

Where we are on biocides

Biocides Day

24 October 2018

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European Chemicals Agency



Biocides characteristics

Very complex

High workload

Limited capacity / resources

Limited political visibility

Small is beautiful – freedom

Luuk van Middelaar in *The Passage to Europe*:

“Thus far, the European Union has been able to “**muddle through**” on a middle ground that keeps the multitude of nations integrated, though still independent.”



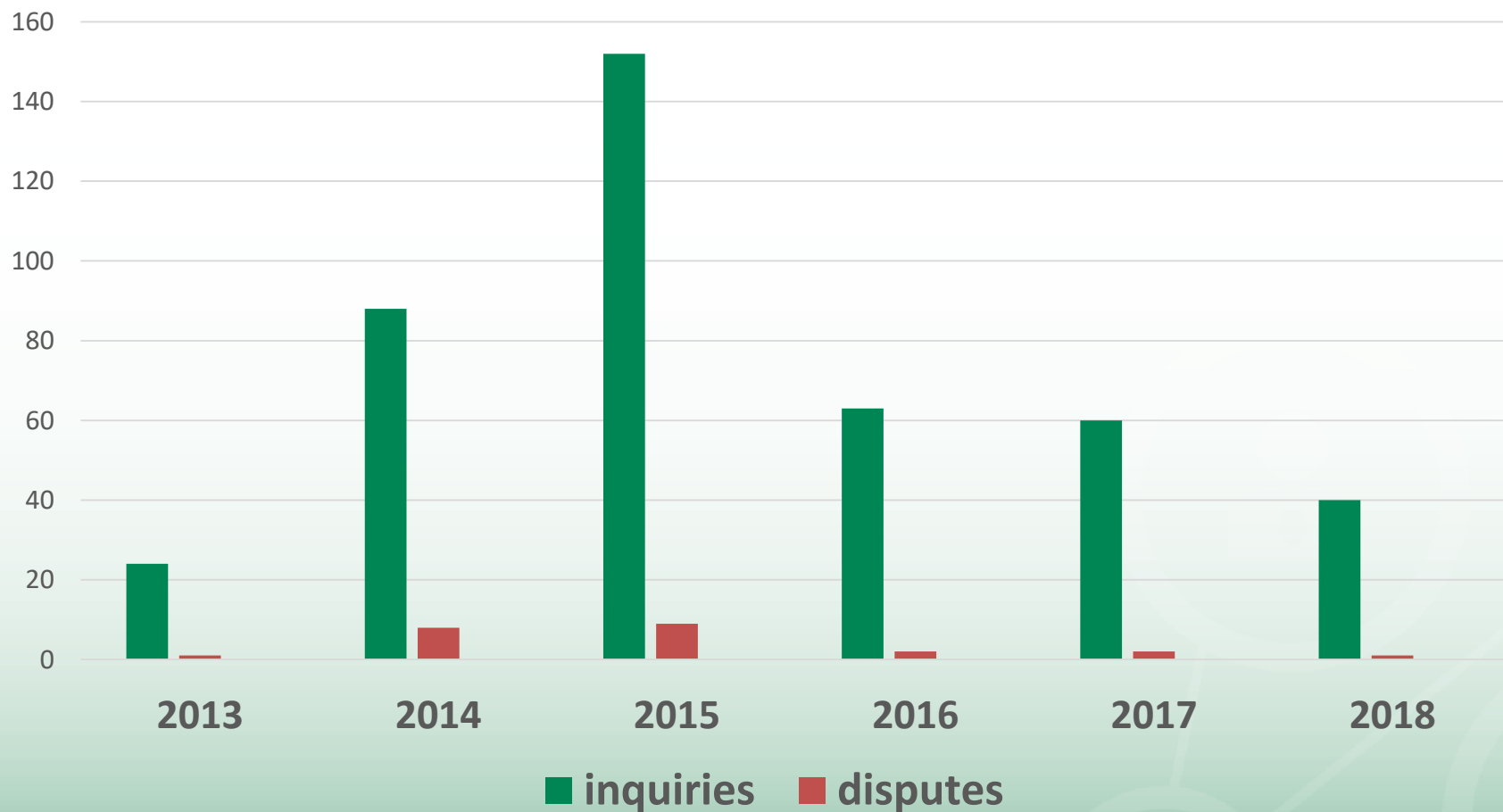
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Five years of operation: 2013 to 2018



- **IT:** R4BP, IUCLID, SPC Editor, EUSES
- **Guidance:** volumes I to IV
- **Transition** periods over
- First **Union** authorisations
- **Appeals**, court case and Ombudsman case

