



International Fragrance Association (IFRA)

IFRA Code of Practice

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1 INTRODUCTION

1.1 What is IFRA?

The International Fragrance Association (IFRA), incorporated in Geneva and with offices in Brussels, was founded in 1973. It represents the collective interests of its members and supports those of the finished fragrance products community. Membership is open to associations of fragrance manufacturers from all countries/regions, and currently includes members from Asia/Pacific, Europe and the Americas¹. IFRA develops and implements a Code of Practice (the Code) that provides recommendations for good operating practice and guidelines on fragrance ingredient safety assessment, and includes fragrance safety Standards² which may limit or ban the usage of certain fragrance materials. The Code has been utilized worldwide since 1973 and is binding on all members.

1.2 The Mission of IFRA

To encourage the compliance of fragrance manufacturers and their products and practices with all relevant legislation – national or international – and with applicable industry codes as well as to promote the highest standards of conduct and safety in the fragrance industry, worldwide, through:

1. Establishment and maintenance of a consistent system of Standards for safe use of fragrances, based on broadly recognized scientific principles with the final objective of protecting the consumer and the environment;
2. Maintenance of the high standards necessary to protect and enhance the credibility of the industry through self-policing;
3. Development and maintenance of open communication and cooperation with national and international government bodies, concerned elements of the medical and scientific community and other stakeholders;
4. Support of the independent safety assessment of ingredients used by the industry;
5. Provision to the membership of timely and comprehensive information on matters of relevance to the industry, consistent with the main mission of IFRA;
6. Promotion of the merits of fragrances in their general enhancement of quality of life;
7. Advocacy of regulatory principles that protect the intellectual property of its members.

1 A current list of IFRA members is included in [Appendix 1](#).

2 The IFRA Standards are included in [Appendix 8](#).



2 **OPERATION OF IFRA**

2.1 **Operation**

IFRA has two arms: a scientific arm and an advocacy/communication arm. The scientific arm is the Research Institute for Fragrance Materials (RIFM), which is a non-profit scientific institute, founded in 1966 for the purpose of generating and evaluating safety data on fragrance ingredients. The scientific foundation of RIFM is built around its independent Expert Panel (REXPAN), which is made up of toxicologists, pharmacologists, dermatologists and environmental scientists, none of whom has any other connection to the fragrance industry, and whose work involves the safety evaluation of fragrance ingredients under conditions of intended use. The results of their evaluations are published in peer-reviewed scientific journals, and their decisions regarding restrictions of use are promulgated through the IFRA Standards.

The IFRA Scientific Committee (SC) and the independent RIFM Expert Panel form the core of the IFRA process upon which the assurance of safe use of fragrance materials is based. The SC provides information to the REXPAN regarding use levels of fragrance raw materials in perfumes for specific product applications; the SC is also responsible for conducting an ongoing series of “volume of use” surveys. Both of these metrics are key elements in the REXPAN analysis of safety data, and risk assessment, for individual fragrance materials. REXPAN decisions regarding any necessary use restrictions for the materials reviewed are communicated to the IFRA membership via Standards that are prepared by the SC, and these are typically released to the membership once a year.

2.2 **IFRA Committees**

A listing of all IFRA committees and its main functions may be found in [Appendix 2](#).

2.3 **IFRA Statutes**

The Statutes of the Association are provided in [Appendix 3](#).



3 THE IFRA CODE OF CONDUCT

3.1 Limit of Responsibility and Liability

The IFRA Standards and recommendations represent a good faith effort to present the most recent scientific opinions and collective experiences of various committees and working groups within and outside IFRA. Although the IFRA Standards and recommendations are based on the best knowledge and expertise available, neither IFRA nor any of its officers or directors shall be liable for their accuracy or for actions taken in applying them, under any circumstance whatsoever. It is the responsibility of individual companies and their employees, with the aid of their IFRA member associations, to determine how to apply the IFRA Standards and recommendations, in accordance with applicable law and other requirements of the countries in which they operate.

