PROGRESS AT A GLANCE: PEER REVIEW OUTPUTS (LAST 5 YEARS)

- Number of published outputs
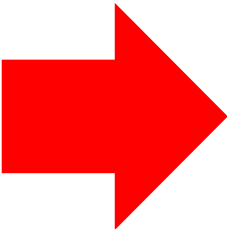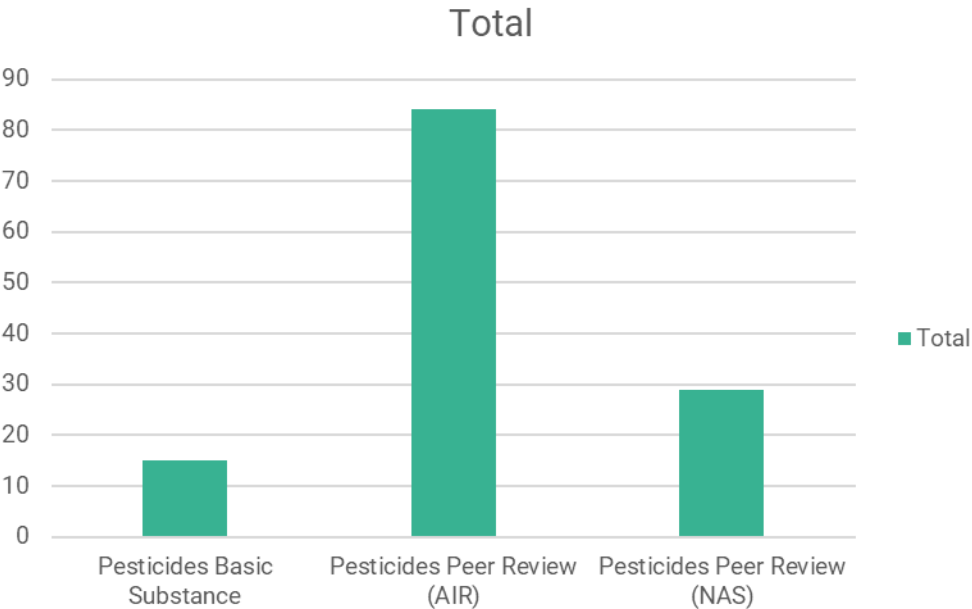
Total

Category	Number of Outputs
🟩 Pesticides Basic Substance	15
🟦 Peer Review (AIR)	84
🟧 Peer Review (NAS)	29
Total	**128**

