

PERFUMER & FLAVORIST

Safety and Regulatory Aspects of the 90's — Environmental Trends

By Kenneth R. Schrankel, International Flavors and Fragrances,
Union Beach, New Jersey

During the last decade, and as we move into the 90's, more and more emphasis and attention is being given to the safety and regulatory aspects of chemicals, not only for those used in consumer products, but those used in industry. Historically, there has always been emphasis on product safety, especially in the area of food and other consumer products. However, industrial and environmental safety have received increased attention since the middle 1970's. One reason for this global activity is an event such as Earth Day, which was first held in 1970, and, more recently, on April 22, 1990. Other events such as the Bhopal incident, Chernobyl nuclear disaster, the Exxon Valdez incident and the issue of acid rain have caused the media to focus attention on the environment.

In general, the increased concern for the environment evolved first in Europe and spread across Europe, including the Scandinavian countries, to North America.¹ This movement not only includes those at the government level, but also includes consumers and environmental activist groups. These latter groups are not content to let governments and industry solve environmental problems.

Therefore, everyone has been, or will be, affected by the continuing global activity occurring in the areas of safety and environmental regulations. The fragrance and cosmetic companies will be under increasing scrutiny and pressure from customers to be more conversant and knowledgeable about issues relating to product safety and environmental safety. The consumers' concerns will influence company marketing and sales platforms for the 90's and beyond. This overview will assist you in better understanding the issues and complexities that the fragrance and cosmetic industries will be facing in a changing consumer environment in the 90's.

Safety and Regulatory Aspects of Fragrances

Fragrances have enjoyed a long history of safe use. It is important to mention that the fragrance industry is unique because of the concept of voluntary industry self-regulation.² The two major international organizations responsible for establishing and maintaining self-regulation in the fragrance industry are the Research Institute for Fragrance Materials, Incorporated (RIFM) and the International Fragrance Association (IFRA). The United States fragrance industry, also self-regulating, is represented by the Fragrance Materials Association of the United States, Incorporated (FMA) (Figure 1).

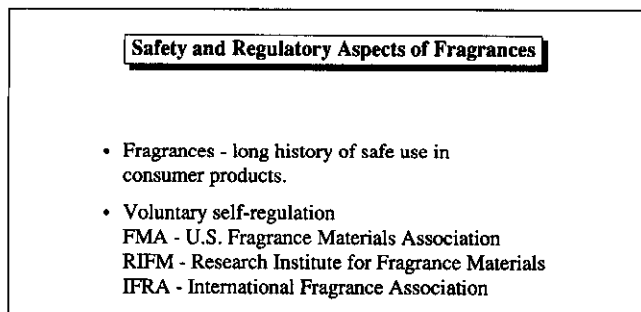


Figure 1.

Fragrance Materials Association (FMA)

The Fragrance Materials Association of the United States was incorporated in the District of Columbia on November 15, 1979, as the successor organization to the Essential Oil Association of U.S.A., Inc.

The mission of FMA, as stated by its Board of Directors, is to represent the collective commercial interests of the U.S. fragrance industry. To this end, the Board has adopted the following objectives:

1. Provide for protection of the industry's trade secrets.
2. Seek uniformity in regulatory matters among states.
3. Develop and maintain contact with appropriate legislative bodies and regulatory agencies on the federal level.
4. Seek consistency with the flavor industry in approach to mutual problems.

FMA's primary service to the U.S. fragrance industry involves legislative and regulatory work on the industry's behalf. Its activities are closely coordinated with those of the Research Institute for Fragrance Materials (RIFM), which undertakes scientific research to support product safety for the industry worldwide. In fulfilling its mission for the industry, Washington based, FMA interacts with governmental bodies and other organizations on all levels - state, federal and international.

Research Institute of Fragrance Materials (RIFM)

RIFM has evolved into an international testing institute for the fragrance industry. Historically, Mr. van Ameringen of International Flavor & Fragrances, Inc. (IFF) initiated the establishment of this organization in the 60's. Individual companies are members of RIFM. The primary objective of

the institute is to gather and analyze toxicological and safety data for fragrance materials. These data are evaluated by an independent Expert Panel - not associated, in any way, with the fragrance industry. The data are published in scientific journals.

