

Global Chemical Legislation: Impact for The Fragrance Industry

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Fragrance Industry – How Are We Organized?

- International Fragrance Association (IFRA)
 - Offices in Brussels
 - Comprised of national/regional associations as well as individual member companies
 - Represents manufacturers of approx. 90% of fragrances sold worldwide
 - Currently does not include membership from China or India
 - Problem: trend for offshore production of aromachemicals

Fragrance Industry – How Are We Organized?

- U.S. Fragrance Materials Association (FMA) is a strong component of IFRA
- FMA has roots going back to 1927
- FMA has very active programs for interaction with sister associations such as SDA, CSPA, PCPC, SOCMA, etc.
- FMA has taken the lead in dealing with State and Federal legislative initiatives

Fragrance Industry – How Are We Organized?

- IFRA Code of Practice
 - Define ‘good operating practices’ for companies
 - Outlines safety evaluation program
 - Committee structures
 - Prohibited/restricted fragrance materials
- IFRA has been in existence for almost 40 years
- For at least 30 years we were ‘invisible’
- In the last decade fragrance has come under heavy scrutiny

IFRA Organization/Strategy

- To better respond to attacks by activists, NGO's, etc., several years ago IFRA reorganized into a) an advocacy arm, and b) a science arm
- For advocacy purposes, IFRA Executive Committee establishes a global strategy, and national associations execute
- Science program is twofold: independent review and Standard setting

RIFM

- Research Institute for Fragrance Materials (New Jersey based) is the focus for the industry science program
 - Industry-sponsored ingredient testing
 - Repository for all safety and environmental data generated by member companies
- All scientific reviews conducted by independent panel of experts

RIFM

- RIFM experts are not compensated by industry, except for basic per diem expenses
- Toxicologists, dermatologists, environmental specialists, pathologists
- By policy, Panel recommendations regarding safety and/or environmental effects of fragrance materials *must* be adhered to by industry members

RIFM/IFRA

- Panel recommendations, based on testing or data review, forwarded to IFRA Scientific Committee
- IFRA SC translates into Standards, which can specify
 - Restricted ingredient use, via concentration max or quality specification; or
 - Prohibited use
- Currently 150+ restricted/prohibited materials, of a base of about 2,200 materials

Doing What We Say

- All members of IFRA bound by the Code of Practice
 - But how do we know if they comply?
- Three years ago a Compliance Program was initiated
 - Marketplace products purchased in all global regions covered by IFRA
 - Of these, 50 chosen at random, by a third party, for analysis

Doing What We Say

- Analysis carried out for IFRA prohibited substances
- So far, no products found to have banned material(s)
- If banned material found, product manufacturer contacted and asked to identify fragrance supplier
 - Fragrance supplier contacted and explanation sought

Doing What We Say

- If supplier agrees to correct, no action taken
- If no agreement, supplier name posted on IFRA website as being in violation of the IFRA Code of Practice
- Future program: analysis of restricted materials to be undertaken
 - Analytical requirements much more complex
 - Contributions from multiple sources

In Summary...

- 40 year industry program
- Independent scientific expert panel
- Extensive database of relevant test data
- Self-imposed compliance program
- But...relative few know about it

Self-Regulation vs. Legislation

- Fragrance industry self-regulatory program losing support in a rush of legislative initiatives over the past several years
- Began in the U.S. with TSCA in 1976
- Fragrance chemicals covered by TSCA *unless* present in a consumer product regulated by another agency
 - Cosmetics
 - Foods
 - Drugs

Self-Regulation vs. Legislation

- TSCA preceded in Europe by the Dangerous Substances Directive (1967)
- Dangerous Preparations Directive followed in 1988
 - Exempted: cosmetics, foods, medicines
- Fragrances used, however, in laundry products, household cleaning products, air care products, etc., subject to these acts

Regulatory Compliance

- As a practical matter, impossible to separate fragrance materials (FM) used only for, e.g., cosmetics, from those used in household
- Therefore, usual practice to register all FM under TSCA/DSD

REACH

- Intended to replace existing legislation for substances and preparations, as well as some others related to these
- European regulators' rationale for creation of REACH:
 - Data gaps: 86% of HPVCs have less than base set data
 - The process takes (far) too much time

REACH

- Burden of proof is on public authorities
- Generally downstream users stay out of the picture, actual uses of chemicals remain unknown
- The system is inefficient: industry is faced with a myriad of directives and regulations
- Administrative burden for new, mostly low volume, chemicals prevents innovation