PEER REVIEW GENERAL ANALYSIS -1
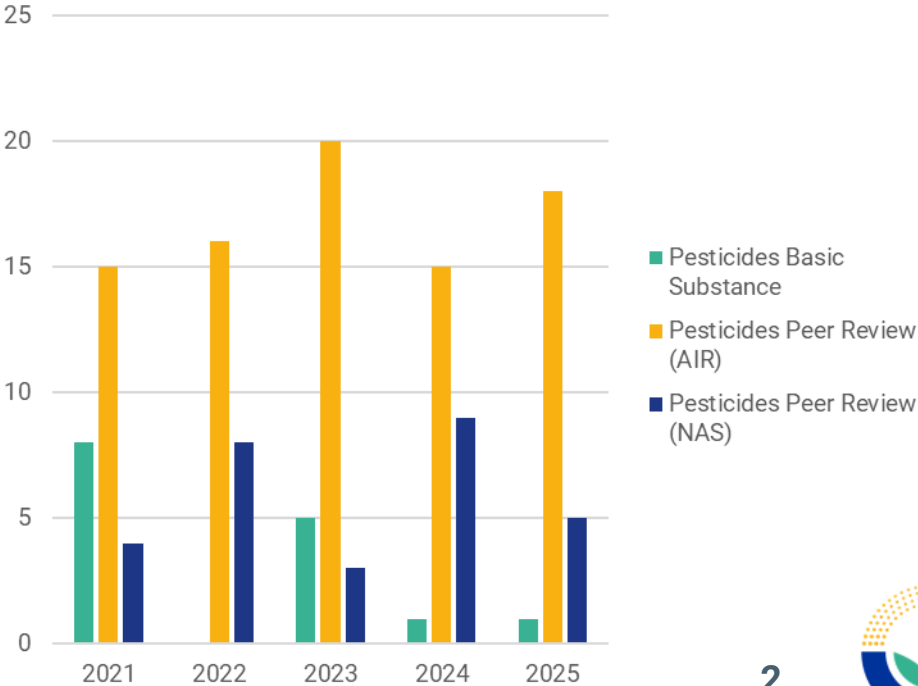
Year	Conclusions Chemicals	BIOCONTROL			Total	Total incl. Ad-hoc mandates
		Conclusions Microorganisms	Basic Technical reports	Conclusions "natural substances"		
2020	13	16	9	5	43	
2021	11	5	8	1	25	
2022	14	4	2	4	24	
2023	16	0	4	0	20	
2024	22	4	1	5	32	
TOTAL	76	29	24	15	**144**	**220**
Average /year	15	6	5	3	**29**	**44**
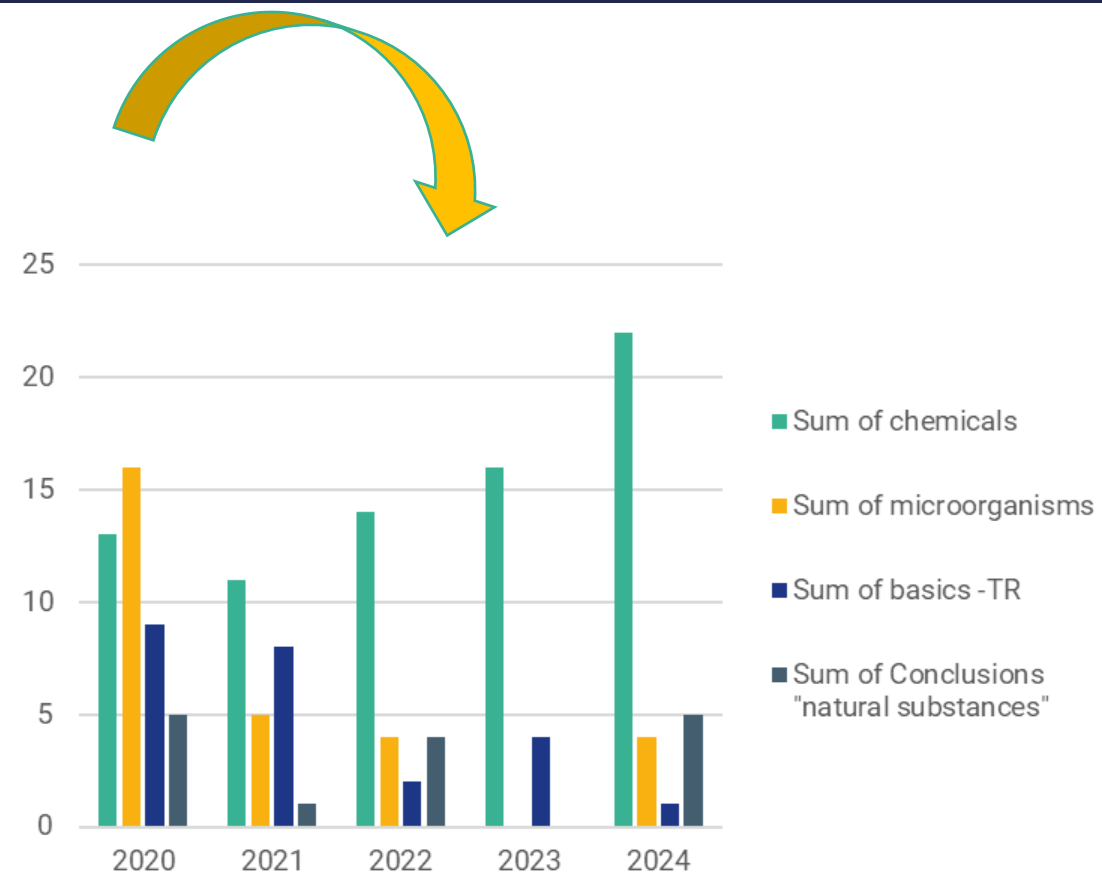
PEER REVIEW GENERAL ANALYSIS -2

