Expert opinions

The Road Ahead

Regulatory matters in California, Canada, Japan and beyond

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If it seemed to you there was a lot going on in the past year or so on the regulatory front, you're right! Let's take a look at several of the key topics of which everyone in F&F should be aware, so that there are no nasty surprises down the road.

California

Ah, the Left Coast strikes again! Senate Bill 484, rebaptized as the California Safe Cosmetics Act, was adopted in late 2005, despite the best efforts of the Cosmetic, Toiletry and Fragrance Association, the Fragrance Materials Association of the United States and the Flavor and Extract Manufacturers Association (FEMA) to inject some reality into this measure. The new legislation will take effect in January 2007 and will require the manufacturers of cosmetic products sold in that state to notify California authorities of the presence of ingredients that have been "… identified as causing cancer or reproductive toxicity." Who could be opposed to such a motherhood-and-apple pie proposal? Well, for starters there is no *de minimus* concentration below which reporting would not be required. So the tracest of trace levels of substances such as butylated hydroxyanisole (BHA) would have to be reported.

And speaking of the "reportable" ingredients, what are they? The legislation identifies five reference sources — such as the Proposition 65 list, the National Toxicology Program report on carcinogens, etc. — that form the basis for a list of reportable materials. A review of these suggests that there are probably about 20 fragrance/flavor materials that are found on one or more of these lists and might, therefore, be reportable.

The only good news associated with this new law is that only those materials that fit the US Food and Drug Administration (FDA) definition of "ingredient" are reportable. This includes ingredients that are added directly; "incidental" ingredients are not included. So, for example, if BHA were used in the production of an aroma chemical and the latter then was used in a perfume mixture, which, in turn, was used in a cosmetic, that BHA would not be reportable because it is incidental. Another problem with this legislation is that its writers never considered that, once in the finished product, it is impossible to distinguish the difference between a directly added ingredient and an incidental one. Nonetheless, the FDA has maintained this distinction for many years in the labeling of cosmetic products, and it is hoped that the California authorities will do the same.

Finally, what do they intend to *do* with this ingredient information that is being sent to them? Well, no additional funds have been allocated to the agency that will be the recipient of the information, and, in fact, that agency has gone on record as opposing this ill-conceived legislation before the final vote was taken. So it is unclear whether anything other than file-stuffing will result here. However, this will not deter the activist legislators who drafted this bill, and we need to be watchful for attempts at the next legislative session to extend the reach of this program.

REACH

Did I say REACH? As in Registration, Evaluation and Authorization of CHemicals? I did. This is the new chemical legislation program in Europe, which is making its way through the tortuous process of legislative approval and is expected to be finalized sometime in 2007. This new law will affect all substances manufactured in, or imported into, the European Union (EU)

in amounts greater than 1 mt (i.e., 1,000 kg) per year, per importer or manufacturer. ("Substances" include essential oils and extracts, crude reaction products and chemically defined substances.) For our industry, all raw materials used in fragrances will be included. At the same time, according to the latest drafts, substances used in food flavors will not be covered, although flavor materials that may be used in nonfood products (e.g., lip and oral care products) will be included.

The REACH process will be prioritized according to usage volumes so that the first wave of materials will be those that are used in the EU at greater than 1,000 mt per year. Also included in this group will be any carcinogens, mutagens and reproductive toxicants (CMRs) that are Class 1 or 2 and have an annual use volume greater than 1 mt. This is in addition to, according to the latest drafts, materials used above 100 mt/year that currently are classified as very toxic to the environment in Europe. The registration process for these materials must be completed within three years of the date that the legislation becomes law. The process includes the submission of a Chemical Safety Report (CSR), which must contain all of the known physicochemical, toxicological and environmental data for the chemical, as well as risk assessments and risk management recommendations. Following the 1,000-mt materials, a period of six years has been established for the registration of the greater-than-100-mt materials, and a further 11 years for the greater-than-1-mt materials.

In the evaluation phase, the authorities will review the data contained in the submissions; any additional testing that might be required would be specified at this stage. Certain subgroups of chemicals will be subject to the authorization step, based on their toxicological and/or environmental profiles. When all is said and done, the overall process is expected to be carried out at least through the year 2018.

In one sense, the REACH program is similar to the US Environmental Protection Agency's High Production Volume (HPV) chemicals program, begun in 1999. The latter program, however, focused on materials used in the United States at volumes greater than 1 million lb per year. The EU program will have a much broader scope, with added layers of complexity. At present, it appears that the direct cost to the flavor and fragrance supplier industry for REACH could be as much as $200-250 million; this does not take into account the costs of product reformulations or the administrative expense to chemical manufacturers/importers. The European flavor and

fragrance industry has aggressively begun a program of adopting the consortium approach that was used so successfully for the HPV program in the United States, and both the European Flavor and Fragrance Association (EFFA) and the International Fragrance Association (IFRA) are working hard to put the necessary structures in place to administer this massive undertaking.

