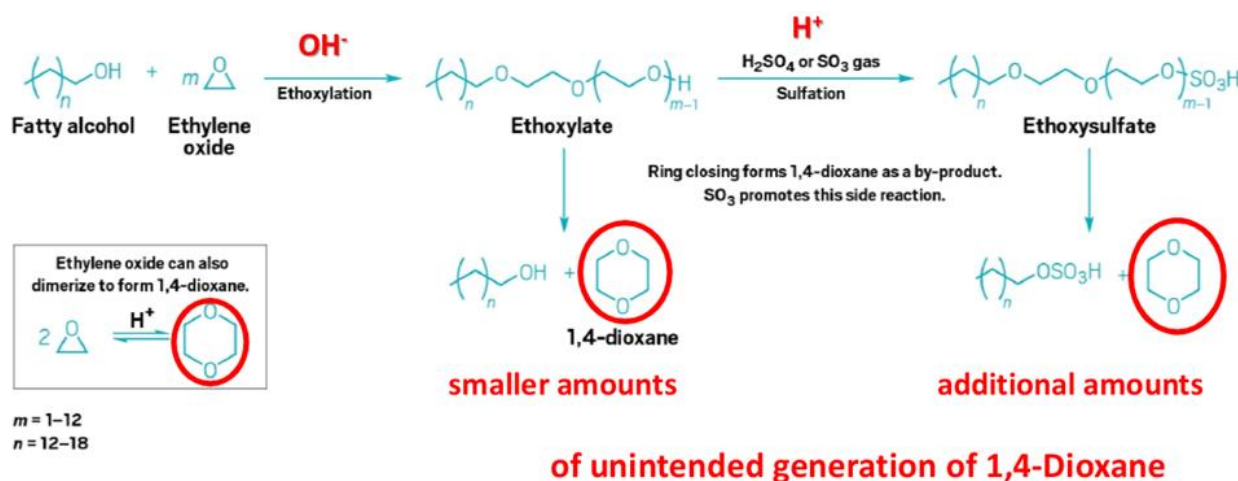


Global Regulatory Status Update 1,4-Dioxane

This document is a summary of information concerning the history of regulatory investigations into the health hazards of 1,4-dioxane and the pending regulatory restrictions on products that contain 1,4 dioxane. This document is not meant as the end-all regulatory statement but is provided, as a courtesy and unofficial summary, to CPDA members, to alert them to the potential changes and disruption that these regulatory restrictions could impose on our industry. Each member should conduct their own in-depth regulatory review, based on official reports and documents of the governmental agencies referenced in this summary before making any decisions for their company.

One by-product of ethoxylation is 1,4 dioxane:



The contaminant 1,4-dioxane can be formed during manufacture of ethoxylated surfactants and remain as trace impurity in end-user products (cosmetics, homecare, agrochemical, construction/mining).

This by product has been classified or defined as:

Human Health

- US EPA: As "likely to be carcinogenic to humans" by all routes of exposure
- EU: As a Class 1B Carcinogen and a Persistent, Mobile and Toxic (PMT) substance

Environment

- Short-lived in the atmosphere.
- May leach readily from soil to groundwater.
- Migrates rapidly in groundwater.
- Is relatively resistant to biodegradation.

In the USA, 1,4 dioxane was evaluated under the TSCA Risk Assessment completed in Dec 2020. It was released for public consultation in July 2023 in a draft supplement to risk evaluation (EPA Document # EPA 740-D-23-001, July 2023; "Draft Supplement to the Risk Evaluation for 1,4 -dioxane. CARN 123-91-1). The evaluation considered exposure from air and water as well as a byproduct/impurity.

The cancer risk estimates:

- >1 in 10,000 for a range of occupational exposures
- > 1 in 1 million for general population exposures

No restrictions were proposed at that time but the right to recommend further risk management measures was reserved. In the meantime, 1,4 dioxane is heavily regulated at the state level in groundwater and surface water.

In New York State, it was discovered that ground water had high levels of 1,4-Dioxane. An assessment determined that it would be difficult and expensive to remove i.e. to attain <1 ppb would require an investment of \$27 million. NY Senate Bill S4389B was passed in December 2019 - "Act to amend the environmental conservation law, in relation to prohibiting household cleansing products, cosmetic products and personal care products that contain 1,4-Dioxane"

NY Bill 1,4-Dioxane Limit Restrictions Summarized

Personal Care and Household Cleaning products	2 ppm by Dec 31, 2022 1 ppm by Dec 31, 2023	2025: Department of Environmental Conservation in consultation with the Department of Health can determine, by rule, if the 'trace concentration threshold shall be lowered to better protect human health and the environment'
Cosmetic products	10 ppm by Dec 31 2022	

In California, the 1,4-dioxane made Prop 65 and the "Cleaning product right to know Act". Manufacturers of cleaning products are required, by these regulations, to intentionally declare added ingredients and non-functional constituents at >100ppm. The 1,4-Dioxane was specifically set at >10ppm and Cosmetic products are Exempt.

