Unpacking the Fragrance Industry:

Policy Failures, the Trade Secret Myth and Public Health

An investigative report by Women's Voices for the Earth
Published November 2015
Updated September 2018

WOMEN'S VOICES FOR THE EARTH
OUR HEALTH. OUR FUTURE. TOXIC FREE.

Table of Contents

Our Mission:
Women's Voices for the Earth has been amplifying women's voices to eliminate the toxic chemicals that harm our health and communities for 20 years. Learn more at: www.womensvoices.org

About the Author:
Alexandra Scranton is the Director of Science and Research at Women's Voices for the Earth. This report is a result of over six years of research and persistent watchdogging of the fragrance and cosmetic industries. Alex also authors WVE's other scientific reports and provides scientific review for the organization's programs. She has a master's degree in Environmental Studies from the University of Montana and a B.A. from Amherst College.

Part I:
In Fragrance Regulation, it's the Fox Guarding the Hen House

Introduction

Currently, the safety of fragrance chemicals is not determined by any governmental agency globally in any comprehensive fashion. Instead the fragrance industry has been trusted to self-regulate, and to establish its own safety guidelines for the use of fragrance chemicals. The current system for fragrance safety is run entirely by the International Fragrance Association (IFRA), the industry association representing fragrance manufacturers, and their research arm, the Research Institute for Fragrance Materials (RIFM).

Despite the obvious inherent conflict of interest present when an industry regulates itself (note that the primary association members of IFRA also serve on the Board of Directors for RIFM, the body that is tasked with determining the safety of fragrance ingredients), the descriptions of the IFRA/RIFM Fragrance Safety program sound robust and thorough. Specifically the program includes four key features:

1. RIFM peer-reviewed science on fragrance chemicals
2. Validation and review of the peer-reviewed science by an independent Expert Panel
3. A comprehensive database of toxicological, eco-toxicological data and physical-chemical properties associated with known fragrance materials
4. IFRA standards determining allowable levels of fragrance chemicals to be used in products

However, the reality of the details of each of these features reveals the safety system to be incomplete, biased, and operating with a problematic lack of transparency which far better serves the financial interests of the fragrance industry than protects public health. The public can and should expect better. In Part I of this investigative report, we unpack the features of the industry's self-regulating Fragrance Safety Program and explain the incredible shortcomings of the Safety Program.

1. RIFM peer-reviewed science on fragrance chemicals

What the Industry says:

"Transparent Science Supports Brand Trust…The Research Institute for Fragrance Materials (RIFM), founded in 1966, is the international scientific authority for the safe use of fragrance materials. RIFM generates, evaluates and distributes scientific data on the safety assessment of fragrance raw materials found in fine fragrances, and other personal and household care products."[i]

The Reality:

Industry research: The vast majority of the scientific studies on fragrance materials are generated by major fragrance manufacturers or RIFM's own laboratories. Largely, these studies have never been published or peer-reviewed and are referenced with citations that read something like:

> "RIFM (Research Institute for Fragrance Materials, Inc.), 1979ff. Primary eye irritation study with 1-(5,5-dimethyl-1-cyclohexen-1-yl)pent-4-en-1-one in rabbits. Unpublished report from Firmenich Incorporated, Report number 50158 (RIFM, Woodcliff Lake, NJ, USA)."

> "RIFM (Research Institute for Fragrance Materials, Inc.), 1973a. Skin irritation and capacity for allergic sensitization for a-amylcinnamaldehyde (amyl cinnamicalde-hyde) determined by four different tests performed on guinea pigs. Unpublished report from Givaudan, May 11. Report number 56004 (RIFM, Woodcliff Lake, NJ, USA)."

> "RIFM (Research Institute for Fragrance Materials, Inc.), 1987. Mutagenicity evaluation of linalyl acetate in the Ames Salmonella/microsome reverse mutation assay. Unpublished report by Lorillard Tobacco Company, January 30. Report number 36497 (RIFM,Woodcliff Lake, NJ, USA)."

Most of the basic science studies on fragrance ingredients are conducted by the manufacturers themselves and have never been published in a peer-reviewed scientific journal. There is no independent review of laboratory practices, appropriate controls, levels of significance or any of the hallmarks of authoritative science, to ensure that the results of these studies have not been manipulated to serve the interests of the manufacturer conducting the testing.

