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ANIMAL HEALTH AND WELLBEING

Brussels – 22 February 2017

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SAFE FOOD

Renewal of Feed flavouring additives Chemically Defined Groups (CDG)

23.01.2024

Introduction

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Objectives of the meeting

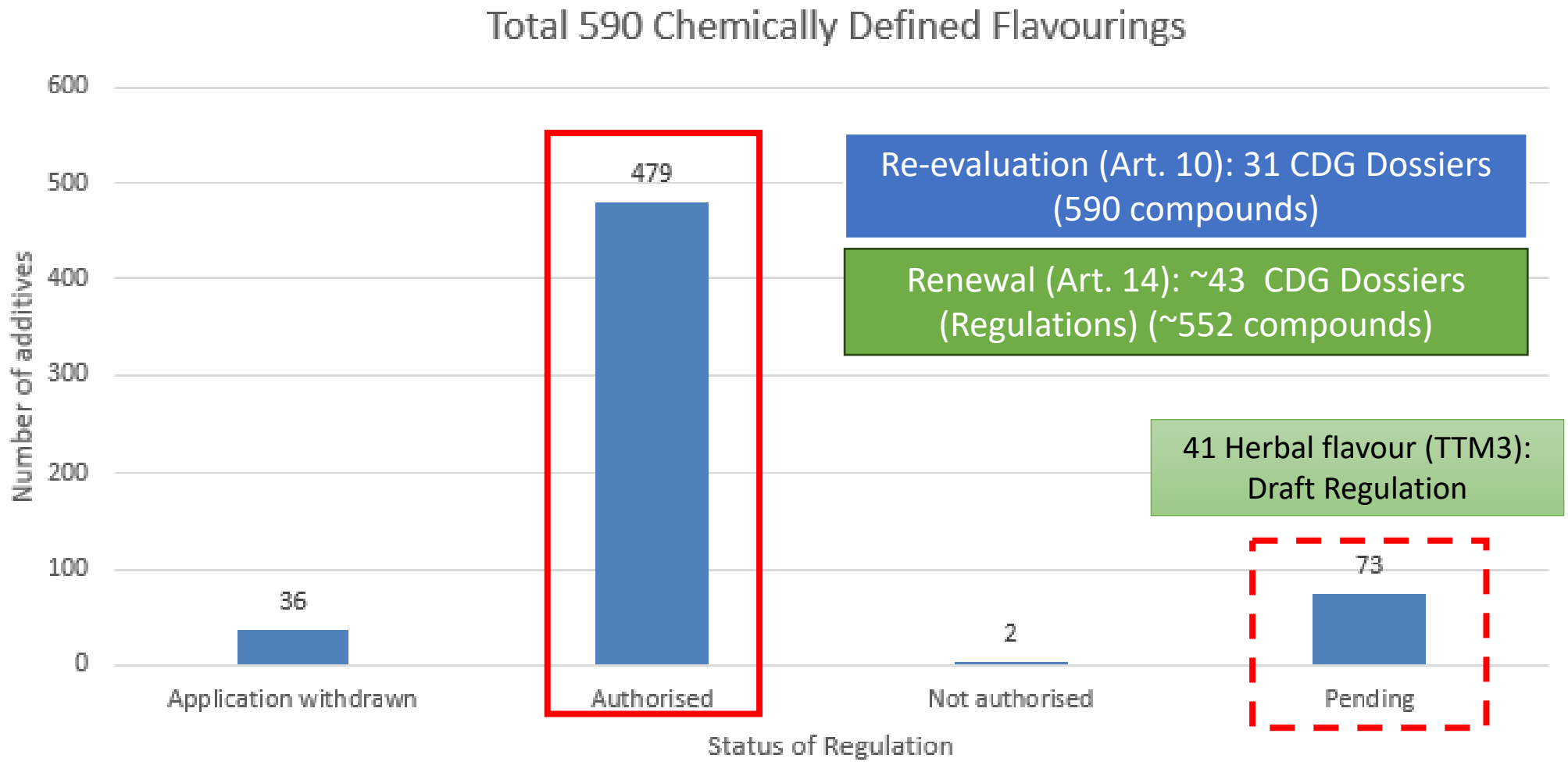
Present and discuss the following elements:

- ✓ Project Overview and Initial Situation
- ✓ Proposal for Renewal Dossiers Submission
- ✓ Initial Insights from the Pilot Dossier (CDG31)

Establish a common ground on crucial project aspects to facilitate the implementation of a streamlined and practical data generation and submission system.

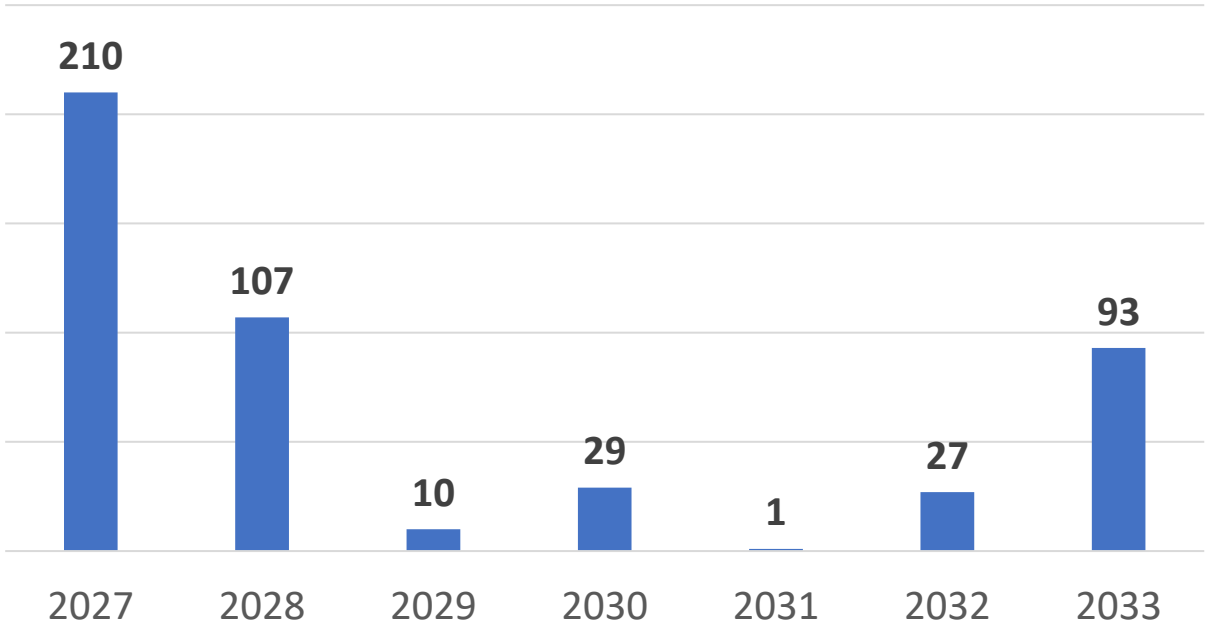
Ensuring the renewal of a sufficient number of flavouring compounds to maintain the current EU feed business system

