

NEW MODELS ON USE LEVELS AND NOT PRESENT ON LABEL DATA

Luca Belmonte, PhD



THE LEGAL FRAMEWORK

Food Additives

(Regulation (EC) No 1333/2008)

Regulates the use of food additives in food products sold in the EU

The regulation provides a list of approved food additives and specifies the conditions for their use in food

The regulation also requires proper labeling of food additives in food products and establishes maximum limits

Food Flavourings

(Regulation (EC) No 1334/2008)

Regulates the use of food flavourings in food products sold in the EU

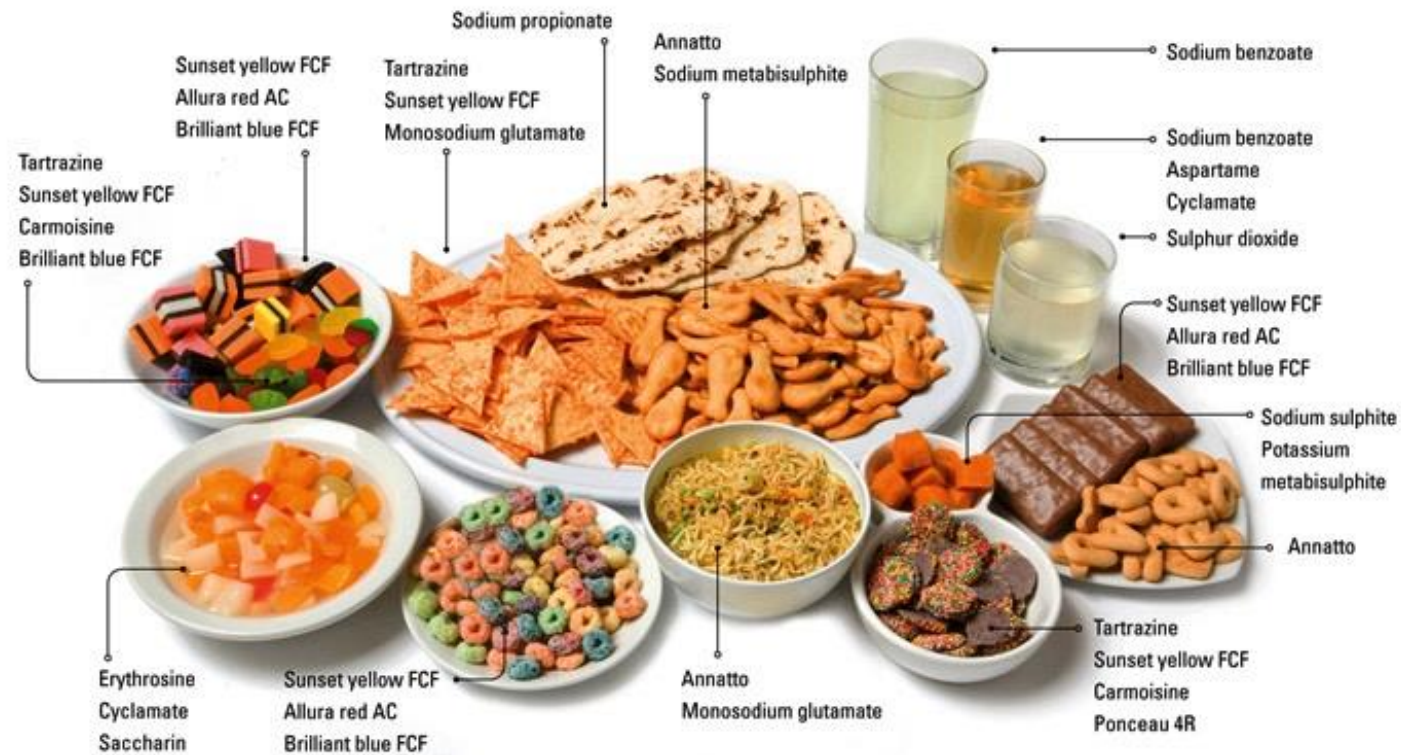
The regulation includes an authorized list of food flavourings and specifies the conditions for their use in food

Establishes specific criteria for traceability for their safe use in food



EFSA TO MONITOR FLAVOURINGS AND ADDITIVES IN FOOD

- EFSA is mandated to develop a **methodology for continuous risk monitoring** of the consumption and on the use of **Food Additives (FA)** and **Food Flavourings (FF)** in the community.



