Progress Report 2024

RIFM®
RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS

We Believe in Exceptional Science, Free Exchange, and Peerless Stewardship

MISSION

RIFM science and research builds international trust in and acceptance of the safe use of fragrance materials.

CORE VALUES

- Scientific Excellence, Objectivity, Integrity, and Leadership
- Collaboration
- Transparency

VISION

RIFM's leadership in state-of-the-art science enables the enjoyment of fragrances around the world.

RIFM®
RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS

Fragrance Safety Begins Here

What does it take to maintain leadership in the science supporting the safe use of fragrance?

Time and resources, scientific expertise, and historical knowledge. A facility for building critical connections. Taking what you know and learn and rendering it accessible to the right people at the right time. (RIFM is deeply committed to transparency – the embodiment of accessibility – ensuring all its published and peer-reviewed science is available for all fragrance safety stakeholders via the open-access website *FragranceMaterialSafetyResource.elsevier.com*.)

GOAL 1

Robust safety assessments provide the foundation of trust in the safe use of fragrance materials. By this, RIFM commits to fast-tracking the completion of assessments for all current discrete and first-round natural complex substance (NCS) ingredients.

GOAL 2

RIFM leads scientific advancement to support the safe use of fragrances. In support of its world-renowned Safety Assessment Program, RIFM remains dedicated to research that refines our understanding of safe use and champions the advancement of animal-alternative methodologies.

GOAL 3

RIFM increases the impact of its science through engagement with strategic stakeholders. Finally, RIFM ensures the broad understanding and acceptance of its science by establishing and nurturing critical connections with science colleagues in academia, industry, and regulatory spaces in key and emerging markets worldwide.

For its science to achieve critical impact, the Research Institute for Fragrance Materials requires a clear path forward, consensus around priorities, and a mutually understood vision for the future.

Earlier this year, the RIFM Board of Directors finalized a thorough revitalization and update of its Mission, Core Values, and Vision (see previous page) and its organizational Goals for the next half-decade.

Three primary Goals build upon the success of the last five years and speak to the Institute's responsibility and commitment to the safe use of fragranced products.

As we'll see during tonight's celebration and through the following pages, the Institute is well on the path to achieving these goals through the cultivation of internal expertise, global collaboration, and strategic investment in research for the benefit of all fragrance safety stakeholders worldwide.

This is where fragrance safety begins.

Robert M. Weinstein, Ph.D.,
RIFM Chairman of the Board
Board Member and Corporate Advisor
Robertet North America

Success After Success

My colleagues at the Research Institute for Fragrance Materials devote their careers daily to the organization's mission to build international trust in and acceptance of the safe use of fragrance materials.

Leading this singular staff has been an extraordinary pleasure this year as they achieved some of the most critical milestones in RIFM's history.

Fragrance safety begins right here at RIFM. Its literal starting point is the RIFM Database. Established four decades ago, this crucial resource houses the world's largest data collection on fragrance and flavor raw materials. The Database Team hit several milestones this year, surpassing 8,000 individual ingredients through 80,000 references, including an astonishing 200,000 human health and environmental studies.

Ensuring the RIFM Database includes the most up-to-date fragrance material study data directly supports RIFM's world-renowned Safety Assessment Program. Standing on that critical foundation, RIFM's Science and Editorial Teams accomplished their most impactful goal: The peer-reviewed publication of safety assessments covering over 2,000 fragrance ingredients.

Meanwhile, RIFM's Science Staff continues to advance research projects designed to refine our understanding of safe use and champion the advancement of animal-alternative methodologies. This year alone, RIFM published several papers expanding our knowledge of genetic and environmental safety and showing how low our exposure to fragrance ingredients via all consumer products truly is.

But, as we like to say, science not communicated is science not done. Over the last year, RIFM staff developed unique webinars, videos, and other engaging content to ensure a clearer understanding of the value of the science supporting the safe use of fragrance ingredients worldwide.

The more effectively we communicate, the more accurately our work is reflected in the trade and mainstream media. We began this year with a mention in Vogue magazine and, more recently, New York Magazine's The Cut interviewed Senior Scientist

Nikaeta Sadekar. We experienced far more trade journal coverage in 2024 than ever before, largely thanks to the publication of the low exposure paper and our efforts to promote it.