3.2 Entry into force of IFRA Standards and Communication Process

- Typically once a year, the IFRA Secretariat communicates the Notification of new or amended Standards (IFRA Amendment) in writing to the IFRA membership (national / regional associations) with a copy to RIFM. This communication would generally occur in the first half of the year. In cases of health or environmental risk, the communication of Standards could be immediate.
- The Standards Notification is always preceded by a consultation phase during which the final drafts of the Standards are circulated within the IFRA membership, and to the customer associations, to allow any data to be shared with IFRA/RIFM that might alter the content of the Standards.
- Two weeks after the communication of the Notification to the IFRA membership, the IFRA Secretariat will inform the major client trade associations.
- The Notification will indicate the date of entry into force (effective date), which is typically one month after the date of the letter of Notification for new submissions, and 13 months after the date of the letter of Notification for existing fragrance compounds (unless otherwise noted).
- The Amendment will be published on the website seven months after the date of the letter of notification to the IFRA membership. Interested regulatory bodies are informed of all changes in the Standards via the website (www.ifraorg.org).
- If not stated otherwise, 60 days after entry into force of a new IFRA Amendment, fragrance manufacturers must inform their customers, in writing, of the potential impact of the new Amendment on fragrances currently being sold to that customer.

3.3 **Compliance**

All national and regional associations that belong to IFRA (including Ordinary and Observer members), as well as individual member companies, must strictly comply with the Code.

A fragrance manufacturer is deemed in violation of the Code when it does not follow mandatory provisions of the Code or when it places on the market a fragrance or a fragrance ingredient that is not in compliance with any Standard because:

- a) It contains or is an ingredient used in violation of a Standard; or
- b) It contains a fragrance ingredient³ that has not been evaluated in accordance with section 4 hereof.

Active enforcement of compliance⁴, by IFRA, shall be based on surveillance of marketplace products utilizing analytical investigations of fragrance composition. Market products shall be randomly selected each year and analyzed by a contract laboratory for ingredients that do not comply with the Code. Suspected violations shall be brought to the attention of the fragrance supplier and, if remediation is not agreed, the violation shall be notified to the pertinent national association and the name of the fragrance manufacturer, if it is an a member of an national or regional association belonging to the IFRA membership, shall be placed on the IFRA website and identified as being non-IFRA compliant.

Potential violations of the Code can also be brought to IFRA's attention by submitting the exact name of the consumer product and the name of its manufacturer (as well as the name of the manufacturer of the therein contained fragrance if known), as well as any analytical evidence of non-compliance; this must be accompanied by a name and contact address of the complainant so that a response can be made following IFRA's investigation of the matter. This information should be sent to IFRA at the address contained in [Appendix 1](#).

3 The formalized methodology for safety evaluation of fragrance ingredients, which is referenced in section 4.2, is in the process of being applied, retrospectively, to a group of fragrance ingredients, which have a long history of safe use. At the conclusion of this process, all ingredients – both new and existing – will have been fully evaluated according to these principles.

4 The Compliance Program was launched in May 2006.

4 SAFETY EVALUATION OF FRAGRANCE INGREDIENTS

4.1 General Principles

Fragrance ingredients must always conform to the requirements of relevant legislation and regulations in countries in which they are to be used.

Fragrance ingredients should only be used when, based on appropriate information and evaluation, it has been concluded that they present no unreasonable risk to human health and the environment and are safe under their intended conditions of use.

Where toxicological testing is performed, properly validated and accepted alternatives to animal experiments should be used wherever possible.

4.2 Testing Program for Fragrance Materials

The safety of fragrance ingredients is assessed within the context of the ongoing safety evaluation program of RIFM. In some cases, in order to complete the evaluation, RIFM may require additional data that may come from the manufacturer(s) or may be generated by RIFM.

Specifics regarding the evaluation of fragrance materials for health and environmental effects may be found in [Appendix 5](#), along with a list of reference documents that provide additional details.



APPENDIX 1 TO THE IFRA CODE OF PRACTICE

IFRA Membership and IFRA Contact

IFRA CONTACT DETAILS

IFRA OPERATIONS

Avenue des Arts 6
B – 1210 Brussels
Belgium

Tel.: ++ 32 2 214 20 60
Fax: ++ 32 2 214 20 69
E-mail: secretariat@ifraorg.org
URL : www.ifraorg.org

IFRA HEAD OFFICE

Chemin de la Parfumerie 5
CH – 1214 Vernier Geneva
Switzerland

Tel.: ++ 41 22 431 82 50
Fax: ++ 41 22 431 88 06
E-mail: secretariat@ifraorg.org

IFRA MEMBERS

ORDINARY MEMBERS

[Australia/New Zealand](#) – [Brazil](#) – [Europe](#) – [Indonesia](#) – [Japan](#) – [Mexico](#) – [Singapore](#) – [United States](#)

