ECHA's results on data quality in REACH

'REACH Compliance – A BfR-Workshop on data quality in registration dossiers'

23-24 August 2018

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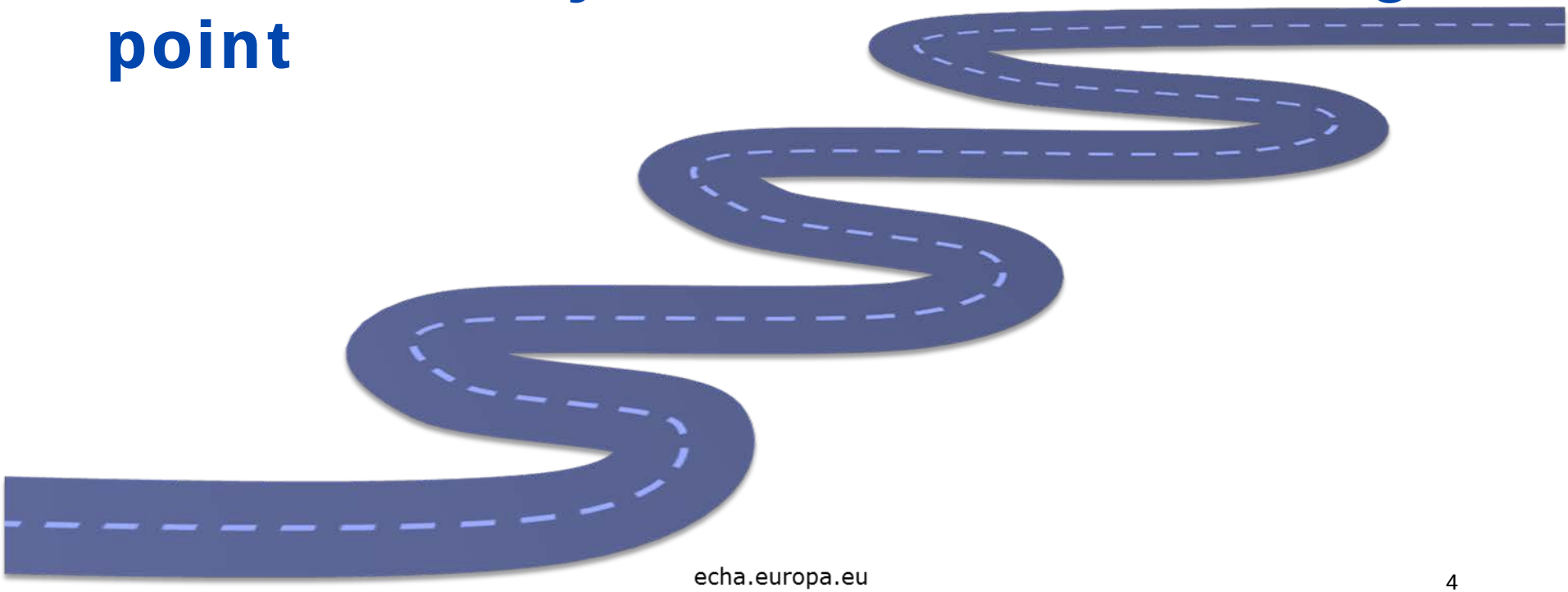
Introductory remarks

At the end of the phase-in period

REACH Registration 2018 – phase-in period succesfully over

To remember: Registration is not the end …

… it is merely the essential starting point



… for the real journey – to demonstrate the safe use of a substance

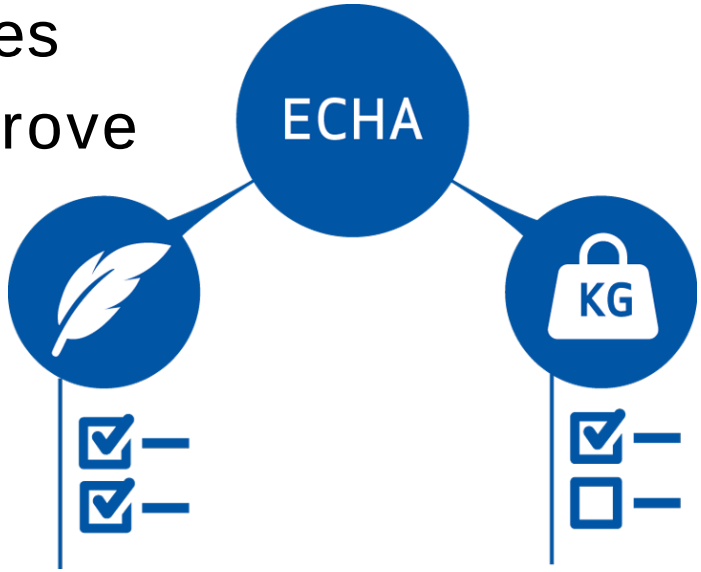
… through it's lifecycle

The data in the dossier - the ’map’ for the journey

- The data in the registration dossier on uses, exposure and hazards determines the starting point – and the length - of the journey
- The quality of the data determines also the resolution of the map - and the visibility of the road
- Having a comprehensive data set is **not** adding weigth to the luggage but gives a predictable destination, better map and a smooth path