Finally, RIFM presented and championed our work to audiences across North and South America, Europe, and Asia, receiving awards and shout-outs at the Society of Toxicology, the World Perfumery Congress, and the Society of Environmental Toxicology and Chemistry. RIFM's Financial and Support Staff provided essential support to guarantee appropriate staff connected with key fragrance safety stakeholders, helping to ensure the broad understanding and acceptance of its science.

Anne Marie Api, Ph.D., Fellow ATS
President

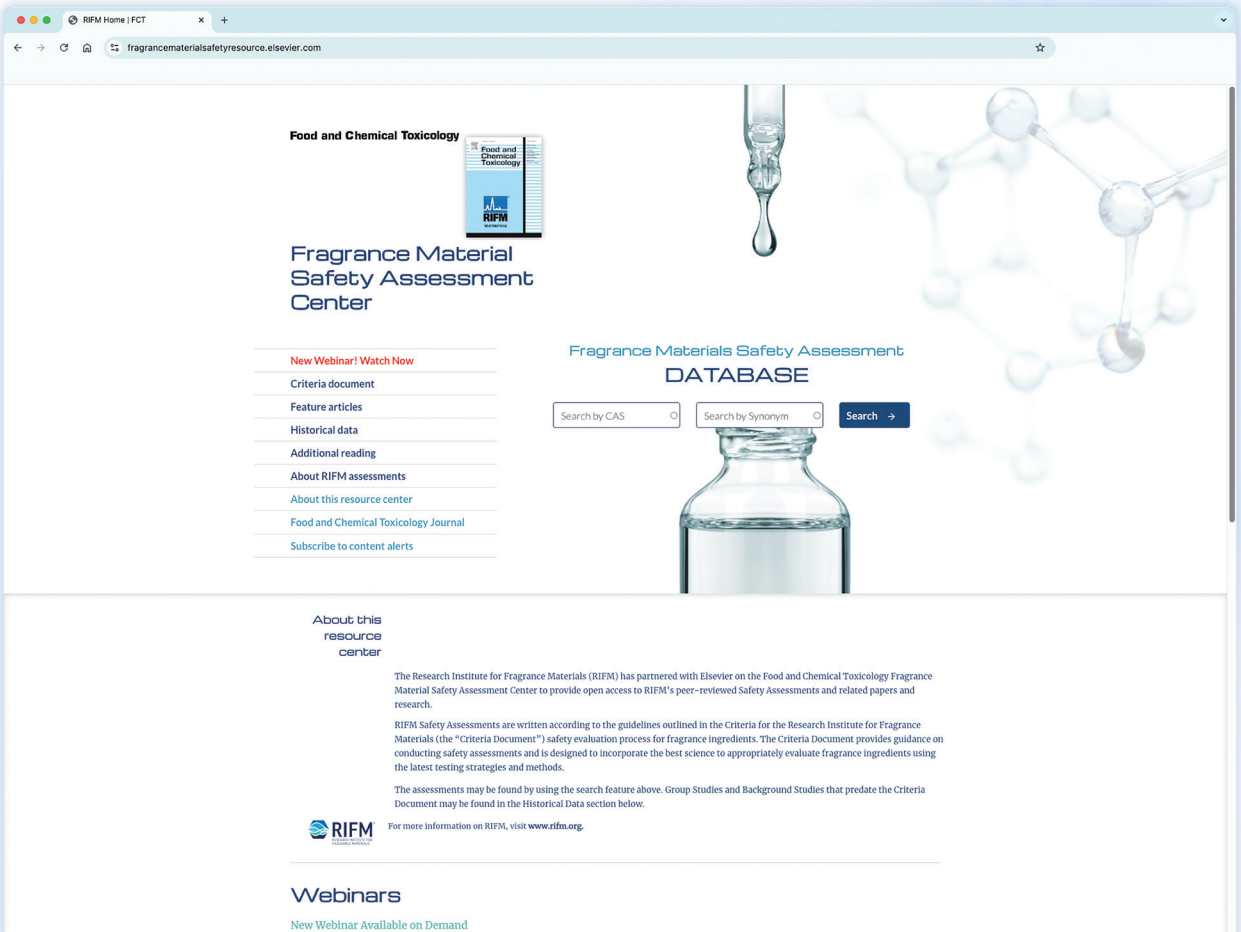
Leading-Edge Science. Accessible To All

Launched in 2015 by the Research Institute for Fragrance Materials (RIFM) in collaboration with science publisher Elsevier's Food and Chemical Toxicology journal, the Fragrance Material Safety Resource Center (fragrancematerialsafetyresource.elsevier.com) provides open access to a wealth of fragrance-safe-use data in the form of thousands of up-to-date peer-reviewed individual ingredient safety evaluations, supportive research papers, and historical group and background studies.

RIFM produces Safety Assessments covering discrete synthetic and natural complex substance (NCS) ingredients. RIFM performs discrete assessments according to the safety evaluation process guidelines outlined in the Criteria for the RIFM Safety Evaluation Process for Fragrance Ingredients. NCS assessments are performed according to The RIFM Approach to Evaluating Natural Complex Substances (NCS).

These two Criteria Documents guide the production of safety assessments and incorporate the best science to appropriately evaluate fragrance ingredients using the latest testing strategies and methods. Both are available for download on the Fragrance Material Safety Resource Center. Recordings of introductory webinars covering both criteria documents are also available via the website.

Those interested in understanding the safe use of specific fragrance ingredients should consult the search feature at the top of the web page. Ingredients can be searched by CAS Registry Number or any of an ingredient's synonyms. Group Studies and Background Studies that predate the Criteria Documents may be found in the Historical Data section further down on the web page.



RIFM by the Numbers

Safety Assessments

342 | Fragrance ingredients with safety assessments posted to RIFM's Database in 2024

324 | Fragrance ingredients with safety assessments accepted for peer-reviewed publication in 2024

1,942 | Total fragrance ingredients with safety assessments on RIFM's Database