Recently, the European Commission Scientific Committee on Consumer Safety (SCCS) reviewed studies on fragrance materials submitted by RIFM, to produce their opinions on the safety of certain fragrance materials. Their assessments of RIFM studies commonly noted the studies' scientific inadequacies, such as incomplete data, inability to confirm identify of the test substance, invalid test protocols, lack of appropriate controls, and more. The SCCS frequently commented that the data submitted could not reliably be used to form a conclusion of safety.[ii, iii]

RIFM peer-reviewed research

The few RIFM papers that have been peer-reviewed have almost exclusively been published in just two peer-reviewed journals, Food and Chemical Toxicology and Regulatory Toxicology and Pharmacology. These papers are either authored by RIFM scientists, (i.e. - employees of the fragrance industry), or they are published by the RIFM expert panel. These papers are not reporting on the results of primary science (that is experiments in the lab) but rather are reviews of the literature, drawing conclusions on the safety of fragrance ingredients based on other scientists work. A significant problem with these safety reviews is that they largely depend on a review of the unpublished reports on fragrance materials described above. This is surprising, as most peer-reviewed journals require that any cited references in a paper must be published papers from scientific journals. In fact the "Guide for Authors" document for Food and Chemical Toxicology states:

> "Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text."[iv]

However, an in depth look at two RIFM reviews on the safety of fragrance ingredients show a wide disregard of this policy. The paper "RIFM fragrance ingredient safety assessment, Linalyl acetate, CAS Registry Number 115-95-7" published in Food and Chemical Toxicology in 2015, includes 42 citations for unpublished RIFM results in the reference list. This represents more than one third of the 123 total references for the paper. Similarly, in the paper.[v] "RIFM fragrance ingredient safety assessment, α-amylcinnamaldehyde, CAS registry number 122-40-7" also published in Food and Chemical Toxicology in 2015, includes 32 unpublished RIFM results in the reference list, making up more than 45% of all the references cited in the reference list.

The fact that these reviews were published in a peer-reviewed journal is questionable, but perhaps not that surprising given that they were only published in two specific journals, both of which commonly publish industry-generated science.

2. The RIFM Expert Panel

What the Industry says:

"All of RIFM's research is reviewed by an independent Expert Panel, an international group of dermatologists, pathologists, toxicologists environmental and respiratory scientists that have no commercial ties to the fragrance industry. The Expert Panel advises RIFM on its strategic approach, reviews protocols and evaluates all scientific findings. Their conclusions form the basis for the Standards set by the International Fragrance Association (IFRA)." [vi]

"The Expert Panel selects its own members, who serve on a rotating basis. It is comprised of internationally known academic dermatologists, pathologists, toxicologists and environmental scientists. Additional expertise is provided by adjunct groups with knowledge in genetic toxicity, respiratory science, reproductive effects, environmental fate and epidemiology. The Panel determines safety of use for fragrance ingredients through consideration of available information and active generation of additional data. Its conclusions are presented to professional, scientific and medical societies and are published in peer-reviewed scientific journals." [vii]

The Reality:

The fragrance industry handpicks the data for the expert panel to review.

The Expert Panel bases its decisions and deliberations of a fragrance chemical on a dossier of scientific information compiled by, and often generated by, RIFM staff.[viii] This means that the information the expert panel reviews has been curated by fragrance industry staff with an inherent bias towards a conclusion of safety for the materials they currently work with.

The Expert Panel has not reviewed all of RIFM's research, nor have they published their findings on all fragrance chemicals currently in use.

The Expert Panel has reviewed and published their findings on a relatively select group of chemicals. There is a noticeable omission of expert panel reviews of any fragrance chemicals which are controversial due to their potential toxicity, including phthalates, synthetic musks, styrene, methyl eugenol and others. It appears that RIFM has either chosen not to request an expert review of the fragrance chemicals of greatest known concern, or, if done, their reviews were never made public. In the case of diethyl phthalate, there is a RIFM peer-reviewed paper; oddly, it is authored solely by Dr. Api, Vice President, Human Health Sciences at RIFM, and does not include any opinions or deliberations by the expert panel.[ix] Similarly for many of the other potentially toxic and controversial fragrance chemicals, there are only considerably older monographs (many published in the 1970s) also solely authored by RIFM staff scientists.

The Expert Panel operates in secret. *

The Expert Panel's meetings are not publicized, and thus are not open to public comment or public oversight. No Expert Panel meeting transcripts or minutes are publicly available to shed light on their deliberations.

**** 2017 UPDATE:** In early 2017, just over a year after the initial publication of this report, RIFM published a new website at: http://fragrancesafetypanel.org/. For the first time in its history, the RIFM Expert panel began publishing agendas and minutes of its meetings. Also posted on this website is a Transparency Policy, dated September 2016, which affirms the Expert Panel's commitment to greater transparency going forward. The policy includes a commitment to solicit written submissions and data from the public on the fragrance materials they plan to review.*

3. The RIFM Database

What the Industry says:

"THE RIFM DATABASE: Through extensive research, testing and constant monitoring of pertinent scientific literature, RIFM maintains the most comprehensive Database, worldwide, of toxicological, eco-toxicological data and physical-chemical properties associated with known fragrance and flavor materials. The RIFM Database covers more than 5,700 substances, categorized by CAS numbers, and contains related synonyms, regulatory, inventory, occupational and industry labeling information." [x]

The Reality:

The RIFM database is not publicly accessible to those outside the fragrance industry. The database is largely available only to members of RIFM, which are companies involved in the manufacture and sale of fragrances. A single limited non-member subscription to the database is available for $20,000 per year for "persons, firms or corporations who are not eligible for membership in RIFM or FEMA but are directly engaged in a business in the fragrance or flavor industry" but only if the request is authorized by a RIFM review committee.[xi] Yet, according to Perfumer and Flavorist magazine, nonmember subscriptions do not include access to Member Company or RIFM sponsored full study reports.[xii] This means that while the numerous unpublished studies on fragrance materials conducted by fragrance manufacturers (described above) are likely included in the database, scientists outside the industry have no access to them in order to assess their credibility.