For authorities the dossier is the ticket – re-routing is possible

- To verify that obligations are met and the safety demonstrated
- To evaluate the substance or take regulatory risk management measures
- To invite registrant to improve the dossier
- To inspect that substance is lawfully on the market



Good quality dossier

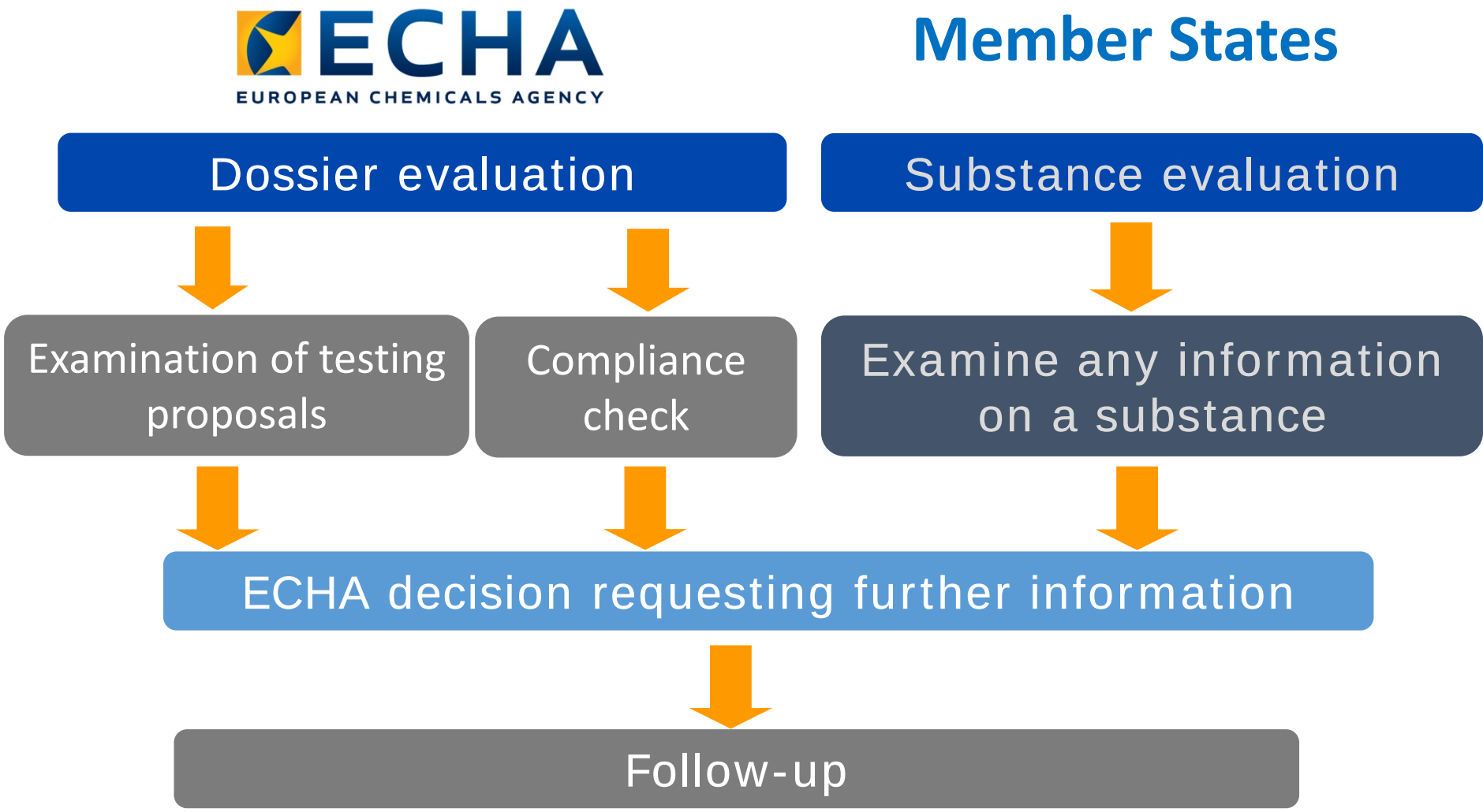
✓ **Demonstrates safe use of the substance**

- Clear scope: substance correctly identified
- Complete: checked by ECHA – by IT or manually
- **Compliant with information requirements**
- Relevant: test material and information
- Transparency, consistency and conciseness
- **Updated with new information and studies**

What ECHA now knows about the quality of REACH registrations?

