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To the EU Regulatory Issue Brief from ATTIA Ltd. representing the Australian Tea Tree Industry.

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Register

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AUSTRALIAN TEA TREE INDUSTRY

ISSUE BRIEF

EUROPEAN CHEMICALS AGENCY
TEA TREE OIL RE-CLASSIFICATION

ATTIA Response To the Damaging Re-Classification of Tea Tree Oil by the European Chemicals Agency.

ATTIA is taking action to support the industry following landmark ruling.

The Australian Tea Tree Industry (ATTIA Ltd; www.teatree.org.au) has swung into action to support the local and European industry through its biggest regulatory challenge – the classification of tea tree oil as a Category 1B reproductive toxin by the European Chemicals Agency (ECHA).

In November 2023, ECHA's Committee for Risk Assessment (RAC) recommended that tea tree oil be classified as Category 1B for reproductive effects (reprotoxin), i.e. fertility – may damage fertility; development – may damage the unborn child. Category 1B was also recommended for skin sensitisation, i.e. may cause an allergic skin reaction.

A substance considered to be a reproductive toxin falls into one of three main classification levels under the Globally Harmonised System (GHS) of hazard identification:

Category	Criteria
Category 1A	Known human reproductive toxicants Based on evidence from humans.
Category 1B	Presumed human reproductive toxicants - largely based on animal studies. • Clear evidence of adverse effects on sexual function and fertility or on development in absence of other toxic effects has been identified; or • If occurring with other toxic effects, the reproductive toxicity is not considered to be a second non-specific consequence of the other toxic effects. • If there is mechanistic information that raises doubt about the relevance of the effects for humans, category 2 is more appropriate.
Category 2	Suspected human reproductive toxicant - Evidence from animal and/or human studies is limited • There is some evidence supplemented with other info and the evidence is not sufficiently convincing to place the substance in category 1. • For example, bad quality of studies.

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Critically, "hazard" is the only thing that is actually considered by ECHA – not the likelihood of the hazard being triggered, so "risk" is not considered.

The committee recommended other tea tree oil classifications, including:
Category 2 – chronic aquatic toxicity, i.e. toxic to aquatic life with long-lasting effects; Category 1 – aquatic acute effects, i.e. very toxic to aquatic life;
Category 3 – STOT SE (specific target organ toxicity– single exposure), i.e. may cause drowsiness or dizziness.

Implications

Should the Category 1B reproductive toxin recommendation proceed, the European manufacturers of cosmetic products containing tea tree oil, and Australian suppliers of tea tree oil, would be decimated. Even if approved as a cosmetic ingredient, every cosmetic product in the EU would be heavily labelled with warnings and hazard statements, and only one cosmetic category would be able to be sold. Category 1B is effectively an end to the use of tea tree oil in the EU except in therapeutic applications as a medicine.

Any regulations against tea tree oil will likely have a knock-on effect for other essential oils, other naturally complex substances, as well as some of the major components of tea tree oil such as p-cymene and terpinolene. P-cymene, a constituent of tea tree oil and a constituent of many essential oils, fragrances & flavourings, is also under Classification review at the time of this publication.

ATTIA is Taking Action.
Extension of Safety Dossier.

For many years, ATTIA members have funded and developed an extensive dossier to provide evidence of the safety of Australian tea tree oil to the EU's Scientific Committee on Consumer Safety (SCCS).

The dossier will now be updated to show that exposure to tea tree oil in consumer products applied topically, as in cosmetics, poses no risk to humans.

Collaboration

ATTIA is engaging in a Tea Tree Oil Taskforce with Consortium HE, and liaises with key European industry associations and manufacturing companies on a regular basis. Other associations, including IFRA and EFEO, have resolved to support this combined effort.

The goal for ATTIA is to have the SCCS determine that tea tree oil is a safe cosmetic ingredient. ATTIA will continue to lead efforts to prepare a suitable SCCS dossier and is cooperating with European associations to ensure that the submission is made to the SCCS as soon as practical, and within the required timeframe.

Abbreviations:

ATTIA Ltd: representing the Australian Tea Tree Industry; CARACAL: Competent Authorities for REACH and CLP; CLP: Classification, Labelling and Packaging; EFEO: European Federation of Essential Oils; EFSA: European Food Safety Authority; IFRA: International Fragrance Association; RAC: Committee for Risk Assessment; REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals; SCCS: Scientific Committee on Consumer Safety (SCCS).

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Why is this Happening?

The classification crisis was triggered by a standard European safety review of a plant fungicide, which uses tea tree oil as its active component.

EU law required that tests be conducted on the active substance (in this case, tea tree oil) to determine whether the substance may have mutagenic, reproductive and/or endocrine effects.

