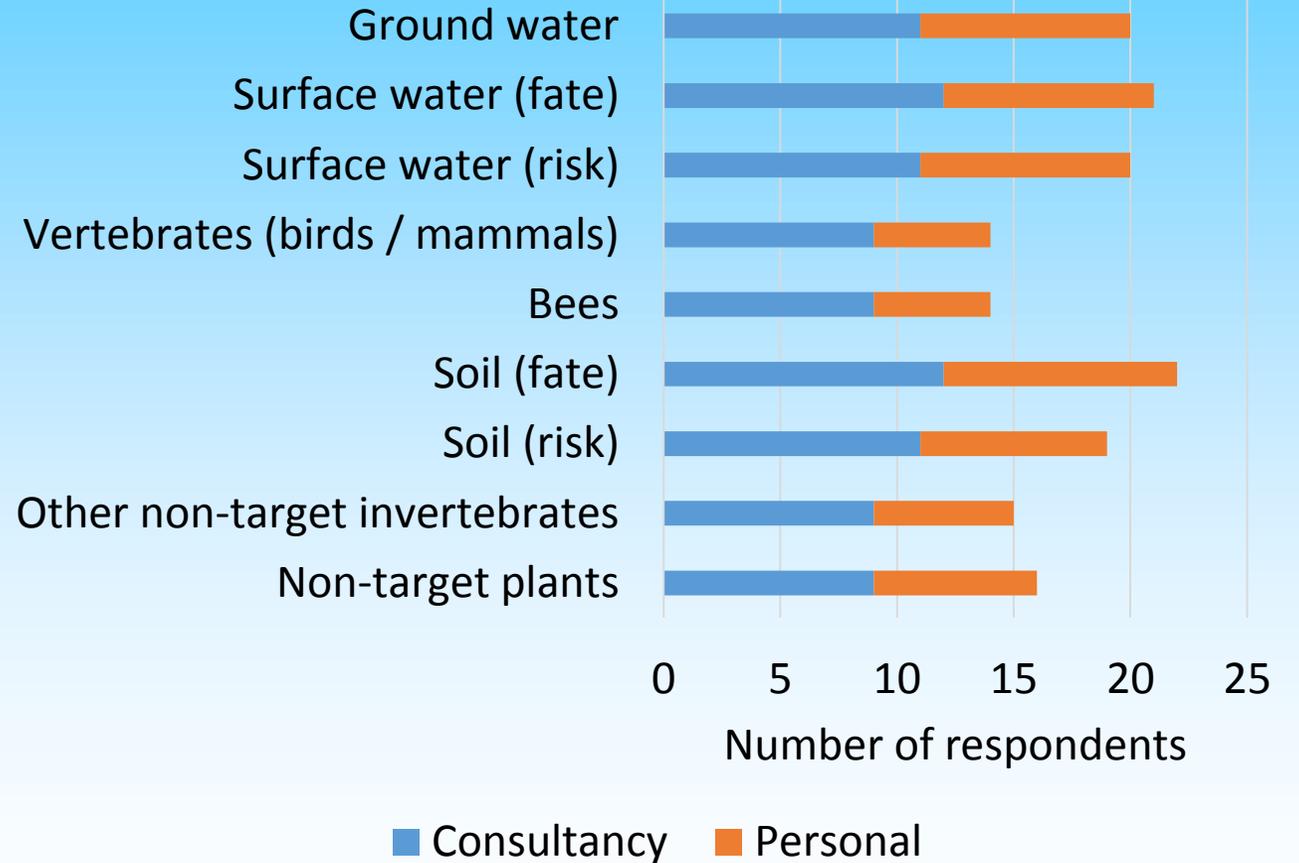