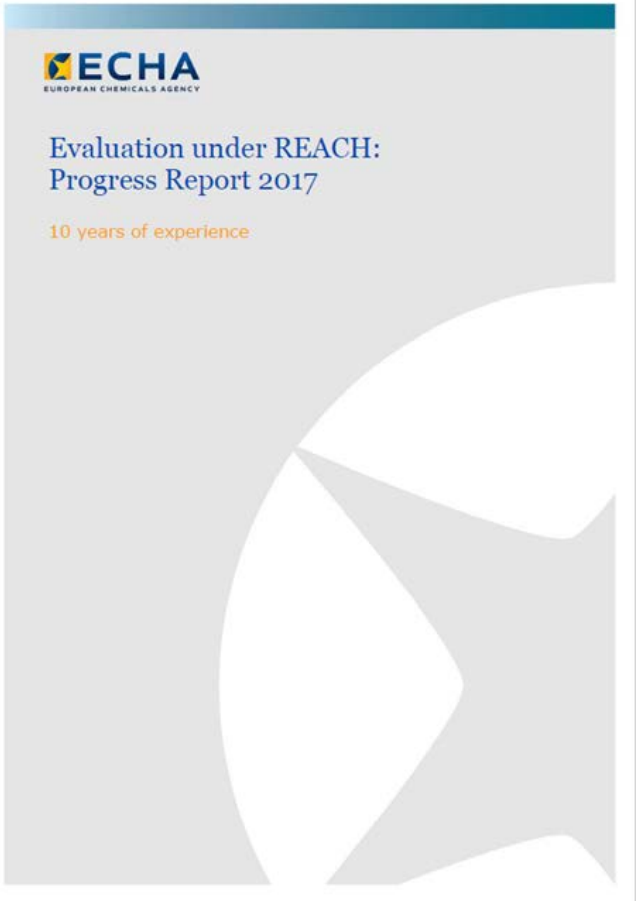
- Learnings from Dossier and Substance Evaluation
- Learnings from other measures

REACH Evaluation processes



Over 10 years of dossier evaluation*)

- 1780 dossiers checked, to various degrees, for compliance
  - In the majority of the cases, non-compliance in one or more endpoints established
- 4170 requests made in ECHA dossier evaluation decisions
- 1442 dossier evaluations concluded, of which 1235 with compliant information
  - High rate of compliance with ECHA decisions!
  - 73 substances flagged for C&L, 11 for substance evaluation



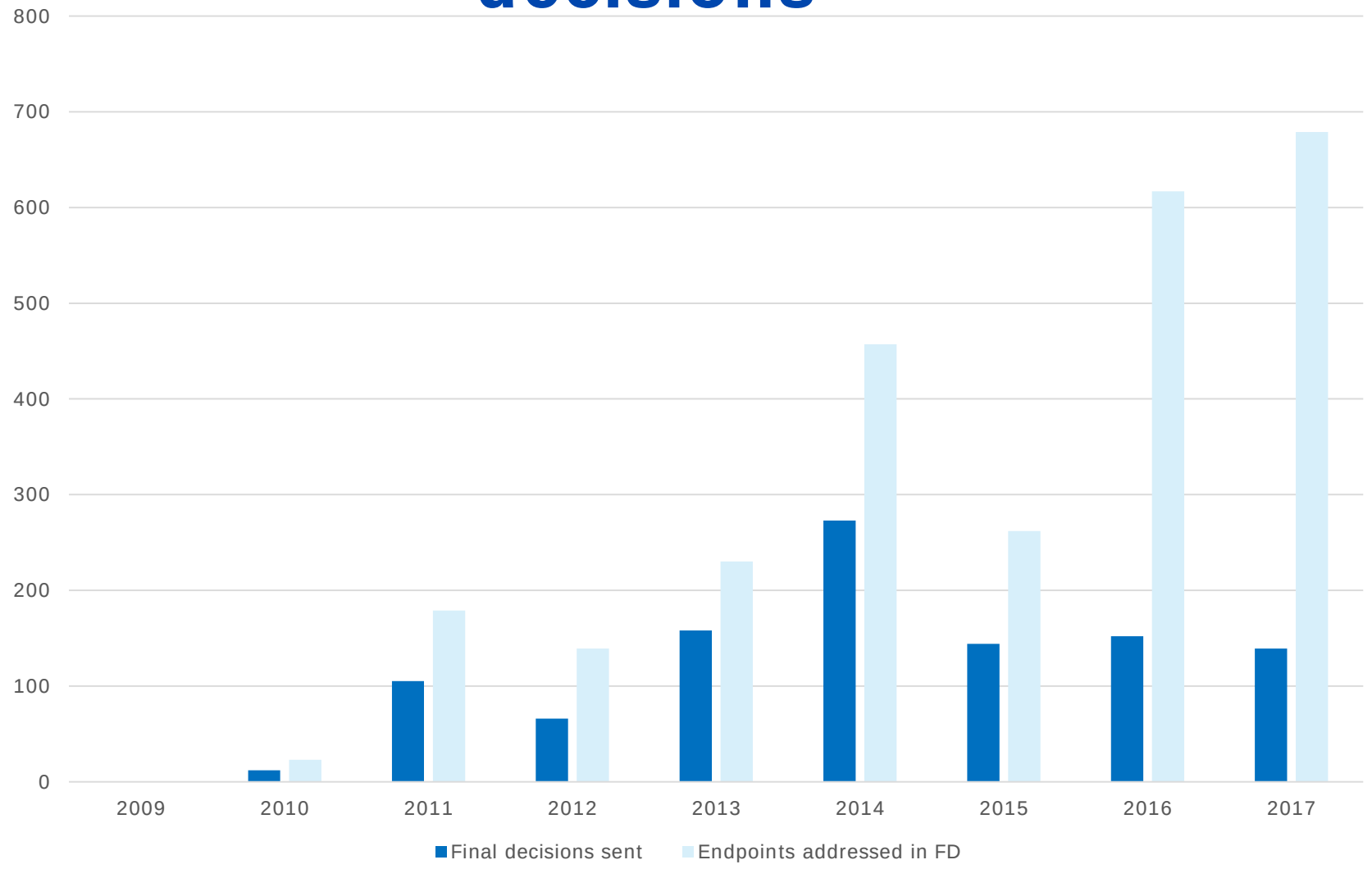
*)https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf/24c24728-2543-640c-204e-c61c36401048