THE PURPOSE OF THE MANDATE

- The purpose of **Mandate B** is to gather data on **FF/FA intake** to assess that their use **does not raise a health concern**
- Thus, a **common methodology for information gathering** by the Data Providers (DPs) shall be adopted
- Additionally,
 - Monitoring of the consumption and use of FF/FA helps in **verifying the dietary exposure estimated** at the time of establishment of the authorization
 - The data collection must be designed for **a broader risk assessment** that in the future will encompass exposure to multiple chemical agents



WHAT'S NEW IN THE MANDATE

- So far, EFSA collected analytical data on **Food Additives**
- Data were submitted from from **Member States** only

- From now on, EFSA will collect data on **Food Flavourings** as well
- Industries will send data through the EFSA centralized data collection pipeline

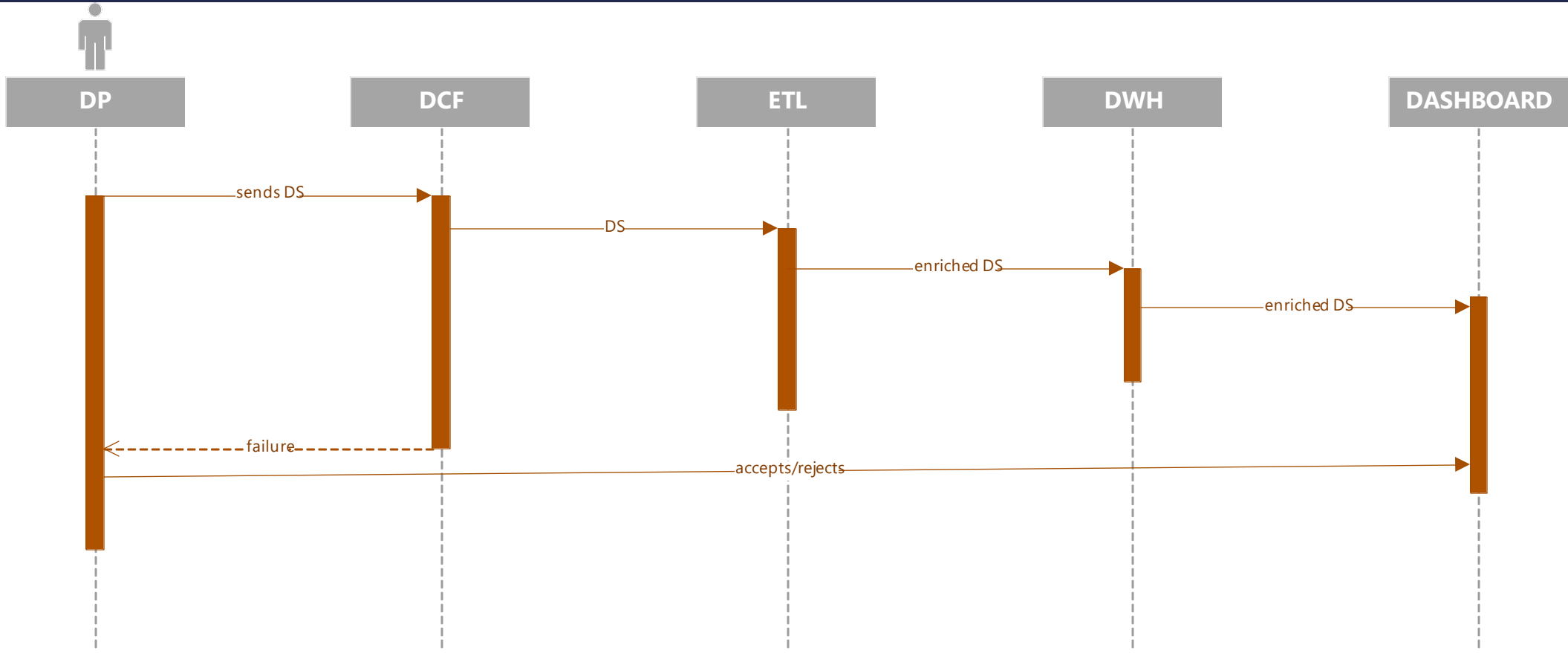
- **Industries** are going to contribute by submitting **two types of data**:
 - **Use level**, a new type of data model
 - **Presence**, a completely new type of data model