4. IFRA standards

What the Industry says:

"The IFRA Standards form the basis for the globally accepted and recognized risk management system for the safe use of fragrance ingredients and are part of the IFRA Code of Practice. This is the self-regulating system of the industry, based on risk assessments carried out by an independent Expert Panel."

"The Standards amount to 186 substances which have been either banned or restricted in their use in fragrance products. All members of IFRA are required, as a condition of membership, to observe the IFRA Code of Practice."

The Reality:

There are no IFRA standards in place for many of the most controversial fragrance ingredients of concern.

There are no restrictions in place for the use of the following known carcinogens: styrene, pyridine, or benzophenone. There are no restrictions on the use of phthalates of any kind. There are no restrictions on the synthetic musks Galaxolide or Tonalide. Similarly, none of these chemicals appear to have been assessed for safety by the Expert Panel.

IFRA standards establishing "safe" levels of skin sensitizers have largely failed, resulting in little to no decreases in reported sensitization or allergy to fragrances.

Largely, the restrictions that have been put in place are intended to eliminate the skin sensitization (or allergy) to fragrance ingredients. Despite decades of IFRA restrictions on fragrance sensitizers in place, there has been no meaningful decrease in the incidence of fragrance sensitization or allergy in the general population.[xiii] In fact, in a 2015 dermatological study in the United States, the rate of positive skin reactions to fragrance was found to increase significantly in recent years.[xiv] Even in children, including those born after many of the restrictions were enacted, there has been no decrease seen in rates of fragrance sensitization. [xv]

Many of the restrictions are guided by a RIFM-developed methodology called the Dermal Sensitization Quantitative Risk Assessment (QRA) to determine the appropriate levels of skin sensitizers allowed in different types of cosmetic products. The European Commission Scientific Committee on Consumer Safety (SCCS) had this to say about the quality of this methodology:

> *"The data provided show that the application of the dermal sensitisation QRA approach would allow increased exposures to allergens already known to cause allergic contact dermatitis in consumers. The model has not been validated and no strategy of validation has been suggested. There is no confidence that the levels of skin sensitisers identified by the dermal sensitisation QRA are safe for the consumer."* [xvi]

IFRA standards are voluntary, with little to no compliance verification required.

IFRA member companies must comply with IFRA standards to maintain their membership, but compliance with the standards is almost never verified. Fragrance manufacturers must provide an IFRA Conformity Certificate to their customers to assure them that the standards are being met for any fragrance product they sell. The IFRA certificate is usually a single piece of paper which simply states that the fragrance compound is in compliance.[xvii] No third-party verification, or even in house testing results are required to be included or referred to in the Certificate. IFRA describes the document as:

"The IFRA Certificate is a document established by the fragrance compound manufacturer and ***based on a trust relationship*** *between the fragrance supplier and its customer. It means that, using this certificate, a fragrance supplier assures to his customer that they work according to the good manufacture practices described in the IFRA Code of Practice."* (Emphasis added)[xviii]

IFRA does facilitate a small independent IFRA compliance program. However, of the hundreds of thousands of different fragranced products on the global market, just fifty products are randomly tested each year for compliance.[xix] The results of the compliance program are not presented on the IFRA website.

Conclusion

While at first glance the industry's Fragrance Safety Program seems robust, a deeper investigation reveals a severe lack of transparency, oversight, and regulation of the materials used in fragrance. The IFRA safety program has valid features, but they are incomplete and inconsistently applied. The holes in the process allow for potentially toxic chemicals to be included in fragrance without further examination. The lack of transparency means the public cannot independently verify the conclusions of the IFRA safety program and must blindly trust in the industry's claims. The result is a safety program that does not adequately protect public health from exposures to fragrance chemicals.