Publications containing data summaries for single fragrance ingredients are sometimes referred to as RIFM monographs. Thus, by an inductive reasoning process, the industry reaches its safety consensus for a fragrance composition based on the test data and history of use derived from the individual substances or ingredients.

The safe use of fragrance ingredients is further supported by RIFM's interaction and cooperation with other associations, agencies and regulatory bodies to exchange information. RIFM maintains a close organizational and liaison association with the International Fragrance Association (IFRA).

International Fragrance Association (IFRA)

IFRA is headquartered in Geneva, Switzerland, and is composed of national fragrance organizations. FMA is a member of IFRA (Figure 1). The purpose of IFRA is to promote the safe use of fragrance materials and to collaborate in the development of practices and voluntary regulations governing the worldwide use of fragrance ingredients

in consumer products. RIFM reports the scientific data to IFRA for interpretation based on commercial practices and applications. The IFRA Code of Practice provides the fragrance industry with the guidelines for the use of fragrance materials under conditions which minimize the risk to health.

The United States Food and Drug Administration (FDA) has had a long and productive relationship with the fragrance industry. FDA continues to endorse the voluntary self-regulatory efforts and leadership of FMA and IFRA in promoting the safe use of fragrance ingredients.² The self-regulation imposed by FMA and IFRA relates not only to the use and application of the fragrance in consumer products, but IFRA encourages basic standards of good manufacturing practices including sanitation, quality control, labelling and storage.

The Green Movement

The Green Movement originated in Germany as a consumer movement and then it evolved into a political action party. Associated with this movement are a number of terms and symbols new to the fragrance and cosmetic industry which relate to promoting a safe environment. The safety and environmental concepts conveyed by these terms and symbols are intertwined, and the interpretation is not always clear. Many times, the concept of consumer safety is confused or mixed with the concept of environmental safety. However, the commercial and marketing sectors seized upon the idea of using positive environmental labels on consumer products. This is viewed as a means to attract and provide consumers with desirable products that satisfy the consumers' environmental concerns and, at the same time, increase market share.

The use of consumer product labels to attract environmentally sensitive consumers has proven to be controversial. This is because one consumer's definition or notion of environmentally sound or compatible product may not agree with another consumer's definition.

An environmental label that appears to be misleading or is used without substantiation is subject to challenge by consumers and governmental authorities. There is also a fear that if too many conflicting labels are employed, either for consumer product safety or for environmental safety, it might confuse and frustrate consumers and thus impede and hinder the environmental movement. Frustrated and confused consumers will eventually lead to the promotion of governmental involvement in regulating consumer product labelling.

Today, the Green Movement, plus the emotional activities associated with it of one year ago, has declined, especially in Europe. The panic associated with companies desiring to participate in the Green Movement has dissipated; nevertheless, companies are still interested in the Green Movement. They, especially the large and highly exposed corporations, have developed a better understanding of it. They realize the risk, i.e., adverse impact on company reputation, associated with labelling only one of their product lines with environmental labels. They un-

derstand a green product line may detract or divert attention away from their other products.

Consumers will always express support for more expensive green products based on consumer surveys.⁹ However, their purchasing patterns do not support their opinions. For this reason, when some Governmental policies in certain European countries are changed, the change in policy is also directed towards modifying consumer behavior leading to a reduction of consumer environmental impact.

Rather than focusing on a specific green product line, some companies seem to be concentrating on the company's public image by describing corporate activities, practices and statements about their commitment to environmental issues. This trend is compatible with consumer attitudes that question the limited impact that green consumer products may have on environmental pollution.

Although the environmental movement continues to gain momentum, corporations and their staffs will be forced to deal with consumer skepticism concerning labelling claims or corporate policies.

Examples of Positive Environmental Labels or Symbols

Blue Angel — Germany was the first country to officially endorse an environmental label or symbol in the late 1970's.³ The Blue Angel symbol is the logo for the United Nations Environmental Program. The Blue Angel scheme was endorsed by the German Federal Environmental Agency and was initially designed as a voluntary program to promote products friendly to the environment.

