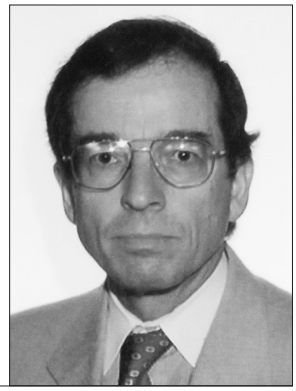
The Fragrance Industry: Self-Regulatory Since 1966



By Maurice Wagner, International Fragrance Association

The fragrance industry formulates and supplies fragrances to consumer product manufacturers, particularly in the cosmetic and household cleaning product sectors. The industry has been maintaining a strict self-regulatory system for more than 30 years. This system aims at ensuring the safety of the substances used. The independent research body, the Research Institute for Fragrance Materials (RIFM), has been evaluating the safety of fragrance ingredients since 1966. On the basis of the safety evaluations by RIFM, the International Fragrance Association (IFRA) has banned or restricted the use of nearly 100 substances. The IFRA restrictions, called standards, are binding on its members. They reflect the practice of the industry and have the same legal value as other sources of law, such as legislation. The whole process is transparent in that RIFM publishes in particular its ingredient monographs and IFRA publishes its Standards very widely. IFRA welcomes any type of institutionalized cooperation between the scientists of RIFM and government scientists, such as the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP), as well as between the industry trade associations and governmental agencies, such as the US Food and Drug Administration or the European Commission.

> "Legally, the mandatory provisions of an industry code of practice of the nature of the IFRA code of practice have the same value as legislation."

The Key Actors

RIFM — global risk assessment institute: Since its inception in 1966, RIFM has been responsible for the safety evaluation of fragrance materials, and has gained a wide and thorough expertise in this area. Fragrance manufacturers in the industry fund the Institute. Its scientific conclusions are taken by an independent international expert panel (REXPAN), currently chaired by a German member of one of the DG SANCO scientific committees, and published in a peer reviewed scientific journal. None of the expert panel members individually has any link to the fragrance industry. REXPAN has evaluated 95 percent—in weight terms—of the substances used by the industry. Further, RIFM publishes monographs and other scientific investigations in the peer-reviewed literature.

IFRA — global risk management association: IFRA, created in 1973, is primarily concerned with the safety of fragrance ingredients for both humans and the environment. The Association is funded by its member associations, to which fragrance manufacturers (representing approximately 95 percent of the total worldwide market) belong. IFRA has issued a code of practice, the main thrust of which is comprised of nearly 100 standards, 40 percent of which ban and 60 percent of which restrict the use of fragrance ingredients. The Association focuses on standards or rules that are required from a consumer health perspective. The IFRA code of practice and the IFRA standards are published in binders and on the IFRA Web site: www.ifraorg.org. As stated before, the IFRA standards are binding on its members.

The Process

The process, which has been evolving since the early 1970s, can be summarized as follows:

A new IFRA standard or the revision of an existing IFRA standard may be triggered by:

- The review by REXPAN of existing Standards or of substances, based on the criteria document pub lished by RIFM (Regulatory Toxicology and Pharma cology 31, 166-181 [2000]);
- new evidence on ingredients from tests done by RIFM;
- new evidence on ingredients from reports of manufacturers;
- new evidence on ingredients from literature reports about tests done by other institutes and researchers;
- other external sources, such as the SCCNFP in the EU.

Once a review has been initiated, the IFRA and RIFM staff put dossiers together, that cover all the requirements of REXPAN to make their assessments.

The IFRA standards must be consistent to the REXPAN assessments. (IFRA has never issued a standard that was not respecting the REXPAN assessment).

 0272-2666/02/0007-0048$04.00/0—

Example of the outcome of the process: IFRA banned musk ambrette in 1994, and was followed by the Commission in 1995 (Commission Directive 95/34).

The legal nature of the IFRA Standards, and its consequence: The sources of law are fourfold and comprise the doctrine, the legislation, the case law and the sectoral practices. The IFRA Standards belong to the latter source of law. Sectoral practices have the same legal value as any of the other sources of law. Legislation is not required on matters covered by generally recognized sectoral practices, like the IFRA Standards.