Unique compliance checks in 2008-2017

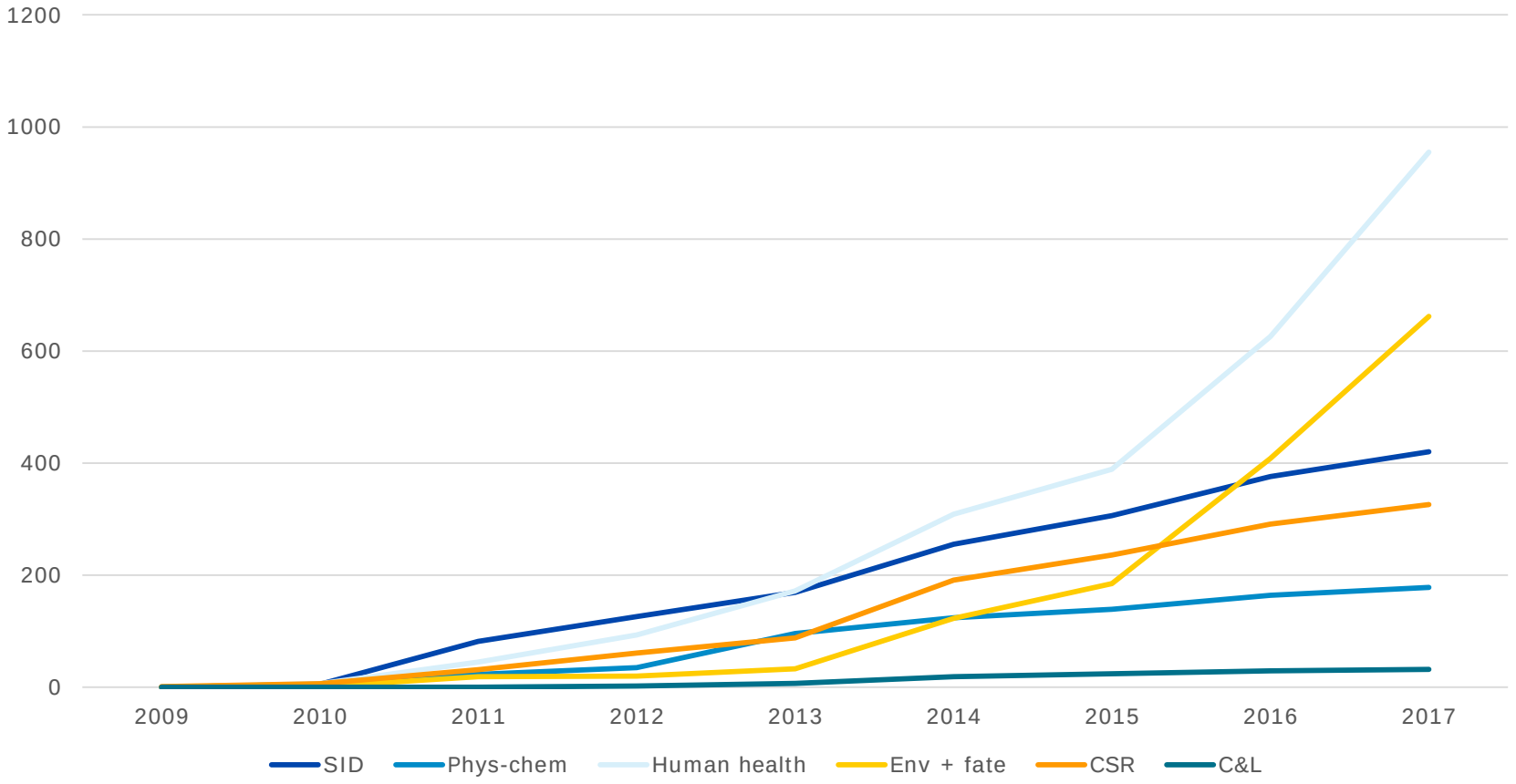
Tonnage band	Performed unique compliance checks				
	Concluded with DD	Concluded without DD	Total	Registration dossiers*	Percentage of registrations checked for compliance (%)
≥1 000 t/a	934	416	1 350	18 408	7.33
100 to 1 000 t/a	332	98	430	11 342	3.79
10 to 100 t/a	45	26	71	5 714	1.24
1 to 10 t/a	31	70	101	6 929	1.46
Total	**1 342**	**610**	**1 952**	**42 393**	**4.60**

* Number of unique registration dossiers; registrations of intermediates and NONSs excluded from the count.