DATA MODELS



THE EFSA CENTRALIZED DATA COLLECTION PIPELINE



Data Provider sends data to EFSA in xml or csv format

Data Collection Framework checks the data are consistent with the Data Structure and the Business Rules

The Data are rearranged and enriched with catalogues terminology

The enriched data set is stored in the DWH

The enriched data are shown to the Data Providers in 7 dashboards



USE LEVEL DATA MODEL

- The **use level data model** is designed to report **use level and presence data**
- *“Use level data are quantities of FF/FA added by food business operators in food product categories expressed as typical, maximum and minimum value”*
 - For example, the typical amount of lactic acid used in soft cheeses or the maximum level of citric acid in cola-like drinks
- To host use level data, a **new data model** has been designed
 - Where possible, SSD2 data elements have been recycled
 - Other data elements nomenclature is derived from SSD2
 - Use level data are reported on FOODEX2 category codes



PRESENCE DATA MODEL

- Both for FA and FF **presence** data will be collected **within the use level data model**
- Specifically, DPs will “tick a box” declaring whether a FF/FA is:
 - **Present**, if the FF/FA is shown on the product label
 - **Not present**, if the FF/FA is NOT shown on the product label
 - **Natural occurrence**, if the FF/FA is contained within the matrix and it has not been added to the foodstuff
- This option is given for all the FF/FAs for which **use level data are provided**

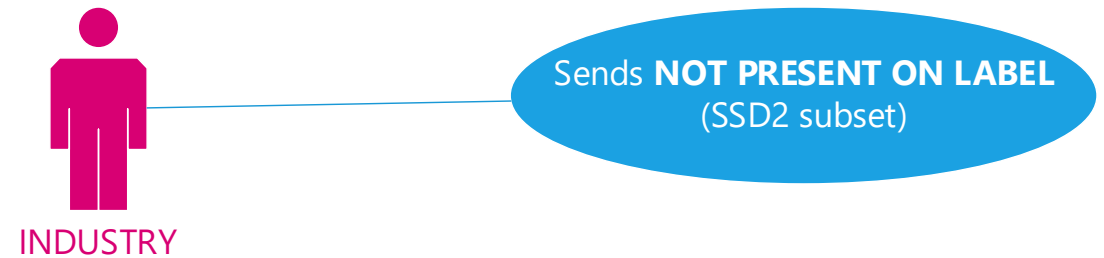
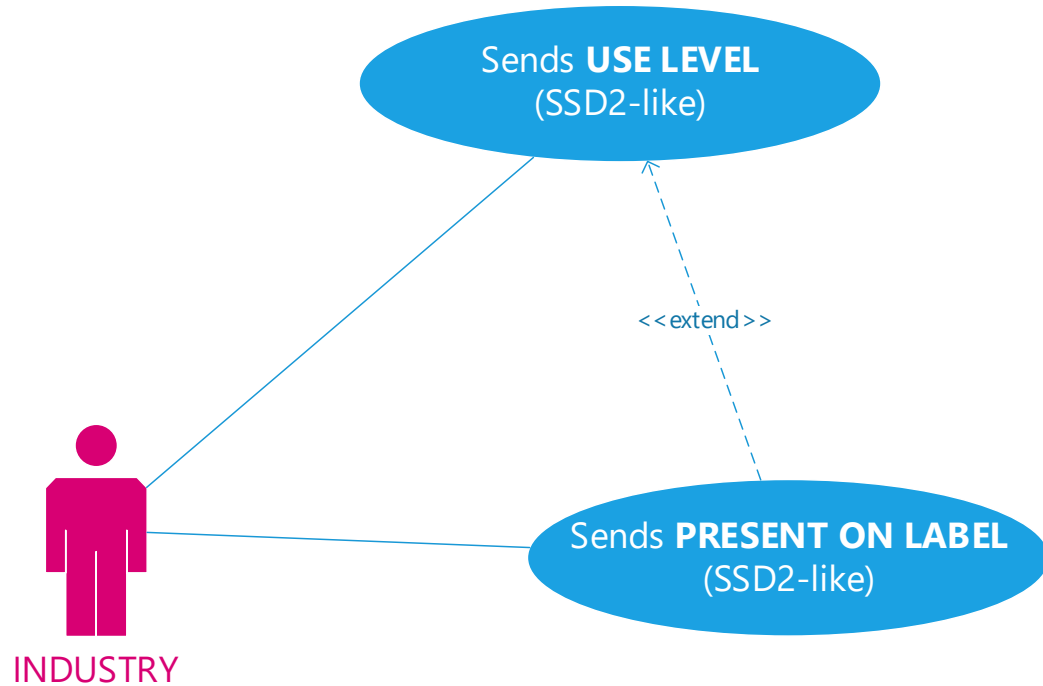