A first needed step to combating these inadequacies is to gain greater transparency around the ingredients used in fragrances. That means that policymakers must recognize that the industry's call for trade secret protection of ingredients is merely a myth that allows them to continue to hide from detailed inquiries about potentially unsafe ingredients. In Part II, we expose this myth.

i. http://www.rifm.org/rifm13/uploads/RIFM-Brochure.pdf
ii. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_167.pdf
iii. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_172.pdf
iv. http://www.elsevier.com/journals/food-and-chemical-toxicology/0278-6915/guide-for-authors#20300
v. http://fragrancematerialsafetyresource.elsevier.com/sites/default/files/115-95-7.pdf
vi. http://www.rifm.org/about.php#.Vbk_jPmAvqU
vii. http://www.rifm.org/expert-panel.php
viii. http://www.ifraorg.org/en-us/about-the-standards#.VfHdj5c0NkU
ix. http://www.ncbi.nlm.nih.gov/pubmed/11267702
x. http://www.rifm.org/rifm13/uploads/RIFM-Brochure.pdf
xi. http://www.rifm.org/uploads/Non-member%20Database%20Sub%20fees%202014v2.pdf
xii. http://www.perfumerflavorist.com/networking/news/company/12594631.html
xiii. Nardelli A, Carbonez A, Drieghe J and Goossens A. (2013) Results of patch testing with fragrance mix 1, fragrance mix 2, and their ingredients, and Myroxylon pereirae and colophonium, over a 21-year period. Contact Dermatitis. Vol. 68, pp: 307-313. 2013.
xiv. Warshaw EM, Maibach HI, Taylor JS, Sasseville D, DeKoven JG, Zirwas MJ, Fransway AF, Mathias CG, Zug KA, DeLeo VA, Fowler JF Jr, Marks JG, Pratt MD, Storrs FJ and Belsito DV. (2015) North American contact dermatitis group patch test results: 2011-2012. Dermatitis. Vol. 26, No. 1, pp: 49-59. Jan-Feb 2015.
xv. Vongyer GA and Green C. (2015) Allergic contact dermatitis in children; has there been a change in allergens? Clinical and Experimental Dermatology. Vol. 40, No. 1, pp:31-34. January 2015.
xvi. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf
xvii. http://www.ifraorg.org/en-us/frequently-asked-questions#.VfHek5c0NkU
xviii. http://www.ifraorg.org/en-us/frequently-asked-questions#.VfHek5c0NkU
xix. http://www.ifraorg.org/en-us/compliance-programme#.VfHgu5c0NkU

Part II:
The Need for Trade Secret Protection for Fragrance is a Myth

Introduction

In Part II of this investigative report: – Unpacking the Fragrance Industry: Policy Failures, the Trade Secret Myth, and Public Health – w, we examine the public health need for disclosure of fragrance ingredients,; debunk the industry myth that fragrance ingredients should enjoy trade secret protections,; and call on policymakers to move past from antiquated policies that only protect industry's interests and towardsto health-protective policies that improve public health.

The public health need for fragrance ingredient disclosure

"Fragrance" is a term found frequently in ingredient lists for cosmetics and other household products. It is a generic term which represents the combination of tens to hundreds of individual fragrance chemicals that can comprise any single "fragrance". All told there are roughly 3,000 different fragrance chemicals commonly in use that can be combined to create a "fragrance".[i] However, the individual fragrance chemicals that make up a "fragrance" are rarely disclosed to the consumer. This lack of disclosure creates a state of ignorance on the part of consumers, scientists, health care providers and their patients regarding what chemicals one is actually exposed to from fragranced products. This is highly problematic given the tens of millions of people with fragrance allergies or sensitivities (roughly 2-11% of the general population by the latest estimates). A smaller percentage of the population found to be highly sensitive to chemical exposure to fragrance often suffer even greater adverse reactions which can include respiratory, neurological and immune system problems. In addition, there are a number of chemicals of concern to public health that are used in fragrance that deserve greater scrutiny. The International Fragrance Association list of fragrance ingredients includes carcinogens such as styrene and BHA, endocrine disruptors such as parabens and synthetic musks, two types of phthalates (diethyl phthalate (DEP) and di-isononyl phthalate (DINP) and others.

Without fragrance ingredient disclosure, consumers of fragranced products cannot know what they are actually being exposed to and cannot avoid chemicals of concern. Those who are sensitive or allergic are unable to diagnose what specific fragrance chemicals are causing their reactions. Instead they are told that they are reacting to "fragrance", which is akin to being told one is allergic to "food", without identifying specific food allergens. The only advice for those allergic or sensitive to "fragrance", or who wish to avoid fragrance chemicals of concern is to avoid all "fragrance".

Given that fragrance use is so ubiquitous in modern culture, the avoidance of "fragrance" is nearly an impossible task. (As one example, a recent survey found that 96% of shampoo brands sold in the U.S. contain "fragrance".[ii]) Other consumers are particularly interested in avoiding chemicals of concern such as carcinogens or reproductive toxins to better protect their health and the health of their children. Fragrance ingredient disclosure would allow individuals and scientists to better understand which fragrance ingredients are the most problematic, and would allow individuals to avoid the chemicals of most concern to their health. This would result in a tremendous public health benefit to millions of people across the country.

Why aren't fragrance ingredients disclosed to the consumer?