Compliance check final decisions

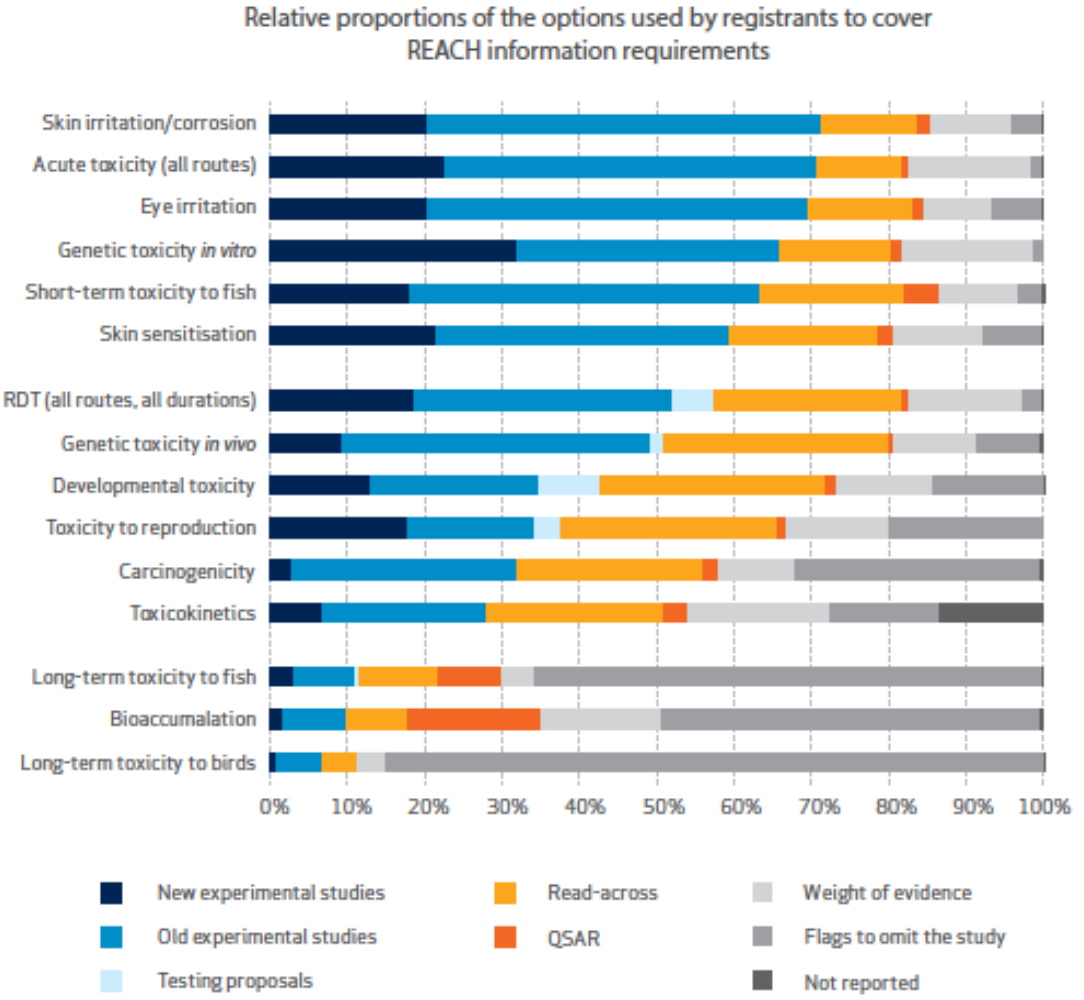


Type of data requested in compliance check decisions 2009-2017

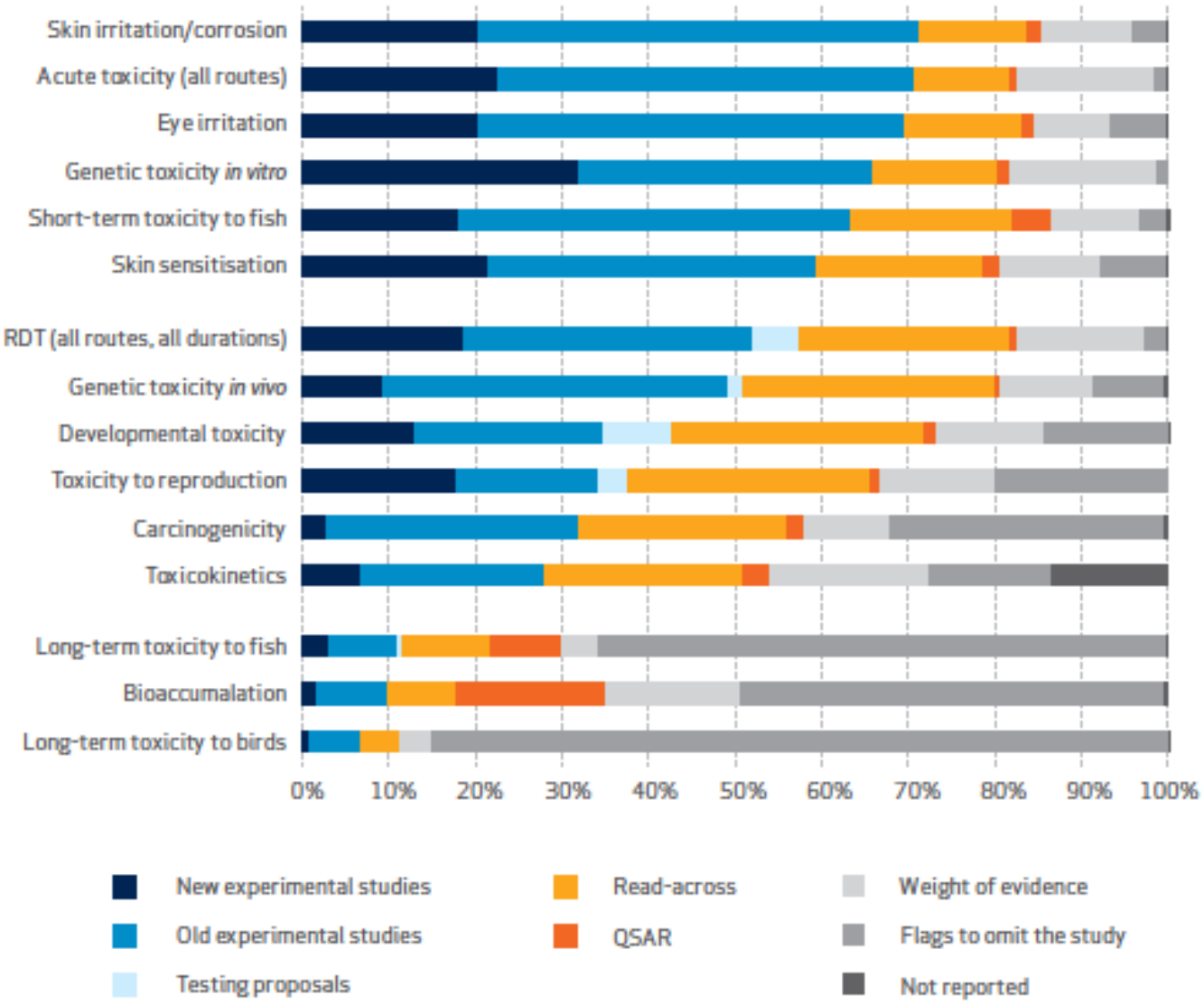


Main reasons for non-compliance

- Waiving of data requirements not correctly justified
- Adaptations (read-across, QSAR, WoE) failing due to incorrect justification or lack of documentation
- Documentation insufficient



Relative proportions of the options used by registrants to cover REACH information requirements



Follow-up dossier evaluation

Outcome of the follow-up evaluation		2012	2013	2014	2015	2016	2017	Total
Article 42(2) notification*	TP	0	72	99	111	118	143	543