OBSERVER MEMBERS

[Argentina](#) – [China](#) – [Colombia](#)

Ordinary Members

AUSTRALIA / NEW ZEALAND

FFAANZ – Flavour and Fragrance Association of Australia and New Zealand

Locked Bag 938
North Sydney, NSW 2059
Australia

Tel.: ++ 61 2 9459 7420
Fax: ++ 61 2 9956 7004
E-mail:

Dee.Neville@australianbusiness.com.au

BRAZIL

ABIFRA – Associação Brasileira das Industrias de Oleos Essenciais, Produtos Quimicos Aromaticos, Fragrâncias, Aromas e Afins

Av. Brigadeiro Faria Lima 1903, cj72
01452-912 São Paulo - SP
Brazil

Tel.: ++ 55 11 3812 4075
++ 55 11 3813 5431
Fax: ++ 55 11 3816 5701
E-mail: abifra@abifra.org.br
URL: www.abifra.org.br



EUROPE

EFFA – European Flavour and Fragrance Association

Square Marie-Louise 49
B – 1000 Brussels
Belgium

Tel.: ++ 32 2 238 99 05
Fax: ++ 32 2 230 02 65
E-mail: secretariat@effaorg.org
URL: www.ffa.be

EFFA represents the following National Associations:

FRANCE

PRODAROM – Syndicat National des Fabricants de Produits Aromatiques

Avenue Riou Blanquet 48
FR - 06131 Grasse
France

Tel.: ++ 33 4 92 42 34 80
Fax: ++ 33 4 92 42 34 85
E-mail: info@prodarom.fr
URL: www.prodarom.fr

GERMANY

DVRH – Deutscher Verband der Riechstoff-Hersteller e.V.

Office in Germany:
Wacholderstrasse 1
DE - 53340 Meckenheim
Germany

Tel.: ++ 49 2225 839155
Fax: ++ 49 2225 839157
E-mail: vddei-vdrh@t-online.de

Office in Brussels:

Boulevard Charlemagne, 96
BE - 1000 Brussels
Belgium

Tel.: +32 2 234 37 37
Fax: +32 2 234 37 39
E-mail: dvai-dvrh@aktuell.be
URL: www.riechstoffverband.de

ITALY

AISPEC – Associazione nazionale imprese chimica fine e settori specialistici – Gruppo Aromi e Fragranze

Via Giovanni da Procida, 11
IT - 20131 Milano MI
Italy

Tel.: ++ 39 02 34565 222
Fax: ++ 39 02 34565 349
E-mail: aispec@federchimica.it
URL: www.aispec.federchimica.it



NETHERLANDS

NEA – Vereniging van Geur en Smaakstoffenfabrikanten

P.O. Box 443

NL - 2260 AK Leidschendam

The Netherlands

Tel.: ++ 31 70 33 78 787

Fax: ++ 31 70 32 03 903

E-mail: heemskerk-nea@vnci.nl

URL: www.nea-nederland.nl

SPAIN

AEFAA – Asociación Española de Fragancias y Aromas Alimentarios

Pº de la Castellana 159-1º A

ES - 28046 Madrid

Spain

Tel.: ++ 34 91 571 1640

Fax: ++ 34 91 571 6163

E-mail: aefaa@aefaa.com

URL: www.aefaa.com

SWITZERLAND

SFFIA – Swiss Flavour and Fragrance Industry Association

Industriestrasse 9

CH - 8305 Dietlikon

Switzerland

Tel.: ++ 41 1 835 76 17

Fax: ++ 41 1 835 76 80

E-mail: nussbaumer.cornelius@luzi.ch

URL: www.sffia.ch

TURKEY

AREP – Association of Flavourings and Essential Oils Producers

Sehit Muhtar Cad. No:36 Cat:4

TR – 34437 Taksim, Istanbul

Turkey

Tel.: ++ 90 212 256 11 40

Fax: ++ 90 212 237 17 46

E-mail: aromsa@aromsa.com.tr

UNITED KINGDOM

BFA – British Fragrance Association

Catherine Street 6

UK - London WC2B 5JJ

United Kingdom

Tel.: ++ 44 207 83 62 460

Fax: ++ 44 207 83 60 580

E-mail: secretariat@bfaorg.org

URL: www.bfaorg.org



INDONESIA

AFFI – Asosiasi Flavor dan Fragan Indonesia

PT Sensient Technologies Indonesia Tel.: ++ 62 21 4585 6710
Artha Gading Niaga Block C/3 Fax: ++ 62 21 4585 0583
JI Artha Gading Boulevard E-mail: paulus.rusli@sensient-tech.com
ID - Jakarta 14240 URL: www.affi.or.id
Indonesia