REACH

- Fragrance industry has centralized its efforts for REACH compliance in the European Flavor and Fragrance Association (EFFA)
- EFFA has formed a series of 49 consortia to manage the process for the industry
- Pre-registration was from June 1 – December 1, 2008

REACH

- Registration deadlines have been established based on chemical hazard and annual tonnages
 - **November 30th, 2010**: production/import > 1000 MT/year (or 100 MT/year and classified R50/53, or 1 MT/year and classified as CMR 1 or 2)
 - **May 31st, 2013**: production/import 100 -1000 MT/year
 - **May 31st, 2018**: production/import 1 -100 MT/year

FRAGRANCE SUBSTANCES PORTFOLIO

FRAGRANCE SUBSTANCES (EXC. 149 NCS)	NUMBER OF SUBSTAN CES	EFFA PRIORITY GROUP	REACH BAND > 1,000	REACH BAND 100-1,000	REACH BAND 10-100	REACH BAND 1-10
PRIORITY A CHEM GPS 32	376	A	50	79	110	137
PRIORITY B CHEM GPS 29	209	B		44	63	102
PRIORITY C CHEM GPS 44	213	C			82	131
PRIORITY D CHEM GPS 25	49	D				49
TOTAL # SUBSTANCES	847		50	123	255	419
NUMBER CHEM GPS 130						

REACH

- NCS = Natural Complex Substances
 - i.e, essential oils
 - Mixtures of many individual materials
- The European Federation of Essential Oils (EFEEO) is taking the lead for registration of NCS
- These 149 substances will be divided into two groups:

REACH

- ‘Type 1’: those which have been analytically characterized to at least 90%
- ‘Type 2’: those which have been analytically characterized to less than 90%
- Data to support the registration of these could be provided by-
 - Tests with the NCS itself
 - Tests on individual components of the NCS
 - Data obtained by read-across

REACH Implications For Fragrance

- Estimated direct costs (i.e., tests to fill data gaps) will run to the many millions of Euros
- Indirect costs to individual companies to create and support infrastructure to execute REACH requirements many more millions of Euros
- Small volume, high impact chemicals at risk
 - Sales may not justify test expenditures

REACH Implications for Fragrance

- Much of formerly U.S.-based production has been moved to India, China
 - Questionable whether these manufacturers will make necessary expenditures for testing
- Conflict with 7th Amendment to the European Cosmetics Directive, prohibiting animal testing
- **...and REACH is just the beginning**

United States

- TSCA reform is in the air
- Critics compare TSCA to REACH and claim that the former is ‘ineffective’
- Given the new administration in Washington, and the steps already taken to undo actions taken by the prior administration, it seems likely that a review of TSCA will be undertaken

United States

- Two key questions if TSCA overhauled:
 - Future status of grandfathered chemicals under original TSCA?
 - If no grandfather, schedule for compliance vis-à-vis REACH schedule?

Ingredient Disclosure

- For consumer products, fragrance has always been accepted as one of several ingredient types (e.g., surfactant mixtures, dyes, etc.) that is not ‘exploded’ for label declaration
- Last year a coalition of NGO’s (Sierra Club, NRDC, WVE) petitioned EPA to force a review, under TSCA Section 21, of air freshener ingredients based on ‘health concerns’

Ingredient Disclosure

- EPA denied the petition, NGO's threatened a lawsuit, and ultimately a compromise was reached
 - Industry provided EPA with a comprehensive list of all ingredients—including individual fragrance components
 - Second round submission: annual tonnages for ingredients
 - All shared with NGO's

California

- SB 484 – cosmetic manufacturers must register with State any ingredients reported as carcinogens, reproductive toxicants
- SB 509 – originally began as an ingredient disclosure bill, affecting a series of consumer products
 - In the end, a toxics review bill

California

- SB 1879 - would establish a process of identifying chemicals of concern and their uses and allow the Department of Toxic Substances Control (DTSC) to restrict/reduce the use of those chemicals of concern and foster the development of alternatives

California

- Sen. Simitian (author of SB 509) promises to return this year with a new proposal for ingredient labeling
- CBI status of fragrances, dyes, other mixtures under attack

Industry Initiatives

- SDA, CSPA and FMA have joined forces to develop a voluntary ingredient labeling program
- This initiative will identify 'base' ingredients, with provision for identification of CBI ingredients generically (e.g., 'fragrance')
 - Air care, automotive, cleaning/polishing/ floor maintenance products
 - Label or website listing

Industry Initiatives

- Fragrance industry developing a model for broad scale identification of individual materials used in fragrances
- FMA working with CSPA in establishing dialogue with Sierra Club
- Industry commitment to greater transparency, to benefit consumer