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# Hexane at a Crossroads: Regulatory Trends and Implications for Green Analytical Chemistry

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# The 2050 biomass challenge

## Meeting global needs requires safe, sustainable and fossil-free resources.

- Nearly 9B people will need safe and affordable oils and proteins.
- Europe must secure food sovereignty with resilient supply chains.
- Cutting fossil dependence is essential for sustainability.
- With biomass demand already higher than supply, efficient processing is critical.

# An industry at deadlock

## The existing methods can't fully answer the market needs

- **Green methods (mechanical press, $scCO_2$ and hot ethanol)**: safe but not scalable - hidden sustainability costs
- **With performance limitation:** low efficiency and higher food losses require larger cultivation areas, counteracting environmental objectives
- **Hexane extraction** : efficient but toxic, fossil-based, with hidden financial costs recently challenged by EFSA and ECHA (SVHC)
- **Consequence** : Missed markets such as bio, infant nutrition, premium feed, clean label segments remains inaccessible

# Ecoxtract

We are a mission-driven company.

We propose a new **safe and sustainable by design solvent and the associated technology.**

Applicable to a wide range of biomasses and adaptable to multiple industries

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## RAW MATERIALS

- OILSEEDS
- PLANTS BIOMASS
- OTHER OIL-RICH BIOMASS

## SUSTAINABLE EXTRACTION PROCESS

- ecomeo — SOLVENT
- ecoxtract — TECHNOLOGY

## EXTRACTED INGREDIENTS

- CRUDE OIL
- DEFATTED CAKES

## APPLICATIONS

- Food
- Feed
- Cosmetics and Fragrances
- Nutraceuticals
- Technical uses

# Ecoxtract technology

## Delivering efficiency with safety and sustainability

### Safe and approved

- Approved for food (EFSA, 2023), feed, cosmetic and biocosmetics (COSMOS) in Europe, Australia, New Zealand
- Proven safe residues in oils and proteins for consumers
- Safer operations for workers and neighborhood

### Scalable and efficient

- Industrial yields equal to hexane (TRL 6 proven)
- Retrofit in hexane plants with limited modifications

### Sustainable and fossil-free

- Uses Ecomeo, a plant-based solvent from renewable biomass
- Can reduce $CO_2$ emissions by at least 3.8 M tons / year if 100% of hexane converted

### Value creating

- Eliminates hidden costs, open access to premium and clean-label markets
- Protected by 4 patents families, know-how and regulatory expertise

# Team & Expertise

Experienced

Partnerships

Network



**Laurence Jacques**
Co-founder
& CEO

**Stéphane Larché**
Chief Financial Officer

**Julie Ducreux**
Process & Engineering Manager

**Karl Iffländer**
R&D Engineer

**Céline Bret**
Chief Business Officer

**Anne-Cécile Signoret**
Regulatory & Public Affairs
Director

**Catherine Caillet**
R&D Engineer

**Margot Faucheux**
Technical Sales Engineer

Our core cross-functional team works with partners, consultants and our network to provide all the support required by our customers

# Ecoxtract milestones

| 2017-2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|---|---|---|

**Company**

- Project started within Minafin Group in 2017
- Minafin's decision to stop investing for focus on pharma BU
- *2-year hold*
- Ecoxtract is an independent start-up
- Recruitment of 7 team members

**Patents**

- Residues measurement methods
- Patent 1 granted in US, Europe, Brazil, Japan, Korea
- Patent 2 pending in 30 countries, accepted in the US, Australia, South Africa…
- More patents to come

**Industrial scale up**

- 1st pilot tests on soy
- 1st small-scale industrial test on canola in Mexico
- 1st full conversion of a hexane plant - NHE (UK)
- Conversion Exinnov plant (France)

**Tox. and ecotox. studies**

- Tolerable daily intake (TDI)
- First feed trials with full defatted hexane-free meals

**Regulatory**

- USDA ORGANIC
- ECOCERT COSMOS APPROVED
- EFSA EUROPEAN FOOD SAFETY AUTHORITY — Dossier submission
- EFSA EUROPEAN FOOD SAFETY AUTHORITY — Positive opinion March 2022
- **Food approval in Europe 26/01/2023**
- FOOD STANDARDS Australia New Zealand — **Food approval in Australia / New Zealand 08/11/2024**
- Health Canada
- FDA

# Hexane

Today, hexane is commonly used as a solvent to extract oils, natural aroma, nutraceuticals and produce defatted proteins or cocoa.

1,2 MT is consumed each year and 300 to 600 kT exit the plants in the human food chain as residu in food and feed.