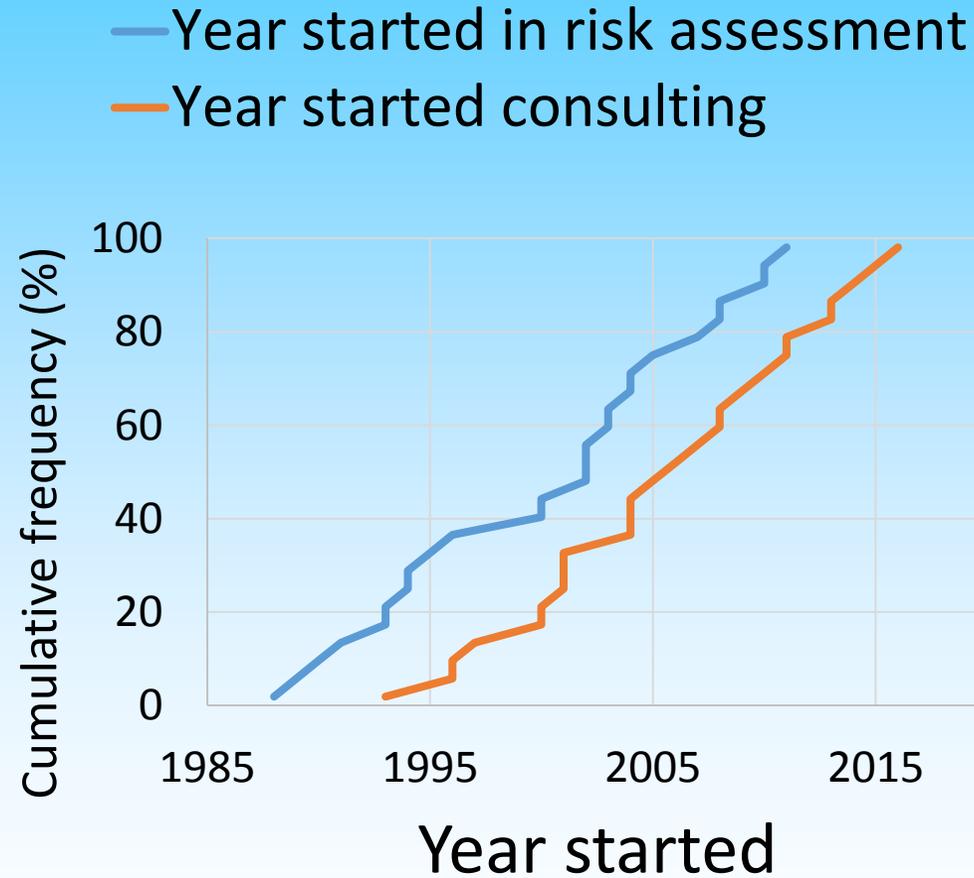
The solution