A Tradition of Keeping Trade Secrets

Labeling simply as "fragrance" is due to the fragrance industry's long held tradition of keeping trade secrets for fragrance formulas. They have historically held these secrets tightly, literally behind lock and key, claiming the formulas to be the lifeblood of their industry. The fragrance industry argument goes something like this:

> "Products of the fragrance industry, like those of other high technology industries, are valuable as a result of intellectual effort invested in their creation… Trade secrets have been the principle means by which our rapidly innovating industry has historically protected its intellectual property." [iii]

Thus, out of respect for the claimed intellectual property needs of the fragrance industry, numerous consumer product regulations globally have specifically exempted fragrance from ingredient disclosure requirements. However, a simple list of ingredients (without percentage amounts) found in a fragrance no longer meets the definition of a "trade secret". The Uniform Trade Secrets Act ("UTSA") defines a trade secret as:

- information, including a formula, pattern, compilation, program, device, method, technique, or process,
- that derives independent economic value, actual or potential, from not being generally known to or readily ascertainable through appropriate means by other persons who might obtain economic value from its disclosure or use; and
- is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[iv]

The Reality of Reverse Engineering

Furthermore, the innovations in reverse engineering technology in recent decades make it possible to create a list of ingredients (and in fact to quantify this list) with incredible precision. Many manufacturers have the technology in-house to analyze their competitor's products in order to better understand, imitate, or improve upon their scents. This fails to meet the definition of trade secret because a list of a fragrance's ingredients is currently "readily ascertainable through appropriate means by other persons who might obtain economic value from its disclosure or use".

In fact, in the International Fragrance Association 2013 report on trade secrets in the fragrance industry they state:

> "The relatively cheap availability of analytic technologies like gas chromatography-mass spectrometry now allow for very detailed analyses of fragrances. Using these latest techniques to support an experienced perfumer, a competitor can rapidly bring close approximations of the original to the market without having to recover the substantial R&D investment of the innovator. This reality was illustrated by perfumer Bernard Chant when he publically divulged some of the key ingredients used in perfumes he created: "I am going to take the liberty of mentioning some key ingredients used in these creations. I feel that in the age of chromatography anyone can identify them, so I am not revealing any secrets."[v]

While an exact replica of a fragrance's formula is unlikely to be discerned by a competitor through chemical analysis, clearly a very close approximation of the formula can be recreated through reverse engineering. For the most part, that level of specificity is more than enough information to create a passable counterfeit product, which is where the economic value lies.

Reverse engineering technology undoubtedly creates vulnerabilities to fragrance manufacturers and is likely responsible for the considerable counterfeit fragrance market. **A simple list of ingredients, on the other hand, provides no new information to counterfeiters, and certainly is a lot less helpful than the specificity that can be obtained by analysis by gas chromatography-mass spectrometry.**

(For additional information regarding top fragrance houses and their ability to reverse engineer, see Appendix A.)

Should the Industry be granted any Trade Secrets?

The fragrance industry may well have trade secrets worth protecting. The creation of any one fragrance can involve a number of factors that could be considered valuable intellectual property, such as: the sourcing and processing of raw materials, innovations in encapsulation and fragrance delivery, and the technical knowledge of how the individual ingredients are combined. This information may not be easily revealed through reverse engineering, and thus would not be "readily ascertainable" by competitors.

Conclusion

Trade secret protection in the fragrance industry has its place, to protect these valuable secrets of the industry. A simple list of ingredients however, without any additional nuanced insider information, is clearly ascertainable by independent means and thus simply doesn't meet the definition of a trade secret. Regulators should recognize that industry's call for trade secret protection is an outdated tradition, rather than a legitimate request; granting this exemption simply perpetuates the trade secret myth and compromises public health.

The disclosure of a simple list of ingredients would have a significant public health benefit to consumers of fragranced products. Individuals would be able to avoid the chemical ingredients they are concerned about (such as carcinogens), as well as any ingredients they react to (such as allergens), without the burden of trying to avoid fragrances altogether.

The bottom line is that trade secret protection of fragrance ingredients is an outdated policy, which poses an unnecessary and harmful barrier to the public's right to know.

i. International Fragrance Association (IFRA) (2015) Ingredients. IFRA Survey Transparency List, Available at: http://www.ifraorg.org/en-us/ingredients 2015.
ii. Scheman, A., Jacob, S., Katta, R., Nedorost, S., Warshaw, E., Zirwas, M. and Bhinder, M. (2011) Hair products: Trends and Alternatives: Data from the American Contact Alternatives Group. Journal of Clinical and Aesthetic Dermatology. Vol. 4,No. 7. pp: 42-46 July 2011.
iii. International Fragrance Association (IFRA) (2013) Valuable Yet Vulnerable: Trade Secrets in the Fragrance Industry. IFRA. February 2013. Available at: www.ifraorg.org/view_document.aspx?docId=23107
iv. https://www.law.cornell.edu/wex/trade_secret
v. International Fragrance Association (IFRA) (2013) Valuable Yet Vulnerable: Trade Secrets in the Fragrance
vi. Industry. IFRA. February 2013. Available at: www.ifraorg.org/view_document.aspx?docId=23107
https://www.law.cornell.edu/wex/trade_secret

Part III:
Chemicals of Concern in Fragrance

Introduction

In Part III of this investigative report – *Unpacking the Fragrance Industry: Policy Failures, the Trade Secret Myth, and Public Health* – we examine the thousands of fragrance chemicals used by the fragrance industry and demonstrate that many of the chemicals have been identified as chemicals of concern by authoritative governing bodies, but are not being examined by the International Fragrance Association and its research arm, RIFM.