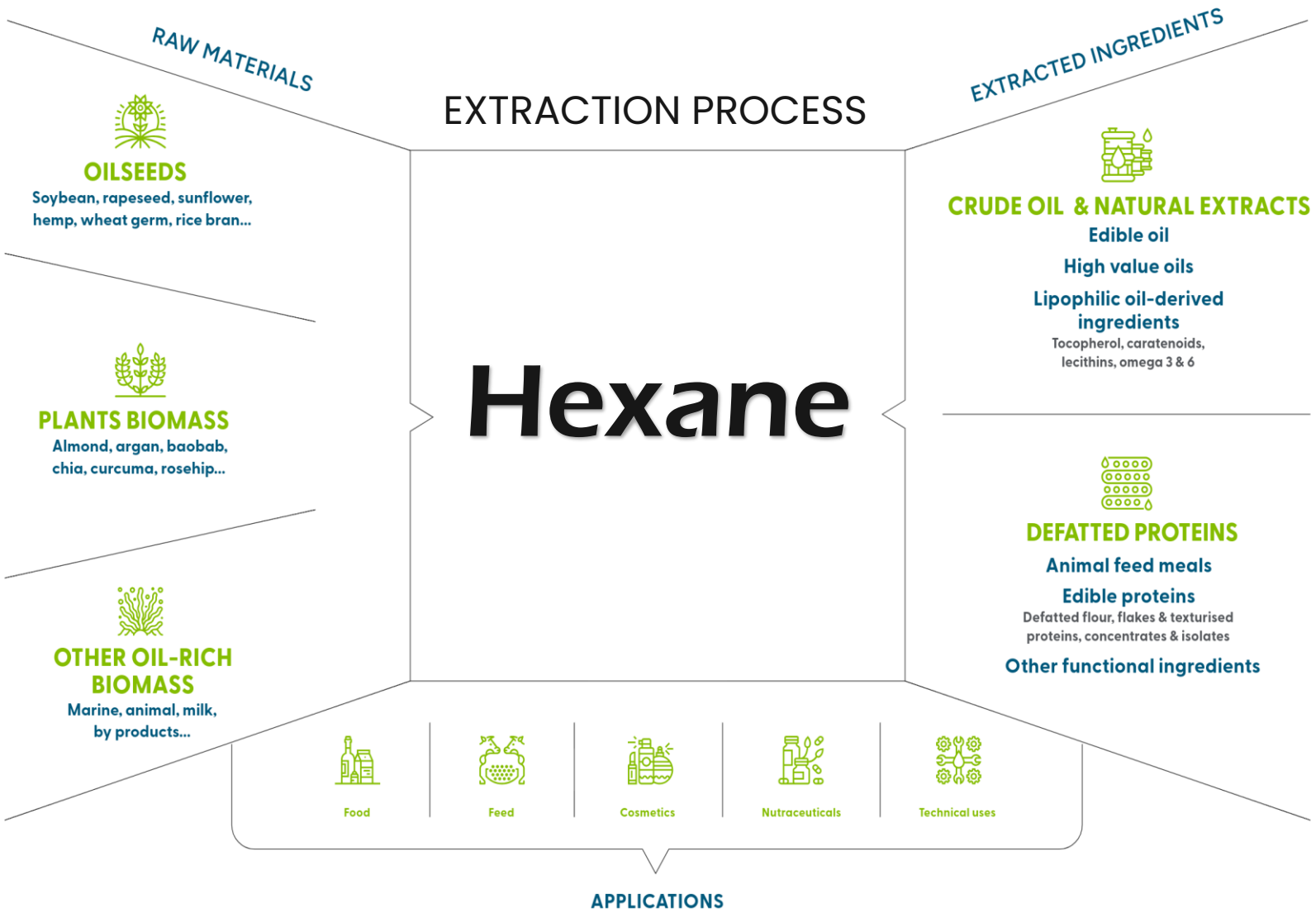
“After processing, small amounts of hexane residue are left behind in the final product and enter the food chain.”

FEDIOL Q&A from September 2025

https://www.fediol.eu/data/24SAF453%20FEDIOL%20QA%20on%20hexane%20-%20for%20public%20-%20rev%2029%20September%202025.pdf

French Parliamentary Report 2026

https://www.assemblee-nationale.fr/dyn/17/documents/cion-eco/l17n134384648_document.pdf