Environmentally Friendly — This label has appeared on a number of consumer products, especially in Europe (Figure 2). This is an ambiguous label which lacks a precise defini-

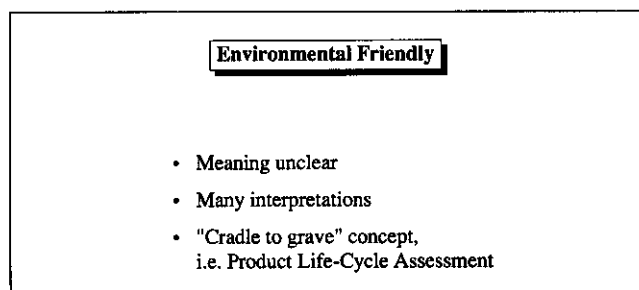


Figure 2.

tion and permits many possible interpretations. The best and evolving interpretation is the "cradle to grave" concept, also called Product Life Cycle Assessment, which focuses on many aspects of the product, starting from raw material production, processes used to manufacture the product, and disposal at the end of the product's life cycle. Using this interpretation, an environmentally friendly product would not be expected to deplete significant quantities of natural resources or contribute to hazardous waste.

Nordic Swan — This is a Swedish symbol applied to those products that meet the criteria established by the Swedish

Standards Institute.⁴ The assessment of each product will focus on the entire product life cycle. Other Scandinavian countries are expected to develop labelling schemes similar to the Nordic Swan.

Biodegradable — This term is often used on product labels to imply that the product is safe for the environment (Figure 3). It means the product or its components will not remain and accumulate in the environment as a result of consumer use. Biodegradation refers to bacterial enzymatic degradation of molecules. In addition to bacteria, fungi, plants and sunlight can play a role in degrading molecules. Unlike some of the environmentally persistent substances, i.e., PCB's, CFC's, fragrance aroma chemicals do not resist biodegradation. Fragrances do not pose a threat to the environment. This is explained in the IFRA Information Letter #337.⁵

Fragrances have a long history of use in soaps and detergents which are released into waste water treatment systems where the individual ingredients are estimated to be readily biodegraded. There is no precise or enforceable definition for classifying fragrances as biodegradable. Current microbial assays indirectly measure biodegradation of single chemicals by measuring the rapid depletion of oxygen from the environment or carbon dioxide production as a result of microbial metabolism of the chemical. Routine testing procedures and validated protocols for testing complex mixtures, i.e., consumer products, are not available.

Biodegradation

- Bacterial enzymatic degradation of molecules.
- Measure loss of oxygen or carbon from the environment.
- Concern for bioaccumulation in the environment and food chain.
- Good methods for testing complex fragrance mixtures do not exist.

Figure 3.

Biodegradation was included in the California environmental advertising bill (Assembly Bill No. 3994) signed into law by Governor Deukmejian on September 27, 1990. The bill amends the Business and Professions Code, to read:

"It is unlawful for any person to represent that any consumer good which it manufactures or distributes is "ozone friendly," or any like term which connotes that stratospheric ozone is not being depleted, "biodegradable," "photodegradable," "recyclable," or "recycled" unless that consumer good meets the definitions contained in this section, or meets definitions established in trade rules adopted by the Federal Trade Commission."

The bill defines Biodegradable as follows:

"Biodegradable" means that a material has the proven capability to decompose in the most common environment where the material is disposed within one year through natural biological processes into nontoxic carbonaceous soil, water or carbon dioxide.

The bill requires anyone making environmental claims about their product to file specified information with the Department of Consumer Affairs to substantiate the claim. This information would be disclosed to the public upon request. Protection of intellectual property was not mentioned in the bill.

Environmental Choice - Ecologo — The Environmental Choice Program is sponsored by the Canadian Minister of Environment (Figure 4). The Environmental Choice Board is appointed by the Minister of Environment to establish criteria for certification of products and services that decrease the burden on the environment. Currently, guidelines exist for ten product categories to which the Environmental Choice Symbol of Certification, The EcoLogo, can be granted. None of the existing product categories include fragrance or cosmetic products.