There are more than 3,000+ chemicals on the International Fragrance Association (IFRA) Transparency List of chemicals used in the industry. To date, there is no single comprehensive published review of the hazards posed by the many chemicals on this list.

However, there are a number of resources which indicate that a large number of the chemicals regularly used in fragrance manufacturing are of concern to public health. The IFRA Transparency List also contains many examples of fragrance chemicals that are restricted or banned in products by government agencies and/or retailers, or are otherwise included on authoritative lists of chemicals of concern.

Fragrance Chemicals and Hazard Warnings

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is an internationally agreed-upon system, which clarifies the hazard classification of individual chemicals and recommends associated labeling of chemicals on chemical safety data sheets. Signal words such as "danger" or "warning" signal the severity of hazard associated with a chemical. Pictograms, such as a "skull and crossbones" are assigned to visually represent hazards of chemicals, and hazard phrases such as "may cause cancer" or "may affect fertility or damage the unborn child" are assigned to more specifically indicate the type of hazard a chemical poses. A review of UN GHS classifications of fragrance chemicals finds that:

- 190 fragrance chemicals have been assigned the signal word "danger" for their Safety Data Sheet.
- 1,175 fragrance chemicals have been assigned the signal word "warning".

- 44 fragrance chemicals require pictogram GHS06 of a skull and crossbones to indicate acute toxicity.

- 97 fragrance chemicals require pictogram GHS08 indicating the chemical is a hazard to human health.

Examples of UN GHS hazard phrases assigned to certain fragrance chemicals include:

H300 Fatal if swallowed
H302 Harmful if swallowed
H304 May be fatal if swallowed and enters airways
H310 Fatal in contact with skin
H311 Toxic in contact with skin
H312 Harmful in contact with skin
H313 May be harmful in contact with skin
H314 Causes severe skin burns and eye damage
H315 Causes skin irritation
H316 Causes mild skin irritation
H317 Causes serious eye damage
H319 Causes serious eye irritation
H330 Fatal if inhaled
H331 Toxic if inhaled
H332 Harmful if Inhaled
H335 May cause respiratory irritation
H361 Suspected of damaging fertility or the unborn child
H372 Causes damage to organs through prolonged or repeated exposure
H401 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects
H411 Toxic to aquatic life with long lasting effects.

Fragrance Chemicals with International Warnings

Fragrance chemicals can be found on authoritative lists (that is lists that have been recognized by regulating bodies) of toxic chemicals around the world.

- 5 fragrance chemicals are included in the National Toxicology Programs 13th Report on Carcinogens
- 7 fragrance chemicals are classified as carcinogens in the IARC Monographs
- 11 fragrance chemicals are California Proposition 65 Carcinogens and Reproductive Toxicants
- 15 fragrance chemicals are on the Washington State Chemicals of Concern to Children list
- 15 fragrance chemicals are prohibited from use in cosmetics in the EU (EU Annex ii)

Canadian Cosmetic Ingredient HotList –

- 6 fragrance chemicals prohibited for use in cosmetics in Canada
- 29 fragrance chemicals restricted for use in cosmetics in Canada

- 4 fragrance chemicals are on the EU Endocrine Disruptors Priority List
- 29 fragrance chemicals are designated Toxic Substances in South Korea

For names and CAS numbers of fragrance chemicals on these lists see Appendix B (available online at: www.womensvoices.org/fragrance-chemicals-of-concern-on-ifra-list/)

Examining the Safety of Fragrance Ingredients Using the GreenScreen® for Safer Chemicals

In order to identify potential chemicals of concern in fragrance we examined the GreenScreen® for Safer Chemicals List Translator scores of the over 3,000 fragrance ingredients currently reported to be in use by the International Fragrance Association. The GreenScreen® List Translator identifies chemicals of concern using information from over 40 chemical

hazard lists developed by international, national, and state governmental agencies, intergovernmental agencies, and NGOs. We discovered that approximately one-third of fragrance ingredients currently in use are flagged as known or potential chemicals of concern on one or more of these authoritative lists of hazardous chemicals. In contrast, we found that relatively few of these listed fragrance chemicals of concern have ever been assessed for safety by the fragrance industry, and even fewer of these fragrance chemicals of concern have ever been restricted or prohibited by the fragrance industry's self-imposed IFRA standards.