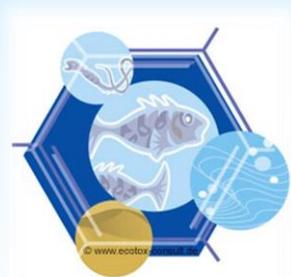
- Survey the consulting community
- Covering themes of:
 - The nature of assessments
 - Conducting assessments
 - Sources of data
 - Interacting with the system
- 31 consultants selected (Enviresearch contacts)
- 26 responses covering 25 consultancies

Who responded?



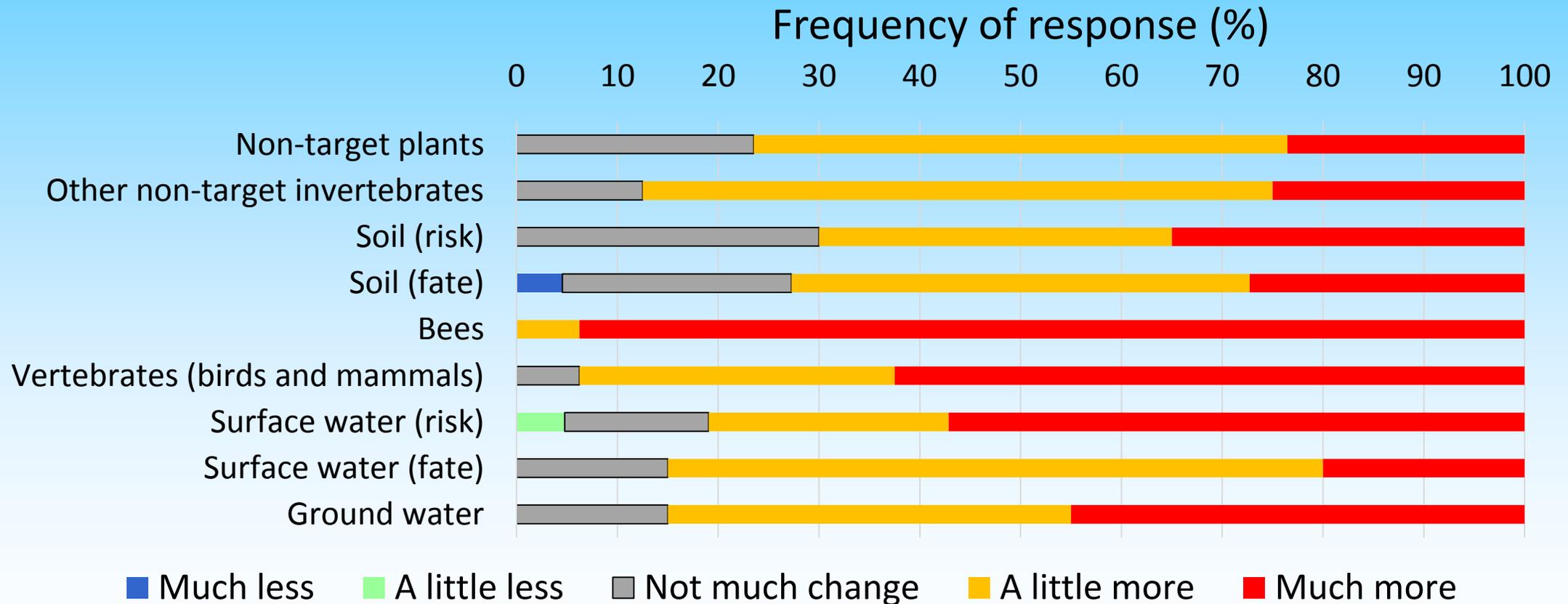
Who responded?





Plus 2 other consultancies
Bruce Callow + 8 other individuals

Are procedures less or more conservative? ($n=16 - 22$)



Stated reasons

Fate: GW

- Consideration of metabolites
- Conservative parameterisation
 - Plant uptake factor
 - New Q10
 - (Mostly) lower interception
 - New kinetic analyses
- Limited higher tier options
- Conservative individual MS and NZ requirements

Stated reasons

Fate: SW

- Additional routes of entry in modelling
 - Dominance of runoff in many situations
 - GEM for protected crops
- Consideration of metabolites
- Conservative STEP 3 scenarios & limited refinement options
- Conservatism will increase again (20 year TOXSWA, higher proposed % drift deposition rates)

Stated reasons

Risk: SW

- More species with high sensitivity are tested
 - → lower RAC
- Higher-tier studies (e.g. microcosm, mesocosm)
 - higher assessment factors
 - imperfect studies rejected
 - population recovery not considered
- TWA exposures in chronic assessments harder to justify
- Additional metabolite data
- Some new mitigations possible (e.g. drift reduction nozzles)

Stated reasons

Birds and mammals

- More conservative lower tiers in GD (EFSA 2009)
 - higher tier work for majority of assessments
 - leads to complex data sets
- Less acceptance of weight-of-evidence / higher tier
- Body weight conversion of NOEL in dietary exposure calculations
 - ppm diet → mg/kg bw
- Greater consideration of sources of uncertainty