Three 90-day animal studies conducted by the fungicide manufacturer, Stockton, demonstrated that tea tree oil – when delivered via gavage to rats, rabbits and dogs at medium to high doses – had adverse effects on male animal reproductive systems. Damage extended to sperm formation, epididymis and testes damage. Rabbits recovered once dosing was complete. Rats and dogs did not. The low dosage administration did not result in reprotoxic effects in the animal studies.

The demonstration of this reproductive effect immediately triggered a further regulatory requirement for the substance to be reviewed under the EU's Classification, Labelling and Packaging (CLP) Regulations.

In December 2022, the European Chemical Agency (ECHA) published invitations to a "Consultation" on a proposed classification of tea tree oil as a Category 2 reproductive toxin.

The decision by the RAC to classify tea tree oil as Category 1B directly contradicts the original recommendation by the Rapporteur Member State Poland, which proposed that tea tree oil be categorised as Category 2. The rationale was that the hazard had been clearly identified but humans do not ingest tea tree oil orally and therefore the risk would not be present.

During the consultation period, which included remaining EU member states, industry associations, and individual manufacturers, 8 out of 10 responses relating to reproductive toxicity stated they did not believe that the oral gavage method of delivery was an appropriate method of dosing to indicate effects on humans – particularly for cosmetics. However, both the Sweden and the Netherlands representatives advanced an extreme rating, suggesting that the classification should be upgraded to Category 1B, despite the lack of human evidence.

Who and what's involved in the decision process?

Scientific Committee on Consumer Safety (SCCS)	**The European Chemicals Agency (ECHA)**	**Committee for Risk Assessment (RAC)**	**Competent Authorities for Registration, Evaluation, Authorisation and restriction of CHemicals [REACH] and Classification, Labelling and Packaging [CLP] (CARACAL)**
This is the EU's advisory body responsible for providing independent and authoritative scientific advice and opinions on consumer safety aspects of non-food consumer products and services – including cosmetic products and their ingredients.	ECHA is responsible for implementing the EU's chemicals legislation, and helps companies comply with specific EU legislation on chemicals or biocides, including REACH regulations, and classification, labelling and packaging issues.	RAC prepares the opinions of ECHA, although the final decisions are taken by the European Commission. The RAC examines the proposals for harmonised classification and labelling and gives an opinion on whether substances may be carcinogenic, mutagenic, toxic for reproduction or a respiratory sensitiser, or other effects.	CARACAL works with the EU and ECHA in the implementation of the REACH and CLP Regulations.

REACH

REACH is a regulation of the EU that considers the risks to consumers that can be posed by chemicals. In principle, REACH applies to all chemical substances, not only those used in industrial processes, so the regulation has an impact on most companies across the EU.

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They must demonstrate to ECHA how the substance can be safely used.

Why ATTIA disputes the Category 1B decision.

ATTIA's position is that the science relied upon for the RAC determination is a flawed consideration of the facts.

1. The data examined animal evidence, not humans.

The basis of the recommendation comes from a review of the data submitted by the fungicide manufacturer, studies from the REACH safety dossier on tea tree oil, the European Food Safety Authority (EFSA), or general published literature.

Three 90-day animal studies demonstrated that tea tree oil, delivered by gavage (force-feeding down the throat) to rats, rabbits and dogs at medium to high doses, had adverse effects on male animal reproductive systems.

However, there is no evidence from studies of any kind or any reports in the literature of a parallel human effect arising from the topical use of tea tree oil or its related constituents.

Defenders of tea tree oil provided studies indicating that if a dietary method of dosing (i.e. incorporated into animal feed) had been used for testing, then no evidence of the reproductive effect would have been found.

One company defending tea tree oil provided evidence which indicated rats are unable to break down terpenic molecules similar to those found in tea tree oil. This results in toxic metabolites remaining in the rat system which seem to interfere with the mechanisms of lipid production required to produce healthy sperm and testes.[1] The fact that rabbits did not experience the same toxicity indicates species-specific responses.

However, the RAC dismissed the arguments that there was sufficient doubt based on the dosing method (gavage v dietary). The RAC rejected the evidence from in vitro hepatic cell testing that the rat is an inappropriate test model for determination of this reproductive effect. If these inter-species differences were proven, a large basis of ECHA's toxicity test results could be challenged and potentially invalidated.

The lack of any evidence of an effect in humans was not considered sufficiently robust to suggest there is no effect on humans.

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2. A hazard is not a risk

In making its decision, the RAC was limited only to considering the absolute hazard that a substance might pose. It does not consider how likely it is that the hazard will be triggered. It does not consider exposure, method of delivery (e.g. oral v topical) or any type of risk assessment.

Hazard vs risk explained

A hazard is something that has the potential to cause harm, whereas a risk is the real likelihood of a hazard causing harm.

Even water is a hazard: drink too much and you may experience water poisoning caused by electrolyte imbalances, or a disruption of brain function.