2,122 | Total fragrance ingredients with safety assessments peer-reviewed and published

Fragrance Safety Resource Center

7,709 | Unique users

24,630 | Sessions

53,073 | Pageviews

15,880 | Downloads

RIFM Database

148 | Contracted studies contributed by RIFM Members in 2024

552 | RIFM-sponsored toxicological studies added in 2024

370 | References captured in 2024

RIFM.org Website

281,279 | Total 2024 actions taken by visitors

107,704 | Total 2024 pageviews

Webinars

732 | Total webinar attendees in 2024

205 | Attendees at RIFM Member webinars

411 | Attendees at public webinars

116 | Attendees at other hosted webinars

Email

78 | Sent in 2024

87,399 | Total unique opens

Online Mentions & Coverage

895 | Mentions of RIFM in 2024

37 | Articles focused on or featuring RIFM

YouTube

13 | Videos posted in 2024

2,206 | Combined views of all 2024 videos

The Science Supporting RIFM's World-Renowned Safety Assessment Program

2024 Publications And In-Progress Research

Championing The Science Of Exposure

Low-Exposure Paper

Published earlier this year, the Low Exposure Paper defines the impact and reality of measured exposure data for fragrance materials: that exposure to fragrance ingredients is remarkably low. A broad communications plan, including Q&As published in trade journals, two widely distributed Press Releases, and a new professionally developed video, was launched to illuminate this critical paper to a wider audience. Additionally, RIFM presented this work at several conferences and meetings this year and looks forward to new opportunities to share this work with more audiences.

Creme-RIFM Model Expansion

Work is ongoing to expand the exposure data beyond the United States and Europe. For example, RIFM has collaborated with A-STAR in Singapore to obtain realistic habits and practices data for consumers in Singapore. Additionally, RIFM is collaborating with Cosmetics Europe to acquire habits and practices data on babies (0- to 3-year-olds). In addition, the habits and practices data are routinely updated every five to six years.

Anticipating Future Regulatory Priorities

Biodegradation Data Summarization Project

Biodegradation data summarization is of particular interest to the United States Environmental Protection Agency (US EPA). Earlier this year, RIFM summarized all the biodegradation data on fragrance materials in the RIFM Database, and a copy of the summarization spreadsheet is available to all RIFM Members. RIFM continues to work with EPA on the scientific data that are available on fragrance ingredients.