Stated reasons

Bees

- Proposed risk frameworks are more conservative
- New data requirements (chronic, larvae, other species)
- New exposure routes
- 7% threshold
- In GD, lack of clarity/ flexibility for higher-tier approaches

Stated reasons

Soil (fate)

- EFSA approaches for lab and field studies
- Wash-off factor
- EU soil depth (5 cm) not always accepted
- Proposed EFSA approach (PERSAM) → more conservative
 - higher-tier assessments will be similar to current scenario

Soil (risk)

- More species with high sensitivity (e.g. Collembola) tested
- Hence more higher tier testing

Stated reasons

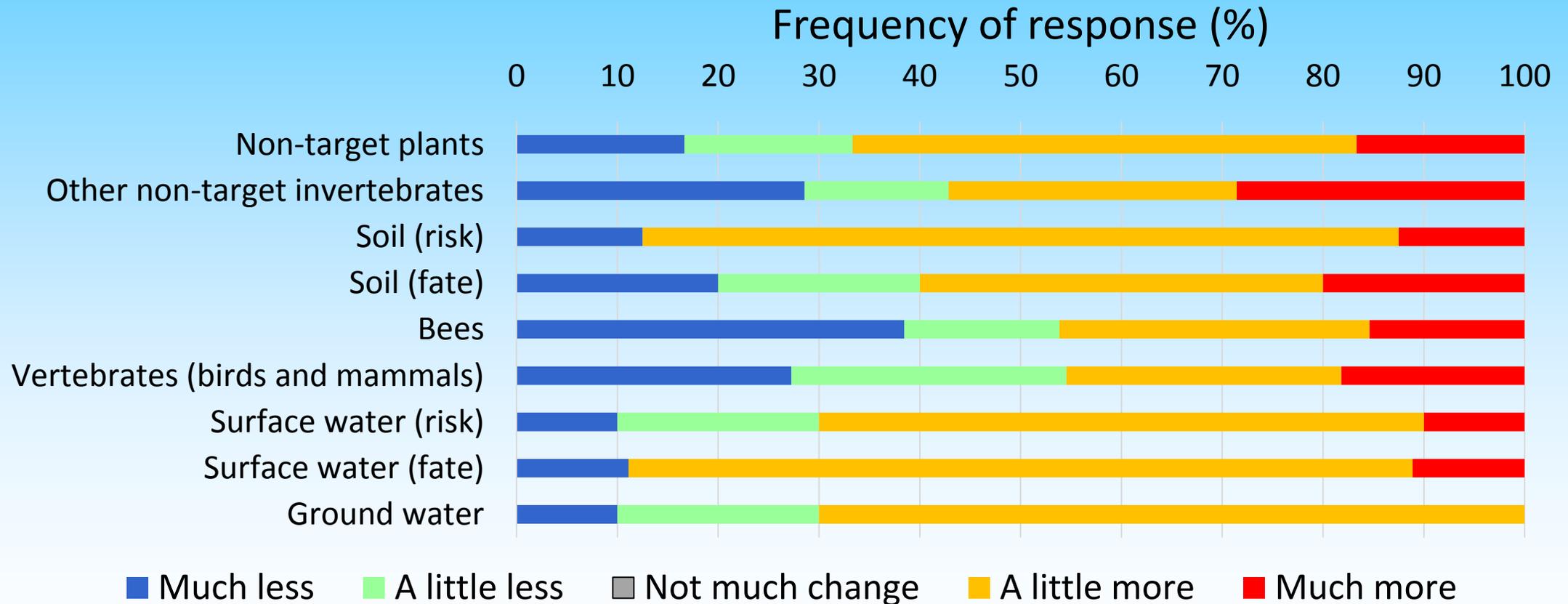
Non-target arthropods (other than bees)

- Concept of population recovery less accepted
 - Especially for off-field drift assessments
- More species tested
- Higher-tier studies (e.g. field) assessed more conservatively