# EU Reg. pressure

3 simultaneous pathways

## Classification and labelling : Proven neurotoxicant

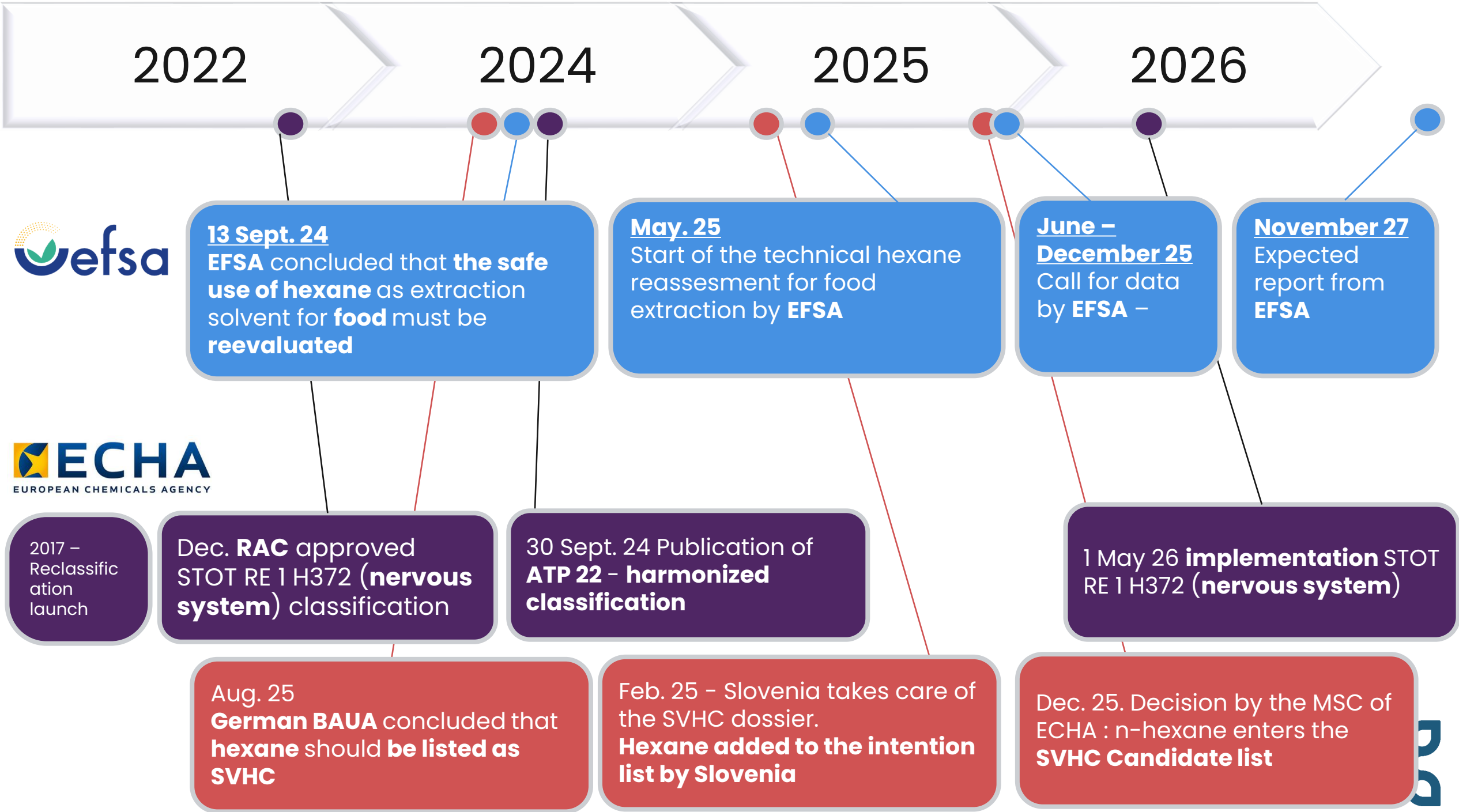
- n-hexane reclassified as STOT RE 1 H372 (nervous system) on 30 Sept. 2024
- Specific Target Organ Toxicity after Repeated Exposure cat. 1 (= highest hazard level)
- Result of a process launched in 2017 by German BAUA
- Labelling of all products containing more than 1% n-hexane : by 1 May 2026

## SVHC (Substance of Very High Concern)

- 20 Aug. 2024, conclusion of the RMOA achieved by the German BAUA: recommendation to list hexane as SVHC
- 5 Feb. 2025, inscription to the SVHC Registry of Intention. 1st step of the SVHC process
- Feb. 2026, inscription to the SVHC Candidate List, 2nd step of the SVHC process

## EFSA report

- 13 September 2024, publication of the technical report and conclusion: not safe when used as extraction solvent for foodstuffs and food ingredients
- May 2025, Mandate to EFSA for the review of the use of technical hexane as a food solvent – result expected in November 2027
- Call for data by EFSA – June to December 2025


2022
2024
2025
2026
efsa
13 Sept. 24
EFSA concluded that the safe use of hexane as extraction solvent for food must be reevaluated
May. 25
Start of the technical hexane reassesment for food extraction by EFSA
June – December 25
Call for data by EFSA –
November 27
Expected report from EFSA
ECHA
EUROPEAN CHEMICALS AGENCY
2017 – Reclassification launch
Dec. RAC approved STOT RE 1 H372 (nervous system) classification
30 Sept. 24 Publication of ATP 22 - harmonized classification
1 May 26 implementation STOT RE 1 H372 (nervous system)
Aug. 25
German BAUA concluded that hexane should be listed as SVHC
Feb. 25 - Slovenia takes care of the SVHC dossier.
Hexane added to the intention list by Slovenia
Dec. 25. Decision by the MSC of ECHA : n-hexane enters the SVHC Candidate list

# SVHC

## Substance of Very High Concern

"Substances that may have **serious** and often **irreversible** effects on **human health and the environment** can be identified as substances of very high concern (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List."