Reproductive Toxicity Summarization Project

RIFM is also working on summarizing its complete reproductive (inclusive of both developmental toxicity and fertility) data.

RIFM Scientists Expand Their Expertise

RIFM Principal Scientist, Genotoxicity, Yax Thakkar, PhD, received his Doctorate in Pathology from New York Medical College in Valhalla, New York.

RIFM Senior Scientist, Repeated Dose and Reproductive Toxicology, Kaushal Joshi, PhD, DABT, earned his Diplomate of the American Board of Toxicology (DABT) certification, becoming RIFM's second toxicologist to become DABT certified after Nikaeta Sadekar, PhD, DABT, who earned her DABT in 2022.

Leading the Charge for Animal-Alternative Methods

Genetic Health

Chicken Egg for Genotoxicity RIFM continues to explore the *in ovo* chicken egg model to help minimize the rate of misleading positives when testing *in vitro* for genotoxicity. A manuscript is nearing completion.

ToxTracker A recently published paper shows how ToxTracker can provide RIFM scientists with information needed to identify the most appropriate animal–alternative follow-up assay for materials testing positive in BlueScreen, such as the 3D skin assay or the chicken egg model, thus eliminating the need to run both tests.

Skin Health

CNIH Assay Modification The Expert Panel for Fragrance Safety advised RIFM to modify the Confirmation of No Induction in Humans (CNIH) assay. The modifications include applying patch test materials as soon as they have been prepared (allowing for no evaporation) and a 48-hour challenge application. RIFM has analyzed two years of data on fragrance materials tested using the original and modified test methods, and a manuscript is nearing completion.

Sensitization of Unsaturated Materials The Expert Panel for Fragrance Safety recommended investigating unsaturated materials' sensitization potential. Materials were selected for evaluation and are being studied in the SENS-IS Assay at Immunosearch.

Skin Sensitization Potency Prediction RIFM continues working with scientists at Edelweiss Connect, exploring its ability to predict the skin sensitization potency of fragrance ingredients. The model combines *in silico* and *in vitro* data supporting integrated approaches to testing and assessment, focusing on the endpoint of skin sensitization.

***In vitro* Skin Absorption Studies (Citral & Salicylates)** *In vitro* skin absorption studies using human skin are integral to the safety assessment program to refine the exposure levels to fragrance ingredients to more realistic values. Recently, RIFM embarked on two research programs to assist in responses to European regulatory requests. Citral and several salicylates are being evaluated in *in vitro* skin absorption studies. In addition, RIFM is conducting *in vitro* skin absorption studies to complete safety assessments.

kDPRA Method RIFM is collaborating with IIVS to study the kinetic direct peptide reactivity assay (kDPRA) for its potential to assign a chemical's skin sensitization potency class. A manuscript is being drafted for peer-reviewed publication.

GARDskin to Derive Potency The GARDskin identifies skin sensitizers by monitoring transcriptional patterns of a biomarker signature in a dendritic-like cell line. A strategy based on dose-response measurements in GARDskin, referred to as the GARDskin Dose-Response assay, has recently been proposed to derive potency information. RIFM and IFF are collaborating to evaluate the reproducibility and predictivity of this assay.

LLNA and Weak Sensitizers RIFM and Givaudan are exploring the relevance of materials predicted to be very weak sensitizers in the Local Lymph Node Assay (LLNA). These data are being compared to results from other NAMs on these materials.

Repeated Dose & Reproductive Safety

Stemina devTOX quickPredict Process and Biobide Teratotox Assay in Zebrafish Embryos Identifying *in vitro* systems can predict key events developmentally to predict adverse events. RIFM has conducted pilot studies on two different *in vitro* models for assessing developmental toxicity: 1) the Stemina devTOX quickPredictTM process and 2) the Biobide Teratotox Assay in zebrafish embryos.

ReproTracker RIFM is investigating a tool by Toxys called ReproTracker®, a human stem cell-based *in vitro* assay that rapidly and reliably identifies developmental toxicity hazards.

Multi-Organ Model for Systemic Effects Another exciting research program in NAMs is RIFM's collaboration with IONTOX LLC to investigate a multiple-organ, integrated *in vitro* model to assess systemic effects.