Non-target plants

- Off-field assessment is a new concept
- The use of seedlings in the toxicity testing for off-field plants

Are procedures less or more realistic? ($n=5 - 13$)



Stated reasons: e-fate

More realistic:

- Crop interception values from larger data sets
- Probabilistic higher-tier approaches for e-fate gaining favour
- Scenario development continues

Less realistic:

- Difficult to override models with 'real' e-fate data (e.g. field leaching)
- Lack of validation of changes to model scenarios
- Vulnerable scenarios drive assessment
- 'Real' field conditions not adequately represented
- Sharp increase in conservatism

Stated reasons: risk assessment

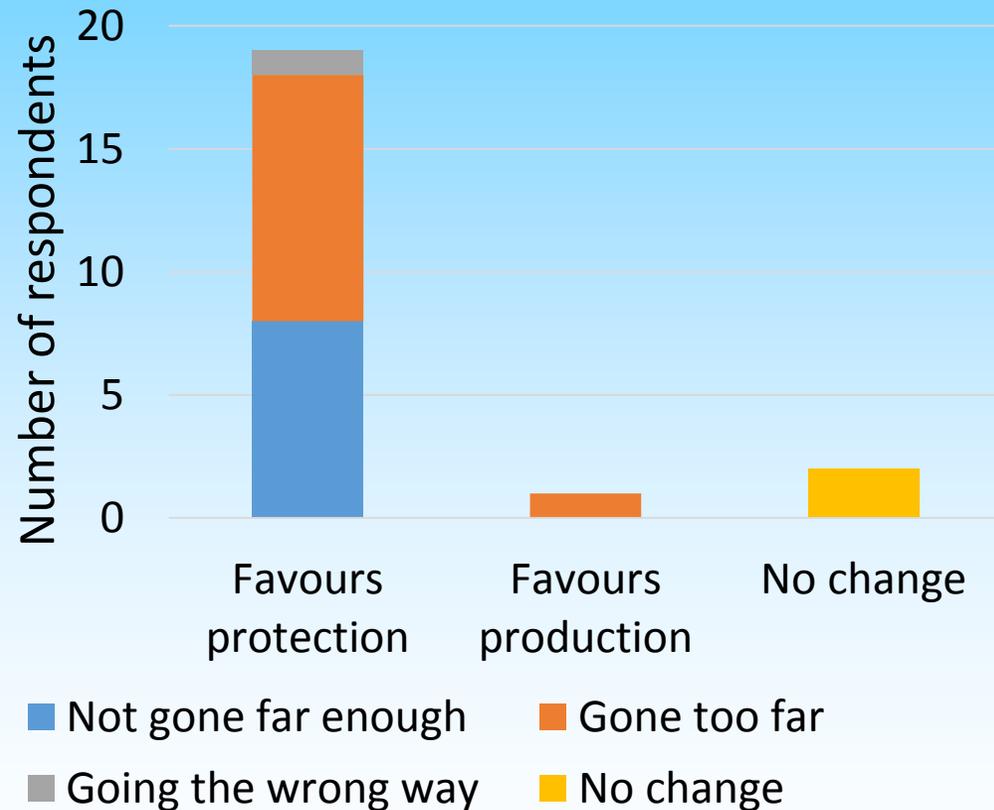
More realistic:

- Long-term and field tests are more informative/realistic
- More routes of exposure considered
- More species considered, better describes real ecology

Less realistic:

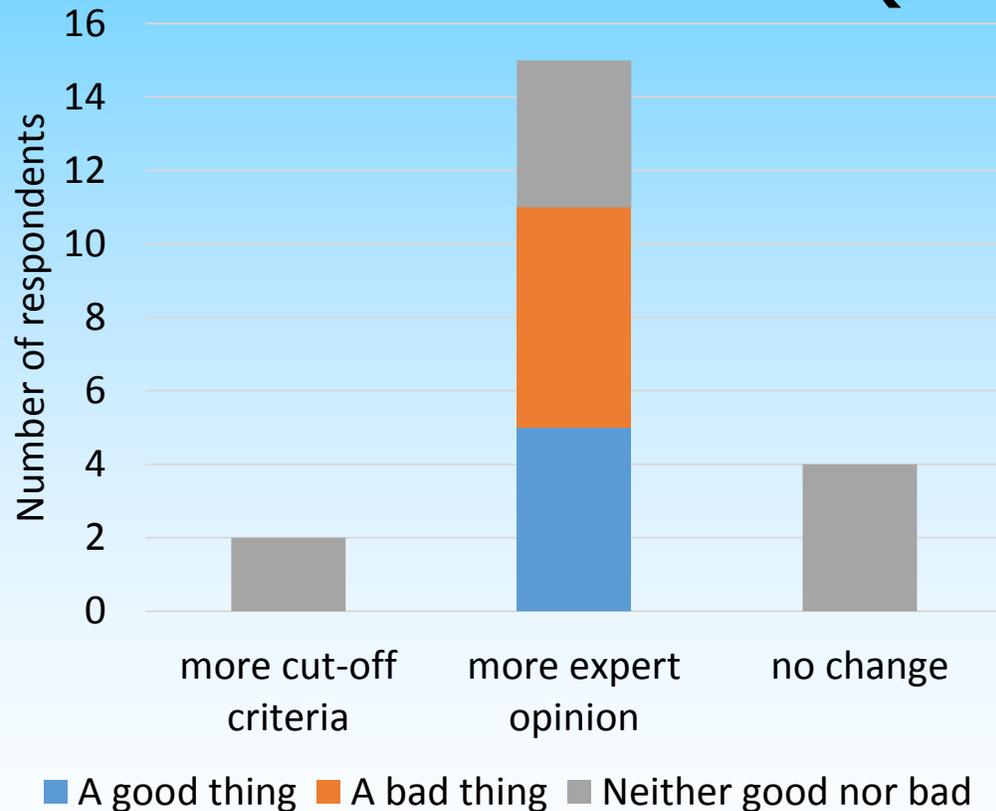
- Use of new data is over-conservative
- Substance intake rates unrealistically high (e.g. bees)
- Exposure estimations don't consider
 - 'real' animal behaviours
 - 'real' agricultural context
- Low/variable acceptance of field studies and higher tier approaches

Have the procedures changed to favour 'Production' or 'Protection'? ($n=22$)