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ECHA
EUROPEAN CHEMICALS AGENCY

## Hexane's listing as an SVHC - Key updates and potential impacts

On December 2025, the European Chemicals Agency's (ECHA) Member State Committee (MSC) has unanimously agreed to identify **n-hexane** as a **Substance of Very High Concern (SVHC)** under **Article 57(f)** of REACH. The decision, marks a regulatory milestone as it classifies n-hexane for its **neurotoxic effects** with an **equivalent level of concern (ELoC)** to other SVHCs. The substance will be formally added to the **Candidate List by February 2026**. ECHA's MSC confirmed that n-hexane meets the criteria of **equivalent level of concern**, considering evidence such as the **irreversibility of effects**, **societal impacts**, and **lack of a safe concentration**. Data from patient follow-ups showed **persistent symptoms even four years after exposure ceased**, strengthening the argument for ELoC. https://echa.europa.eu/documents/10162/5b7eeb8a-a1e1-22eb-6851-5fff9ea8fe1b

## Potential impacts:

- **Without an exemption, hexane's availability in the EU could be severely restricted, for all uses, including laboratory uses and food extraction, unless a specific authorization is granted.**

# SVHC, what can be expected?

**inclusion in Annex XIV**
**(authorized substances)**

Sunset date

**Ban**

on Placing on the Market or Use

Specific **authorization dossier** required for continued usage…

However, the authorization is **limited in time** and **consumer safety** must be **proven**

**Encouragement to replace with safer, more sustainable alternatives**

# Timeline example

## Bisphenol A

- 60 registrants under REACH Regulation
- 1 Million Tons / year in Europe
- Defended by Plastics Europe.

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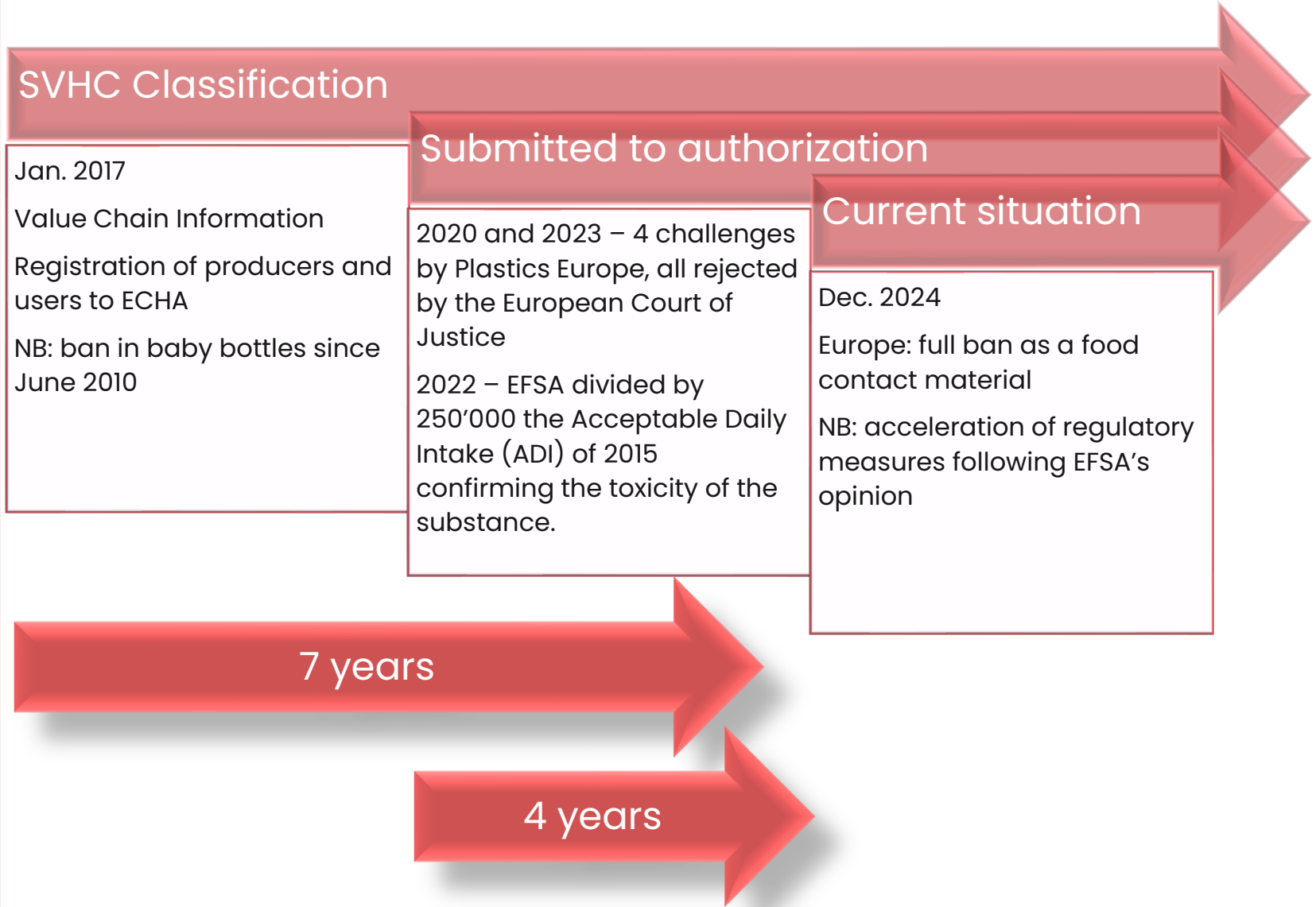
## Few SVHC have ever been used for food uses : bisphenol A, phtalates and n-hexane