Project overview



Project overview

Expiry date of 479 authorised CDGs



Project management:

- More than 10 EU based companies involved in the project (applicants)
- Project coordination through FEFANA and consultant
- Harmonised procedure for all submissions
- Single point of contact for all dossiers

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CDG renewal applications

Contents

1. Project requirements

EFSA

- Consider new EFSA guidances
- Fill data gaps 2010 dossiers
- Manage safety evaluation
- Generate sufficient data

Dossier

- Letter of access for re-authorisation dossiers
- Definition of minimum requirements
- Batches (> 1 year old)
- ELS covering 10 years

Applicants

- Achieve scientifically robust dossier
- At a realisable price
- With feasible work load

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1. Project requirements

- **Dossier submission:**
  - Re-authorisation: by **Chemical Defined Group (CDGs)**
  - Renewals: by **Authorising Regulation**

- **General concept:**
  - Renewal = Nothing has changed since the first authorisation
  - Requirements according to existing Authorising Regulations
    - Target animal species & feed levels
    - Conditions of use
    - Manufacturing process
    - Labelling requirements
    - Other provisions

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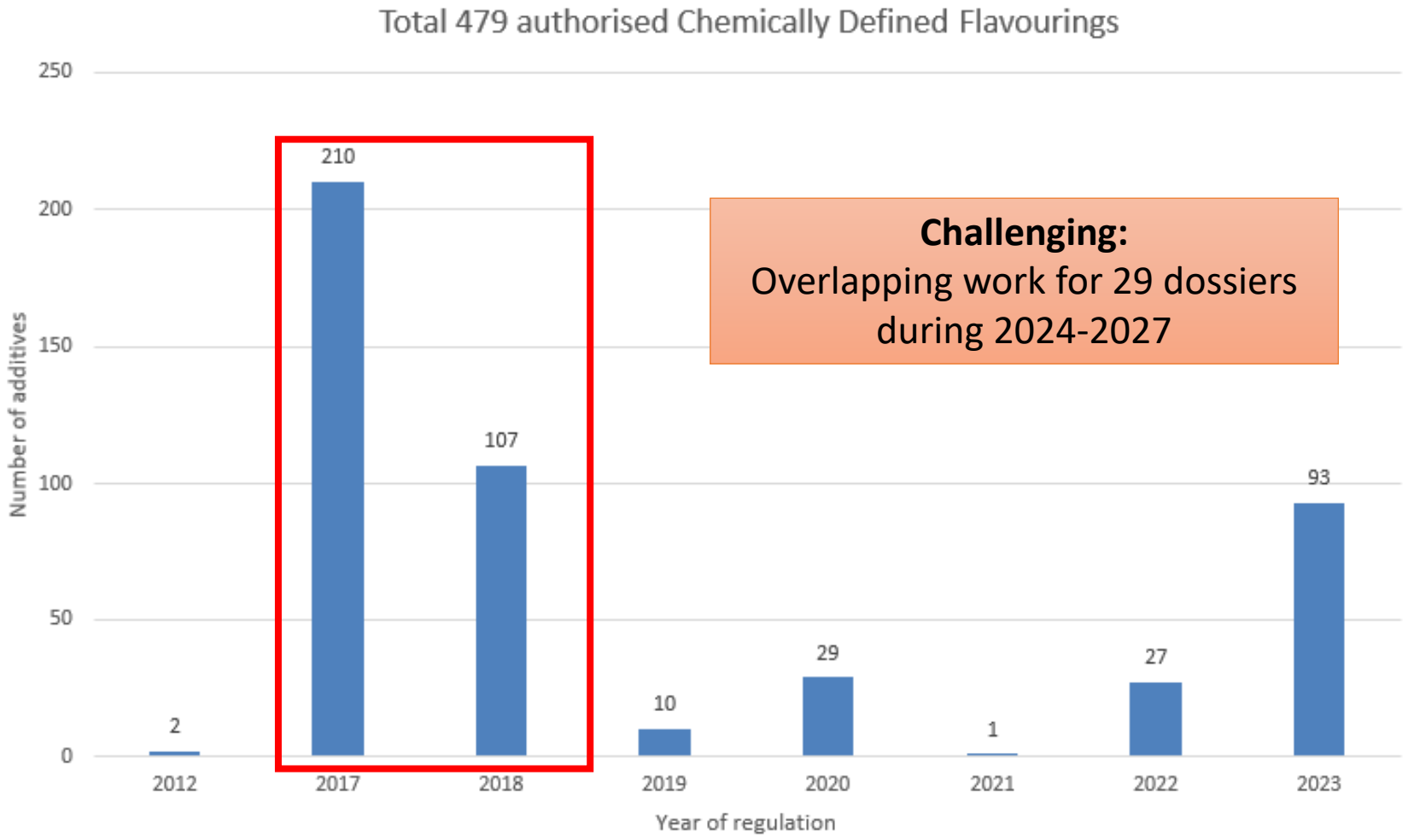
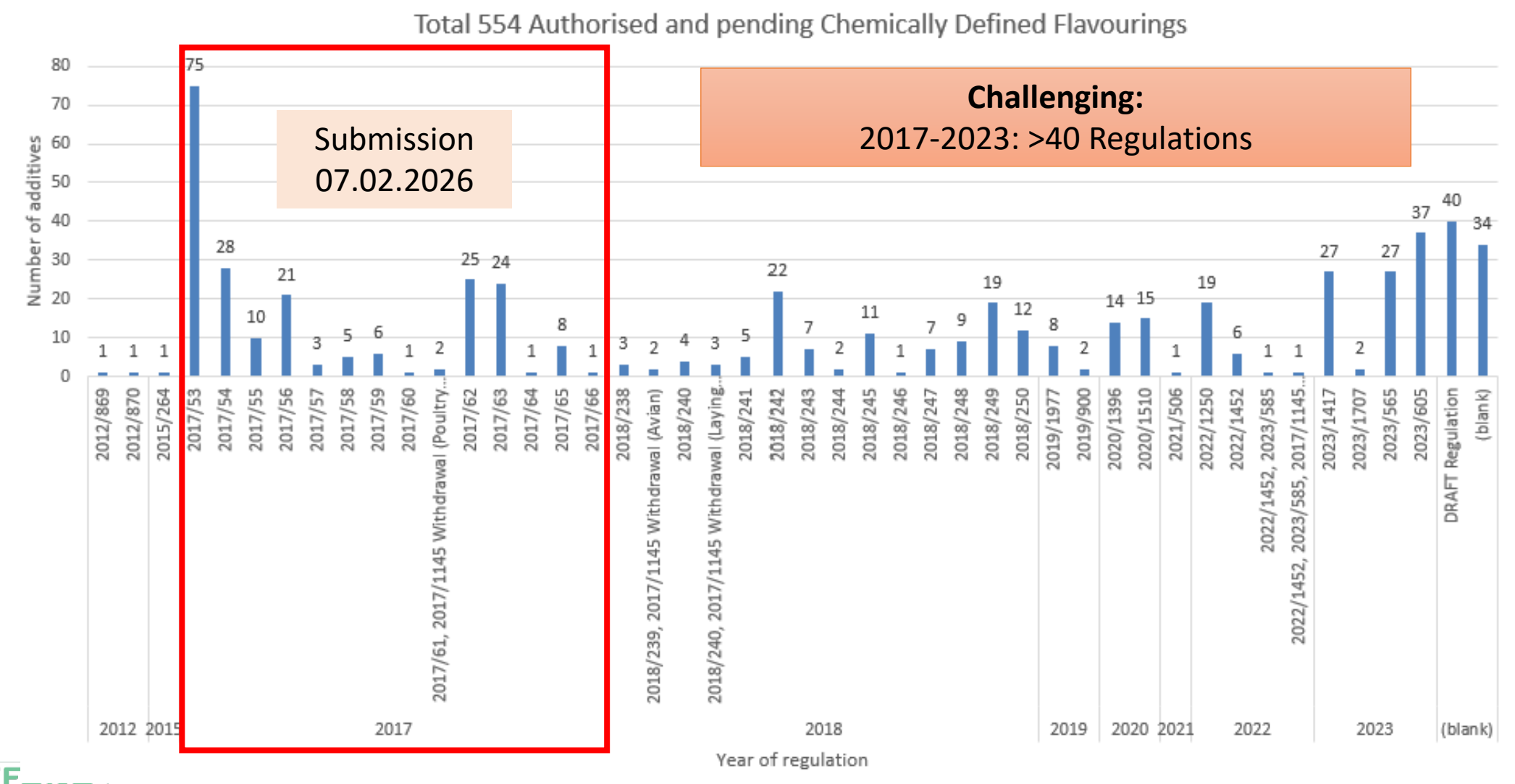
2. Challenges and proposed solutions