PROCESS	QUESTION NUMBERS IN PEER REVIEW
Pesticides Peer Review (AIR)	70
Pesticides Peer Review (NAS)	26
Total	**96**

Process	Average of Days Spent in Clock stop*
Pesticides Peer Review (AIR)	**637**
Pesticides Peer Review (NAS)	**134**

Average of last 5 years
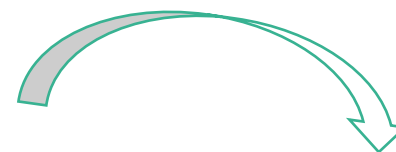
Key Insight: Microorganisms in peer review

4

PEER REVIEW CONSULTATIONS : CURRENT STATUS & NEXT STEPS

Current approach:

- Launching 2 peer review consultations per month.

Current Queue:

- **32** DARs/RARs are under revision by the RMS.

- Around 7 DARs/RARs are likely to be ready from the intake perspective (CC/ACC) in the incoming months.
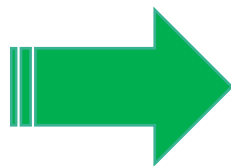
Key Observation:

- There is a growing queue of active substances ready for scientific check and peer review consultations.

Active Substances in the intake phase
(Status on 31 October 2025)

Number of Active Substance

Total

FEEDBACK FROM FRONT-DESK & WORKFORCE PLANNING (FDP)

- Additional DARs/RARs are under RMS revision, indicating a need for efficient processing to avoid bottlenecks.

- Example of DARs/RARs currently in the pipeline:

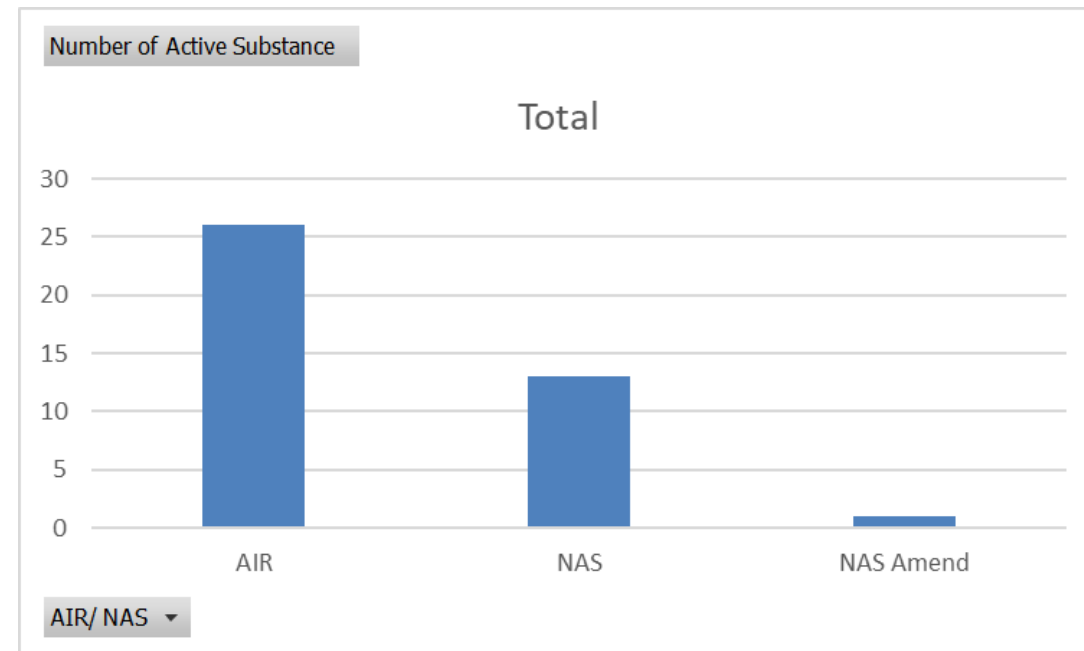| Reg	Active Substance	Question number	AIR/ NAS	RMS
POST TR	Hexythiazox	EFSA-Q-2022-00081	AIR IV	FI
PRE TR	Florylpicoxamid	EFSA-Q-2021-00334	NAS	DK
POST TR	Pyroxsulam	EFSA-Q-2023-00209	AIR	DK
PRE TR	Chlormequat Chloride	EFSA-Q-2017-00302	AIR IV	AT
POST TR	Antoferine	EFSA-Q-2023-00584	NAS	MT
PRE TR	lambda-cyhalothrin	EFSA-Q-2020-00359	AIR V	SE
POST TR	Black Pepper Oleoresin	EFSA-Q-2023-00057	NAS	AT
POST TR	Dimpropyrizad	EFSA-Q-2022-00253 EFSA-Q-2022-00185	NAS	AT
POST TR	Terbuthylazine	EFSA-Q-2022-00488	AIR	ES
PRE TR	Ametoctradin	EFSA-Q-2020-00619	AIR V	DE
PRE TR	Sulfuryl Fluoride	EFSA-Q-2017-00822	AIR IV	AT
PRE TR	Polypeptide, ASFBIOF01-02	EFSA-Q-2021-00491	NAS	NL

