From 2013:
« Unauthorised myths »
of Applications for authorisation

Hugo Waeterschoot – Eurometaux
Erwin Annys /Amaya Jánosi – Cefic

Seminar on Applications for Authorisation
Helsinki – 17 June 2013

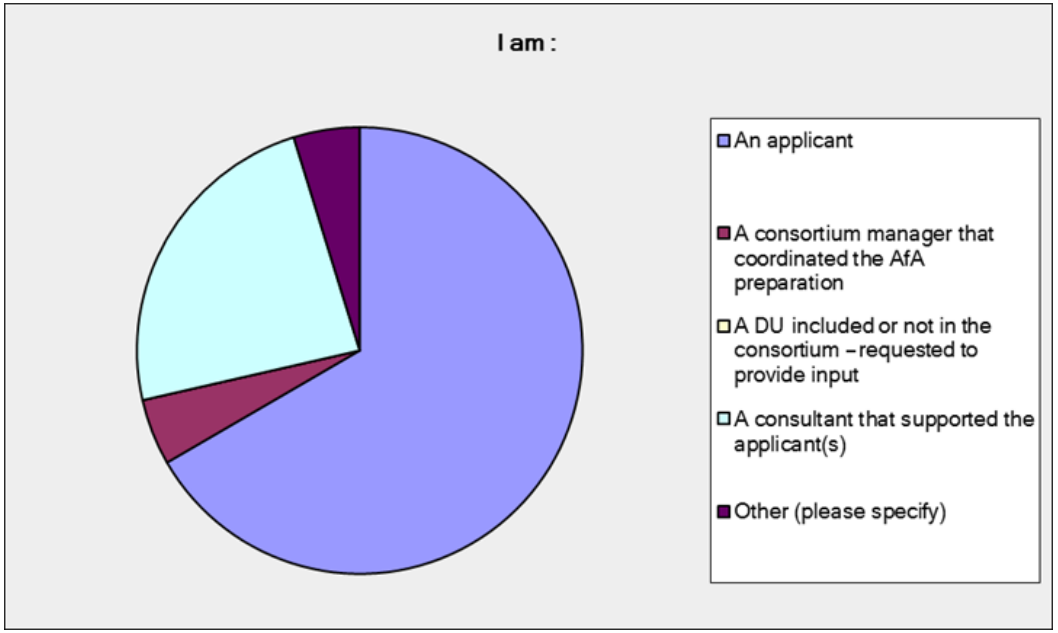
To today:
Overview of applicant's experiences

Hugo Waeterschoot – Eurometaux
Erwin Annys /Amaya Jánosi – Cefic

Stock-taking conference on the implementation of REACH authorisation
Helsinki, 13 – 14 November 2017

- Experiences with the chromate applications for authorisations
  - Representative for the process
  - Based on a Monkey survey

Conclusions

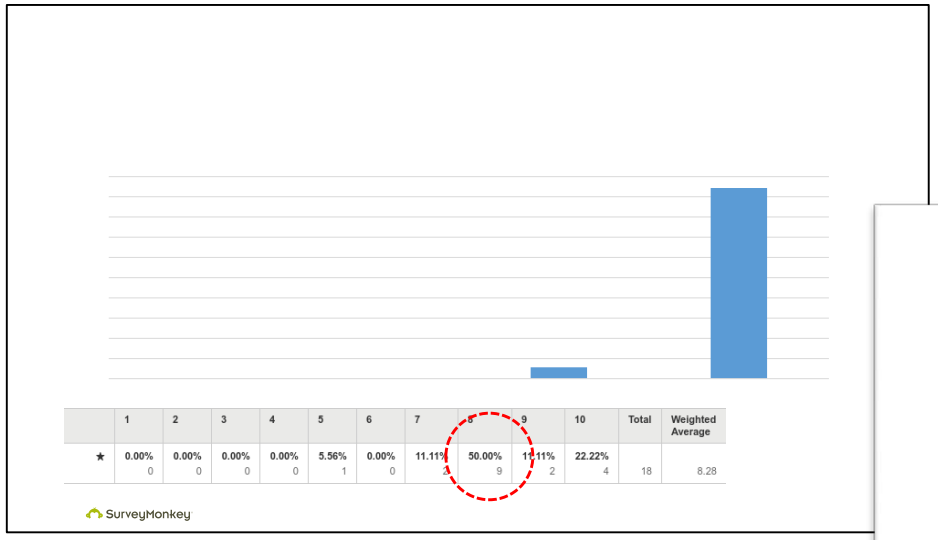


REPRESENTATION

- Reasonably good coverage
- All levels of submission covered
- All levels of applicants (M/I/ORs/formulators/DUs)