Ecomark — The Japanese have implemented an environmental labelling program. It includes the "cradle to grave" management concept of the environmental effects of consumer products. The program also promotes consumer education to enhance public awareness of environmental problems. The EcoMark logo is not only used as a product label, but for programs promoting environmental aware-

Safety and Regulatory Aspects of the 90's

Environmental Choice

- Eco Logo - "three doves intertwined in the shape of a maple leaf".
- Guidelines and certification criteria by product category.
- Canadian Standards Association - assesses product against the criteria.

Figure 4.

ness. The Japanese program employs many of the concepts of Germany's Blue Angel labelling scheme. The message conveyed by the EcoMark symbol is, "Let's save the earth and its environment with our own hands."³

Natural — Fragrance manufacturers are sometimes requested to certify their fragrances as "natural". This relates to the consumer's perception to consider items that are labelled as "natural" to be beneficial and safe. The fragrance industry has declared that there is no link between the natural status of fragrances and their safety.⁶ IFRA has provided the fragrance industry with a narrow definition and guidelines for developing natural fragrances (Figure 5). It permits the use of natural materials isolated by physical means but recommends that synthetic diluents and antioxidants be disclosed to the manufacturer of the consumer product.

Further, synthetically reconstituted essential oils, synthetic nature identical ingredients and chemically modified natural raw materials should not be used in natural fragrances. Natural fragrances do not have any advantages over fragrances containing synthetic ingredients. However, several clear disadvantages in comparison to "regular" fragrances (mixture of natural and synthetic ingredients) have been identified. The negative aspects include stability problems, and a reduced number of ingredients available for the creation process. As a result, the consistency in odor quality, availability of raw materials and performance is difficult to guarantee for natural fragrances. Also, natural ingredients usually cost more than synthetic ingredients, and promotion of natural fragrances may lead to the depletion of some natural resources.

Natural Fragrance

IFRA Information letter 325 - October 1989

- Fragrances made with natural ingredients are no more safe than those made with synthetic ingredients.
- Synthetic diluents or other technical aids should be declared to the consumer product company, i.e., antioxidants.
- Synthetically reconstituted oils, synthetic nature-identical ingredients and chemically modified natural raw materials should not be used.

Figure 5.

"Hypoallergenic" Fragrance

IFRA information letter 326 - October 1989

- No precise definition of "Hypoallergenicity".
- No fragrance should be promoted by a fragrance manufacturer with a "Hypoallergenic" claim.

Figure 6.

Hypoallergenic — Fragrance manufacturers are sometimes requested to provide "hypoallergenic" fragrances or fragrances suitable for use in "hypoallergenic cosmetics". There is no precise definition of "hypoallergenicity" (Figure 6). The Food and Drug Administration attempted to develop a definition for hypoallergenic cosmetic products but the proposed rule was never finalized.⁷ A "hypoallergenic" product is generally considered to be less allergenic than a standard product. However, the allergenicity of a standard product is not defined.

The positioning of consumer products as "hypoallergenic" is often intended to make them attractive to consumers seeking additional safety and protection. There is no guarantee that a single consumer will not suffer any allergic reaction to these so-called "hypoallergenic" products. Claims relating to the relatively low allergenicity or hypoallergenicity of fragrances of cosmetic products will detract from the image and acceptability of other products. IFRA recommends that no fragrance should be promoted by a fragrance manufacturer with the explicit or implied claim that it is "hypoallergenic". Until evidence is presented to the contrary, fragrance compounds which comply with the IFRA guidelines are acceptable for use in those types of cosmetic products for which manufacturers request "hypoallergenic" fragrances.⁸

The Need For Harmonization

Other organizations and institutions are in the process of evaluating and developing environmental labelling schemes for consumer products. These include corporate private label programs, i.e., Green Seal and Green Cross, the U.S. Environmental Protection Agency (EPA), the European Community (EC) and several states. The states have focused on labels that promote recycling and use of biodegradable products.

The EC has developed a draft regulation titled: "Proposal for a Council Regulation on a Community Environmental Labelling Scheme (Eco-Labeling)", XI/286/90, Rev. 2. The purpose is to encourage the development of products with less environmental impact during their development and life cycle (Figure 7).