KEY PRIORITIES IN PEER REVIEW PLANNING

What's ahead:

- Accelerate peer review and increase the throughput of active substances without delays.

Planning:

- Launch of **3 PCs,** when feasible (starting from **January 2026**)
- Priority on **NAS** (ongoing approach)
- **Increasing number of biopesticides:** ~35% of pending applications are for **microbial substances**
- Support **innovative NAS**: peptides, RNAi, bacteriophages are ongoing
- Ongoing applications for approval as basic substances

THE IMPORTANCE OF (GOOD QUALITY) DOSSIERS

- The **dossier** is the starting point of any regulatory assessment
  → its quality and completeness: a direct function of the **quality (and speed)** of the risk assessment

- Applicants' dossier often lack the necessary quality:
  → delays in the (RMS) assessment/peer review (need of "clock stop" events)
  → gaps/issues not finalized in the EFSA conclusion
  → impact on the decision-making process (need of follow up mandates)

CHALLENGES & POSSIBLE SOLUTIONS

- **Challenges** for applicants (and risk assessors):
  - Increasing complexity of the risk assessment (e.g. new emerging endpoints, nano, biodiversity, one-health)
  - Availability of suitable methodologies
  - Regulatory VS science evolution (new assays VS regulatory tests; waiving of data requirements)

- Possible solutions:
  - More open dialogue with applicants: EFSA TF to support applicants
    - Applicants source of knowledge and expertise
    - meaningful pre-submission activities
    - Applicants' hearing

  - Simplification: "re-engineering" of the steps of the peer review process (?)

MAPPING OF DATA REQUIREMENTS VS DATA GAPS

- An analysis of 20 EFSA conclusions (**chemicals** a.s., NAS and renewals) covering January 2024 - June 2025 was conducted by EFSA.

- Mapping of the requests of additional data set <u>during the peer review process</u>:
    - whether/which are the most recurring ones
    - the set requests of additional data:
        - had been addressed?
        - data gaps still retained in the EFSA conclusion?
        - "brand new" gaps identified in the EFSA conclusion?