JAPAN

JFFMA – Japan Flavor and Fragrance Materials Association

Sankei-Nihonbashi Bldg 6F Tel.: ++ 81 3 3516 1600
4-7-1, Honcho Nihonbashi Chuo-ku Fax: ++ 81 3 3516 1602
JP – Tokyo 103-0023 E-mail: jffma@nifty.com
Japan URL: www.jffma-jp.org

MEXICO

ANFPA – Asociación Nacional de Fabricantes de Productos Aromáticos, A.C.

Descartes No. 54 - piso 5 D-502 Tel.: ++ 52 525 47636
Col. Anzures – Delg. Miguel Hidalgo Fax: ++ 52 525 47858
MX - 11590 Mexico, D.F. E-mail: anfpa@avantel.net
Mexico URL: www.anfpa.org

SINGAPORE

FFAS – Flavour and Fragrance Association of Singapore

Firmenich Asia Tel.: ++ 65 6347 2643
c/o 10 Tuas West Road Fax: ++ 65 6863 4687
SG - 638377 Singapore E-mail: arne.lugeon@firmenich.com
Singapore

UNITED STATES

FMA – Fragrance Materials Association of the United States

1620 I Street, N.W. – Suite 925 Tel.: ++ 1 202 293 5800
US - Washington D.C. 20006 Fax: ++ 1 202 463 8998
E-mail: groberts@therobertsgroup.net
URL: www.fmafragrance.org



Observer Members

ARGENTINA

CAFEPA – Cámara Argentina de fabricantes de Productos Aromáticos

Defensa 251

4° Piso, Apto 19

AR - 1010 Buenos Aires

Argentina

Tel.: ++ 54 11 4331 9866

Fax: ++ 54 11 4331 9866

E-mail: ernesto.bertschi@givaudan.com

CHINA

CAFFCI – China Association of Fragrance, Flavor & Cosmetic Industry

Room 127

East Chang An Street

CN - 100 740 Beijing

China

Tel.: ++ 86 10 65 23 95 58

Fax: ++ 86 10 65 24 16 17

E-mail: caffci@caffci.com.cn

URL: www.caffci.com.cn

COLOMBIA

ANDI – Cámara de Sabores y Fragancias

Calle 35 No 4-81

CO – Bogotá

Colombia

Tel.: ++ 57 1 232 36 05

Fax: ++ 57 1 287 44 19

E-mail: cboffuzzi@andi.com.co

URL: www.andi.com.co





APPENDIX 2 TO THE IFRA CODE OF PRACTICE

IFRA Committees

Scientific Committee (SC)

Mission: To monitor the safety evaluation activities of IFRA with the objective of assuring the continued safe use of fragrances by the membership and the user community, in particular:

- To develop and implement procedures, as necessary, to achieve the primary mission;
- To develop, evaluate, communicate and implement product safety information (in conjunction with the Communications Working Group and other IFRA Committees and Procedures);
- To monitor regulation as it develops in different regions/countries to assess its potential global impact;
- To act in liaison with RIFM concerning safety evaluation; to request appropriate research and testing to support industry needs; and to assist in the implementation of recommendations arising from RIFM's activities;
- To document the Standards to be adopted by IFRA based on the scientific conclusions of the independent RIFM Expert Panel (REXPAN);
- To collect, monitor and publish on a regular basis the usage of and exposure to fragrance ingredients within specified geographical areas from which priorities for evaluating and/or testing raw materials can be established; and
- To safeguard the uncompromising integrity of RIFM and the independence of its Expert Panel, through adherence to a defined protocol for operation and communication.

Joint Advisory Group (JAG)

Mission: To ensure effective interaction among scientists belonging to the consumer goods manufacturer and fragrance industries on all aspects relating to the safe use of fragrance ingredients.

Environmental Task Force (ETF)

Mission: To advise the fragrance industry, through the SC, regarding the environmental safety of fragrance materials and to assist in the identification and management of environmental issues related to their use.