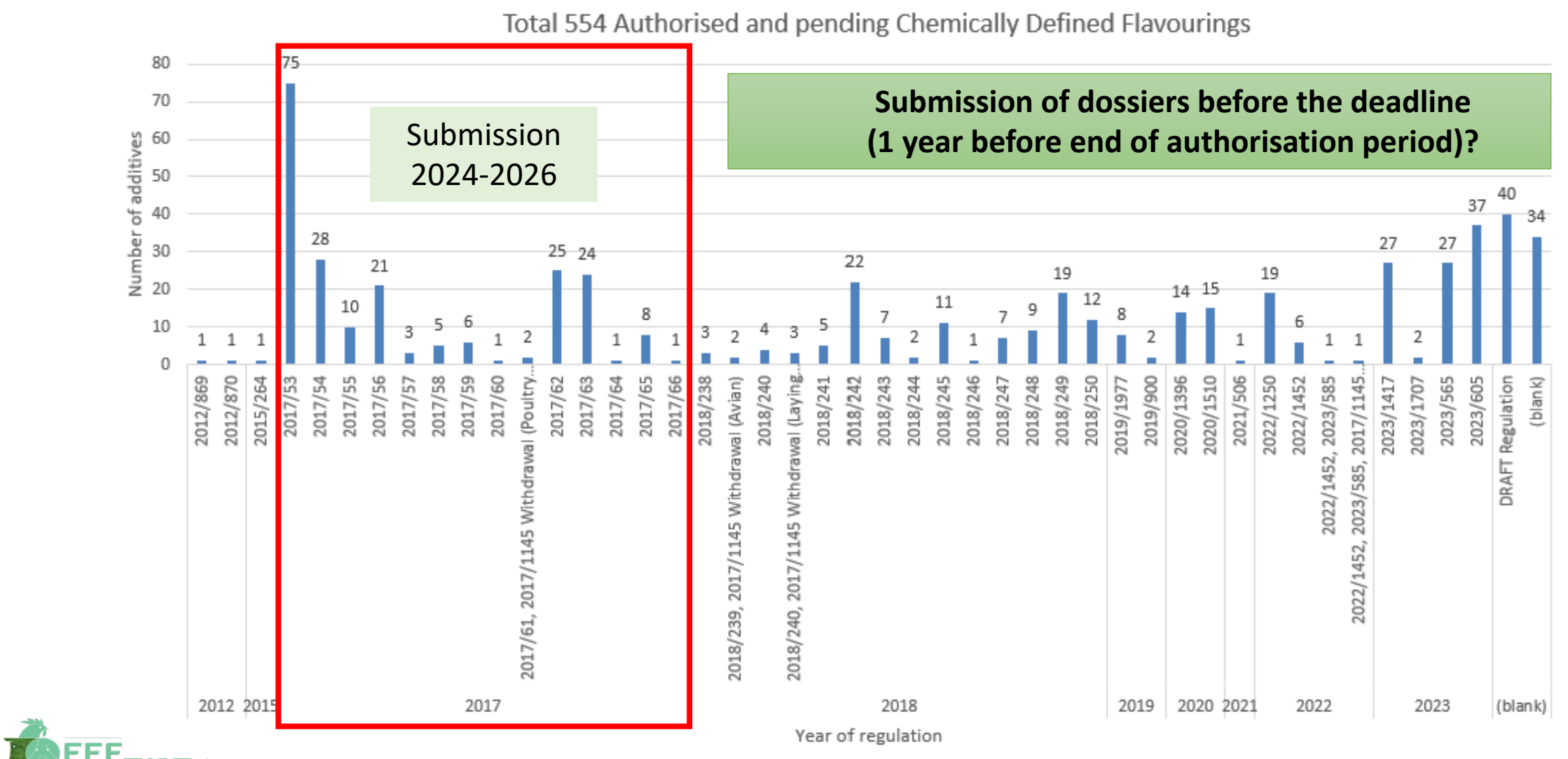
Challenging:
Overlapping work for 29 dossiers during 2024-2027

Dossiers to be submitted 1 year before end of authorisation period

2. Challenges and proposed solutions



2. Challenges and proposed solutions



2. Challenges and proposed solutions

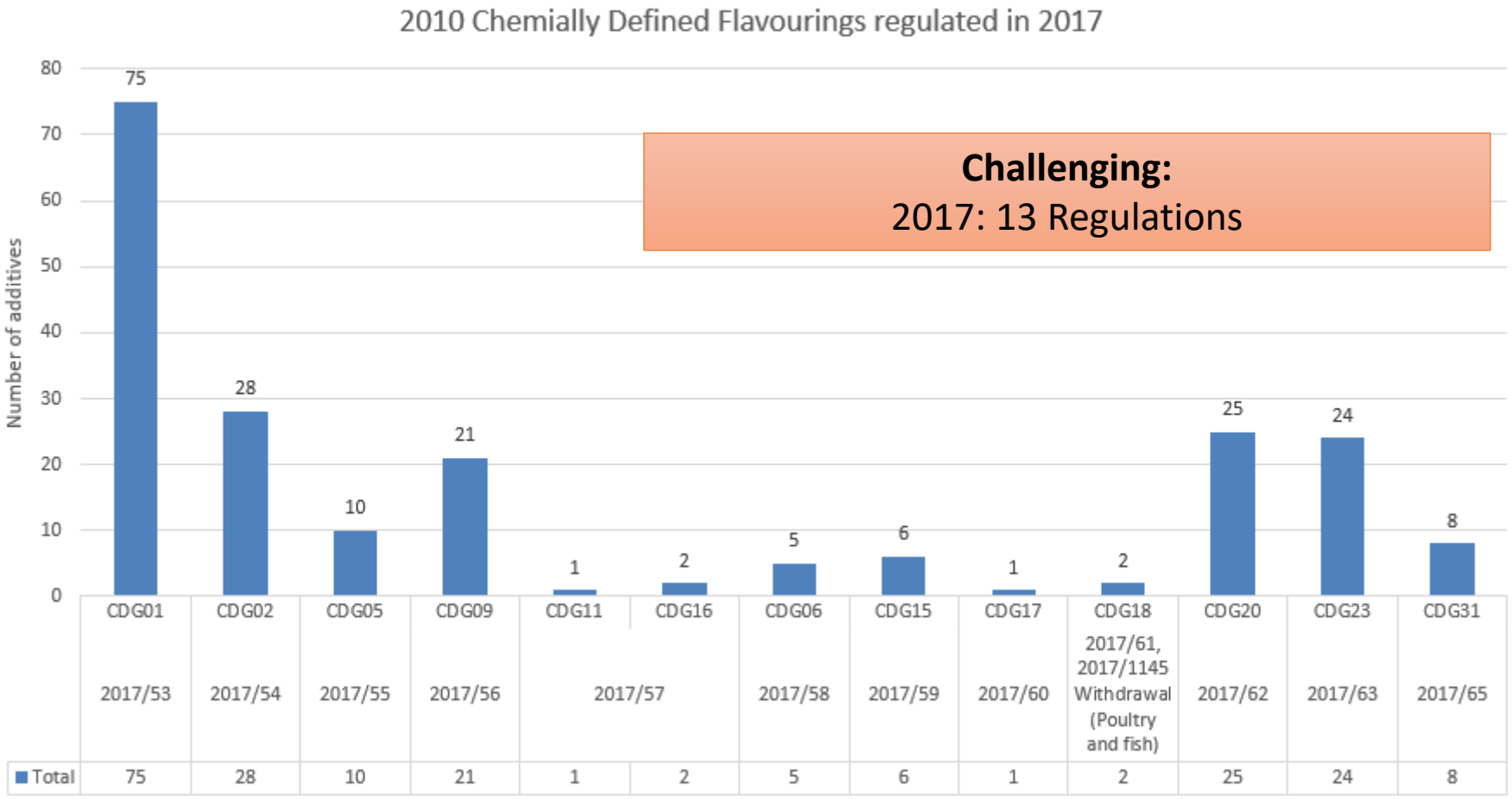
- **Time schedule: *Pilot dossier CDG31 (EC Regulation 2017/65)***
  - Dossier is already under preparation with the goal to gain experience.
  - Batches should be recent (not older than one year from the date of submission of the application); but we are not able to produce “future batches”.