# EFSA

The safety of hexane as food extraction solvent must be reevaluated.

The information reviewed by the SCF in 1996 is now deemed **insufficient to draw a reliable conclusion on the safety of technical hexane**.

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https://www.efsa.europa.eu/en/supporting/pub/en-9001

EFSA urges for…

- The **identification** and **specification** of technical hexane
- A **new comprehensive toxicological review exploring more endpoints** as n-hexane is absorbed when ingested
- A reassessment **of hexane current authorization for food**

- **1 mg/kg** is the maximum limit of residues authorized in the oil, considering the analytical possibilities from the industry [in 1996]. Estimated consumers exposure to technical hexane is 0,1 mg/kg/day (from proteins).

➢ **EFSA** simulated exposures scenarios show **higher exposures particularly for infants and toddlers**

**No safe dose is established: no ADI (Acceptable Daily Intake).**

**=> how can the consumers safety be garanteed ?**

# EFSA report shifts responsibility onto hexane producers and users

Article 3 (b) (iii) of Regulation (EC) No 1333/2008 on **food additives**

- Residues of the processing aid may be present in the final product if ***they do not present any health risk***

Article 2 (h) of Regulation (EC) No 1831/2003 on **feed additives**

- Residues of the processing aid may be present in the final product provided ***these residues do not have an adverse effect on animal health, human health or the environment***

Article 14 of Regulation (EC) No 178/2002, **general principles**:

*"**Food shall not be placed on the market if it is unsafe**"*

**Hexane is not safe and no TDI/ADI available!**

efsa

CODEX ALIMENTARIUS

Food and Agriculture Organization of the United Nations

World Health Organization

*« The safety of the processing aid should be demonstrated by the producer or the user of the substance. »*

Hexane producers and users must have **safety dossiers** (*) ready to demonstrate that residual levels pose no unacceptable risk and to justify its continued use.

(*) covering human health with an **ADI**, animal health and the environment.

# Implications for the (bio)analytical chemistry

## Need for better hexane residue measurement methods for food, feed, cosmetics

- Current methods are outdated
- The main method is fifty years old
- Better tools are available

## Need for hexane-free methods

- Many analytical uses of hexane are technically substitutable today, without compromising analytical performance, reproducibility or regulatory acceptance.

## Need for more laboratories able to monitor hexane metabolites in urine and blood

- Hexane biomonitoring in European general population is on the rise

# Much better LOQ's are achieved for other contaminants

- The current LOD and LOQ are not consistent with the regulatory limits.
- Methods for hexane are outdated.
- The oil residue method LOQ is **1 Million time higher** than the **PFAS** method LOQ.
- 1 mg = 1 000 µg = 1 000 000 ng.

| Substance | Substrate | Regulatory limit EU | LOD (Limit of detection) | LOQ (Limit of quantification) | Analytical tool |
|---|---|---|---|---|---|
| **N-hexane** | Oil | 1 mg/kg | 1 mg/kg | 1 mg/kg | GC-FID |
| **N-hexane** | Feed meal | 1000 mg/kg | 100 mg/kg | 300 mg/kg | GC-FID |
| **PFAS total** | water | 500 ng/kg | 0,2 to 1 ng/kg | 1 to 5 ng/kg | HPLC-MS |
| | | | 0,5 to 2 ng/kg | 2 to 10 ng/kg | LC-MS/MS |
| **PFOA and PFOS** | water | 100 µg/kg | 0,2 to 1 ng/kg | 1 to 5 ng/kg | HPLC-MS |
| | | | 0,5 to 2 ng/kg | 2 to 10 ng/kg | LC-MS/MS |