Committee for Occupational Safety, Health & Environment (SHE)¹

Mission: To promote an overall strategy for continuous improvements in the flavor and fragrance industry's safety, health and environmental programs and initiatives by:

- Exchanging information and experiences with occupational safety, health and environmental programs, incidents and accidents in the workplace;
- Preparing and issuing guidance on occupational safety, health and environment issues

¹ Joint Committee with IOFI, the International Organization of the Flavor Industry.



relevant to the flavor and fragrance industry;

- Communicating, as appropriate, with national/regional member associations and/or relevant bodies in IFRA and IOFI;
- Reviewing both existing and proposed legislation relevant to occupational safety, health and environment, and to advise members accordingly.

N.B.: The environmental fate of fragrance ingredients following their use in consumer products is dealt with by the ETF and the SC.

Communications Working Group (CWG)

Mission: To advance and enhance the image and reputation of the fragrance materials industry among our customers, regulators and the general public. The CWG does this by a series of measures including:

- Coordinating the communications activities of national/regional member associations to assure that the industry speaks with a consistent voice on matters of common concern;
- Providing technical advice and assistance to the management, staff, and members of IFRA and RIFM;
- Staying abreast of political, regulatory and legislative developments relevant to the industry's public posture and status;
- Coordinating with customer trade associations;
- Managing public relations consultants employed by IFRA;
- Developing a crisis management plan for IFRA and the fragrance industry;
- Providing a forum for discussion and resolution of issues with the communications community as well as issues between the communications group scientists, management and others.

The Communications Working Group develops an overall public relations strategy taking into consideration the goals of IFRA and RIFM as well as the available resources.

The Communications Working Group includes cross-disciplinary membership, including senior business managers, as well as communications, regulatory and scientific experts.

IFRA's efforts are further supported by other Committees and Task Forces as required.



APPENDIX 3 TO THE IFRA CODE OF PRACTICE

IFRA Statutes

International Fragrance Association

Adopted by the IFRA
General Assembly on
October 15, 1998
Amended on October 21, 1999
October 19, 2000
October 18, 2001
February 15, 2005
April 21, 2005
October 25, 2006

Name, Head Office

Article 1

An international, not-for-profit association with scientific objectives is established under Swiss law [art. 60 et seq. of the Civil Code (CC)] with the title of "International Fragrance Association" (IFRA) with headquarters in Geneva, hereafter "Association".

Purpose

Article 2

The purpose of the Association is to serve and advance the collective interests of the fragrance industry, worldwide, with the final objective to protect the consumer and the environment.

Article 3

The Association may conduct its activities on the national territory of a member association only with the consent of the national association concerned.

Membership

Ordinary Member

Article 4

Regional associations are eligible for Ordinary Membership, subject to the approval of the General Assembly, in accordance with Article 10. Where no regional association exists, national associations are also eligible for Ordinary Membership subject to the approval of the General Assembly in accordance with Article 10. The rights and obligations of Ordinary Members are as provided for in the law governing the Association.

Observer

Article 4a

The national association of the fragrance industry of a country which is not an Ordinary Member may participate as an Observer in the work of the Association, provided such association has previously obtained approval of the General Assembly. This status must be approved annually by the General Assembly.

An Observer has the following rights:

- to obtain the documents and reports drawn up by the Association,
- to consult the Scientific Director on matters within his competence,
- to attend and participate in meetings of the General Assembly without having the right to vote.
- to attend and participate in Committee meetings, but only on a consultative basis.

Observers are required:

- to pay an annual fee determined by the Assembly,
- to inform the Association about all relevant developments in their countries.

Observers bind themselves to comply with the Statutes, Internal Rules, decisions of the Board and of the General Assembly.

Observers may be expelled from the Association in accordance with Article 6 of the statutes and they have the right to resign from the Association under Article 5.

Candidate Member

Article 4b

The national association of the fragrance industry of a country which is not an Ordinary Member may participate in the work of the Association as a Candidate Member, provided such national association has obtained the prior approval of the General Assembly. Candidate Members have no voting rights.

Candidate Members are entitled to receive from the Association:

- selected information of interest for their country
- advice and support in their contacts with their government
- invitations to address specific topics and problems.

Candidate Members are obligated to provide the Association with:

- information on planned and enacted legislation
- information on local trade practices
- assistance and participation in discussions with governmental officials.

