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FOOD SUPPLEMENTS - EFSA TMA UPDATES

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FOCAL POINTS TAYLOR MADE ACTIVITY ON FOOD SUPPLEMENTS

- Food supplements is identified as specific area of interest by EREN and Sc. Committee
- Project idea presented and endorsed at 87th Advisory Forum (15 March, 2023)
- The Project was organsied via Tailor-Made Activities of EFSA focal points (05/2024 - 05/2026)

TAILOR-MADE ACTIVITIES

- Activities addressing **specific priorities** of MSs and EFSA
- **Proposed by MSs and/or EFSA**, including their communities
- Fit with **EFSA's remit and strategy**
- Bring **short- and mid-term benefits** to the EU food safety ecosystem
- Support the establishment of **long-term partnerships**
- Support **preparedness** for future risk assessment work
- Follow an **inclusive and choice-driven** approach

Identification of **emerging risks** associated with food supplements, other than vitamins and minerals

Potential '**Info feed' for HoA**

OBJECTIVES

- Creation of a community of knowledge (WP1)
  - Analyse information from nutrivigilance systems and poison centres for correlated food supplement intake and adverse health effects (WP2)
  - Using the EFSA Compendium of Botanicals, identify plant-based substances of concern with predicted toxicity only (i.e. no experimental evidence) (WP3)

1. **List of substances predicted CMR**
2. **Keep the substances with reliable toxicity prediction**
3. **Use the Compendium to trace back plant species containing these substances**
4. **Map whether food supplements containing these substances or made of plants containing these substances exist and are marketed in Europe**
5. **If possible, get information on the levels of the substance(s) of concern in the food supplement**

QSAR REPRODUC
1537 BOTANICA

(+) experimental	(+ Predi 3 QS syste	
38 Compounds Toxicant (Experimental)	**23 Comp** Toxic (Predi	
Hyoscyamine	scopolet	

Hyoscyamine

Botanics

1-12/12

- Atropa acuminata Royle ex Lindl.
- Atropa belladonna L.
- Brugmansia sanguinea (Ruiz & Pav.) D.Don
- Cestrum nocturnum L.
- Hyoscyamus albus L.
- Hyoscyamus muticus L.
- Datura metel L. // Datura alba F.Muell. // Datura
- Duboisia hopwoodii (F.Muell.) F.Muell.
- Duboisia leichhardtii (F.Muell.) F.Muell.
- Duboisia myoporoides R.Br.
- Mandragora officinarum L.
- Scopolia japonica Maxim.

Night-Flowering Jasmine: Health Benefits, Uses And Side Effects Of Parijat

Dt. Ashish Rani, Nutrition and Dietetics, Aakash Healthcare shares parijat's uses, effects and benefits.

Immunity Booster

1. Due to ethanol's presence, parijat flowers and leaves act as immunostimulatory to boost immunity.
2. Treat arthritic knee pain and sciatica.
3. Sciatica and arthritis are the most painful conditions. The anti-inflammatory characteristics and essential oils in Parijat leaves help treat arthritic knee pain.
4. Anti-allergic, antiviral, and antibacterial properties
5. The antiviral, antibacterial, and anti-allergic properties of parijat oil are excellent.

Apart from these, Parijat also works excellent in the following conditions:

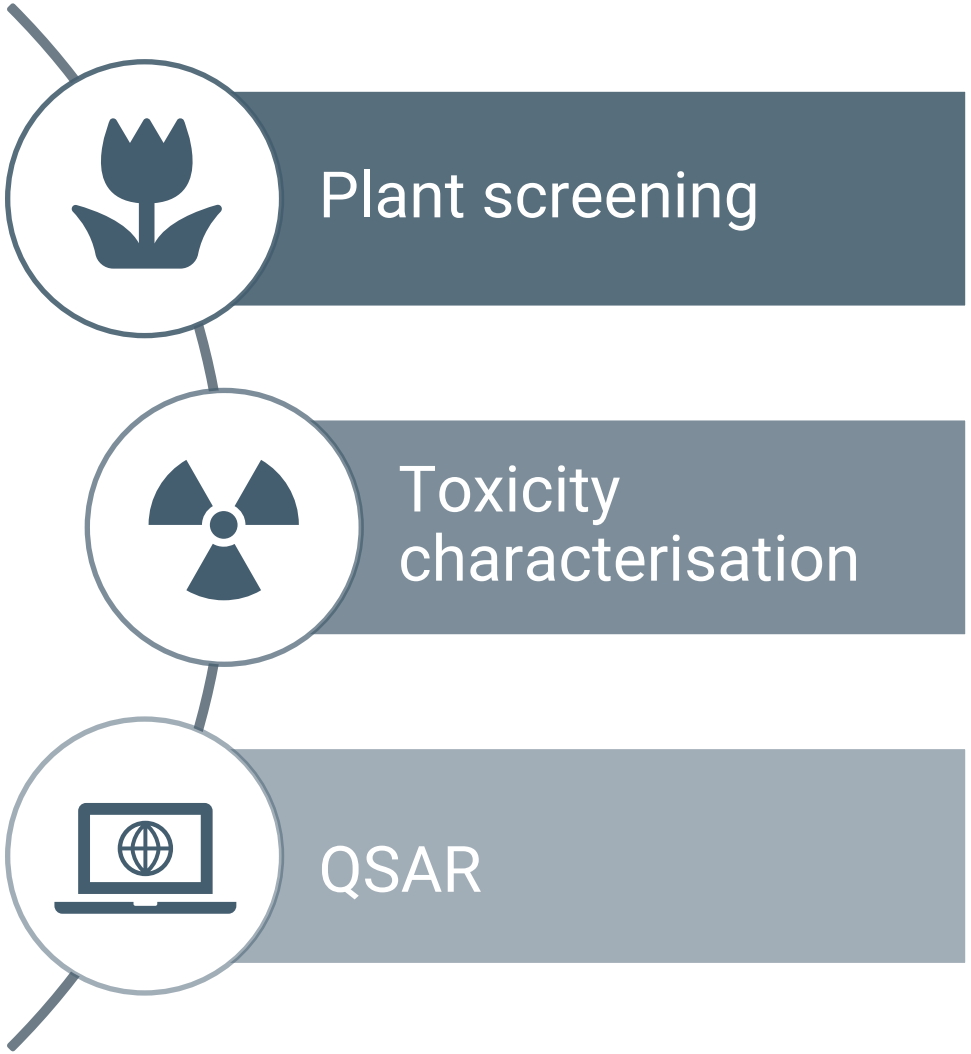
Aside from its primary uses, Parijat also proves to be a versatile remedy, effectively addressing a range of conditions:

Works as a laxative

Best skin healing properties

Manages anxiety

PREDICTED TOXICITY (QSAR) AND INFO FROM BOTANICALS



2701 plant species

White list
966 species

1735 species
Yellow list

Systematic Literature Search

COMBO

~1500 natural substances

~1500 natural substances

Systematic Literature Search

CHEM-COMBO

~450 natural substances with tox data

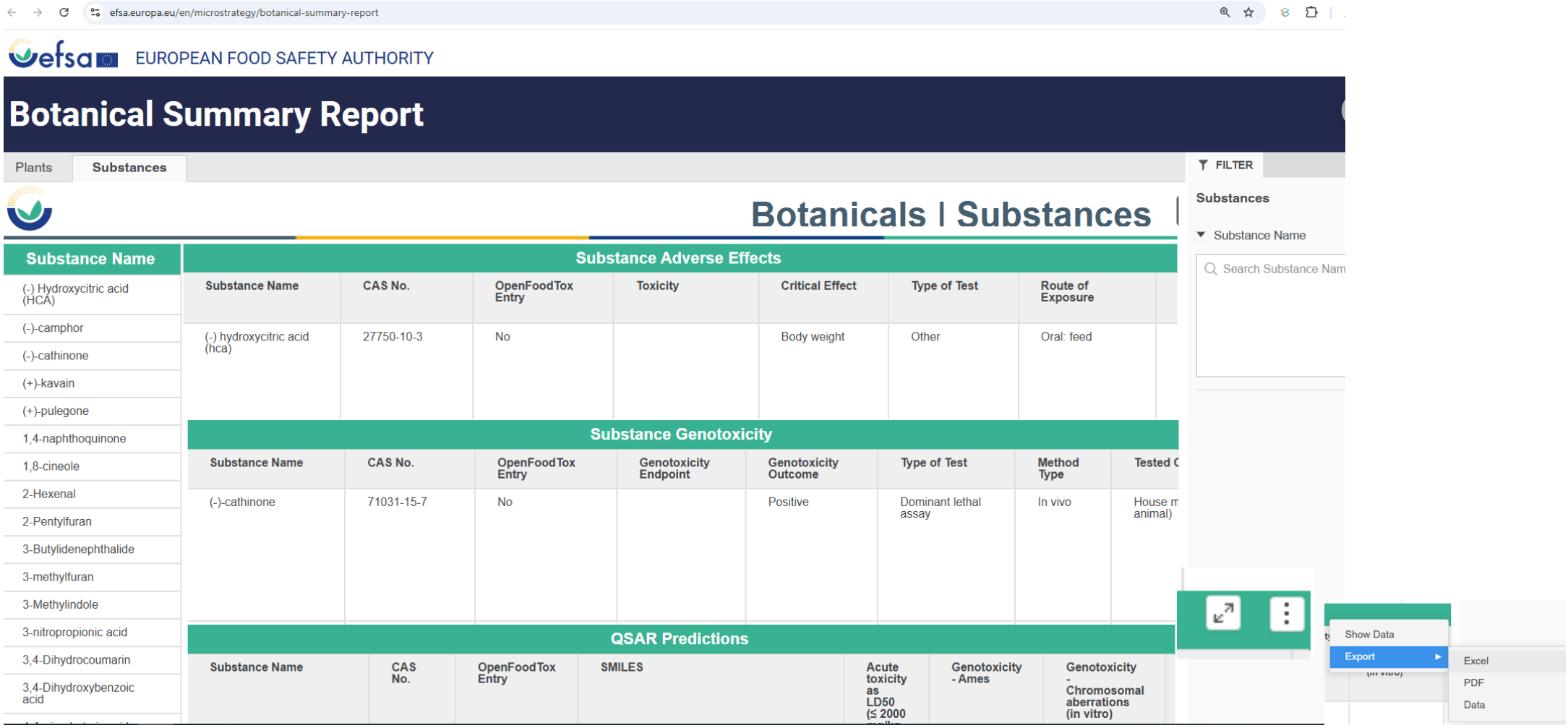
~1500 natural substances

Danish EPA

VEGA and T.E.S.T. QSAR models

positive and reliable QSAR results in the database

EFSA BOTANICAL SUMMARY REPORT ON THE WEB



https://www.efsa.europa.eu/en/microstrategy/botanical-summary-report

QSAR PREDICTIONS OF CONCERN (SELECTION)

- Carcinogenicity (17 substances)
- Reproductive Toxicity (21 substances)
- Genotoxicity – 2 stage protocol (14 substances)

Selection based on predicted toxicity at least 2 QSAR tests

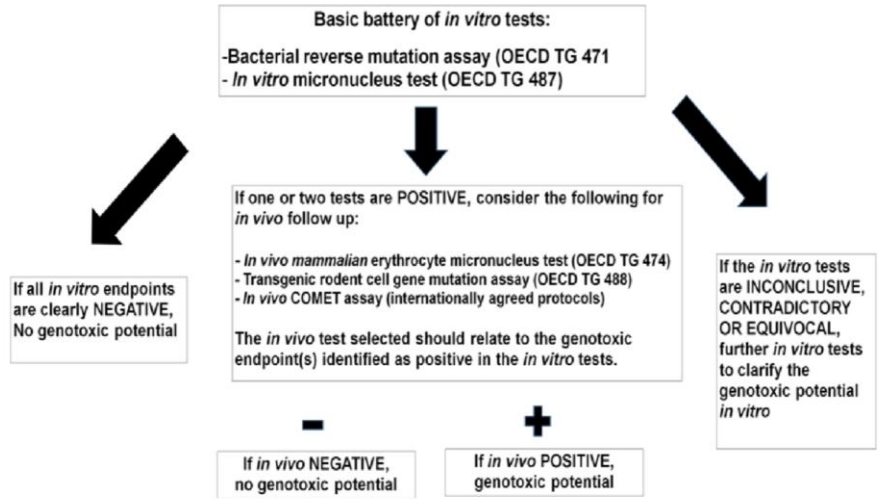


Figure 1. Schematic representation of the genotoxicity testing strategy recommended by the EFSA Scientific Committee

OECD TG 471	OECD TG 487		
Genotoxicity - Ames	Genotoxicity - Micronucleus (in vitro)		
OECD TG 474	**OECD TG 489**	OECD TG 473	OECD TG 478
Genotoxicity - Micronucleus in mice (in vivo)	Genotoxicity - Comet Assay in mice (in vivo)	Genotoxicity - Chromosomal aberrations (in vitro)	Genotoxicity - Rodent Dominant Lethal (in vivo)