But if you consider the likelihood of this actually happening – and the amount of water you would need to consume to have these effects – it makes sense that water is not a risk that requires regulation.

Water is also a key ingredient in cosmetics. Using the logic applied to the category 1B decision, where only the presence of a hazard is considered (not the risk), any product containing the hazard – water – could also be considered for a Category 1B rating.

3. The logic applied to "hazards" is flawed

Tea tree oil was assessed through the lens of "the presence of a hazard" in the substance, rather than the risk of danger occurring in humans.

Using this logic, drinking water is a choking hazard, eating meals cooked with herbs is a hazard, and salt should be classed as Category 1B reprotoxin following findings that high-dose sodium and/or sugar had a significant impact on sperm production and sperm physiology in rats.[2]

Given that the main constituents of tea tree oil are found at some level in many of the common herbs and spices ingested by humans for thousands of years without any indication of a reproductive effect, ATTIA would challenge the complete dismissal of the metabolic pathway argument by the RAC reviewers.

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Foods containing tea tree oil constituents	Implications
Oregano Basil Cardamom Turmeric Cloves Black pepper Cumin Nutmeg Mango	If tea tree oil is classified as a 1B reprotoxin, then logic suggests this should lead to foodstuffs containing these same components being effectively banned too.

4. Humans don't ingest tea tree oil orally

Because the original data related to a fungicide, the review considered human exposure through dietary means. However, humans would not ingest the medium to high dosage levels used in the animal tests: based on human bodyweight, the dosage that would need to be ingested to compare with the levels used in the tests would be enormous.

In fact, the initial classification report (a preceding report that triggered the RAC process) recommended Category 2 status because tea tree oil is not ingested by humans and animal dietary studies in related molecules confirm that gavage provides different reproductive outcomes in animals compared with dietary ingestion.

Data Summary

- There is no evidence of a human reproductive effect from ingesting the terpenic compounds found in tea tree oil. In fact ingestion of common herbs and spices containing the compounds suggests the exact opposite.
- There is no evidence of human reproductive effect from the topical use of tea tree oil.
- There is *in vitro* study evidence to suggest a mechanistic difference in the way that rat vs human livers process terpine compounds.[1]
  - ATTIA hopes to engage a laboratory to perform i*n vitro* studies to prove this difference, specifically for tea tree oil components.

References:

1. *Natsch A et al. A species-specific metabolism leading to male rat reprotoxicity of Cyclamen aldehyde: in vivo and in vitro evaluation. Food Chem Toxicol 2021; 153: 112243.*
2. *Adekunbi DA et al. Consumption of high sucrose and/or high salt diet alters sperm function in male Sprague–Dawley rats. Egypt J Basic Appl Sci 2016;3:194–201*

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What's next?

The RAC recommendation is not the end of the process.

ATTIA will work with relevant parties to counter the Category 1B classification as a reproductive toxin by drawing counter arguments and new data to the attention of EU regulators at two further opportunities.

1. SCCS: We will submit a comprehensive Safety Dossier to the SCCS.

2.CARACAL: The recommended classifications are not law until the recommendations of the RAC Plenary meeting are reviewed by another review committee called CARACAL (Competent Authorities for REACH and CLP).

New data can potentially be submitted to CARACAL including:

- new toxicological evidence showing that rats do not physiologically process tea tree oil the way humans do, and that the ability to safely break down tea tree oil constituents is a mechanistic response and is not influenced by the method of exposure i.e. either orally or topically

- data outlining the socio-economic effects of the Category 1B classification and potential banning of tea tree oil usage in the EU.

CARACAL will look at the 2023 RAC recommendations and decisions made sometime between July and November 2024, and will be a critical opportunity for ATTIA and the EU industry to stop the reclassification of tea tree oil.

Meantime, ATTIA will:

- collaborate with EU companies and industry bodies to generate new data

- finalise the development of the safety dossier for lodgement with the SCCS

- work with EU manufacturers and industry associations to provide persuasive political and economic arguments to alert governments to the economic fallout of the classification

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- defend tea tree oil in other regulated markets who will be watching the EU situation unfold.

The Cosmetic Regulations permit an application for an exemption to continue as a cosmetic ingredient even though classified as CMR 1B. The timeline for the processing of the exemption application is potentially:

- Notify that the proposed CMR substance will be applying for an exemption
- Lodge safety dossier with SCCS within 6 months of the publication of the RAC Opinion (published 9th February 2024)
- Lodge exposure dossier covering all possible exposures to consumers across the EU from all sources
- Lodge food safety information
- Lodge evidence that tea tree oil cannot be substituted with another ingredient or ingredients in cosmetic products

It will be difficult and expensive to defend tea tree oil, but Australian Tea Tree growers, ATTIA, and supporting EU cosmetic manufacturers are committed to this defence. It absolutely can be achieved.

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