IFRA

This year will be a big one for IFRA, as it will undertake two major steps in changing the way in which it conducts business. The first is that, with the announcement of the 40th Amendment to the IFRA code of practice, a fundamental change will be made in the way in which fragrance ingredient use restrictions are calculated and administered. In the past, restrictions of usage were based on three types of considerations: whether the fragrance would be left in contact with the skin; whether it would be rinsed off the skin; or whether there was no (or very little) contact with the skin. The new approach, which is based on the philosophy of quantitative risk assessment (QRA), will be based on the determination of dose of fragrance ingredient used per unit area of skin and takes into account a variety of factors relating to product vehicle, interindividual variability, skin site, etc. The biggest difference is that there will be 11 different product categories for which usage restrictions will be calculated. Although more complicated, it is believed that this approach will give the perfumer much greater flexibility when creating for a wide variety of product forms.

The new QRA approach is intended to be used in each annual IFRA amendment going forward. Currently, restricted materials will also have to be converted to the new approach, and the approach to be taken for this is presently under discussion by representatives of the fragrance supplier and finished product industries.

The second big step for IFRA will be the implementation of a formalized compliance program that will work in conjunction with the IFRA Code of Practice to provide assurance that the organization's members are complying with the Code. In order to maintain confidentiality of product identity, a third-party entity will manage the administration of the compliance program, and a third-party analytical lab will test marketed products (which have had product IDs removed) for surveillance of any IFRA-banned or restricted ingredients. In the case of finding a disallowed material, the fragrance supplier will be contacted and allowed the opportunity for explanation and remediation. In the case of a supplier failing to remedy the situation, appropriate steps will be taken by IFRA with that supplier.

Canada

The regulatory scene in Canada continues to heat up. A list of about 1,100 chemicals has been proposed by Environment Canada for deletion from the domestic substances list (DSL). These are materials that originally were nominated for the DSL in the 1980s, but subsequently have been determined by the authorities not to have the appropriate documentation to support their inclusion. About 300-400 of these materials are flavor/fragrance ingredients. This proposed deletion list has been circulated to our industry and every opportunity made available to submit supporting evidence to justify leaving these materials on the DSL.

The "screening and categorization" of DSL materials continues apace. The US Flavor and Fragrance HPV Consortium (FFHPVC) formed a Canadian consortium in order to focus resources on this need, and both the RIFM and FEMA have met with Canadian regulators, worked with the industry coordinating group in Canada and made written submissions to the Canadian authorities. The intent for the Canadian initiative is to use the US HPV model, which was based heavily on structural analogy of chemicals to support their safety. At present, Environment Canada seems to be in agreement with the approach, and it is

hoped that this will reduce the overall amount of testing of materials that might be required in order to maintain these materials on the DSL.

Japan

The Japanese Flavor and Fragrance Manufacturers Association (JFFMA) has identified about 500 materials that have use only in Japan, but which should be reviewed and approved at a global level. To that end, there is a plan to conduct a "group GRAS" (generally recognized as safe) program within FEMA for these materials, to be followed by a Joint FAO/WHO Expert Committee on Food Additives (JECFA) review. Meanwhile, the JFFMA continues to work closely with the Japanese regulatory authorities to achieve approval for more materials that currently are approved globally, but are not contained on the list of approved materials for use in Japan. The International Organization of the Flavor Industry (IOFI) has played a key role in working together with the JFFMA to expand this list of Japanese-approved materials.

Korea

The Korean FDA has proposed a positive list of synthetic flavor materials for incorporation into their flavor legislation. This list contains all chemically defined FEMA/GRAS flavoring substances on lists 1-22, but it is unclear if there is a mechanism to update this as new substances are approved by the JECFA. A "transition period" of two years has been announced for the official implementation of this list. Meanwhile, the IOFI will try to convince Korea to recognize the JECFA approach for ensuring that this list is updated regularly to include all newly approved substances.

Europe

The process for administration of the EFFA/IOFI/IFRA labeling manual, which deals with the hazard labeling of flavor and fragrance materials in accordance with the dangerous substances directive, has been changed. As the classifications in this publication address the European directive only, and not hazard classifications under other jurisdictions (except for some countries that automatically follow the European example), it has been agreed that EFFA will become solely responsible for this publication. In turn, EFFA has decided to evolve this document into a "code of practice." The yearly revisions of the labeling manual deal with decisions made by an EFFA committee regarding hazard classification of flavor and fragrance ingredients. Future editions of the manual will incorporate the hazard classification of complex mixtures — such as essential oils — for the first time, which will affect safety data sheets, product labels and other parameters.

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