	CCH	2	77	136	148	201	129	692
Statement of non-compliance**	TP	2	10	27	16	17	21	93
	CCH	8	22	17	26	16	25	114
Non-compliant cases still open (recorded by the year the non-compliance was notified to the Member State authorities)***	TP	0	0	2	2	10	17	31
	CCH	1	2	2	7	8	18	38
Flags for future regulatory actions		**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Proposal for harmonised classification and labelling	TP	0	1	10	17	4	19	51
	CCH	0	0	4	1	1	16	22
Candidate for substance evaluation	TP	0	0	4	3	0	1	8
	CCH	0	0	2	0	0	1	3

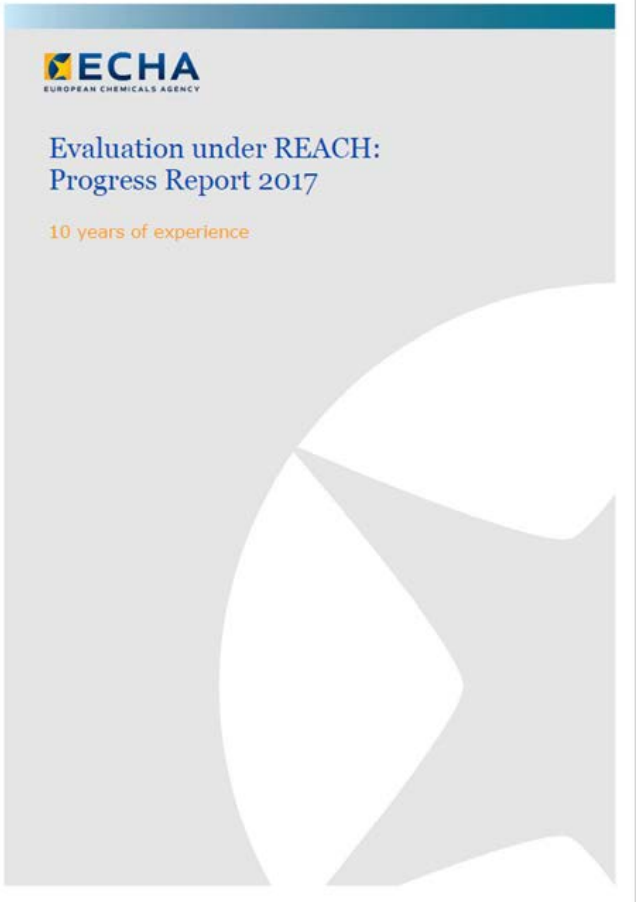
* Information requirements were complied with by the deadline.