INFO FROM NUTRIVIGILANCE WP2

- Selecting the high severity and causality case reports
- Identifying the composition of involved food supplements
- Collecting of literature data for each ingredient-adverse effect pair
  - summarized through a PECO framework
  - sorted according to inclusion/exclusion criteria (incl. study, administration, specification)
  - sorted on the base of bibliographic score (quality of info) – B0,B1,B2

- List of ingredients (botanicals) , adverse effects (and type), score, and #cases

Ingredients	Adverse effects	Adverse effect type	Bibliographic score	Number of reported cases
Acacia	Acute diarrhea, shock, death	Gastro-enterology	B0	1
Activated Vegetable Coal	Convulsive seizures	Neurology	B0	1
Alpha lipoic acid	Rhabdomyolysis	Rheumatology	B0	1

INFO FROM BOTANICALS (WP3)

- Selecting the substances of concern
- Identifying the plants containing the selected substances
- Searching for plant-containing food supplements on the (national) market
- Ranking the substances of concern

Plants	Suspected Genotoxicity	Suspected Carcinogenicity	Suspected Reprotoxicity
Abrus pulchellus subsp. cantoniensis (Hance) Verdc. // Abrus cantoniensis Hance		Chrysophanol	
Acacia concinna (Willd.) DC.	Furfural		
Acacia rigidula Benth.			Phenylethylamine
Acalypha indica L.			Dicoumarol
Aframomum melegueta K.Schum. // Amomum melegueta Rosc.		Indicine	
Akebia quinata (Houtt.) Decne.	Furfural		
Aleurites moluccanus (L.) Willd. // Candle nut (as plant)			Scoparone
Alnus incana (L.) Moench			Esculetin

Plants	National registration system	Web search	Web search	National registration system
Abrus pulchellus subsp. cantoniensis (Hance) Verdc. // Abrus cantoniensis Hance	0	0	1 to 5	0
Acacia concinna (Willd.) DC.	0	0	1 to 5	0
Acacia rigidula Benth.	0	0	1 to 5	0
Acalypha indica L.	0	0	1 to 5	0
Aframomum melegueta K.Schum. // Amomum melegueta Rosc.	6		>5	4
Akebia quinata (Houtt.) Decne.	0	0	>5	0
Aleurites moluccanus (L.) Willd. // Candle nut (as plant)	0	0	0	0
Alnus incana (L.) Moench	15		>5	5

SELECTED EXAMPLES

Plant	Suspected Genotoxicity	Suspected Carcinogenicity	Suspected Reprotoxicity	Adverse effect	Type of adverse effect	Bibliographic score	National registration system FR	Web search FR	Web search NL	National registration system BE
Passiflora edulis Sims	Harmine			Convulsive seizures	neurology	B0	1739	0	>5	973
				Anaphylaxis Grade 2	Allergology	B1				
Hibiscus sabdariffa L.	Furfural			Subfulminant hepatitis, death	Hepatology	B0	464		>5	263
Citrus paradisi Macfad	Meranzin		Limettin Meranzin Scoparone	Rhabdomyolysis	Rheumatology	B0	718	0	>5	339
Laurus nobilis L.			Dehydrocostus lactone	Rhabdomyolysis	Rheumatology	B0	238	0	>5	102
Artemisia dracunculus L.			Herniarin	Acute cytolytic hepatitis	Hepatology	B0	110	0	1 to 5	47
Paullinia cupana Kunth		Lycopsamine		Anaphylaxis	Allergology	B0	2805	0	>5	1954
				Hepatic cytolysis	Hepatology	B0				
				Metabolic coma of hypernatremic origin	Other	B2				

FURTHER STEPS AND PERSPECTIVES

- Investigate critical botanical ingredients if reported via nutrivigilance
- In – depth investigation on market presence, products, eventual exposure/consumption or purchase data on identified critical pairs ingredients-substances

Plan 2026 for in depth investigation

- Identify products with high impact (accounting for the botanicals and substances)
- Identifying eventual composition and impact of involved practices (e.g. concentration, heat ..)
- Characterize potential issues accounting for eventual doses, prolonged use, or use by sensitive groups (children, pregnant women)

- Connects with iDATA future project of data collection on food supplements