Will early submissions have an impact on the periods of current authorisations?

Project start	02 2024	02 2025
Batch date	2024-2025	2025-2026
Deadline submission	Before 02 2026	07.02.2026
Re-evaluation: End of authorisation period	07.02.2027	07.02.2027
Renewal: end of authorisation period	?	07.02.2037

2. Challenges and proposed solutions

- **Submission of renewal dossiers**



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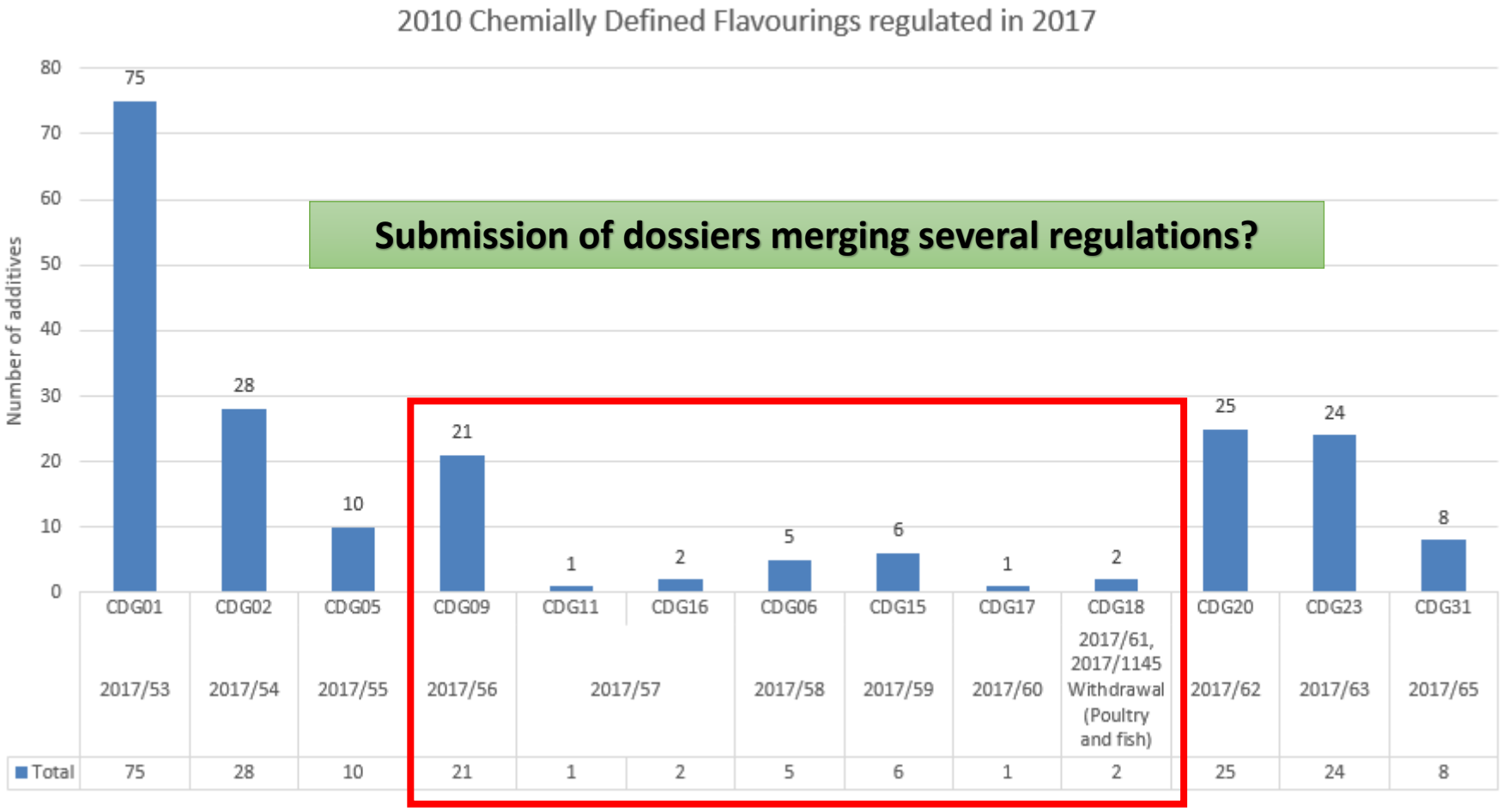
- **Submission of renewal dossiers**