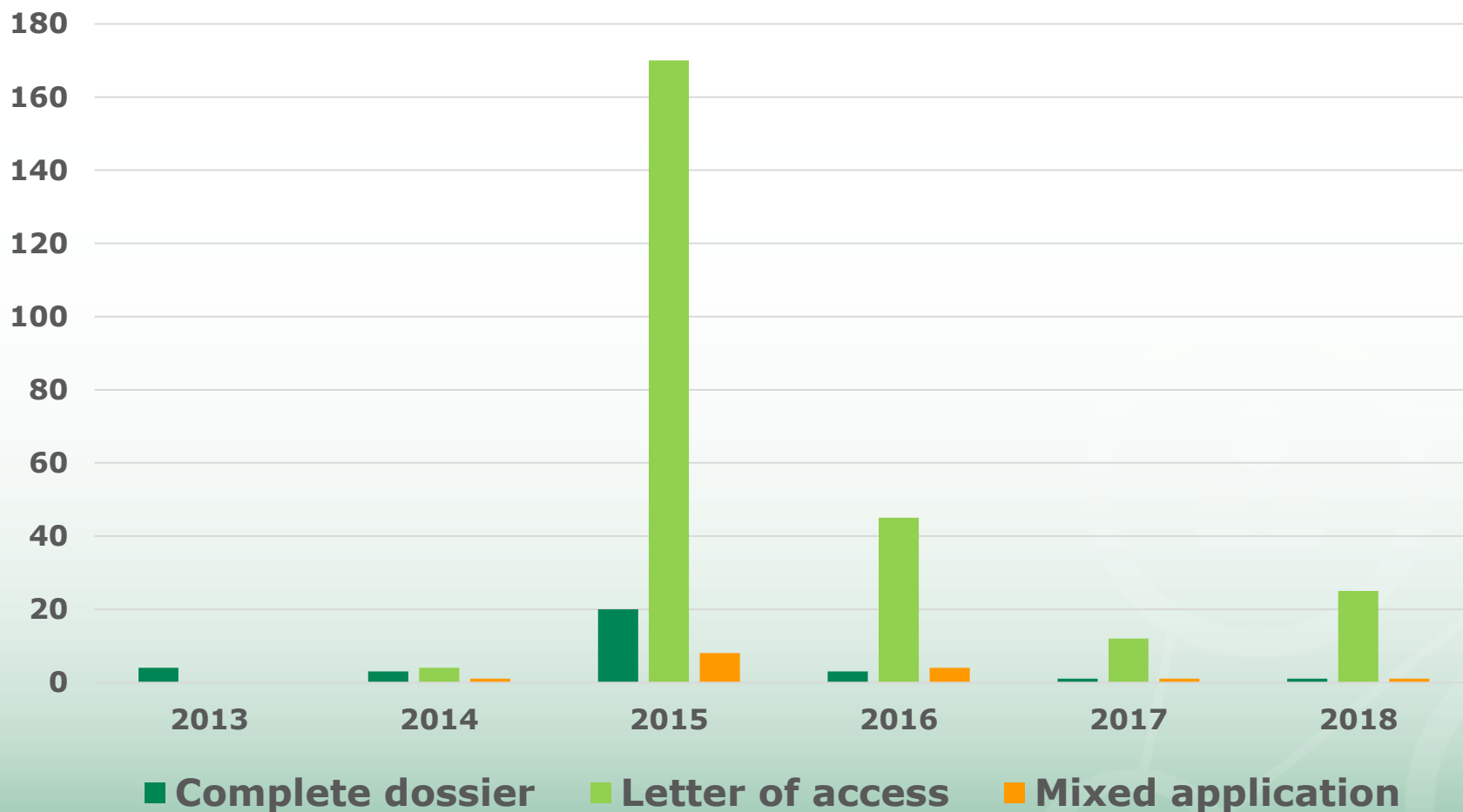
Data sharing: disputes and inquiries



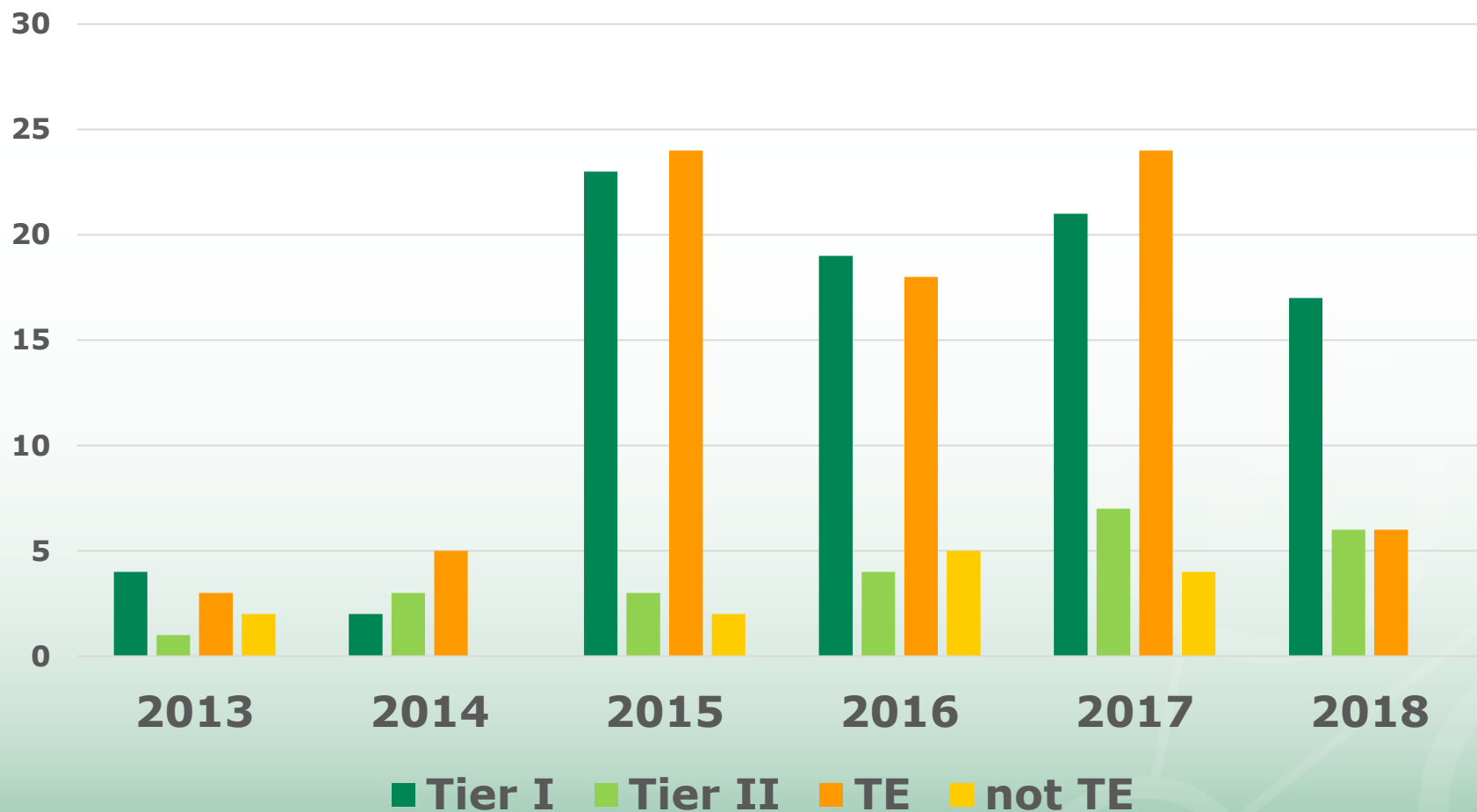
Data sharing: disputes and appeals

disputes	submitted	closed	permission to refer granted		withdrawn	appeals
			yes	no		
2013	1					
2014	8	7		4	3	
2015	9	7	2	3	2	3
2016	2	5	3	2		3
2017	2	2		1	1	
2018	1					1

List of active substances and suppliers (Article 95)



