Hazard vs. Risk:

EU's Green Deal Fragrance Misstep

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Abstract

The European Union's Chemical Agency intends to promote a hazard-focused approach to chemical regulation moving forward. The present policy paper provides a brief glimpse of the disastrous consequences of this decision on essential oils. Customers will switch from natural repellents based on essential oils to synthetic solutions that harm people and the environment. The 2.21 billion dollar natural beauty cosmetics and perfumes industry is at risk; 255,000 employees and 1.71 million jobs could stay in limbo. Bulgaria, France, Italy, and Spain stand to lose a combined 892 million euros in export revenue and at least 68,500 farmers and workers. Policymakers should therefore encourage the switch from hazard-based to realistic risk-based policies.

Introduction

As part of the Green New Deal, the European Union's Chemical Agency (ECHA) plans to promote a "sustainable-by-design" point of view outlined in the Chemicals Strategy for Sustainability adopted on the 14th of October 2020. The ECHA aims to achieve its goal by adopting a hazard-based mentality. According to the hazard model, the mere presence of one potentially dangerous component in a product is enough to justify restricting its sale or preventing it from entering a specific sector (officially termed "pre-market measures").

Regulations like REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) and CLP (Classification, Labelling, and Packaging) embody this way of thinking within the EU. Both documents claim identifying and classifying a potentially harmful ingredient within specific danger categories are the only steps needed to restrict a substance. The guidance accompanying the texts makes this dedication to hazard-based thinking clear: "The classification of chemicals is to reflect the type and severity of the intrinsic [emphasis added] hazards of a substance or mixture," not " the actual exposure of humans and the environment to the substance or mixture displaying this hazard."

The method seems intuitively attractive as a solution. There is no need to expose humans or the environment to repeated trial and error. Let scientists test a new ingredient under the controlled conditions of good laboratory practice. Specialists can anticipate chemical properties from test-data analogs (using similar substances which should have similar effects on the same organisms) or use specialized number-based Q(SAR) prediction models to guess the biochemical features of a material. With the power of such tools, the hazard-based approach can block dangerous materials and prevent unfortunate accidents from occurring in the first place while simultaneously guaranteeing that future substances are safe for everyone on Earth.

The promises of hazard evaluation are too good to be true. While theoretically sound, no amount of testing under laboratory conditions can control for real-life reactions to hazard-based policies. Consumers and producers are not passive recipients waiting for a ruling to descend on their lives. They will adapt to the restrictions by substituting the use of one substance for another or exiting the market altogether. Despite its best intentions for the environment, the approach creates the opposite of what it set out to do - a riskier, economically ineffective, and more polluting world.

If the counter-argument sounds too abstract and unlikely, a practical example will better illustrate the consequences of the ECHA's new strategy for ordinary consumers and producers. Essential oils are steam and water-distilled or manually pressed extracts from various plants' twigs, leaves, woods, seeds, fruits, flowers, bark, and roots. Two-hundred-thirty-seven oils meet this definition, including common household names like lavender, citronella, and rose. They are present in anything from scented candles and perfumes to insect repellents. Such versatility makes them a perfect case study for exploring the broad ramifications of ECHA's policies.

In the wake of the Strategy for Sustainability, the ECHA will place essential oils under the new REACH and CLP category of persistent mixtures in the human body. Under this new classification, if just one molecule of 600 in the oil could be harmful when analyzed under conditions that never hold in the real world, the entire product may be labeled dangerous and restricted.

The rest of the policy paper will explore just some of the negative economic, environmental, and social consequences of the ECHA's plan for essential oils.

It removes a moderately-effective bug repellent. In higher concentrations (at least 10% emulsified formula), essential oils are effective short-to-medium-term repellents (1 to 4 hours) against various pests. Of course, essential oils are not perfect. Their benefits may be impressive, but they wear off after several hours (though creams or microcapsule formulas can extend their lifespan). And they can cause skin irritation or minor allergic reactions.

Nevertheless, robust scientific evidence shows how citronella, sage, or cinnamon products are decent alternatives for DEET, picaridin, and IR3535. For one, essential oils are a good tool for warding off mosquitoes, including disease-transmitting species like Aedes aegypti. A study on 11 different plant essential oils found that sage performed exceptionally well against mosquitos, with sage-derived ointments offering complete protection for one hour, matching commercially-approved repellents. Another article cites petitgrain emulsions providing 270 minutes of protection against no less than three species of mosquitos. At the same time, other research provides evidence of the efficacy of specific essential oils against ticks. An article published in Nature employed 20 different sampled substances in its tests. It found clove and cinnamon lotions repelled tick bites for longer than one hour.

And unlike more synthetic substances, a review of multiple studies on the topic emphasizes their use as environmentally friendly and their benefits as synergistic. Plant combinations with different dosages can prolong and amplify their positive effect, with mixtures providing 59% coverage for up to four hours. All the while, pollinators, and other friendly insects remain unscathed.

However, by labeling products like sage potentially dangerous, the Strategy for Sustainability will cause consumers to pick artificial and possibly more harmful substitutes over essential oils. A large study looked at 66 academic articles on package warnings to determine how much different types of labeling affected consumer behavior.

Fifty of the observed results related to chemical substances in particular. Customers tend to ignore health labels on cigarette packs encouraging people to moderate or quit the habit. But they pay attention to a skull and crossbones and a description of immediate trouble on an item's packaging. As the study found, people tend to avoid merchandise labeled as unsafe for use. It is easy to see how the hazard approach will incentivize customers to quit essential oils in favor of alternatives like DEET. That is despite the fact DEET can affect the human nervous system if used in large quantities (inhibiting the critical enzyme of acetylcholinesterase in the brain) and has a more lasting impact on plants and animals.