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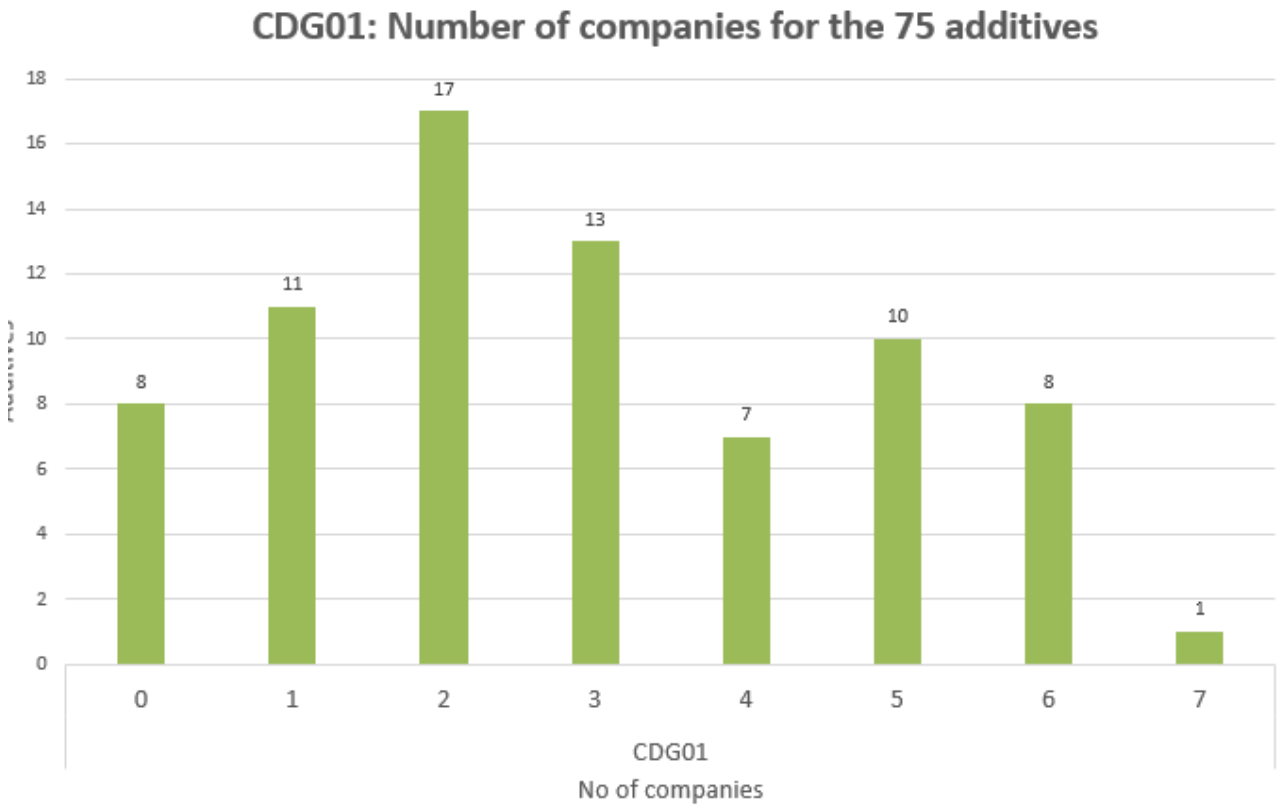


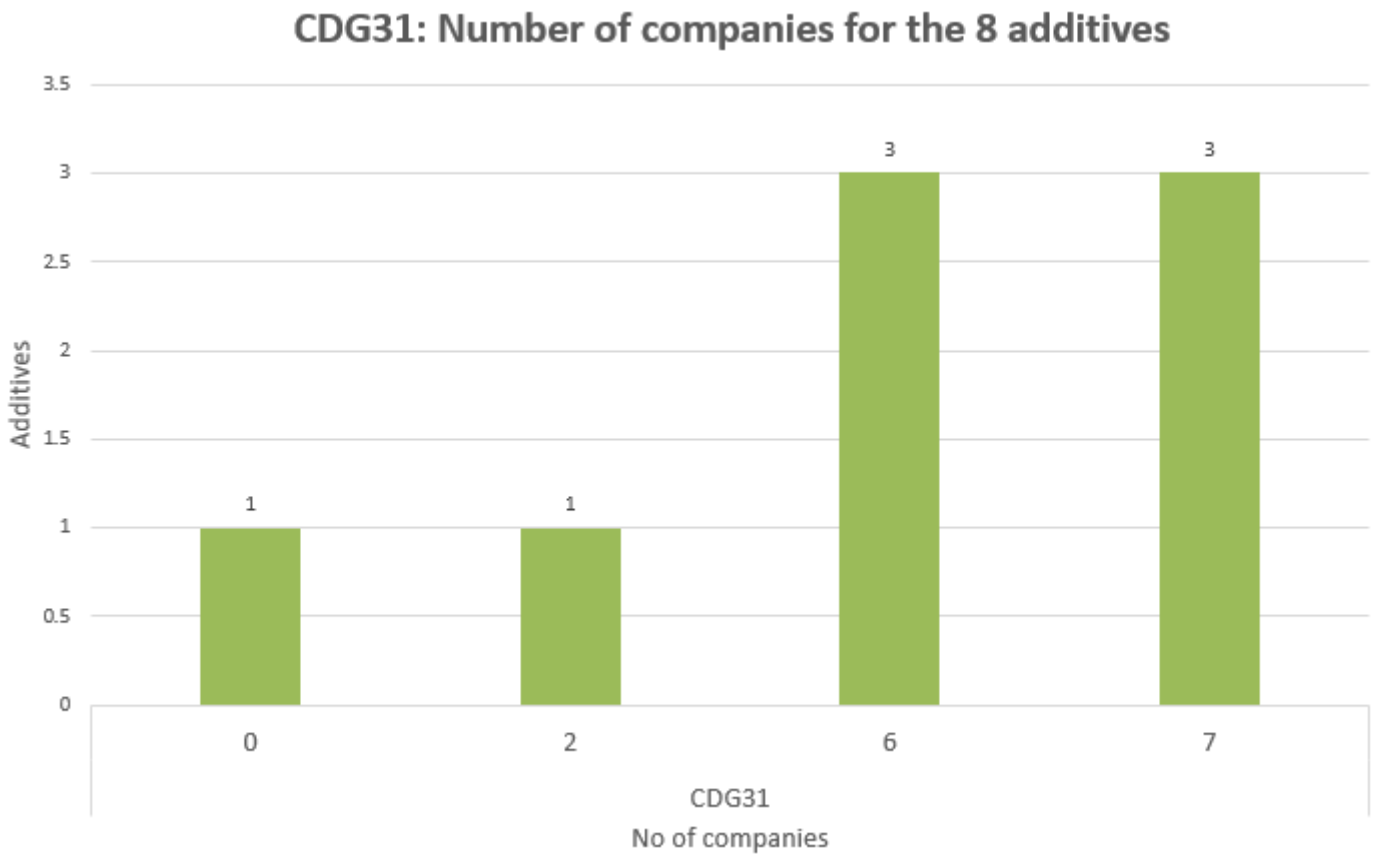
Challenging:
Number of additives and companies