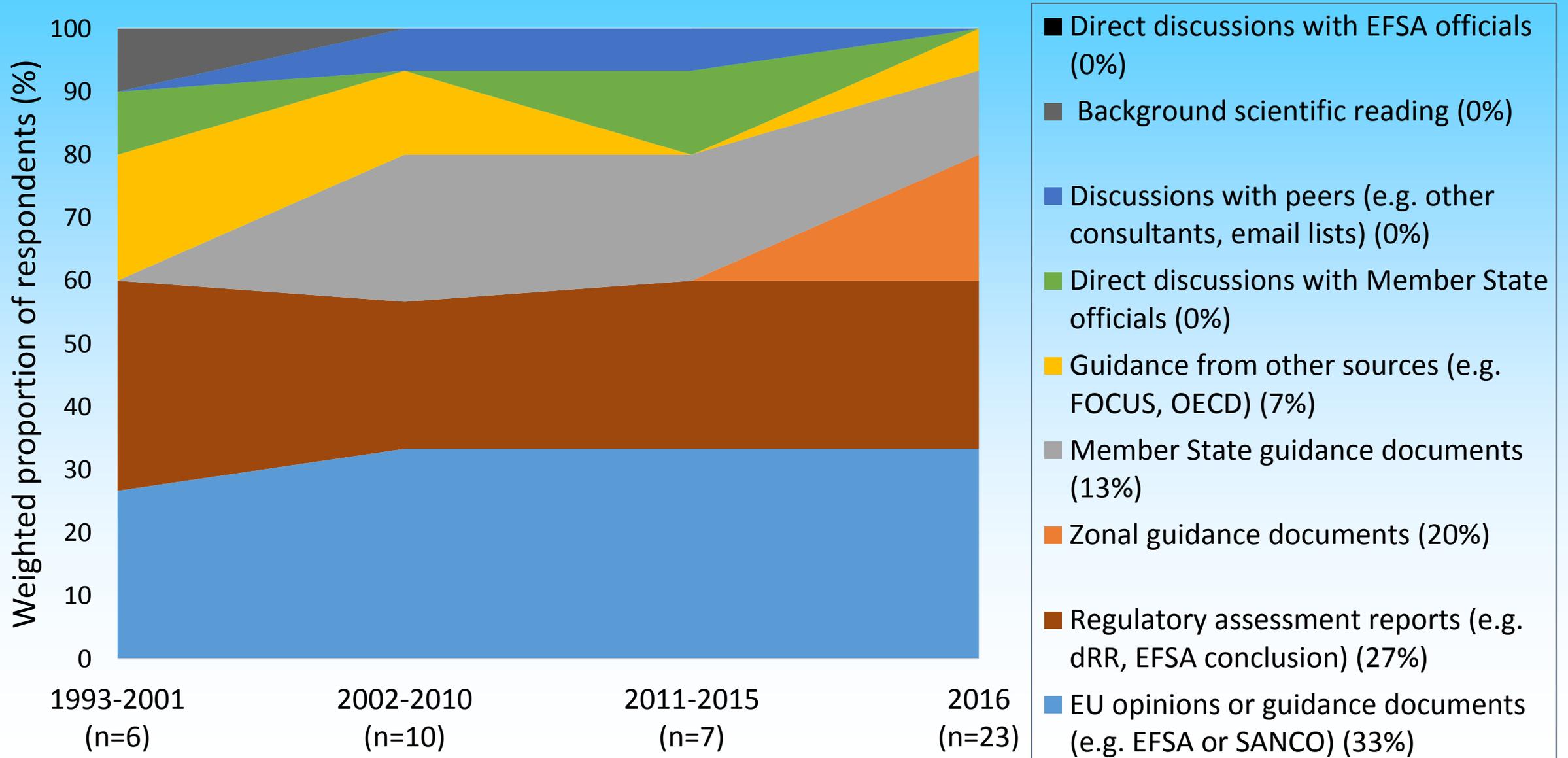
- It is good that guidance documents aim for better environmental protection
- It is bad that the amount of detail and effort might not be resulting in higher quality decision-making

What drives the assessments: numerical cut-off or expert opinion? ($n=21$)



- Newer guidance is more realistic so cut-off triggers used less
- Still some trigger values, e.g. PBT, ground water
- Availability of experts is limited on all sides

Top 4 sources of advice & information



Guidance documents: what do we think about them? ($n=25$)

Most agreement

What I asked	% agree
Are well published so people can find the right guidance quickly.	56
Have become more consistent in terms of their data requirements.	56
Have become thoroughly comprehensive across all areas.	52

Least agreement

What I asked	% agree
Have become more consistent in terms of their protection goals.	32
Have become clearer and easier to follow.	20
Are logically structured so similar themes are linked.	16
Take into account all relevant points of view.	4

Guidance documents: what have they enabled? ($n=24$)

Most agreement

What I asked	% agree
Have made assessments more consistent between applicants.	63
Have made assessments more consistent between Member States.	42
Allow people to include the latest scientific understanding in their work.	42

Least agreement

What I asked	% agree
Have allowed higher tiers of assessment to become acceptable by regulators.	38

Guidance documents: how have they changed your work? ($n=22$)