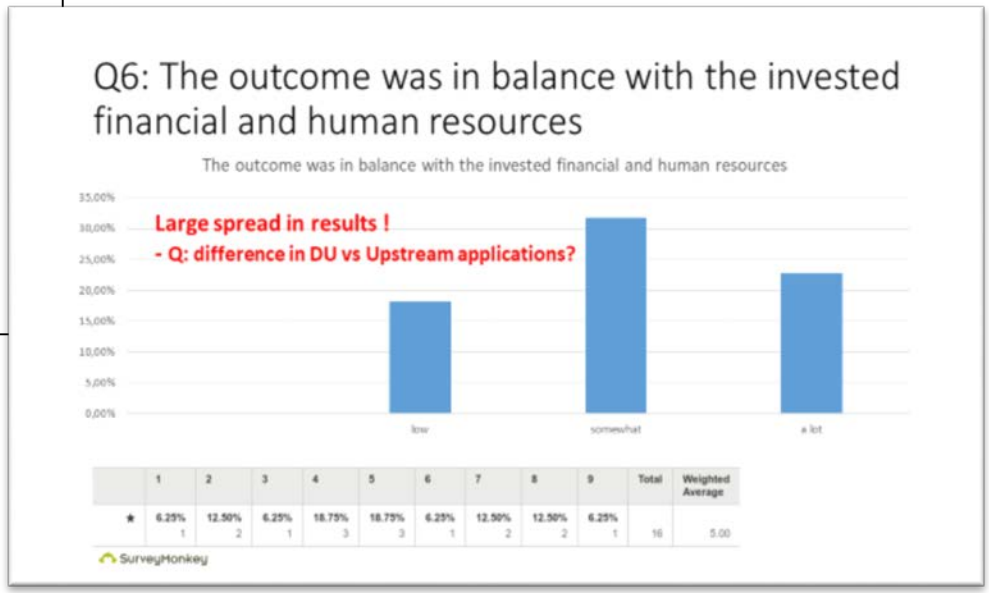
Conclusions

- **Expectations versus outcome**:
  - Highly confident in the submission and 50 % happy about outcome, 25% not
  - Quite an investment in financial and human resources, “somewhat” balanced with outcome



	1	2	3	4	5	6	7	8	9	10	Total	Weighted Average
★	0.00% 0	0.00% 0	0.00% 0	0.00% 0	5.56% 1	0.00% 0	11.11% 2	50.00% 9	11.11% 2	22.22% 4	18	8.28

SurveyMonkey



	1	2	3	4	5	6	7	8	9	Total	Weighted Average
★	6.25% 1	12.50% 2	6.25% 1	18.75% 3	18.75% 3	6.25% 1	12.50% 2	12.50% 2	6.25% 1	16	5.00

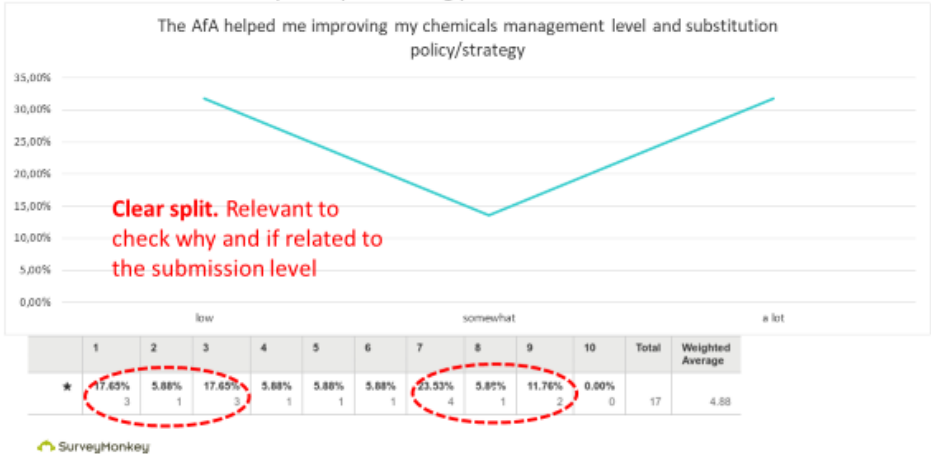
SurveyMonkey

Conclusions

- **Applicants Risk Management:**
  - Dispersive answer on "*if practical RMM improved due to the AfA*"
  - Contrary views on if it improved substitution strategy