Article 13(2) states, "The ECO-label shall not be awarded to substances and preparations classified as dangerous in accordance with Directive 67/548/EEC." This means some products would not qualify for the ECO-label because they contain a certain hazardous ingredient, even present at low

EC Eco-Labeling

- Proposal for a Council regulation on a community environmental labelling scheme
- Objectives
 - Promote development of products which have a reduced environmental impact during manufacturing, distribution, consumption and disposal
 - Minimize:
 - use of material resources and primary energy
 - Emissions into air, water and soil
 - Generation of waste and noise
- Exemptions
 - Foods, beverages and pharmaceuticals

Figure 7.

concentrations, considered safe based on the intended use of the product. The meaning of Article 13 needs further review. Since some materials of interest to the fragrance industry have already been classified as dangerous and are listed in Annex I to the Dangerous Substances Directive. In addition, other substances not listed in Annex I may also be classified as dangerous under the definitions of the Directive.

The Green Movement has caused consumers to adjust their life styles towards a "greener" way of living (10,11). As a result, new consumer products will continue to be developed to accommodate the life styles, attitudes and demands of "green" consumers. However, industry will be under increasing pressure to maintain credibility and avoid the use of misleading and confusing labels. To some extent, the failure to maintain credibility in advertising and labelling associated with the Green Movement has caused consumer enthusiasm for the United Kingdom's Green Movement to decline. This is because of skepticism about the validity of products carrying green labels and the suspicion that the Green Movement is a means to exploit or "con" the consumer.⁹

More and more consumers will be asking for a definition of a "green" product. That, plus the confusion associated with labelling claims, will cause them to look towards governments to establish labelling schemes with specific criteria and regulations governing advertising claims. In addition, the United States National Association of State Attorney Generals, led by Minnesota Attorney General Hubert Humphrey III, held a spring 1990 meeting in St. Louis to discuss the issue of misleading or false label claims. They concluded that a need exists for uniform standards and definitions for environmental labelling and advertising claims.

Based on the world-wide activity associated with positive environmental labelling schemes, and the consumers concern for the environment, it would be desirable to harmonize and standardize the labelling criteria worldwide. This will eliminate inconsistencies from one market to another and eliminate consumer confusion and backlash. An international harmonized labelling scheme will sustain and promote the environmental movement. The efforts of the recently formed United States Inter-Association Coalition on Environmental Labelling is encouraging establishment of national uniform labelling criteria and exchange of infor-

Volatile Organic Compounds (VOC) Regulations

- Clean Air Act - ozone reduction
- Reduce VOC emissions from consumer products
- VOC definition - any material with a vapor pressure greater than 0.1 mmHg at 21°C (many definitions)
- New Jersey, California, New York and other states

Figure 8.

mation about environmental labelling developments.

Hopefully, this effort may lead to international harmonization. If industry and consumers must comply or cope with a multiplicity of labelling schemes, each having its own set of criteria, it will lead to consumer confusion and a subsequent lack of enthusiasm for positive environmental labelling by both consumers and industry. It has been mentioned that environmental labelling schemes *might be replaced by a tax* on those products that are deemed to be less desirable for the environment. A taxing scheme would eliminate the consumer confusion element, but still provide a difficult bureaucratic system for industry compliance. In general, once consumers perceive that the majority of the consumer products are safe and friendly for the environment, the value of positive environmental labels will decline drastically.

Volatile Organic Compound (VOC) Regulations

The regulation of Volatile Organic Compounds (VOC) is another area where there has been emerging legislative activity, especially in the United States and Canada. This activity is being driven by the concern for clean air and the failure of certain states and metropolitan regions in the United States to satisfy regional requirements of the United States Clean Air Act. A major emphasis is focused on reduction of ambient ozone (Figure 8). A number of states, including California, New Jersey and New York, are actively developing regulations to reduce the VOC emissions from consumer products such as paints, coatings, air fresheners, hair spray and antiperspirants.