Internal TTC (iTTC) Project RIFM continues to collaborate with Cosmetics Europe to develop iTTCs, which are safe-use levels representative of internal exposures, for human safety assessment. A Working Group has been established comprised of multiple stakeholders (RIFM, cosmetics and chemical industries, the EPA and Joint Research Centre, and academia) with relevant experience and expertise to evaluate the requirements to establish an iTTC.

Environmental Safety

Environmental Framework 2.0. RIFM has updated the Framework to incorporate new methods and techniques to improve transparency and enhance the safe use of fragrance materials. This manuscript is nearing completion and will be submitted soon.

EcoTTC. RIFM is developing a fragrance material Ecological Threshold of Toxicological Concern (ecoTTC) using existing RIFM data on neat ingredients. The ecoTTC is analogous to traditional human health-based TTCs but with derivation and application to ecological species.

The Chances2 Project and assessment of biodegradation and persistence of natural complex substance (NCS) materials. RIFM is working on two exciting environmental NCS research projects to advance our environmental assessments: a) the Chances2 Project (KREATiS; LPL; University of Côte d'Azur), using a block approach to evaluate the ecotoxicity of NCS utilizing a combination of *in vivo* and *in silico* methods, and b) the assessment of biodegradation and persistence of NCS materials (Technical University of Denmark) by combining evaluation of a whole UVCB (substance of unknown or variable composition, complex reaction products, or biological materials) degradation testing with the determination of specific constituent degradation kinetics.

Respiratory Health

Human Precision-cut Lung Slices (hPCLS) Model The *ex vivo* hPCLS model is obtained from the lungs of healthy human donors and is the only model known to successfully retain the complexity of human lung tissue encompassing the heterogeneous cell population. RIFM has collaborated with Rutgers University and IIVS on this model.

Deep Lung Tissue Project RIFM's respiratory sensitization research program aims to identify respiratory sensitizers and separate respiratory sensitizers from skin sensitizers and non-sensitizing irritants. To this end, RIFM is investigating a new model developed by Dr. Arno Gutleb, which includes four different cell types cultured together to represent deep lung tissue in humans.

***In Vitro* Respiratory Irritation Models** RIFM conducted a pilot test using chemicals with complex physical-chemical properties on three *in vitro* respiratory irritation models in collaboration with Charles River Laboratories, the Institute for *In Vitro* Sciences (IIVS), and Fraunhofer ITEM. Further plans include developing suitable *in vitro* models for the risk assessment of inhalation exposure to fragrance ingredients.

Enhance & Bolster Data for Inhalation TTC. RIFM has partnered with The Fraunhofer Institute, the EPA, Cosmetics Europe, and Procter & Gamble to enhance and bolster the data for the inhalation TTC. The project aims to create a harmonized dataset appropriately subcategorized to develop new inhalation TTC limits by leveraging cheminformatic approaches and other NAMs.

Odor Threshold Project. The primary goal of the odor threshold project is the establishment of odor and irritation detectability. RIFM is working with the Monell Chemical Senses Center to use state-of-the-art precision olfactometry to establish or update the odor detection and irritation thresholds for various chemicals used in potential fragrance materials.

Photosafety

Photoallergenicity Collaborations with IIVS, SenzaGen, and Shiseido are ongoing to better understand and reliably predict photoallergenicity. The collaboration with IIVS and Shiseido investigates the use of the photo-Direct Peptide Reactivity assay (photo-DPRA), photo-KeratinoSens, and photo-human cell line activation assay (photo-h-CLAT). The collaboration with SenzaGen explores their GARDskin assay for photoallergy.

Chemistry and Read-Across

Read-across for cancer hazard classification. RIFM collaborated with scientists at Procter & Gamble on a manuscript that details the importance of practicing prudent discretion when using read-across for cancer hazard classification, using isoeugenol and methyl eugenol as a case study. This manuscript was submitted for peer-reviewed publication.

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Senior Associate Scientist, Chemistry

Everything You Need – at Your Fingertips

The RIFM Flavor and Fragrance Database

The RIFM Database is the most comprehensive worldwide source of toxicology data, literature, and general information on fragrance and flavor raw materials, containing information on more than 8,000 individual ingredients, including approximately 200,000 human health and environmental studies.