Methods for measuring PFAS are 1'000'000 times more sensitive

# We achieved better LOQs for our solvent Ecomeo on oils, meals and on animal products

- We hired laboratories who developed new methods to assess the residues in oil and meals and the transfer of residues in animal products

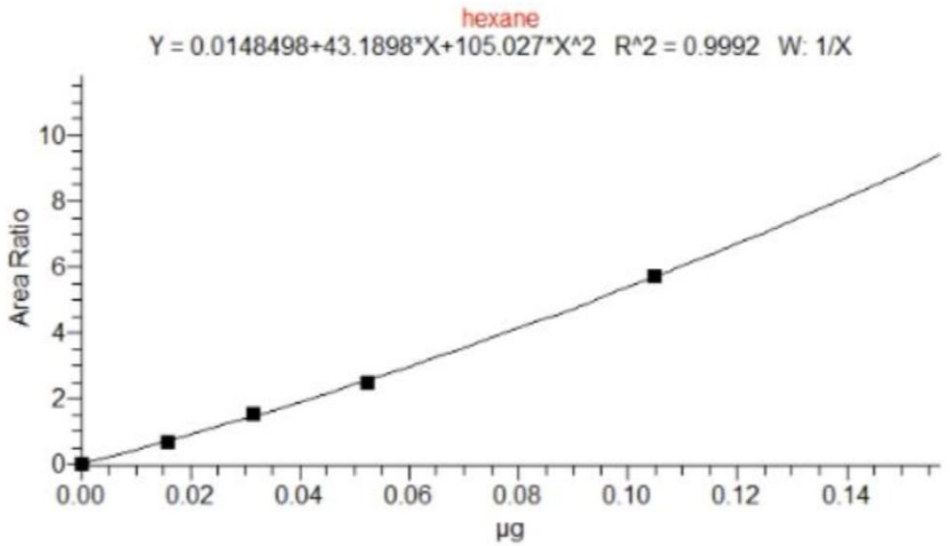
| Substance | Substrate | Regulatory limit EU | LOD (Limit of detection) | LOQ (Limit of quantification) | Analytical tool |
|---|---|---|---|---|---|
| **N-hexane** | Oil | 1 mg/kg | 1 mg/kg | 1 mg/kg | GC-FID |
| **N-hexane** | Feed meal | 1000 mg/kg | 100 mg/kg | 300 mg/kg | GC-FID |
| **2-methyloxolane** | Oil | 1 mg/kg | 5 to 20 µg/kg | 10 to 50 µg/kg | GC-MS Headspace |
| **2-methyloxolane** | Feed meal | 1000 mg/kg | 5 to 20 µg/kg | 10 to 50 µg/kg | GC-MS Headspace |
| **2-methyloxolane** | Milk | | 2,5 µg/kg | 10 µg/kg | GC-MS Headspace |
| **2-methyloxolane** | Eggs | | 2,5 µg/kg | 10 µg/kg | GC-MS Headspace |
| **2-methyloxolane** | Meat | | 2,5 µg/kg | 10 µg/kg | GC-MS Headspace |

# We developed new methods on GC-MS - Headspace for n-hexane measurement

- We hired 2 different laboratories to develop new methods :
  - Lab 1 : a university laboratory
  - Lab 2 : a privately owned laboratory
- They worked on the following matrixes :
  - Feed meal
  - Oil and fat
  - Eggs
  - Milk
  - Meat fat

# Method development

- **Lab 1** : no difficulty to develop the methods on milk (LOQ 10 µg/kg; LOD 5 µg/kg), on oils and fat (LOQ 10 µg/kg; LOD 5 µg/kg),
- **Lab 2** : difficulties to develop the method on oils and fat, milk, eggs and meat – problem of contaminated blanks – need to operate in a hexane-free environment
  - Act 1: Implementation of a thorough equipment cleaning system
  - Act 2: Change of solvent used to prepare the standard solution.
  - Act 3: Optimization of the MS acquisition method.
  - Act 4: Optimization of incubation conditions.
  - Act 5: Addition of an ultrasound step for the oil matrix.
- **Lab 2** : after adjustment, managed to develop the method on milk, eggs and poultry fat (LOQ 10 µg/kg; LOD 5 µg/kg) but not on vegetable oil.