✓ Up to **75** additives in a dossier (CDG01)

✓ Up to **10** companies per additive (CDG22)

2. Challenges and proposed solutions

- **Data required for each additive**



Challenging:
Number of additives and companies

Data sets for 8 additives in CDG31:

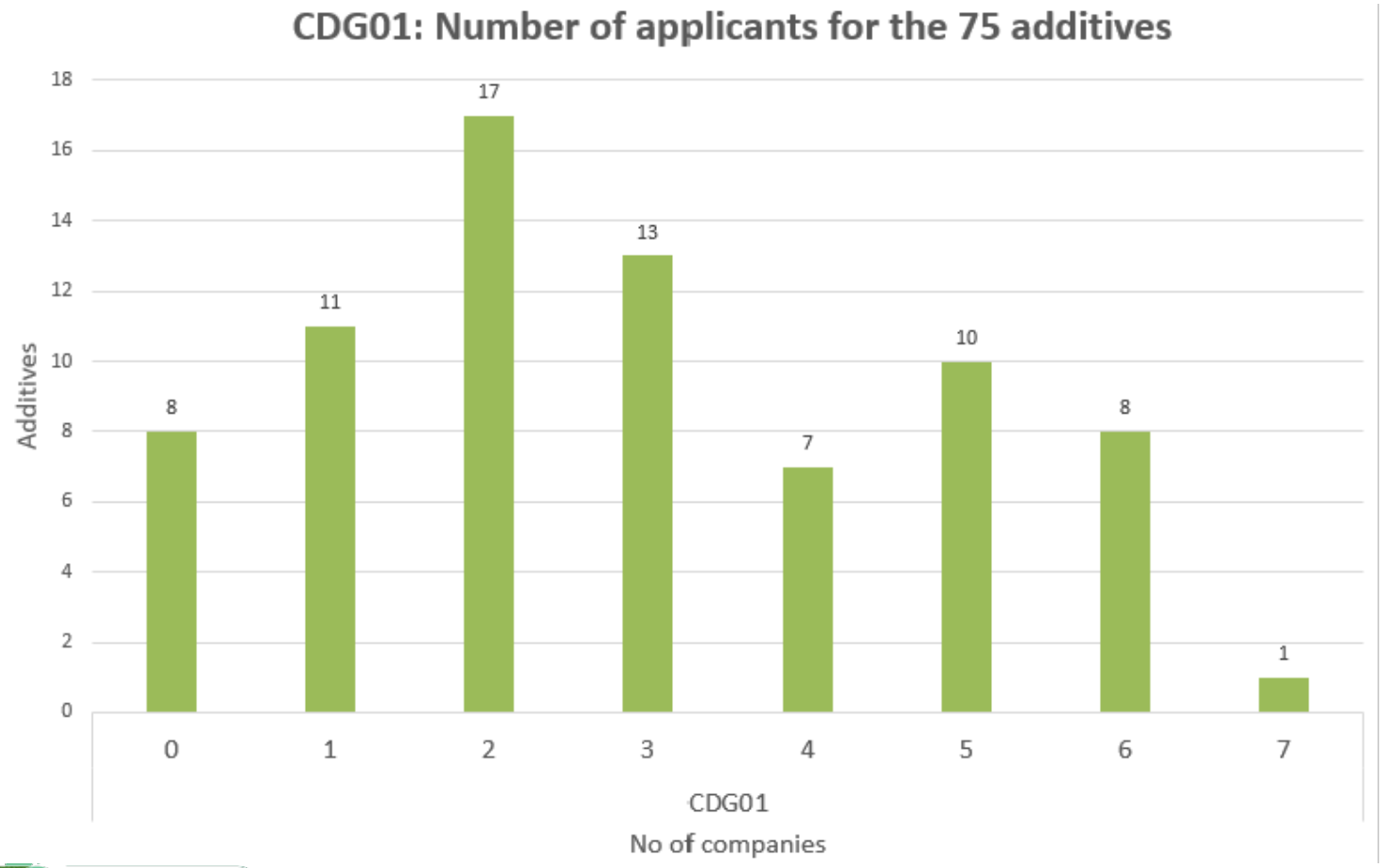
1 Additive: No interest = 0
1 Additive: 2 companies = 2
3 Additives: 6 companies = 18
3 Additives: 7 companies = 21

Total 41 data sets per additive from different application members

Not feasible to follow a very time consuming and complex project & data management

2. Challenges and proposed solutions

- **Data required for each additive**



Data sets for 75 additives in CDG01:

8 Additives: No interest = 0
11 Additives: 1 company = 11
17 Additives: 2 companies = 34
13 Additives: 3 companies = 39
7 Additives: 4 companies = 28
10 Additives: 5 companies = 50
8 Additives: 6 companies = 48
1 Additive: 7 companies = 7