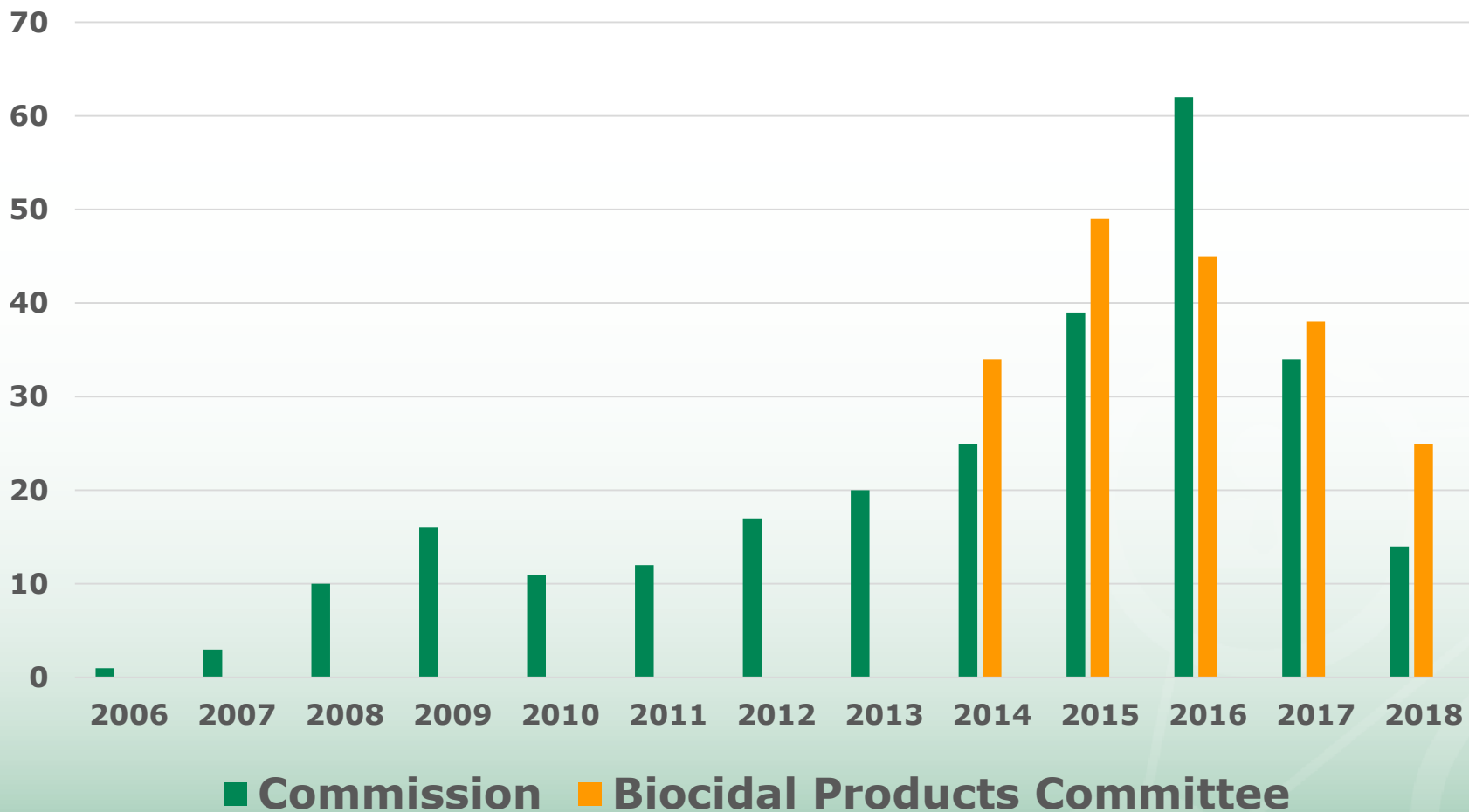
Technical equivalence applications



Review Programme: 39% finalised



Speeding up the Review Programme



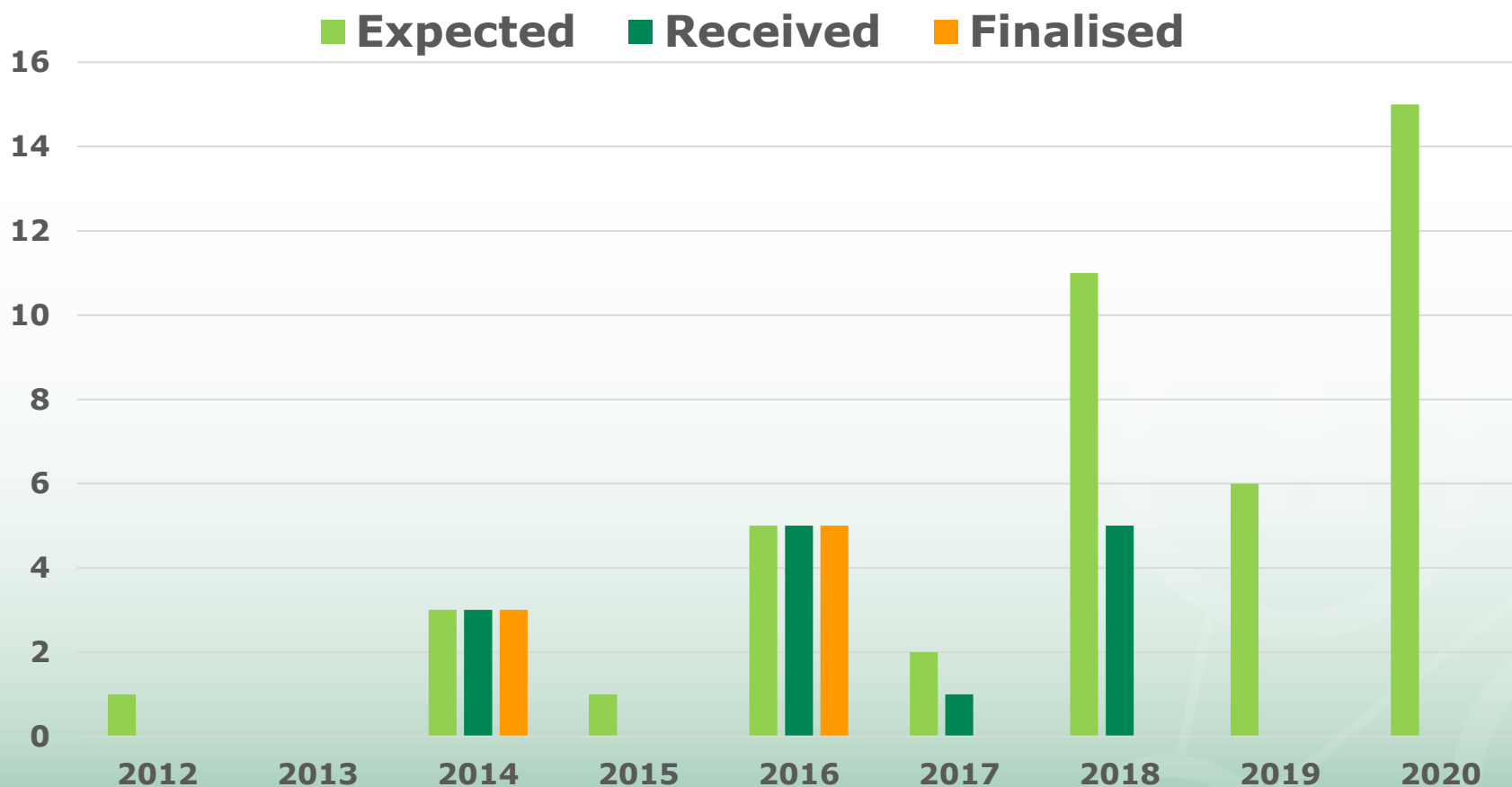
Approval of active substances

- **Approved: 255** active substance and product-type combinations (144 active substances, of which 6 micro-organisms)
- **Non-approval decisions** based on evaluation and peer review: **15** active substance and product-type combinations
- Of all active substances for which an opinion adopted by Biocidal Products Committee: **19%** meet the exclusion criteria and **12%** are candidates for substitution

Review Programme workload: 377

I: Dec 2015	8	14	16	18	19	21	Total
	2	0	0	15	6	1	24
II: Dec 2016	3	4	5				
	29	34	10				73
III: Dec 2018	1	2					
	18	55					73
IV: Dec 2019	6	13					
	35	20					55
V: Dec 2020	7	9	10				
	21	30	22				73
VI: Dec 2022	11	12	15	17	20	22	
	41	32	0	1	0	5	79

Renewal of active substance approvals: 5 active substance/product-type combinations not supported



Impact of endocrine disruptor criteria

- From now on, no Commission decision without an assessment against the new ED criteria (except for non-approval proposals)
- Commission approval decisions on hold for **11** active substances for **33** active substance and product-type combinations, due to ED assessment
- Two evaluations received by ECHA from Member State authorities since August 2017
- Co-formulants for product authorisation

Approval of *in situ* active substances

- Additions to the Review Programme:
55 active substance and product-type combinations for **28** active substances (Article 93 and 94; redefinitions)
- Majority for *in situ* generated active substances
- Do we make it too complex?