Q7: The AfA helped me improving my Risk Management Measures to minimise exposures/emissions

Q8: The AfA helped me improving my chemicals management level and substitution policy/strategy



  - Applicants believe that another risk management option is more appropriate

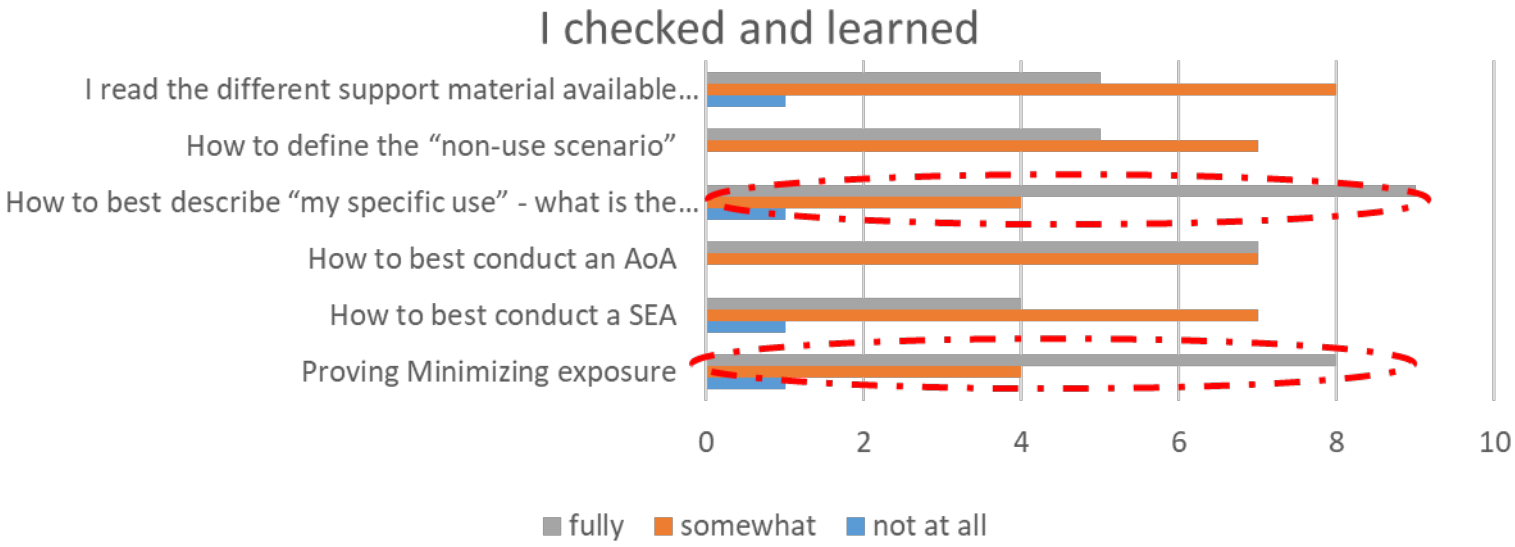
Conclusions

- **Support to applicants:**
  - ECHA guidance appreciated as “starting material”
  - ECHA support appreciated :
    - **PSIS** as a tool to confirm to companies the suggested strategy of the involved consultants
    - **Trialogue**: to debate the feasibility of the suggested alternatives and an platform to exchange questions/information with ECHA and rapporteurs
    - **Interactions** during the Committee consultations