In 2019, California Department of Toxic Substances Control (DTSC) issued a document entitled "1,4-Dioxane in Personal Care and Cleaning Products". This document identified 1,4-dioxane as a contaminant of concern, citing the disposal risk rather than a direct consumer risk. The DTSC continues to gather information, evaluating public comments, and assessing alternatives on this by product.

In Europe, REACH officials the chemistry as SVHC (Substance of Very High Concern) due to CMR (Carcinogenic, Mutagenic and Reprotoxic chemical) and PMT (Persistent Mobil Toxic substance) classifications. In April 2023, German authorities submitted a proposed intention to ECHA (European Chemical Agency) to restrict 1,4-dioxane in surfactant raw materials with a proposed level set at a maximum of 1 ppm with requirements and mandate that wastewater discharges from surfactant producers should be "free-from" 1,4-dioxane. It was cited that "once in water [the 1,4-dioxane] cannot be removed" and "River Rhine shows permanent detectable levels". CESIO (EU surfactant manufacturing trade association) have submitted comments on the restriction proposal and will conduct an independent socio-economic analysis (SEA). Formal restriction proposal is expected October 2025 (delayed from original April 2024 estimate).

In EU 1223/2009 (cosmetic product regulations) Annex II lists 1,4-dioxane as a prohibited substance in cosmetics products. However, Article 17 of that regulation, allows 1,4-dioxane at “technically unavoidable levels”. The SCCS Opinion 2015 and ICCR Working Group 2017 proposed:

Phase 1: ≤25 ppm in finished products

Phase 2: ≤10 ppm in finished cosmetic products over a ‘suitable transition period’

At this time, no formal date was agreed to, but EU REACH (Germany restriction proposal) will have overarching impact.

In the European Agrochemicals industry, EU No 1107/2009 (plant protection product regulations) 1,4-dioxane is NOT listed on Annex III – ‘co-formulants which are not accepted for inclusion in plant protection products’. However, as a category 1 CMR, the limit for acceptable presence as unintentional impurity in finished product is 0.1%w/w.

Within the United Kingdom, the UK REACH will assess all substances submitted for SVHCs in line with EU REACH. UK HSE and Environment Agency are working on a regulatory management options analysis (RMOA). RMOA will investigate risks and recommend the best approach to protect human health and the environment. In Feb-April 2022: UK HSE launched a 60-day call for evidence on the manufacture, import, hazard profile, use and exposure, e-fate, waste disposal requirements and recycling opportunities for 1,4-dioxane. At the current time of this summary, 1,4 dioxane was not formally listed an SVHC under UK REACH and no specific restriction limits have been proposed.

Summary

If this EU REACH restriction is imposed unmodified between now and October 2025, the date it is due to be published in its final form on the ECHA website, it will have a huge impact on the surfactants industry. The potential limits of 1ppm in surfactant raw material instead of the current 1 ppm in finished products, as per the restriction in New York state, will be devastating. Below is a list of chemistries that will potentially be affected by this regulation:

Alcohol ether sulfates	Alkyl ether carboxylates and derivatives
Alcohol Alkoxylates	Ethoxylated Sulphosuccinate derivatives
Alcohol ethoxylates	Alkylphenol ethoxylates
Fatty acid ethoxylates	Castor oil ethoxylates
Fatty amine ethoxylates	Sorbitan ester ethoxylates (polysorbates or Tweens)
Tristyryl phenol ethoxylates	Phosphate esters of ethoxylated alcohols

An estimate of the surfactants volume in Europe that could potentially be in jeopardy if the maximum 1 ppm 1,4-dioxane proposed restriction on surfactants ends up being imposed is at least 1 million MT out of 3 million MT total surfactants produced in Europe annually. Therefore, by extrapolation, the volumes worldwide could possibly be in the range of 3M MT. There are, of course, other surfactants that could be used in some formulations that would replace these chemicals, but there is not the industry infrastructure in place to produce this extraordinary volume in the short to mid-term.

JUNE 19th, 2020 → ASEAN: Cosmetics – 25ppm California: household prod -10ppm (by declaration)	DECEMBER 31st, 2022 → NY State-household and Pers. Care cleansing products-2ppm Australia: recommends 10 ppm consumer products	June 19th, 2023 → ASEAN Cosmetic Prod – 10ppm	DECEMBER 31st, 2023 → NY State household and Personal Care Cleansing Products – 1 ppm	Oct. 2025? FORMAL European Union Proposal?
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