** No information provided or an unacceptable adaptation was provided.

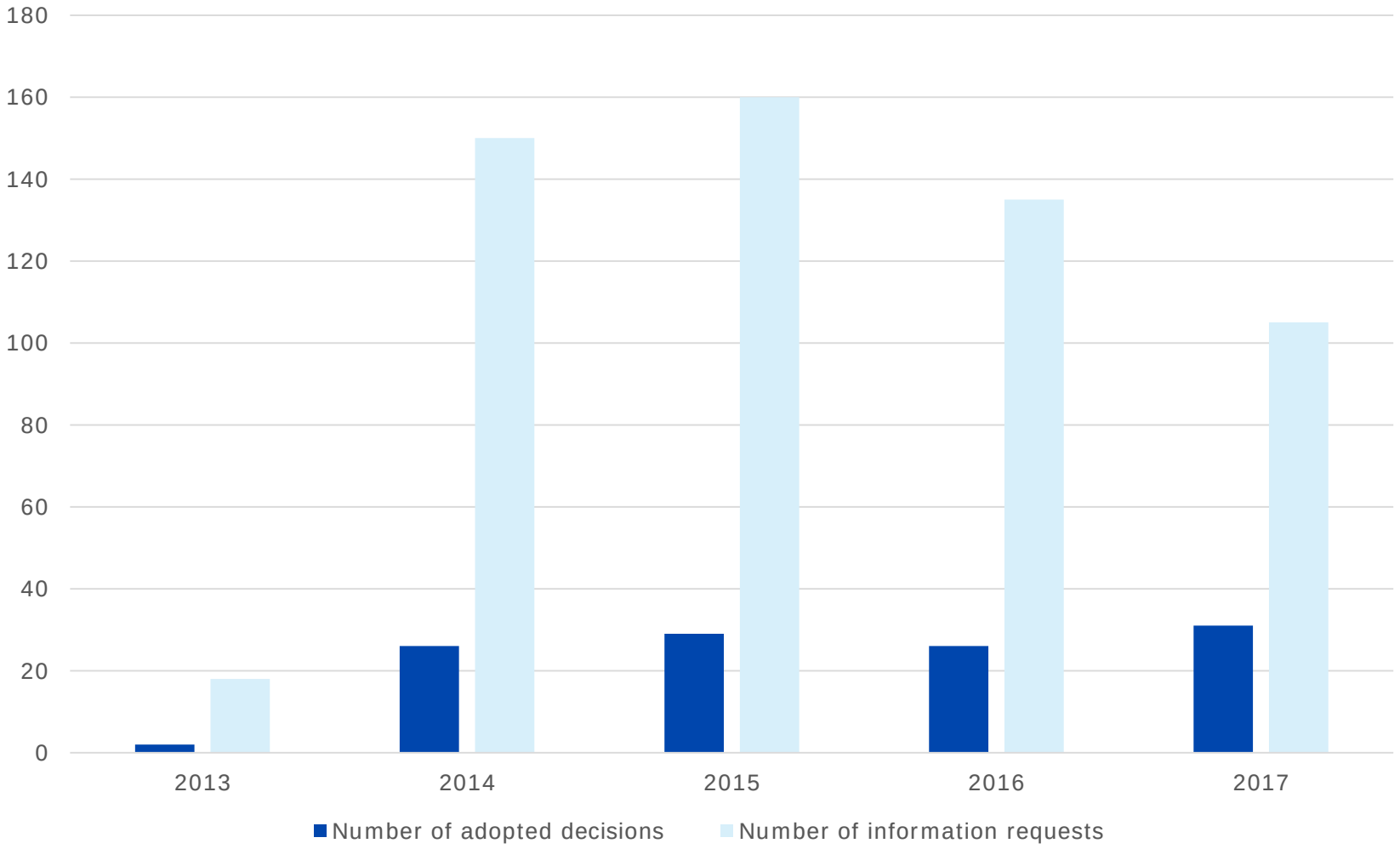
*** No (or no adequate) information was provided by the deadline. ECHA invited MS authorities to consider enforcement actions towards the registrant. The requested information still has not been provided.