DATA OF FF/FA NOT PRESENT ON LABEL

- The “**not present on label**” data model is designed to report only **data not present on label**
- “***Data not present on label** are data about FF/FA that are not on the product label and that **are not** submitted together with **any analytical or use level data**”*
 - For example, Aspartame not used in a soft-drink of a specific brand for which aggregated values are missing
- To host these data, a **new data model** has been designed
 - The data model is a subset of **SSD2**
 - Two brand new data elements have been added
- This option is given for all the FF/FAs for which **no use level data are provided**



WRAP UP: THE TWO POSSIBLE SCENARIOS



- An industry **submits use level** along with **presence data**

- An industry **submits data** for FF/FAs **not shown on the product label** only
- **No legal obligation** for presence data submission



EXAMPLES

DATA SUBMISSION



HIGH LEVEL EXAMPLE OF USE LEVEL DATA

matCode	matText	onLabel	paramCode	paramText	functionOf	typicalLevel	unit
A03FJ#F33.A 0C1T	Soft drink, orange flavour, LEGISLATIVE- CLASSES = FA-14.1.4 Flavoured drinks	yes	RF-00000103-ADD	Citric Acid	acidity regulators	XXXXX	mg/L
A03FJ#F33.A 0C1T	Soft drink, orange flavour, LEGISLATIVE- CLASSES = FA-14.1.4 Flavoured drinks	natural occurring	RF-00000046-ADD	Ascorbic Acid	preservatives	KKKKK	mg/L

- Reporting of a 2 FAs:
 - The first is added to a food category (or product)
 - The second natural occurs in the foodstuff matrix
- NOTE: Only few columns (out of 29) of the current data model are displayed



HIGH LEVEL EXAMPLE OF DATA NOT PRESENT ON LABEL

matCode	matText	onLabel	paramCode	paramText	functionOf	typicalLevel	unit
A03FJ#F33.A 0C1T	Soft drink, orange flavour, LEGISLATIVE- CLASSES = FA-14.1.4 Flavoured drinks	no	RF-00000248-ADD	Potassium Sorbate	preservatives	XXXXX	mg/L

- Reporting of a FAs not added to the food category
- NOTE: Only few columns (out of 19) of the current data model are displayed



SUMMARY

- EFSA is mandated to develop a **methodology for continuous risk monitoring** of the **FF/FA consumption**
- To this goal, data on FF/FA are going to be collected from the industries in a harmonized framework
- Data submission is going to be done through the EFSA centralized data collection pipeline
- **Industries** contribute by sending two different types of data:
 1. **Use level** along with **presence data**
 2. Data of FF/FA **not present on label**
- **Presence data**, although highly recommended, will **not be mandatory**



TEAMWORK

- **Team**

- Luca BELMONTE, EFSA/iDATA
- Stefania SALVATORE, EFSA/iDATA
- José Angel GOMEZ RUIZ, EFSA/MESE
- Alicia GUTIERREZ LINARES, EFSA/iDATA

- **Acknowledgments**

- Valentina BOCCA, EFSA/iDATA
- Elisa FASANELLI, EFSA/iDATA
- Davide GIBIN, EFSA/iDATA
- Alexandra TARD, EFSA/FIP
- Francesca RIOLO, EFSA/MESE
- Carla MARTINO, EFSA/FIP



STAY CONNECTED

SUBSCRIBE TO

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



FOLLOW US ON TWITTER

[@efsa_eu](https://twitter.com/efsa_eu) [@methods_efsa](https://twitter.com/methods_efsa)
[@plants_efsa](https://twitter.com/plants_efsa) [@animals_efsa](https://twitter.com/animals_efsa)



FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



FOLLOW US ON INSTAGRAM

[@one_healthenv_eu](https://instagram.com/one_healthenv_eu)



CONTACT US

efsa.europa.eu/en/contact/askefsa