Total 217 data sets per additive from different application members

2. Challenges and proposed solutions

- **Scenarios: Minimum number of documents per data set**

Data description	Minimum files per additive	Minimum files For 7 additives & 7 applicants (CDG31)	Minimum files For 75 additives & 7 applicants (CDG01)
Batch to Batch variations (CoAs)	5	5 x 41 = 205	5 x 217 = 1085
Impurities	3	3 x 41 = 123	3 x 217 = 651
Dusting potential	3	3 x 41 = 123	3 x 217 = 651
Particle size distribution	3	3 x 41 = 123	3 x 217 = 651
Bulk density	3	3 x 41 = 123	3 x 217 = 651
Flow chart / manufacturing process	1	1 x 41 = 41	1 x 217 = 217
SDS	1	1 x 41 = 41	1 x 217 = 217
Label	1	1 x 41 = 41	1 x 217 = 217
Reports on adverse events	1	1 x 41 = 41	1 x 217 = 217
Total of documents	**21**	**861**	**4557**

2. Challenges and proposed solutions

- **Transparency Regulations, e-SFCP**
  - Submission and management of a large number of dossiers and files on e-SFCP in accordance with the Transparency Regulation.

- **EURL**
  - Submission of declaration forms early and over a longer period of time (> 6 weeks before the submission deadline)

Discussion with e-SFCP and EURL-Team could be needed?

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1. Project requirements
2. Challenges and proposed solutions
3. Pilot dossier CDG31 (EC Regulation 2017/65)
4. Summary & conclusions

3. Pilot dossier CDG31 (EC Regulation 2017/65)

Reasons for a pilot project

- **Development of dossier, work processes and schedules**
  - Sufficient data to avoid additional requests for information

- **Gain experience, before the main project starts:**
  - Data collection and management
  - Instructing employees on dossier work processes
  - Collaboration with external laboratories and cooperation partners
  - Identification of bottlenecks and optimisations for the main projects

3. Pilot dossier CDG31 (EC Regulation 2017/65)

- **Reasons for choosing CDG31 as a pilot**
  - Produced by chemical synthesis and from natural sources
  - d-Limonene (FL 01.045), a key component of botanicals
  - Included in the same EFSA Flavouring Group Evaluation (FGE.78)

EC No	FFAC Dossier	Sub-group	FLAVIS No	EU Register name	Feed level (mg/kg)	Physical state	FOOD Evaluation Group
2017/65	CDG31	CDG31.1	01.002	1-Isopropyl-4-methylbenzene	25	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.2	01.003	Pin-2(10)-ene	5	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.2	01.004	Pin-2(3)-ene	5	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.2	01.007	beta-Caryophyllene	5	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.2	01.009	Camphene	5	Solid	FGE.78Rev02
2017/65	CDG31	CDG31.1	01.010	1-Isopropenyl-4-methylbenzene	1.5	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.2	01.029	delta-3-Carene	5	Liquid	FGE.78Rev02
2017/65	CDG31	CDG31.1	01.045	d-Limonene	25	Liquid	FGE.78Rev02

3. Pilot dossier CDG31 (EC Regulation 2017/65)

Proposal for the dossier

- Data for each additive will be provided by one responsible member
- Include as many (summary) tables as possible
- Simplified approaches: Representative data, read-across, etc.

- **Sect II:**
  - Minimum data set: CoAs, Impurities, DP, PSD, density, flowchart, SDS, label
  - Impurities: batches including standard impurities and as derived by the flowchart
- **Sect III:** Adverse event reports, ELS reports (single and grouped additives)
- **Sect IV:** Referring to re-evaluation dossier
- **Sect V:** Not applicable

3. Pilot dossier CDG31 (EC Regulation 2017/65)

Extensive Literature search (ELS)

- **Read-across from structurally similar compounds**
  - Consider risk assessments of the same chemical class: e.g. chemical group 31 (aliphatic and aromatic hydrocarbons)
  - Consider JECFA, EFSA FEED, EFSA Flavouring Group (FGE), RIFM evaluations or other literature to identify group of chemical similar compounds
  - Data evaluation for read-across analogs

3. Pilot dossier CDG31 (EC Regulation 2017/65)

- **Natural sources**

Extract of CDG31

CG	EFSA Op sub-group	Dossier name2	EFSA Manufacturing route	EC No	Manufacturing process
CG31	CDG31.1	1-Isopropyl-4-methylbenzene (FL 01.002)	Chemical synthesis or by fractional or steam distillation of essential oils.	2017/65	Produced by chemical synthesis.
CG31	CDG31.2	Pin-2(10)-ene (FL 01.003)	Chemical synthesis or by extraction from natural sources	2017/65	Produced by chemical synthesis.
CG31	CDG31.2	Pin-2(3)-ene (FL 01.004)	Chemical synthesis or by extraction from natural sources	2017/65	Produced by chemical synthesis.
CG31	CDG31.2	Camphene (FL 01.009)	Chemical synthesis or by extraction from natural sources	2017/65	Produced by chemical synthesis.

- Quality differences between the chemical and naturally derived additives are minimal.
- The manufacturing process has not been modified since the previous evaluation by EFSA.
- The safety evaluation of the re-authorisation dossier applies.

Contents

4. Summary & Conclusions

1. **Project requirements**
   - Dossier must meet the various requirements
   - Concept for the Renewals = Nothing has changed since the first authorisation

2. **Challenges and limitations**
   - The number of dossiers, substances and applicants, the deadlines for submission, and general requirements (Transparency Regulation, e-SFCP) are a major challenge
   - The given limitations require adaptation to the work processes

3. **Pilot dossier CDG31 (EC Regulation 2017/65)**
   - The experiences of the pilot dossier will be transferred to all other renewal dossiers

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THANK YOU!