The fragrance manufacturers follow the IFRA Standards, although they are not formal pieces of legislation, which shows that they accept that the IFRA Standards have as much weight as a formal piece of legislation.

Questions and Answers

How about the transparency of the RIFM-IFRA process? RIFM has been publishing monographs on the substances evaluated for many years. The IFRA Standards are published on the IFRA Web site. The IFRA code of practice has been distributed very widely, including among regulatory bodies; all those who have the code receive updates.

How about the cosmetic companies? The cosmetic industry, which the fragrance industry supplies with fragrances, does not belong to IFRA. In Europe, however, certificates of conformity are being established by the cosmetics companies in accordance with an agreement between COLIPA (the European cosmetics industry association) and the European Fragrance and Flavour Association (EFFA) (which belongs to IFRA), which requires that the consumer products comply with the Cosmetics Directive and the IFRA code of practice. This means that the cosmetics companies follow the IFRA Standards.

What conditions must be fulfilled to belong to IFRA? Is IFRA an open association?

The membership to an IFRA member association is open to any company that agrees to apply the IFRA safety Standards to its operations and to pay a membership fee.

How about the policing approach of IFRA? Because we are talking of a voluntary approach, all members belonging to IFRA know before joining that they must follow the safety standards. This said, IFRA has had very few cases of non-compliance over the years. The Association's code of practice contains a self-policing chapter. In practice, if and when IFRA is informed about a suspected infringement to the code, the staff investigates the facts and gets in touch with the operator in question as required. In the few cases that have been drawn to the attention of IFRA in the past, a satisfactory resolution has been achieved. The ultimate sanction of non-compliance is the expulsion.

The client companies are always expecting that their fragrances comply with the IFRA Standards (see How about the cosmetic companies?): they materially play the role of an external auditor. Any regulatory body can check the compliance of the fragrances on the market with the

IFRA Standards. The Association knows, for instance, that this is common practice in Denmark and Germany. IFRA is not aware of any complaint from any government body.

How about banning in the EU legislation substances that IFRA banned earlier?

Legislating on IFRA-banned or restricted substances would signal — both inside and outside Europe — that the IFRA standards are no longer binding. Some producers could interpret any such EU bans to mean that as long as a substance is not banned by the Cosmetics Directive, the IFRA Standard does not count. The consequence would be that consumers would benefit from the new IFRA Standards much later than they do now; in other words, the consumer would be less well protected.

Legally, an industry code of practice of the nature of the IFRA code of practice has the same value as legislation. If, however, European institutions wanted to have a provision in a piece of legislation, they could add a provision in the directive whereby the fragrance compounds must always comply with the IFRA code of practice. Such an approach would be in the spirit of the Simpler Legislation for the Internal Market initiative (SLIM).

What is the situation in the United States? The US FDA is aware of the IFRA self-regulatory approach based on RIFM assessments and has never seen any need to take any additional legislative or regulatory initiative.

Concluding Remarks

The IFRA self-regulatory approach is:

- open: any scientist who wishes to contribute has an opportunity to do so;
- transparent: all the conclusions of IFRA are publicly available;
- working: the past 30 years have shown that IFRA is willing to take the initiative of restricting or banning the use of ingredients (several European governments already make checks of the system: if they had complaints, they would let IFRA know);
- quick and efficient: it prevents the problems linked to the transposition of EU directives into national legislation, and applies all over the world at the same time.

The efficacy of the IFRA self-regulatory approach is clear: in the EU, the compliance with the IFRA Standards is one of the elements of the safety assessment for cosmetic products. In addition, two Commission decisions in 2001 provided that the compliance to the IFRA code is one of the criteria to meet for the grant of an egological-label.

The fragrance industry has been financing the risk assessment work for over 30 years, which has saved a lot of money to the national and regional authorities.

Address correspondence to Maurice Wagner, IFRA, 49, Square Marie-Louise, B-1000 Brussels, Belgium.■