The California Air Resources Board (CARB) has held a number of workshops on reducing VOC emissions from consumer products in order to finalize a regulation which limits the VOC content for numerous consumer products. However, the proposed CARB regulations exempt fragrances and colorants in certain consumer products up to a combined level of 2 percent by weight. Air fresheners comprised entirely of fragrance are exempt from certain CARB requirements in the proposed regulation. The CARB draft regulations treat fragrances as a single entity to preserve the trade secret status of fragrances. The draft regulations define fragrance as follows — "fragrance means a substance or complex mixture of aroma chemicals, natural essential oils, and other functional components with a combined vapor pressure not in excess of 2mm/Hg at 20°C, the sole purpose of which is to impart an odor or scent,

Regulation for Reducing Volatile Organic Compound Emissions from Consumer Products

California Air Resources Board (CARB)

Definition of Fragrance

Fragrance means a substance or complex mixture of aroma chemicals, natural essential oils and other functional components with a combined vapor pressure not in excess of 2mm Hg at 20 degrees Celsius, the sole purpose of which is to impart an odor or scent, or to counteract a malodor.

Figure 9.

or to counteract a malodor" (Figure 9).

The volatility of a fragrance is based on the vapor pressure contribution of each component in the fragrance mixture. In general, as the carbon atom number of a molecule increases, the vapor pressure decreases, meaning the molecule is less volatile. The CARB definition still permits the use of low molecular weight materials, i.e. molecules with less than 10 carbon atoms, but in lower quantities. This means the fragrance industry will have to give more attention to understanding the vapor pressure of individual fragrance ingredients and the vapor pressure of fragrance mixtures. In some cases, the industry may be forced to restrict the usage of certain materials to comply with the VOC regulations.

While there is no practical or routine method for measuring the vapor pressure of fragrance mixtures, the vapor pressure can be estimated based on the components of the mixture. Most fragrance mixtures have a vapor pressure of less than 2mm/Hg at 20°C.

Canada, Holland, and the European Community (EC) are also developing VOC regulations. The proposed Canadian Management Plan for Nitrogen Oxide and VOCs referred to as "NoxVoc" was circulated in March, 1990. The final "NoxVoc" draft prepared by the Federal/Provincial Long Range Transport of Air Pollutants Steering Committee will be reviewed by the Canadian Council of Ministers of the Environment (CCME) in November. The final draft dated October 4, 1990 states on Page 102 - "Initiative VI03 - program to reduce VOC emissions from consumer products (excluding windshield washer and coatings) by 20% by 1997. Pharmaceutical products, fragrances and flavors are excluded from any changes, at least in the near future, due to the apparent difficulty of reformulating these products. If the future findings indicate that they are a significant source of VOCs and that some reductions are possible they could be targeted for long-term reduction."

The Dutch Ministry of the Environment has developed a plan for reducing the VOC emissions by 50% in comparison to 1981 emissions by the 2000. The project referred to as KWS 2000 (KWS=Dutch for VOC), focuses on industry, small businesses and households, and includes consumer products such as cosmetics. The Netherlands' policy includes strategy aimed at developing VOC emissions regulations in concert with other European countries such as Belgium, England and Germany.

The EC has established a task force on VOC to prepare

Canada

- CEPA - Canadian Environmental Protection Act
 - Domestic Substances List (DSL)
 - Notification of new chemicals
- WHMIS - Workplace Hazardous Material Information System
 - Material Safety Data Sheet (MSDS)
- Management plan for Nitrogen Oxide and Volatile Organic Compounds, i.e. NoxVocs - proposed March, 1990

Figure 10.

proposals for an international strategy for controlling VOC emissions. Germany and France are very much involved in the task force.

The U.S. Environmental Protection Agency recently published the "Proceedings From a 1989 Symposium on Regulatory Approaches for Reducing VOC Emissions From the Use of Consumer Products (Document number is EPA-450/3-90-008, January 1990)".

International Regulations

Numerous international regulations have been, or are being, developed which will impact the fragrance, flavor and cosmetic industries. A few of the most important regulations will be mentioned.

Canada recently approved the Canadian Environmental Protection Act which requires the establishment of a chemical inventory (Figure 10). The draft inventory has already been developed and is undergoing final review. The Canadian Chemical Inventory is referred to as the Domestic Substances List (DSL). Fragrance companies will be required to notify their new chemicals for listing on this inventory. This inventory is similar to the inventory required by the Toxic Substances Control Act (TSCA) in the United States and the Existing Inventory of New Chemical Substances (EINECS) in the EC. In addition, Canada had developed legislation for a Workplace Hazardous Material Information System (WHMIS) which specifies Material Safety Data Sheets for chemicals and materials in the workplace.