This analysis appears to show that the fragrance industry's priorities for addressing potential chemical hazards are truly out of synch with the priorities of governments, scientific bodies and NGOs around the world working to improve chemical safety.

Findings:

Of 3,000+ fragrance chemicals that were reported to be used by fragrance manufacturers:

- 11 fragrance chemicals are rated Benchmark-1: "Avoid - Chemical of High Concern"
- Another 28 fragrance chemicals are rated LT-1: List Translator Likely Benchmark 1
- And another 1,203 fragrance chemicals are rated LT-P1: List Translator Possible Benchmark 1
- A total of 1,242 fragrance ingredients (roughly one-third of all fragrance chemicals currently in use) are included on one or more authoritative lists of chemicals of concern.

For names and CAS numbers of fragrance chemicals of concern and their GreenScreen® scores see Appendix C (available online at: www.womensvoices.org/greenscreen-for-safer-chemicals-list-translator-scores-for-fragrance-chemicals/)

What is the fragrance industry doing to assess and manage fragrance chemicals safety?

The fragrance industry's safety program includes publishing safety assessments of fragrance ingredients and issuing voluntary standards restricting or banning the use of certain fragrance chemicals of concern. Between 2003 and 2018, RIFM, the Research Institute for Fragrance Materials, published safety assessments on almost 500 unique fragrance ingredients in the Food and Chemical Toxicology Journal. These safety assessments were the results of deliberations by the RIFM Expert Panel. Of the over 3,000 fragrance materials in use, RIFM prioritized these 500 chemicals to be assessed for safety in the last 15 years and for the results of these assessments to be published.

How do RIFM's assessment priorities compare to GreenScreen® List Translator scores?

None of the 11 fragrance chemicals rated Benchmark 1 have been assessed for safety with a published safety assessment by RIFM.

None of the 31 fragrance chemicals rated LT-1 have been assessed for safety with a published safety assessment by RIFM.

Less than one third of the 1,201 fragrance chemicals rated LT-P1 have been assessed for safety with a published safety assessment by RIFM.

The fragrance chemicals prioritized for safety assessment by RIFM largely do not reflect the lists of chemicals of concern prioritized around the world by scientists, governments and NGOs working on chemical safety.

How do IFRA standards compare to GreenScreen® List Translator scores?

Similarly, in the last several decades the fragrance industry has prioritized several hundred fragrance chemicals by issuing IFRA Standards which either restrict or completely prohibit their use. The IFRA standards are used widely, with fragrance manufacturers commonly certifying that their products are compliant with IFRA standards to substantiate

their safety. Similarly, manufacturers of fragranced prodcuts frequently tout the safety of their fragrances by assuring their compliance with IFRA standards. However, the priorities for issuing IFRA standards differ significantly from the priorities of international bodies assessing the risks of chemicals. IFRA has rarely issued standards (restrictions or prohibitions) on fragrance chemicals of concern prioritized around the world by scientists, governments and NGOs working on chemical safety.

There are **0** IFRA standards issued for any of the 11 Benchmark 1 rated fragrance chemicals.

There are just **3** IFRA standards issued for any of the 27 LT-1 rated fragrance chemicals.

There are just **83** IFRA standards restricting or prohibited any of the **1,203** LT-P1 rated fragrance chemicals.

A fragrance that is compliant with IFRA standards may still include unrestricted levels of chemicals found to be of concern by international authorities.

Conclusion

Very few of the fragrance chemicals of concern on these lists presented above have been reviewed by the RIFM Expert Panel in the last 15 years. Even fewer IFRA standards exist which restrict the use of these fragrance chemicals of concern. While these chemicals have been prioritized by numerous governmental bodies, scientific authorities and NGOs due to their potential toxicity, these same chemicals have not been prioritized by the IFRA/RIFM safety program.

RIFM claims to be “the international scientific authority for the safe use of fragrance materials”. Numerous governmental agencies have deferred to RIFM’s expertise to ensure the safety of fragrances for consumer use. Unfortunately, RIFM is not living up to the responsibility it has been granted. At the very least, one would expect the fragrance chemicals of greatest concern to human health to be at the forefront of RIFM’s safety program. The publicly available data shows us that this is simply not the case.

For more information see **Appendix B** and **Appendix C** (available online at: womensvoices.org/fragrance-chemicals-of-concern-on-ifra-list/ **and** womensvoices.org/greenscreen-for-safer-chemicals-list-translator-scores-for-fragrance-chemicals/)

GreenScreen® Definitions

GreenScreen® for Safer Chemicals is a method for chemical hazard assessment designed to identify chemicals of high concern and safer alternatives. In an assessment, a chemical is assigned hazard levels for each of 18 human and environmental health endpoints such as carcinogenicity, reproductive toxicity, endocrine activity, aquatic toxicity, persistence and others. Those hazard level assignments are then rolled up into a benchmark score indicating preferability.