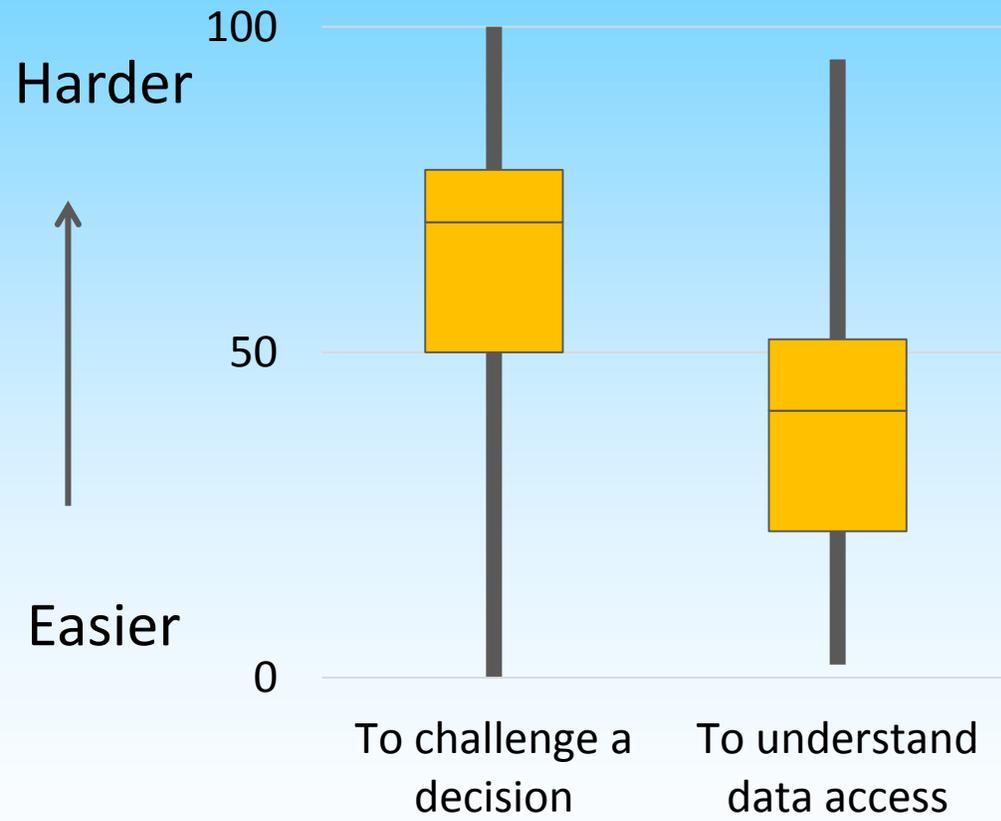
Most agreement

What I asked	% agree
They increasingly restrict my innovation in conducting assessments.	45
They have made me more confident that my work will be acceptable.	41

Least agreement

What I asked	% agree
They increasingly lead to multiple assessments with marginal differences between them.	36
They allow me to conduct more assessments than before.	27
They have improved the quality of my work.	23
They encourage me to delay assessments so I don't miss an update to the guidance.	14

Interacting with the system ($n=25$)



- Dealing with regulators
 - Harder to challenge a decision
 - A clear and 'final' answer from an official is rare
 - The system is more rigid
 - EFSA officials do not respond to requests for information
- Data access
 - Easier to understand data access
 - Data now more available
 - Understanding access is not easy for the inexperienced

Conclusion (1/2)

- More conservative in exposure and effects assessment
- More realistic in some areas, less in others
 - There are good and bad points
- More dependent on expert knowledge, but expertise is in short supply
- Information is primarily gained from various guidance documents and assessment reports for products and active substances

Conclusion (2/2)

- Data access has improved
- Data requirements have increased
- Current guidance is good in becoming
 - More comprehensive
 - More consistent
- However current guidance suffers from being
 - Too conservative at lower tiers
 - Too complex to use
 - Restrictive in its approach (especially for higher-tier)
- More direct interaction with regulators would be welcome