- Example of calibration curve for the eggs

# 5 new methods availables

| Substance | Substrate | Laboratory | LOD (Limit of detection) | LOQ (Limit of quantification) | Analytical tool |
|---|---|---|---|---|---|
| **N-hexane** | Oil and fat | Lab 1 | 5 µg/kg | 10 µg/kg | GC-MS Headspace |
| **N-hexane** | Milk | Lab 1 and lab 2 | 5 µg/kg | 10 µg/kg | GC-MS Headspace |
| **N-hexane** | Eggs | Lab 2 | 5 µg/kg | 10 µg/kg | GC-MS Headspace |
| **N-hexane** | Poultry fat | Lab 2 | 5 µg/kg | 10 µg/kg | GC-MS Headspace |

- Lab 1 method on oil and fat able to measure n-hexane and 3-methylpentane

# Milk of cows fed with controled diet (INRAE)

- Cows fed either with 20% hexane extracted meal or with 20% Ecomeo (2-MeOx) extracted meal as protein supplement
- The hexane extracted feed meal contained 10 mg/kg hexane residue
- The Ecomeo extracted feed meal contained 1000 mg/kg 2-MeOx residue
- All the feed formulas contained 4% of «productivity mixture » with hexane extracted meal
- Result : n-hexane passes easily into milk. It can also pass after the cow changed diet. The diet had no impact on milk productivity.
- Read for more information https://www.journalofdairyscience.org/article/S0022-0302(25)00239-5/fulltext

## Results

**Table 1.** N-hexane and MeOx detection in milk according to diet.

| | Diet | | $X^2$ *P*-value |
|---|---|---|---|
| | HEX | 100MeOx | |
| N-hexane residues detection in milk |  |  | 0.083 |
| MeOx residues detection in milk |  |  | 0.44 |

 solvent residues detected in milk (< 10 ng.g$^{-1}$).  solvent residues not detected in milk.

# Need for hexane-free methods development

- Analytical chemistry consumes 1700 T hexane/y

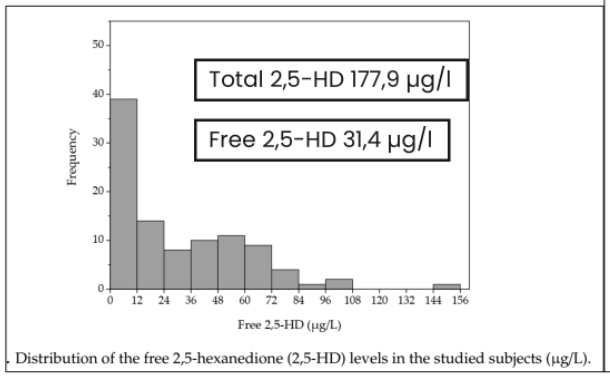
| Analytical Protocol | Field | Frequency of Use | Use of Hexane | Estimated Global Hexane Consumption (t/year) |
|---|---|---|---|---|
| Oil content determination – oilseeds (ISO 659, AOCS Am 2-93) | Agri-food / oils | Very frequent (industrial QC, research) | Soxhlet / Randall extraction | 150 – 500 |
| Oil & Grease in water (EPA 1664B and equivalents) | Environment | Very frequent (regulatory monitoring) | Triple liquid-liquid extraction | 180 – 250 |
| Total fat in meat and meat products (ISO 1443, AOAC) | Agri-food / food safety | Frequent | Soxhlet extraction | 70 – 250 |
| Column chromatography (silica / alumina) | Chemistry, lipids, natural products | Very frequent (R&D, QC) | Main eluent (100–1000 mL/run) | 100 – 300 |
| Flash chromatography (preparative / semi-prep) | Chemistry, ingredients | Frequent | Non-polar eluent (hexane/EtOAc) | 80 – 200 |
| Normal-phase HPLC (hexane-based) | Fine chemistry, lipids | Moderate to frequent | Mobile phase (1–3 L/day/instrument) | 40 – 120 |
| FAME preparation / lipid GC analysis (vial solvent) | Agri-food / nutrition | Very frequent | Sample dissolution solvent | 15 – 40 |
| TPH / hydrocarbon extraction (soils, wastes) | Environment | Moderate | Solid-liquid extraction | 15 – 60 |
| Cleaning of chromatographic columns and glassware | All laboratories | Very frequent but diffuse | Rinsing / purging solvent | 10 – 30 |

# Need for more hexane biomonitoring capacities

- Proven contamination of human urine and blood by hexane metabolite (2,5-hexanedione)
- More studies to come to better characterize the general population contamination

## Salamon et al. - 2019

- 99 non-occupationally-exposed adult italians
- Urinary level of free 2,5-HD
  - Average = 31.4 µg/l eq 0,117 mg/kg bw/day
- Urinary level of total 2,5-HD for 76 subjects
  - Average = 177.9 µg/l = 18% free 2,5-HD