Over 5 years of substance evaluation

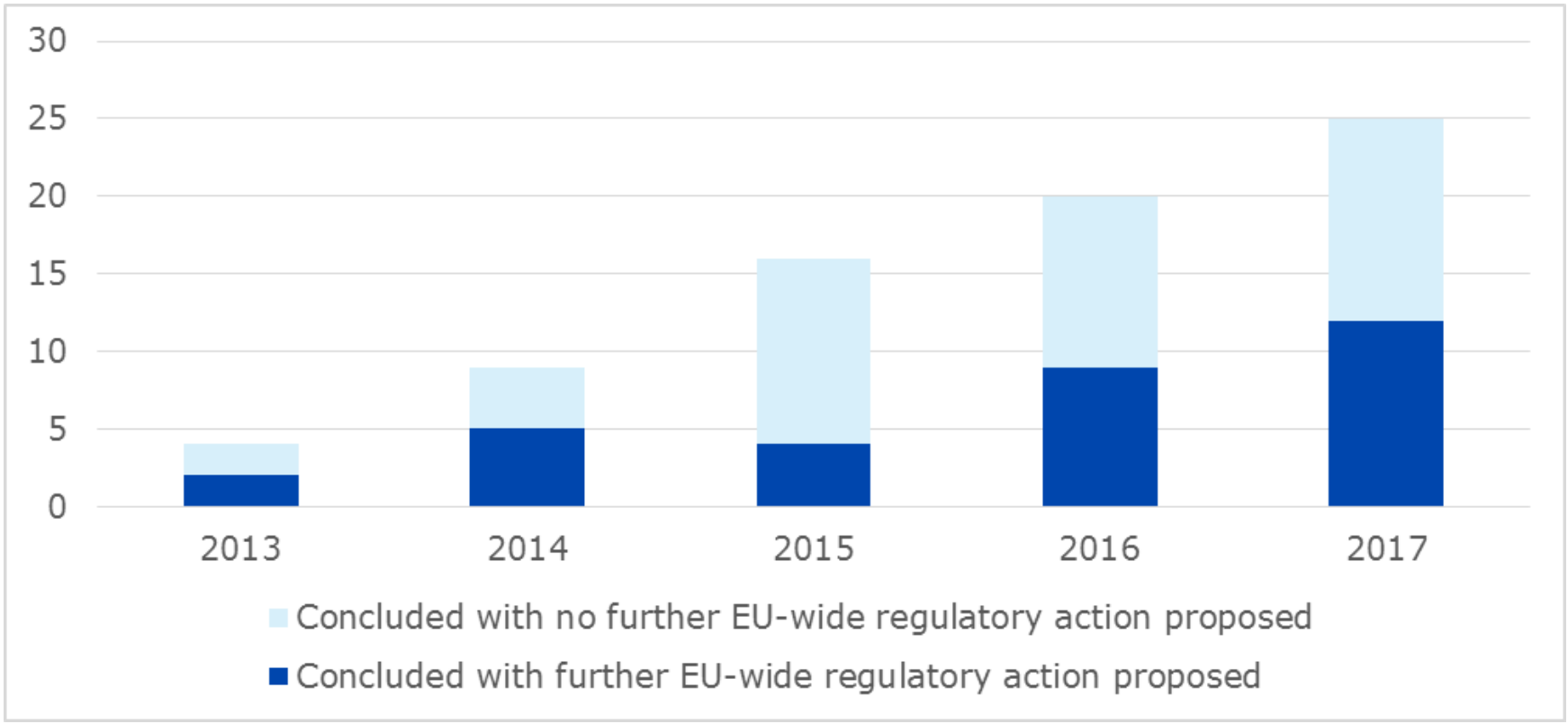
- 221 substances evaluated by Member States
- Leading to ECHA decisions with information requests in 159 cases
- 25 evaluations concluded



Substance evaluation



Substance evaluation conclusions



Our knowledge and experience on dossier quality is also based on …

- Improved submission tools & completeness check
  - What you get in is now much better and more structured
  - SID information improved by targeted measures
  - Compliance with harmonised classification at a very high level
- Effective screening & priority setting
  - Common (IT & manual) screening is applied to all substances and is able to find those meriting further assessment and action
  - Addressing substances increasingly in groups
  - Use and exposure information gradually improving
- Risk Management Option Analysis work
- Member States' supporting activities
  - "REACH Compliance" –project results taken into account by ECHA
- Experience in (inducing) updates by Industry
- Enforcement of REACH provisions and ECHA's decisions

Concluding remarks

Overall conclusions

- A lot has been done – but we still miss critical data on higher tier endpoint to allow drawing conclusions on the need for further action
  - Compliance check on >100 tn dossiers needs to continue
  - All substances are going to be assessed to a different degree and conclusions drawn within the next years
- The common screening, using also external data, is the key in setting the right priorities for further action
- Addressing substances in groups and using dossier and substance evaluation in parallel are among the measures that can improve the overall efficiency of Evaluation
- Compliant, up-to-date data is the legal requirement and the basis for authorities:
  - Registrants can act proactively, not to wait for being prompted
  - High time to re-visit 2010 and 2013 dossiers and update them with the current knowledge on uses, exposure and hazards!

Call to review and improve the registration dossier - and to keep it up-to-date

- Uses and volumes change
- Exposure and risk management measures evolve
- New information on hazards are generated
- New knowledge on hazards and risks emerges
- Improved methods, models and tools are put in place
- New EU and international assessments are published
- ...

✓ **Demonstrating safe use is a dynamic goal**

Thank you!

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