The RIFM Database Team added 570 toxicological study reports submitted by RIFM members over the last 12 months, and there are now over 80,000 references in the Database associated with those materials.

Additionally, the Team added more than 120 RIFM-sponsored laboratory studies in the human health and environmental realms in 2024.

Earlier this year, **RIFM hosted The RIFM Database – Everything You Need at Your Fingertips,** a webinar focused on finding information on discrete chemicals, natural complex substance (NCS) materials, chemical clustering, and some of the exclusive data summaries and tools available to all RIFM Database subscribers. The event drew over 200 fragrance safety stakeholders.

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Director, Technical Information & Services

Meghan Barreto
Scientific Literature Specialist

Mary Mircovich
Scientific Literature Manager

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Scientific Literature Specialist

Molly Gilmore
Programmer / Developer

Evelyn Mozo
Scientific Literature Specialist

(Visit **rifm.org/the-rifm-database-everything-you-need-at-your-fingertips** for a link to a recording of the webinar.)

RIFM's data is a precious resource, much of it from its generous members; to ensure its data's protection, RIFM undertook an independent cybersecurity audit in Q2 of 2024.

RIFM Database staff has continued to focus on supporting RIFM's Safety Assessment program, liaising with the IFRA NCS Task Force to clarify NCS composition, and managing the development and maintenance of multiple software programs dedicated to the Safety Assessment process.

RIFM continues to provide RIFM-sponsored studies to its members for REACH and other "REACH-like" registrations. It has been selling these studies to non-members for regional programs in the European Union and now expanding to new regions like Turkey and Korea, and the sales help fund our science.

Ensuring RIFM Meets Its Goals

The Finance & Operations Team

With a revised organizational Strategy and Plan for 2024 (see Fragrance Safety Begins Here, page 6), **the Finance Team worked tirelessly this year to ensure the Institute was prepared to deliver.**

As part of its 2024 Strategy, RIFM pledged to complete assessments for all discrete and first-round natural complex substance (NCS) ingredients by 2018. To help ensure this, the Finance Team worked with RIFM's Safety Assessment Team members to get all necessary upcoming lab testing accounted for and on the books, avoiding potential delays.

Ensuring RIFM's scientists achieve their goal of increasing the impact of RIFM's science through engagement with strategic stakeholders, the Finance and Operations Team supported an unprecedented number of event participations, where RIFM scientists and staff established and nurtured critical connections with science colleagues in academia, industry, and regulatory spaces via some two dozen events in 2024 across the Americas, Asia, Europe, and the Middle East.

Steven Manzi
Chief Operating Officer

Tracy Foley
Operations Manager

Julie Blanker
Executive Assistant

Advancing RIFM's Science

The Communications & Editing Team

Engagement across RIFM's platforms continues to grow, and communications and publications over the last 12 months broke all records and hit significant milestones, most notably the peer-reviewed publication of safety assessments covering more than 2,000 fragrance materials.

RIFM's **2nd Annual Science Symposium**, held last November, engaged RIFM's largest online audience, with more than 315 participants in attendance. Mainstream and trade media coverage in 2024 has more than doubled that in 2023, beginning with a shout-out in the January 2024 issue of Vogue and culminating with over two dozen articles and features on RIFM since then.

The Communications Team helped spread the word about RIFM's most significant publication of the year, the **low-exposure paper**, which was written in collaboration with data scientists at Creme Global. The low-exposure campaign included two press releases (one about the publication and one about the paper winning a coveted award at this year's **Society of Toxicology** conference). Additionally, RIFM targeted several emails and LinkedIn posts that engaged more-than-usual readers and developed a professional video that member companies and other fragrance safety stakeholders are now sharing with their respective audiences.

Finally, in anticipation of a heavier-than-usual event year, RIFM developed two brochures: **So the World Can Enjoy Fragrance**, an overview of what RIFM does and why it matters, and **Become a Leader. Become a RIFM Member**, which details RIFM's value for potential members. Copies of both are available tonight.

Gary Sullivan
Marketing and Communications Manager

Olive Chon
Marketing Communications Specialist

Faiz Siddiqi
Senior Editor

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