WHY THIS MAPPING EXERCISE

o Clustering the most recurring data gaps can inform on which specific areas "quality deficits" are identified in the dossiers:
  o possibility to plan targeted support activities (focused pre-submission meeting?);
  o need of new/better guidance documents?
  o reconsideration of relevance of data requirements?

o Reflections for risk assessors (MSs/EFSA) on how and why setting requests for additional information (*must have* VS *nice to have*)

o Overall goal: enabling to deliver a **timely and fit for purpose risk assessment**

GENERAL OVERVIEW

Substances

Substance	Data request present in the ADR	Data Gap
Bensulfuron-me...	152	37
Halosulfuron-m...	138	55
Paraffin oil (CA...	116	20
Triclopyr	114	35
Formetanate	111	20
Amidosulfuron	107	22
Clomazone	97	33

Data request by section

- Environment... 15.3%
- Phys-chem 18.5%
- Mamtox 26.5%
- Ecotoxicology 28.0%
- Residues 11.7%

Addressed by section

- Residues 65.7%
- Mamtox 85.8%
- Ecotoxicology 77.8%
- Phys-chem 67.0%
- Environmental ... 66.3%

Data request present in the ADR and Data Gap

Chapter (from the evaluation table):
- Methods of analysis
- Bees and non-target a...
- Comments on confide...
- Aquatic organisms
- Fate and behaviour in ...
- Toxicological data on ...
- Route and rate of degr...
- Residue trials in plants...
- PEC in surface water a...
- Physical and chemical ...
- Residue definition
- Terrestrial non-target ...
- Physical and chemical ...

|	
Substances	20
Chapters	53
Data request	1723
% of total DR	100%
Data gap	435
% of total DG	100%
Addressed	75%

Chapter (from the evaluation table)	Data request	Data gap	Addressed
Methods of analysis	154	55	64%
Bees and non-target arthropods	89	38	57%
Comments on confidential Vol 4 (including batches and impurities)	101	33	67%
Aquatic organisms	195	31	84%
Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues	60	28	53%
Toxicological data on metabolites	67	27	60%
Route and rate of degradation in soil	78	26	67%
Residue trials in plants and identification of critical GAP	49	21	57%
PEC in surface water and ground water	44	14	68%
Physical and chemical properties of the active substance	26	13	50%
Residue definition	22	13	41%
Terrestrial non-target higher plants	27	11	59%
Physical and chemical properties of the plant protection product	22	10	55%
Total	**1723**	**435**	**75%**

TYPES OF DATA GAP PER CHAPTER

Chapter (from the evaluation table) ▲	Data request	Data gap ▼	Addressed	Data gap Section 9	% Data gap Section 9	Data gap Section 10	% Data gap Section 10
Methods of analysis	154	55	64%	2	4%	53	96%
Bees and non-target arthropods	89	38	57%	10	26%	28	74%
Comments on confidential Vol 4 (including batches and impurities)	101	33	67%	10	30%	23	70%
Aquatic organisms	195	31	84%	23	74%	8	26%
Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues	60	28	53%	19	68%	9	32%
Toxicological data on metabolites	67	27	60%	20	74%	7	26%
Route and rate of degradation in soil	78	26	67%	9	35%	17	65%
Residue trials in plants and identification of critical GAP	49	21	57%	9	43%	12	57%
PEC in surface water and ground water	44	14	68%	10	71%	4	29%
Physical and chemical properties of the active substance	26	13	50%	0	0%	13	100%
Residue definition	22	13	41%	11	85%	2	15%
Terrestrial non-target higher plants	27	11	59%	11	100%	0	0%
Physical and chemical properties of the plant protection product	22	10	55%	0	0%	10	100%
Metabolism, distribution and expression of residues in plants	37	9	76%	8	89%	1	11%
PEC in soil	24	9	63%	6	67%	3	33%
Acute toxicity	24	8	67%	1	13%	7	88%
Earthworms and other non-target soil macro- and mesofauna	33	8	76%	3	38%	5	63%
Other comments incl. available monitoring data/ Ecotoxicology	50	8	84%	2	25%	6	75%
Birds and other terrestrial vertebrates	69	7	90%	1	14%	6	86%
Storage stability of residues	22	7	68%	4	57%	3	43%
Adsorption, desorption and mobility in soil	30	6	80%	2	33%	4	67%
Identity	35	6	83%	0	0%	6	100%
Other comments incl. available monitoring data/Environmental Fate and Behaviour	21	5	76%	0	0%	5	100%
Total	**1723**	**435**	**75%**	**181**	**42%**	**254**	**58%**

