Recent Regulatory Changes and Trends in Europe Regarding Hexane Extraction

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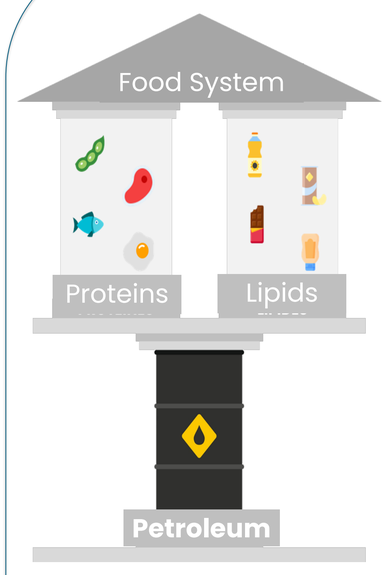
Europe leads regulatory change: toxic ingredients can be banned within less than 10 years, as shown by bisphenol A, banned in 2024 despite a large industrial use. What's next for hexane in light of Europe's regulatory momentum?

Context



***n*-hexane**

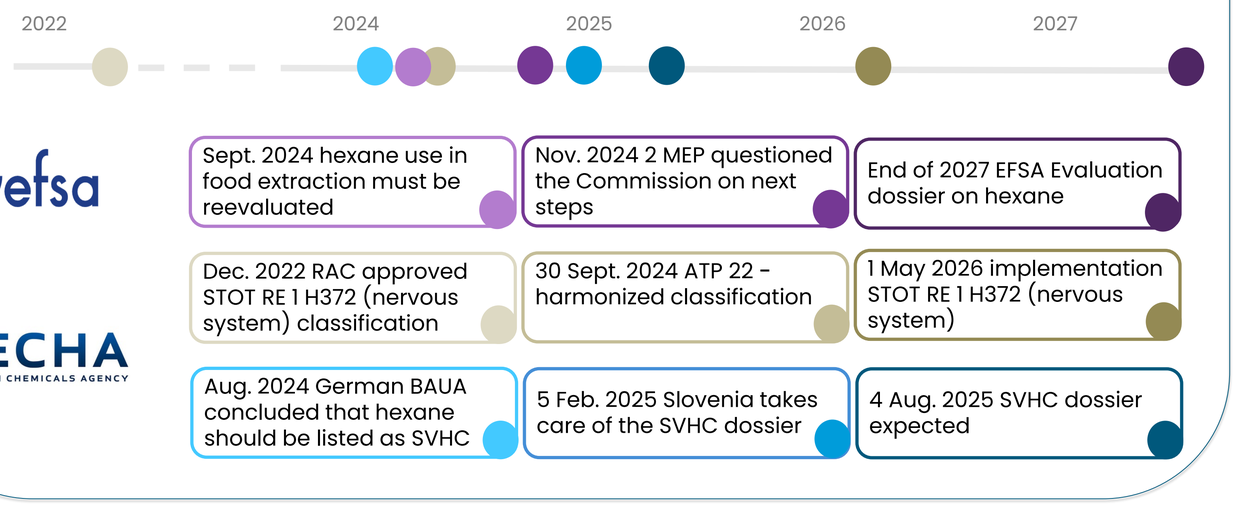
Hexane is a **petroleum-based** solvent that is widely used in the food industry to extract **oils, flavors, and natural ingredients**.

Hexane is also extensively used in **animal feed**, particularly for obtaining high-protein soybean meal used in livestock farming.

It leaves **residues** in processed products such as oils, plant proteins, milk, and plant extracts.

Regulatory Landscape in Europe

EFSA recommends to **reevaluate n-hexane's use in food extraction**.
ECHA classification confirms severe health concerns:
neurotoxicity and **suspected reprotoxicity**.
SVHC (Substance of Very High Concern) **Registry of Intention**.



SVHC - Substance of Very High Concern ECHA

Substance that may have **serious** and often **irreversible effects** on **human health and the environment**.

- A substance identified as an SVHC will be added to the **Candidate List for eventual inclusion in the Authorisation List (REACH - Anex XIV)**
- After a **sunset date**, if no robust safety dossier supports its authorization (which would only be temporary), **a substance can no longer be placed on the EU market**

Key points to note:
Industries wishing to defend hexane's use should prepare comprehensive dossiers and provide supporting arguments to prove the safety of its use.

Potential impacts:

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

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 consumer safety be guaranteed ?

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

CODEX ALIMENTARIUS

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 producers and users must have **safety dossiers** (*) 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.

EFSA scenarios

EFSA released 3 worst case exposure simulation based on current European Maximum Residue Limits of hexane in food (MRLs). These MRLs apply only to **foods of plant origin**.

1. The first simulation derived from a report by a business operator.
2. In the second simulation, EFSA Regulatory MRL scenario, MRLs that are specified by the Directive to be applied to food ingredients were applied to the food as consumed.
3. Alternative regulatory MRL scenario. This scenario assesses the hypothesis that the MRLs would apply to the ingredients instead of the food as sold to the final consumer.

Population group	Max 95th percentile		
Infants	1559	1550	380
Toddlers	697	780	310
Other children	266	320	190
Adolescents	144	160	100
Adults	125	120	80
Elderly & very elderly	101	80	70

unit: µg/kg/day

Exposure in the general population (recent robust studies) vs EFSA scenarios

Scientific publications report the levels of hexane's metabolite, 2,5-hexanedione (2,5HD). The correlation between free 2,5-HD and systemic exposure to n-hexane is based on the study by Ruiz-García et al. (2020), considering that 25% of hexane is absorbed. Additional details are available upon request.

Salamon et al. 2019

Ages ranges	#	Calc. exposure to hexane µg/kg bw/day
<30 yrs	24	774
30-50 yrs	54	720
> 50 yrs	21	751
Total	**99**	**756**

EFSA Exposure Scenarios are exceeded...

By 6 to 9 times
(EFSA adults vs 30-50 yrs old)

Xing-Fu et al. 2016

Ages ranges	#	Calc. exp. to hexane µg/kg bw/day
6-12 yrs	1245	1082
13-16 yrs	1520	1115
17-20 yrs	1258	989
21-30 yrs	1516	1052
31-45 yrs	1503	876
46-69 yrs	1193	821
Total	**8235**	**1000**

- **By 3 to 6 times for children**
- **By 7 to 11 times for adolescents**
- **By 7 to 13 times for adults**

(EFSA adults vs 17-20 yrs old / 21-30 yrs old / 31-45 yrs old / 46-69 yrs old)

Children are the most exposed to n-hexane
(EFSA exposure scenarios and the recent Chinese study)

With EFSA revisiting its safety evaluation,
With ECHA classifying n-hexane as STOT RE 1,
With its inclusion in the SVHC Registry of Intent,
And with population exposure exceeding by far EFSA's scenarios,
The safe use of hexane is increasingly difficult to justify.
Restrictions, or even a full ban, can't be excluded in Europe.