Conclusions

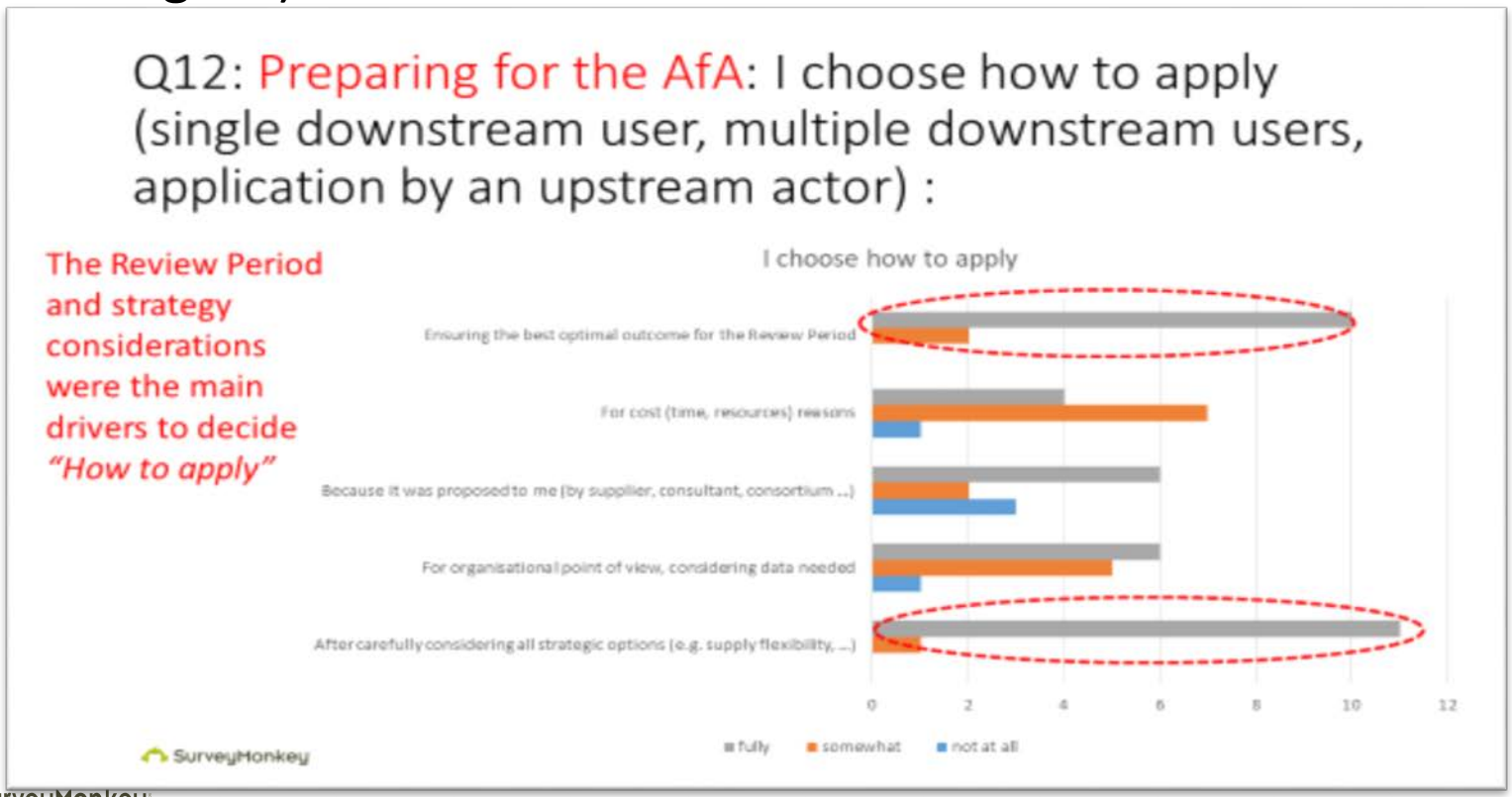
Learning process:

- The AfA drafting provided learning on proving minimised exposure and describing the uses better
- Consultants were helpful in identifying outstanding weaknesses
- Interesting to read the whole application



Conclusions

- **Submission and Submission model:**
  - Chosen based on sector needs recognising Review Period and strategic considerations
  - Interactivity during process appreciated (PSIS, PC, Q's, Trialogues)



Conclusions

- **Handling in the Committees**
  - Data submitted felt recognised and final opinion clear and obvious
  - BUT big discrepancies between applicants on how they see the effectiveness of the RAC and SEAC reviews
  - Confidentiality remains assured

Conclusions

On potential reapplying learning lessons

- **Better planning** seems the main required improvement step
- Responsibilisation/interaction with the **supply chain** needs improvement
- Applicants/Consultants seem to have a **clear view *on what to improve*…** but not fully in line with Committees' recommendations for some conditions (eg. splitting uses, SEA, AoA, …)

Q22: If reapplying I would: On AfA preparation:

	Yes	No need for	Not relevant	Total	Weighted Average
Would better plan which data, whom and by when starting to gather it	100.00% 11	0.00% 0	0.00% 0	11	1.00
I would define my uses in more detail	18.18% 2	81.82% 9	0.00% 0	11	1.82
I would split my uses further to reflect differences in AoA status or SEA relevancy	9.09% 1	81.82% 9	9.09% 1	11	2.00
More effort in demonstrating the minimisation of exposure	63.64% 7	36.36% 4	0.00% 0	11	1.36
Document my CSR better	50.00% 5	50.00% 5	0.00% 0	10	1.50
Document and/or motivate my AoA better	27.27% 3	72.73% 8	0.00% 0	11	1.73
Document and/or motivate my SEA better	18.18% 2	81.82% 9	0.00% 0	11	1.82
Decrease the use of Confidential information	9.09% 1	81.82% 9	9.09% 1	11	2.00

SurveyMonkey

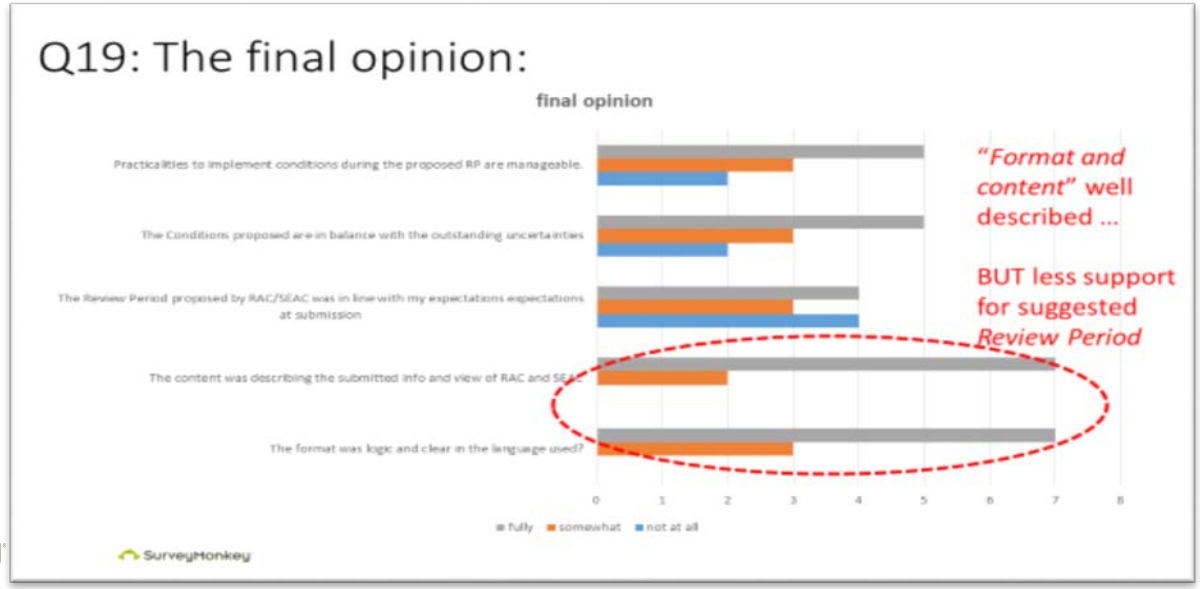
Seemingly clear view on what to improve (planning data gathering and minimisation of exposure).

BUT: does those that are not considered as needing improvement corresponding with the view of RAC/SEAC?

SurveyMonkey

Conclusions

- **Final opinion:**
  - Format clear and content well described
  - Criticism about setting the Review Period
  - Relative understanding for the Conditions set but:
    - In some cases questions if they are achievable (in time and consequences)
    - How would they be enforced?



Open questions on re-applying

- How to fulfil criteria defined for the Review Period?
  - How to implement conditions requested? techniques, timing, cost, feasibility, ...
  - How to get prepared to submit a review report? – data collections, who to involve, by when, ...
  - Which kind of data would be useful to feed in the review report, in the reapplication?

The issue: upstream applications

- Gather data asap – clarify what is needed from all actors
- Need time to set up inventory of uses
- Collect contextual data to better explain exposure scenarios
- Communicate more on the process – clear communication plan
  - Hire a communication expert checking the application
  - Provide a more systematic way of working = better project management
- Don’t loose efficiency due to confidential data
- Start first with standardised approach, then iterate
- Better explain consequences of remaining uncertainties

Let's avoid new myths ?

- Measured exposure and appropriate description?
- Analysis of alternatives and availability for whom?
- Non-use scenario in the socio-economic analysis?
- How to reapply?