THE 5 MOST RECURRING CHAPTERS
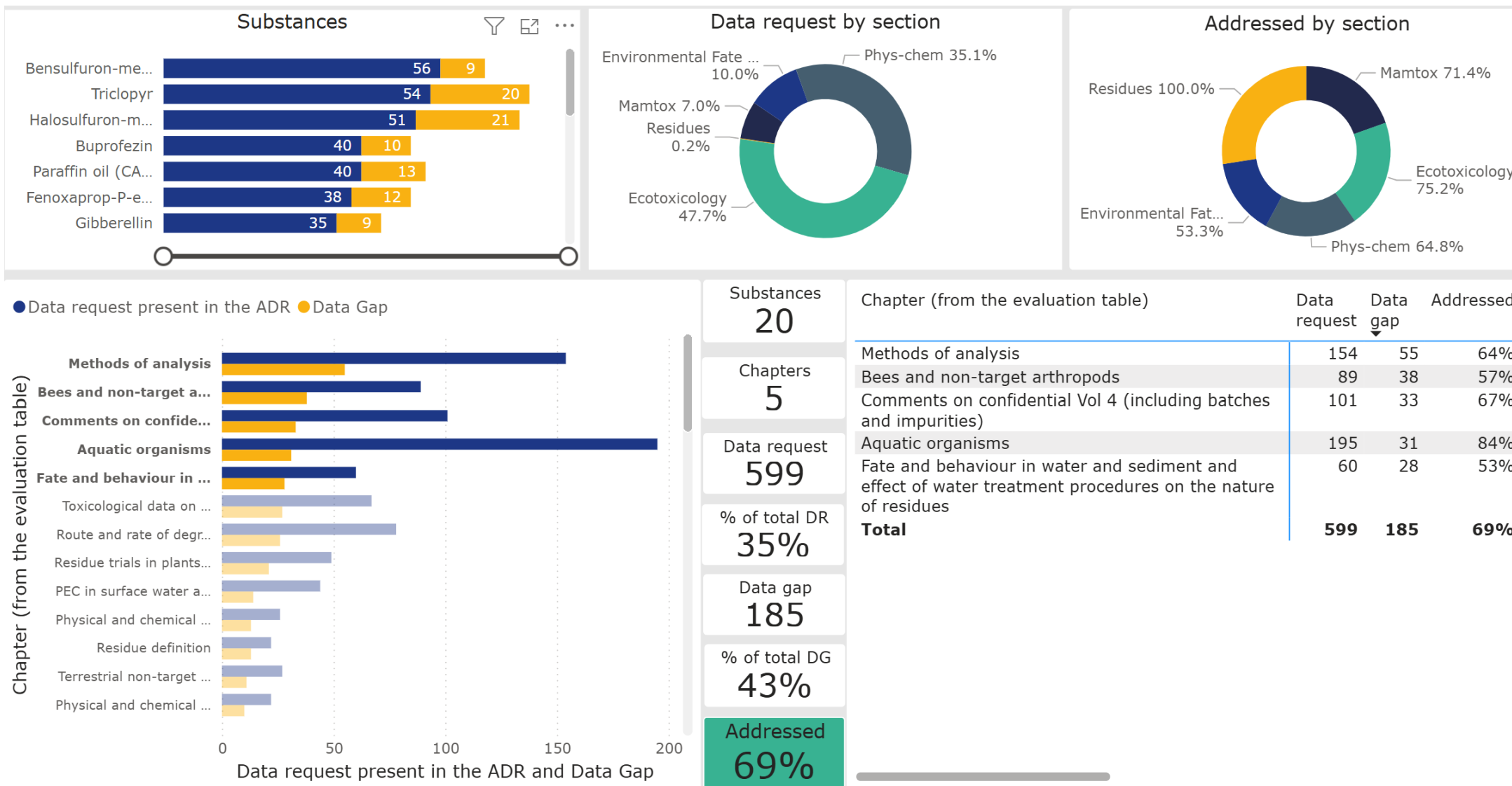
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