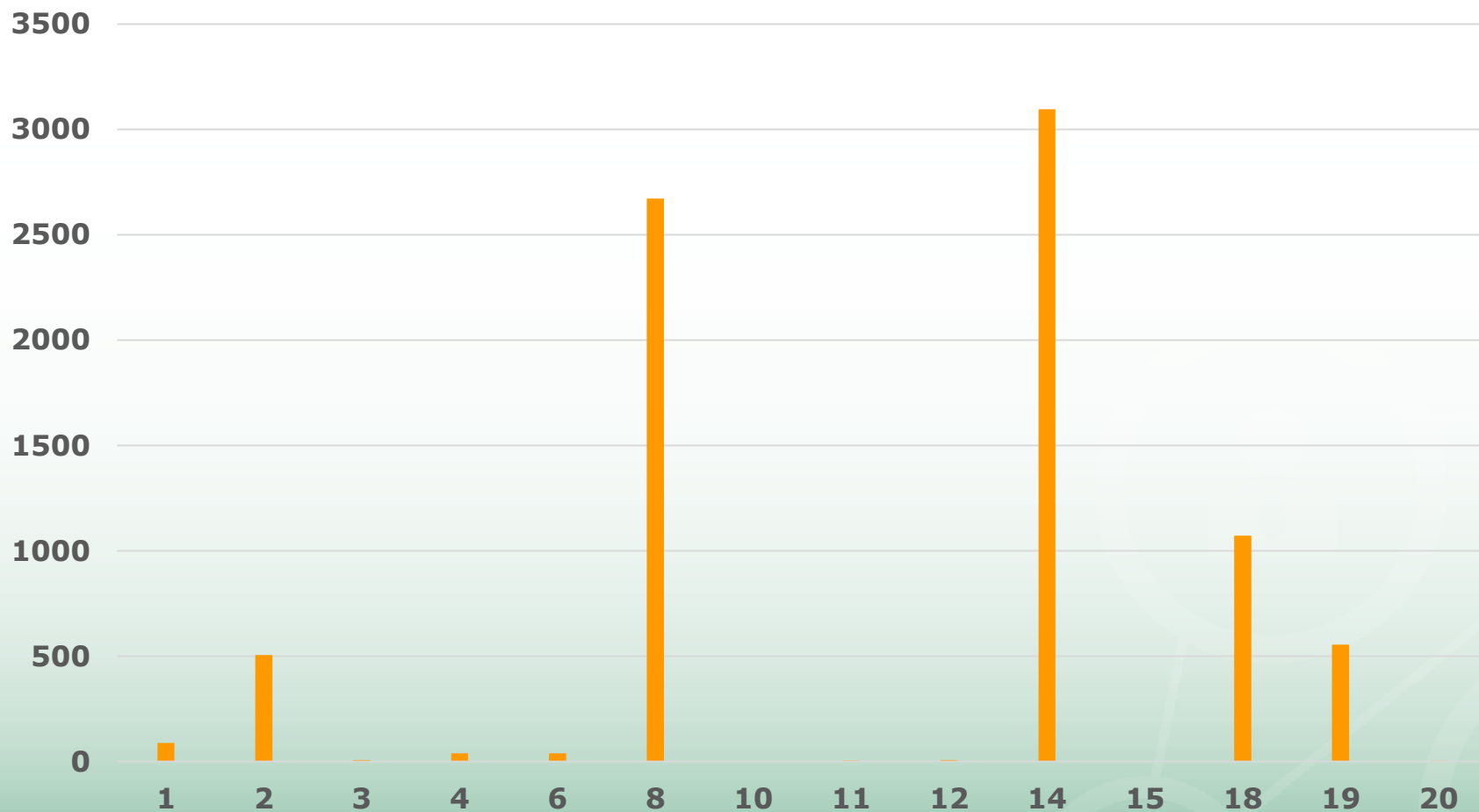
New actives substances

- **Biocidal Products Directive:** 3 active substances for **13** active substance and product-type combinations under evaluation by authorities
- **Biocidal Products Regulation:** limited number of applications
- almost no new chemistries

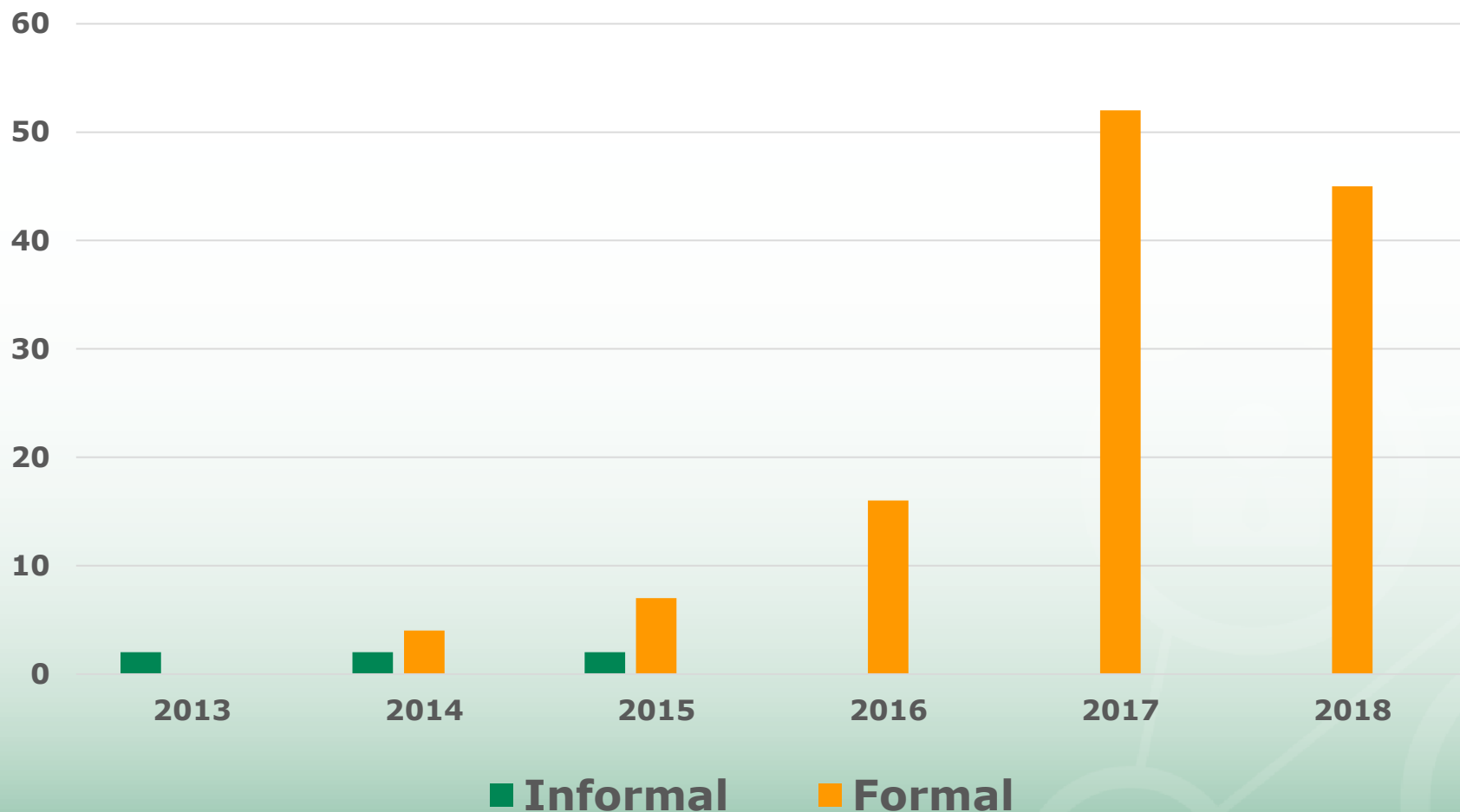
Product authorisation

- **National** authorisations: granted for **7 900** biocidal products (families)
- **Union** authorisations: granted for **2** biocidal product families and **2** for the same biocidal product family
- **Simplified** authorisation: **82** biocidal product authorisations granted
- Renewals for rodenticides and wood preservatives
- National regimes for product authorisation