It would wreak havoc in the European perfume and cosmetics industries. More than just repellents, essential oils are integral to perfumes, toiletries, and makeup accessories, creating the 'clean beauty' cosmetics market as we know it today. Nine hundred ninety-two indispensable ingredients in the industry come from these natural extracts. Their hydrophobic, anti-inflammatory, anti-microbial, and anti-oxidant properties make them ideal as emulsions that are easy to apply, hygienic, long-lasting, and suitable for diverse skin types. For example, peppermint and lavender do not just emit a pleasant smell. Their anti-oxidant features mean they decelerate the cell degradation process (of great potential for any anti-aging gel). As non-steroidal anti-inflammatories, they help reduce pain with minimal complications. And their anti-fungic and anti-microbial nature helps keep a customer's skin clear of unwanted acne or infections. Unsurprisingly, the oils combine into the 3,225 fragrances that grant world-famous perfumes like Givenchy and Channel their unique odor and shampoos and makeup kits their vibrant colors.

Restricting or banning essential oils threatens the entire 'clean beauty' industry. In 2022, the European natural market was valued at 2.21 billion euros, projected to increase by 860 million euros to a total of 3.11 billion euros in 2026. The sector's rapid growth was made possible partly by the current EU cosmetics law, which allows for

using essential oils under the label of complex natural substances. Once that legislation changes in the new ECHA framework, many oils will no longer be allowed on the market, forcing producers to look for alternatives. However, other options are also likely to be restricted, if not under REACH, then under existing EU Regulation 2021/1902 (prohibiting any use of 23 substances as potentially carcinogenic or toxic). The hazard-based approach will put entire perfumeries and cosmetic firms out of business, jeopardizing billions of euros and potentially hundreds of thousands of jobs (with certain ramifications for 255 000 directly employed in the beauty sector and two million indirect jobs).

It would hurt small and medium businesses (SMEs) the most. The negative consequences of the ECHA's plan do not stop at the beauty industry. The European arm of the essential oil market is worth 3.53 billion euros, with an estimated annual growth of 5.3% to 9%. The sector is already consolidated around major players and enterprises because of the demanding requirements of complying with REACH regulations – 85% of the firms that could sign up to the rules were larger firms. Yet, thanks to hazard-based ideas, the industry will become even more dominated by big companies, as small businesses operate with thinner profit margins and suffer more from every additional regulatory burden. The probability of what the EU anti-trust dubs "abuse of market dominance" (influencing prices to a greater degree than other actors engaged in exchange) will thus increase, courtesy of the EU's own actions.

It would impact some countries in the EU more than others. The ECHA's plan threatens to derail the economic development of the European Union's poorest state, Bulgaria. Bulgaria is one of the world's top lavender oil producers, cultivating over 40,000 acres of lavender in the Rose Valley region and exporting 99% of its product to France, Germany, Austria, and the US. The country is the world's top producer of rose oil, responsible for creating between 800kg to 2 tonnes of the product a year for the big cosmetics and perfumery

companies. The change in regulation threatens the livelihoods of the 35,000 employed in harvesting roses in the world-famous Rose Valley. It also scuppers the 92 million euros in total exports Bulgaria gains from essential oils. The ECHA could accidentally make the poorest country in the EU even poorer.

But Bulgaria is not the only country affected by the new rules. France is Europe's second-largest producer of lavender and the third-largest exporter of essential oils globally (only behind the United States and India). It stands to lose no less than 458 million euros in global trade because of the ECHA's plans. Another country affected would be Italy, with 174 million euros potentially lost. Southern Italy represents 95% of the world's total supply of bergamot, with 4500 families in the Calabria region responsible for cultivating the herb. The families' cooperatives and small ownership companies cannot hope to comply with the new dispositions without enormous costs. Lastly, Spain's exports stand at 168 million euros. Spain is a world leader in lemon oil production, with no less than 20,000 farmers handling and processing lemon oil. Both their jobs and Spain's export gains are now on the line.

Conclusion

What holds in theory does not necessarily apply in practice. In pursuing absolute safety, the hazard approach endangers the health of European consumers, the survival of several European industries, and the economic progress of European countries. For these reasons, policymakers should help the ECHA rethink the Strategy for Sustainability and shift from a hazard to a risk-based management approach. Risk-based judgments understand that real-world substances don't fall into a strict dichotomy of "dangerous" or "not dangerous" based on their simple presence and characteristics. Exposure and the conditions of that exposure matter. A chemical is likely more or less harmful if the concentration of that chemical reaches a certain level or if the person is in the presence of that substance for a longer time.

In this sense, risk-based thinking is more realistic than its counterpart. Instead of controlled laboratory conditions, policymakers must engage with empirical evidence from real-world toxicological data. This data allows them to think in comparative rather than absolute terms. Policymakers can now see that restricting certain substances may unintentionally replace one potential problem with a larger one and that the scientific risks may not be worth the economic, political, or social risks.

EU policies should use risk-based assessments to create health guidelines grounded in the scientifically safe level of intended use. Moreover, they should weigh a product's pros and cons while considering the alternatives' advantages and disadvantages. By doing so, they will encourage and inform consumer and commercial decision-making, abandoning the futile desire for absolute control.

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