Benchmark 1 (BM-1):
Avoid - Chemical of High Concern

A score of “Benchmark 1 (BM-1): Avoid - Chemical of High Concern” means the chemical has been found to meet the GreenScreen® Benchmark-1 criteria, and indicates the highest level of concern.

Currently, full GreenScreen® assessments are only available for a limited number of chemicals. In lieu of complete assessments, the GreenScreen® List Translator provides preliminary information to help screen for potential chemicals of concern. The GreenScreen® List Translator assesses hazards of a chemical using information from over 40 chemical hazard lists developed by international, national, and state governmental agencies, intergovernmental agencies, and NGOs. The authoritative lists used by GreenScreen® include the European Union Substances of Very High Concern Candidate List, both the IARC Carcinogens and National Toxicology Program (NTP) Report on Carcinogens (RoC) lists, the Globally Harmonized System of Classification and Labeling (GHS) lists of several countries, and many more.

LT-1 - List Translator Likely Benchmark 1

A List Translator score of "LT-1" means the hazard classifications for a given chemical meet one or more of the GreenScreen® Benchmark-1 criteria and would most likely be a Benchmark-1 chemical.

LT-P1 - List Translator Possible Benchmark 1

A List Translator score of "LT-P1" means the chemical is a "possible benchmark 1". Further research is needed to determine if the chemical is indeed a GreenScreen® Benchmark-1.

Appendix A - Reverse engineering capacity of the major fragrance manufacturers

As further evidence of reverse engineering capacity, the major fragrance manufacturers occasionally promote their capacity to recreate fragrances. Largely, this is in reference to their technological abilities to capture and then identically recreate the scent of a living flower in their laboratories. (By synthetically recreating the scent of a natural sample, a manufacturer avoids the potentially harmful effects and costs of over-harvesting rare flowers.) But it is clear that the technology employed to capture the scent of a live flower would be equally accurate at capturing and recreating the scent of a competitor's product.

Below are examples from four of the largest fragrance manufacturers globally describing their technologies:

International Flavors & Fragrances (IFF): "Living Flower Technology"

"To capture the fragrance of live flowers, a glass globe is placed over a blooming bud with a retractable needle positioned as close to the flower as possible without touching it. The scented atmosphere immediately surrounding a flower is called "headspace."

The molecules emitted from the flower at that moment bind to the tip, Patel says. It takes 30 minutes to get an accurate reading, then the results are fed into a computer that creates a fragrance profile.

From there, the fragrance can be re-created again and again and again.

"We're producing nature-identical molecules, produced synthetically," explains Clint Brooks, IFF senior vice president of research and development." [i.]

Givaudan: ScentTreks

"Using a biotechnical innovation known as headspacing, company scientists set off into jungles and swamps on what Givaudan calls ScentTreks, carrying a device that looks something like a goldfish bowl. Instead of plucking a rare orchid and transporting it back to a lab to extract its essential oil, the scientists invert the device over the flower in situ to capture an exact synthesis of its smell. The orchid is left completely intact, growing exactly where it was." [ii.]

Firmenich: NaturePrint®

Page 14 of Firmenich's 2008 Sustainability Report includes a photo of the headspace of a flower being sampled with this caption:

"Volatiles of a Rosa Gallica captured using Solid Phase Micro-Extraction in order to create a NaturePrint®. Nature-Print® relates to flavors and fragrances created by Firmenich Flavorists and Perfumers based on accurate templates of volatiles from natural products." [iii.]

Takasago: Cutting-edge analytical technologies

"In order to discover the very best key components, we promote the development and use of cutting-edge analytical technologies. Beneficiating of the collaboration of our talented perfumers and flavorists expertise we have been able to unravel for instance the ingredients delivered in the delicate odor of a living flower, or the most tasteful flavor compounds in foods.

Analytical apparatuses like GC-MS, MDGC-MS, GC by GC-MS, GC-Olfactometry coupled with GC-MS, GC-AED, HPLC, LC-MS, NMR permit among others to directly look into the nature and to discover these essential ingredients from solid, liquid and gas environments. It becomes possible as well to directly measure how these key materials are delivered from a matrix over the time. " [iv.]

What Does this Mean?

All of these technologies could also be used to create a specific quantified list of ingredients for any competitor's fragrance product. **The result would clearly be more specific and useful in copying a fragrance than a simple list of ingredients ever would.**

[i.] http://www2.ljworld.com/news/2004/jul/04/living_flower_technology/
[ii.] http://content.time.com/time/specials/packages/article/0,28804,1882059_1882224_1882012-2,00.html
[iii.] http://www.firmenich.com/uploads/files/sustainability_reports/Firmenich_Sustainability_Report_2008.pdf
[iv.] http://www.takasago.com/en/rd/analysis/index.html