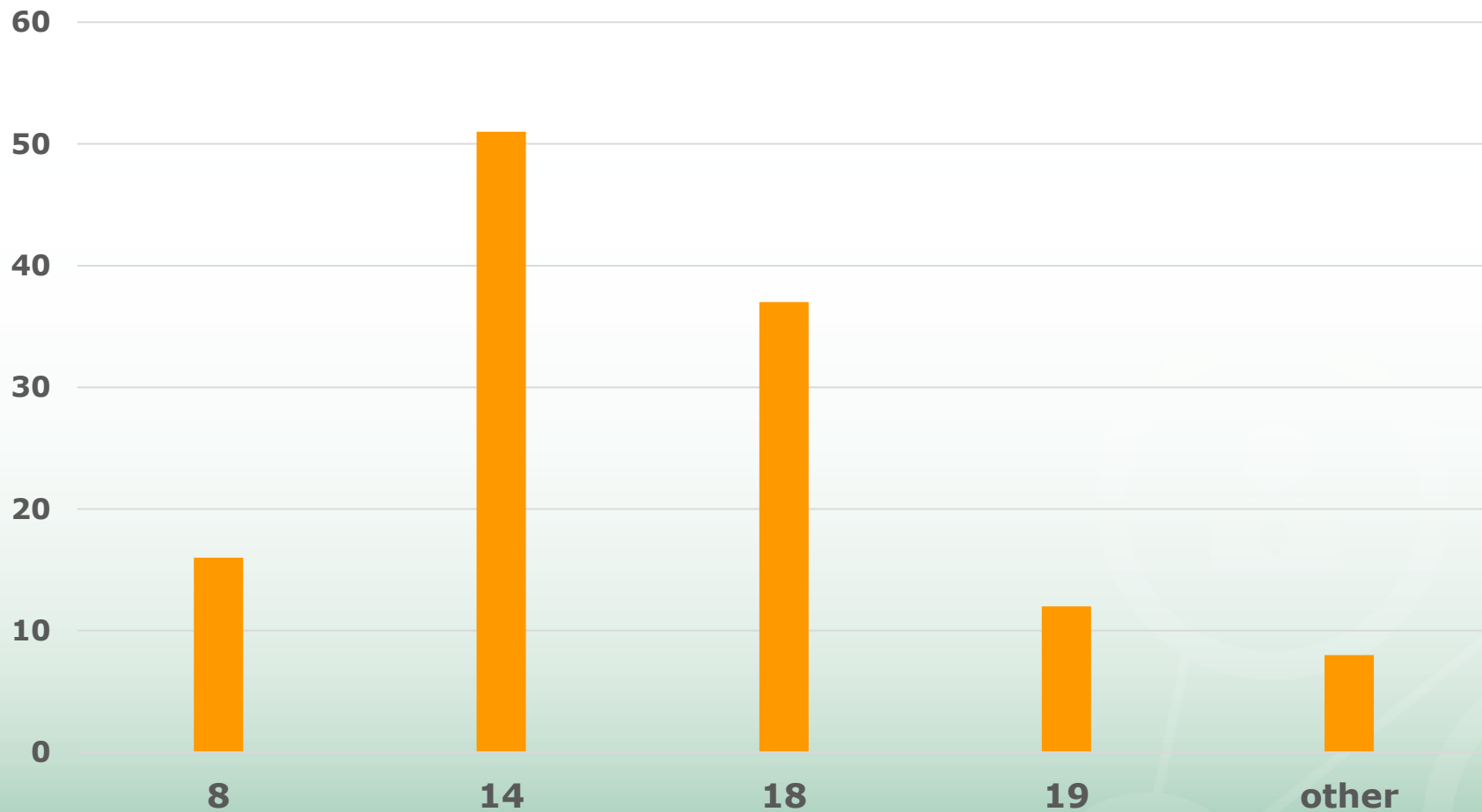
National authorisations by product-type



Coordination Group: referrals



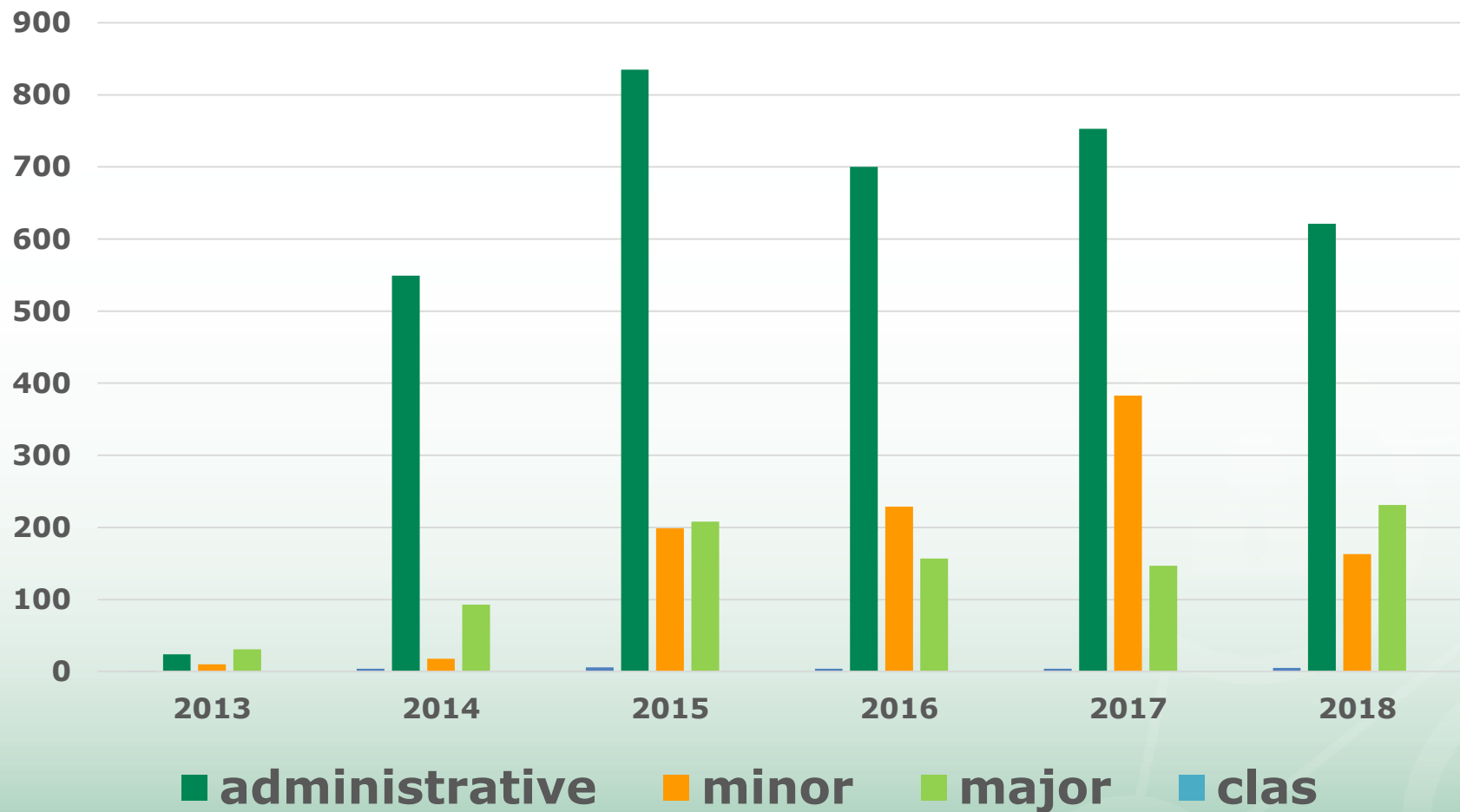
Referrals by product-type



Referrals: success

Total	124
Consensus: product can be authorised	112
Consensus: product cannot be authorised	0
Referral withdrawn	2
Disagreement referred to Commission	7
Disagreement referred by Commission to BPC	2
Under discussion	3

National authorisation: changes



Union authorisation

	Status of applications submitted in:				
	2015	2016	2017	2018	Total
	12	18	43	7	80
ECHA acceptance					
Validation			12	2	14
Evaluation	4	15	31	5	55
Peer review	3	3			6
BPC opinion	3				3
COM decision	2				2

Same biocidal products for Union authorisation

	Status of application submitted in:				
	2015	2016	2017	2018	total
		2	7	47	40
ECHA acceptance					
Validation			3	10	13
Evaluation	0	7	44	30	81
ECHA opinion					
COM decision	2				2

Access to documents

2015	10 requests: <ul style="list-style-type: none">• 7 active substance related• 2 product related• 1 for meeting documents
2016	9 requests: <ul style="list-style-type: none">• 7 active substance related• 2 product related
2017	18 requests: <ul style="list-style-type: none">• 11 active substance related• 4 product related• 2 for meeting documents• 1 for internal procedures (Article 95 list)
2018	50 requests: <ul style="list-style-type: none">• 4 active substance related• 46 product related: 35 documents available and disclosed, 33 product assessment reports and 2 SPCs

Conclusions

- Review Programme did speed up but we have to keep the momentum
- Union authorisation: prevent formation backlog
- MSCAs need to focus on the Review Programme → this will free up resources used in national regimes
- Need to reduce complexity → in-situ, ED and SPC

Thank you

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