Distribution of the free 2,5-hexanedione (2,5-HD) levels in the studied subjects (µg/L).

applied sciences
MDPI
Article

**Urinary Levels of Free 2,5-Hexanedione in Italian Subjects Non-Occupationally Exposed to n-Hexane**

Fabiola Salamon *, Andrea Martinelli, Andrea Trevisan, Maria Luisa Scapellato, Giovanni Battista Bartolucci and Mariella Carrieri

**Table 2.** Urinary levels of free 2,5-HD in all samples and differentiated by gender, class of age, smoking habit, area of residence, traffic intensity and BMI.

| | Sample Size | Geometric Mean ± GSD (µg/L) | Mean (µg/L) | Selected Percentile (µg/L) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | 5th | 25th | 50th | 75th | 95th |
| **Total** | 99 | 19.1 ± 2.8 | 31.4 | <12.0 | <12.0 | 20.3 | 54.3 | 77.9 |
| **Gender** | | | | | | | | |
| Males | 52 | 17.9 ± 2.7 | 31.8 | <12.0 | <12.0 | 20.6 | 58.2 | 85.5 |
| Females | 47 | 18.1 ± 3.0 | 31.0 | <12.0 | <12.0 | 20.3 | 52.2 | 72.2 |
| **Age** | | | | | | | | |
| <30 years | 24 | 19.8 ± 2.7 | 30.3 | <12.0 | <12.0 | 21.5 | 49.4 | 79.7 |
| 30–50 years | 54 | 19.8 ± 2.9 | 32.1 | <12.0 | <12.0 | 23.9 | 53.1 | 74.2 |
| >50 years | 21 | 17.0 ± 3.1 | 30.9 | <12.0 | <12.0 | 14.3 | 65.0 | 77.4 |
| **Smoking habit** | | | | | | | | |
| No | 65 | 17.1 ± 2.7 | 27.0 | <12.0 | <12.0 | 15.9 | 47.4 | 69.0 |
| Smokers | 34 | 23.8 ± 3.1 | 39.9 | <12.0 | <12.0 | 33.0 | 59.9 | 97.4 |
| <5 cigarettes/day | 15 | 24.9 ± 2.7 | 35.5 | <12.0 | <12.0 | 37.9 | 57.9 | 66.2 |
| 5–10 cigarettes/day | 8 | 16.3 ± 3.1 | 27.5 | <12.0 | <12.0 | 14.4 | 42.4 | 71.7 |
| 11–20 cigarettes/day | 11 | 29.5 ± 3.8 | 54.9 | <12.0 | <12.0 | 57.9 | 84.6 | 128.0 |
| **Residence** | | | | | | | | |
| Industrial | 1 | - | - | <12.0 | | - | | |
| Urban | 74 | 17.7 ± 2.9 | 29.9 | <12.0 | <12.0 | 16.7 | 52.4 | 75.9 |
| Rural | 24 | 25.7 ± 2.7 | 37.3 | <12.0 | <12.0 | 31.4 | 58.5 | 81.0 |
| **Traffic intensity** | | | | | | | | |
| Low | 34 | 26.3 ± 2.8 | 39.9 | <12.0 | <12.0 | 36.4 [a] | 60.5 | 89.3 |
| Medium | 48 | 15.6 ± 2.8 | 27.1 | <12.0 | <12.0 | 13.3 | 40.3 | 76.6 |
| High | 17 | 17.9 ± 2.6 | 26.9 | <12.0 | <12.0 | 15.9 | 47.4 | 68.4 |
| **BMI** | | | | | | | | |
| <25 kg/m$^2$ | 65 | 16.9 ± 2.8 | 27.8 | <12.0 | <12.0 | 16.0 [b] | 47.0 | 68.3 |
| 25–30 kg/m$^2$ | 23 | 27.6 ± 2.9 | 41.9 | <12.0 | <12.0 | 39.4 | 85.0 | 93.6 |
| >30 kg/m$^2$ | 11 | 18.4 ± 2.9 | 31.3 | <12.0 | <12.0 | 15.9 | 44.3 | 90.7 |

[a] $p = 0.03$, Low traffic intensity vs medium traffic intensity (Mann–Whitney test); [b] $p = 0.03$, BMI < 25 kg/m$^2$ vs 25 < BMI < 30 kg/m$^2$ (Mann–Whitney test).

# Conclusion

- Hexane use is challenged both by ECHA and EFSA in Europe.
- Its recent classification as SVHC shows that its use will be more and more restricted in the coming years.
- These evolution offers opportunities for the green analytical chemistry community to develop new methods
    - To better quantify hexane residue
    - To reduce hexane exposure in laboratories


Thank you!
We will take your questions!
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