The European Community (EC), which was established by the Treaty of Rome in 1957, is committed to the removal of technical trade barriers and providing uniform consumer protection by 1992. In general, the EC Commission drafts laws and directives for achieving these goals. The member states of the EC are obliged to incorporate the content of each directive into their own national legislation within a specific period of time. A brief description of some of the directives affecting the fragrance, flavor and cosmetic industries will be mentioned.

The so-called 6th Amendment, Directive 79/831, which concerns the laws, regulations and administrative provisions

relating to the classification, packaging and labelling of dangerous substances, established the requirement for a chemical inventory referred to as the European Inventory of Existing Chemical Substances (EINECS). It requires that all chemicals imported or manufactured in the community be listed on EINECS. The EINECS is a closed inventory, as substances can no longer be added to this inventory. It includes those substances which were placed on the EC market before September 18, 1981. Substances listed on EINECS may be marketed in the EC by supplier or manufacturer.

The Directive (79/831) makes a distinction between new and existing substances. For getting a new material listed on the Inventory, a pre-market notification is required to be filed with the Competent Authority of the member state where the manufacture or importation is to take place at least 45 days before the new substance is placed on the market in the EC. The 6th Amendment also describes the toxicology data and technical information requirements for the Notification Dossier. Annex I of the 6th Amendment lists the hazard classification for some existing substances, i.e. Risk (R) & Safety (S) phrases. Future Annex I updates will list the hazard classifications for new substances.

The European List of New Chemical Substances (ELINCS) is expected to be published in late 1990. Actually, the legal requirement in the 6th Amendment states that the first publication of ELINCS must occur within six months after the publication of the official EINECS list, which was published on June 15, 1990 in the Official Journal No. 146A. New substances can be listed by their trade names on ELINCS, to protect trade secrecy.

For materials intended to be marketed at greater than one ton per year in the EC market, the 6th Amendment requires the EC supplier/manufacturer to submit a dossier "base set" of technical and toxicological data to the competent authority(s). These requirements may be modified once the proposed 7th Amendment is finalized. If a second supplier/manufacturer wishes to market the same substance which is not on EINECS but has already been notified on ELINCS, the second supplier must also prepare a dossier for notification to the competent authority(s). To reduce animal testing and duplication of effort, the draft of the 7th Amendment recommends that the first and second supplier agree, through some as-yet-unknown mechanism, to share toxicological data and other information.

The proposed 7th Amendment to the 1967 EC Directive for Harmonizing the Classification, Packaging and Labelling of Dangerous Substances 67/548/EEC was recently published in the Official Journal, February 13, 1990. It further refines some of the legal requirements in existing directives with respect to notification procedures (Figure 11). It also focuses on methods for classifying materials dangerous to the environment and proposes a label for those products that pose a hazard to the environment.

The EC is in the process of reviewing a draft Directive for Safety Data Sheets. This Directive would prescribe the

EC 7th Amendment

- Draft proposal
 - Official Journal C 33/3, February 13, 1990
 - Amending Directive 67/548/EEC
 - Classification packaging and labelling of dangerous substances
- Notification Procedures
 - Toxicology data requirements
 - Limited Notification
- Ecotoxicological properties; degradation and toxicity to fish and daphnia; label dangerous to the environment
- MSDS and product labelling

Figure 11.

requirements for Material Safety Data Sheets similar, in principle, to the U.S. Occupational Safety and Health Agency (OSHA) Hazard Communication Standard and the Canadian Workplace Hazardous Material Information System (WHMIS). A major difference between U.S. and EC regulations in this area is the hazard classification scheme. In general, the various regulations necessitate a different MSDS format for each geographical region, including Canada. Also, differences exist with respect to selected data elements and language. Development of the EC MSDS Directive is moving very rapidly with the target date for adoption of the Directive by March 31, 1991. The directives' provision would be effective June, 1991.

A similar activity is occurring with respect to the International Labor Organization (ILO), part of the United Nations structure. The ILO, at its June, 1990 meeting, adopted a "convention" on workplace safety. This "convention" (or treaty) must be ratified by the U.N. member countries. The ILO MSDS activities stimulated a concern for trade secret protection.

The EC Commission recently adopted on July 4, a Council Regulation on the Evaluation and the Control of Environmental and Health Risks of Existing Substances which will be published for review and discussion this fall. Annex I of this regulation provides a list of existing substances produced or imported within the EC community in quantities exceeding 1000 tons per year.

Although, the flavor and fragrance industry may use a few of these materials, and in limited quantities, manufacturers or importers of a substance on the list will be required to supply the Commission with toxicology/technical information which they possess on the materials, and/or conduct additional tests concerning health and environmental effects of the substance. If the requested information is not supplied to the EC within a specified time, then the EC may suspend further marketing and use of the substance in the community.

Other non-EC countries in Europe are closely watching the EC activities and promulgating their own regulations. Most recently, Switzerland and Austria have established chemical inventories. The Austrian chemical legislation

EC Cosmetic Directive

Proposed 6th Amendment

Discussions focus on:

- Definition of a Cosmetic ?
- Inventory of ingredients?
 - Open or closed inventory?
 - Notification of new ingredients?
 - Defined end-uses and toxicology data requirements?
 - Inclusion of fragrance ingredients?
- Cosmetic product dossier on file?
- Ingredient labelling?

Figure 12.

specifies the establishment of a poison substances list.

Two years ago, Australia passed legislation requiring Material Safety Data Sheets and establishment of a chemical inventory. During the summer of 1990, the Australian Parliament developed legislation specifying requirements for notifying new chemicals to the Australian Chemical Inventory.

The 6th Amendment to the existing EC Cosmetic Directive 76/768 is under preparation and a draft was circulated earlier this year. It is still the subject of many discussions (Figure 12).

One issue is the definition of a cosmetic product versus a medical product which may be administered for "restoring, correcting or modifying physiological functions in human beings". Another issue, is the requirement to establish a cosmetic ingredient inventory requiring notification of new substances, including defined end uses and toxicological data. The purpose of the inventory remains to be determined. Further, it is unknown whether the inventory will be "open" or "closed", and the impact on fragrances is also uncertain. The proposed amendment requires that a cosmetic product safety dossier be on file with the producer for examination by the authorities. Also, ingredients labelling for cosmetic products, i.e. either complete or partial, is covered by the directive. It is not possible, at this time, to predict the conclusion of these discussions.

Although they fail to qualify as international regulations, we must be aware of the potential impact of some recently developed state legislation. This includes the Hazard Elimination through Local Participation (HELP) legislation which is being developed in New Jersey. The HELP legislation authorizes local planning committees, worker and community groups to conduct environmental and public health-oriented inspections of local factories.

California's Proposition 65 continues to evolve. These activities may spread to other states or countries. However, California Governor Deukmejian's announcement on September 8, 1990, opposing Proposition 128 (known as "Big Green" and listed on the November ballot) may slow the spread of this type of activity. He stated "This measure would force California's farmers and businesses to comply with hundreds of new regulations, placing us at a competi-

tive disadvantage with our counterparts in other states and nations." The numerous California environmental initiatives on the November ballot are causing confusion in the minds of consumers and environmental lawyers.¹²

In conclusion, it is important for the fragrance industry to continue to endorse and adhere to the IFRA guidelines and continue to support the self regulatory concept of the industry. Positive labelling associated with the Green Movement is very inviting and appealing, but this appears to be an invitation for more regulations because consumers and environmentalists have become suspicious of the validity of some of these labels. Therefore, government agencies and regulators view this as another area ripe for regulation. The concern for safety in the environment is sweeping the globe and will continue to cause additional legislation to be developed in various parts of the world. Whenever possible, harmonization of the legislation should be promoted. It is important for the fragrance industry and member companies to maintain an Eco-conscious attitude. The fragrance industry must monitor and provide guidance during the legislative activity. Once the regulations are finalized, it is too late for input.

References

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Address correspondence to Kenneth R. Schrankel, Ph.D., International Flavors & Fragrances, 1515 Highway 36, Union Beach, NJ 07735, USA.

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