The General Assembly shall decide each year whether an association can remain a Candidate Member. Candidate Members have the right to resign from the Association according to article 5. They bind themselves to comply with the Statutes, the Internal Rules and the decisions of the Board and the General Assembly of the Association.

Supporting Member

Article 4c

Individual companies that are members of a national or regional association that is an IFRA member, and that manufacture, market, or distribute fragrances or fragrance ingredients at other than retail may apply for membership in IFRA as Supporting Members. A Supporting Member has the following rights:

- to obtain the documents and reports prepared by IFRA,
- to consult the Scientific Staff and Director,
- to attend and participate in meetings of the General Assembly without having the right to vote,
- to attend and participate in Committee meetings, but only on a consultative basis.



Supporting Members are required to pay an annual fee determined by the General Assembly.

Supporting Members may be expelled from the Association in accordance with Article 6 of the statutes and they have the right to resign from the Association under Article 5.

Article 4d

Regional groupings of countries are eligible for membership on conditions and terms to be determined and approved for each individual case by the General Assembly.

Article 4e

Companies with headquarters in regions or countries with no association belonging to IFRA can join IFRA as Supporting Members provided that they shall be sponsored by two companies which belong to a national or a regional association.

Such Supporting Members are entitled to receive from the Association any relevant safety related information and to seek advice from the Association on safety related matters.

Such Supporting Members are required to pay a reasonable annual fee to the Association.

The Board decides every year whether each such company may remain a Supporting Member. The Supporting Members have the right to resign from the Association according to article 5. They bind themselves to comply with the Statutes, the Internal Rules and the decisions of the Board and General Assembly of the Association.

Withdrawal and Exclusion

Article 5

Members may withdraw from the Association only after sending their resignation by registered letter to the General Secretary, at least six months before the end of the fiscal year.

Article 6

Any member not conforming to any part of the Statutes or By-laws may be expelled by decision of the General Assembly acting in accordance with Article 10. The member in question shall always have the right to present its defence prior to such action.

As a condition of continuing membership in the association, all members are required to subscribe to and comply with the Standards on fragrance ingredient use set forth in the Code of Practice of the International Fragrance Association (IFRA). In case the Board of Directors finds that a member has not complied with the IFRA Code of Practice, it may, in its discretion, terminate the membership of such member or take appropriate action.

Article 7

A member who leaves the Organization by resignation, expulsion or for any other reason shall have no claim on the funds of the Association but shall remain liable for its subscription for the current year.



General Assembly

Article 8 - Powers

The General Assembly has full powers to accomplish the purpose of the Association.

Article 9 - Members

The General Assembly consists of all members of the Association. Regional groupings will be represented as decided by the General Assembly in application of art. 4d.

Each Ordinary Member of the Association shall designate a delegation as its official representative to the General Assembly. Should a region or a country have more than one association, these associations must appoint a single delegation.

The names of delegates to the General Assembly must be communicated to the General Secretariat. Such appointments may be changed at any time.

The voting rights of the Ordinary Members are proportional to their share of the IFRA dues. Each Delegation is empowered to vote on all matters debated during meetings of the General Assembly, unless delinquent in the payment of its dues to the Association on the date of such vote.

A delegation may represent only one other delegation, provided however that a proxy has been delivered in writing to the General Secretariat before the meeting.

Article 10 - Quorum and Voting

The General Assembly may conduct a meeting only if delegations representing two-third of the voting rights are present or represented. If this quorum is not reached, another General Assembly must be scheduled between the eighth and fifteenth day following the adjourned meeting and subsequently, until a quorum is obtained.

Any decision of the General Assembly shall require a three-quarter majority vote of the Ordinary Members present or represented by proxy.

It is possible to act on matters which are not on the agenda in cases of urgency and with the consent of a three quarters majority of Ordinary Members present or represented by proxy. The addition of an urgent matter to the agenda will be proposed not less than 48 hours before the meeting.

Article 11 - Meetings

The General Assembly shall meet in ordinary session once a year under the chairmanship of the President of the Association, on a date and at a place determined during the previous General Assembly.

The President of the Association may call an extraordinary General Assembly at any time. He must call such a meeting upon a request of at least one fifth of the membership.

Any Ordinary Member of the Association may add topics to the agenda provided that a request for same be received by the Secretariat at least twenty days before the scheduled meeting date. The General Secretariat will immediately send notice of such additions to the other members.

Administration

Article 12

The Association shall be administered by a Board of Directors.

Subject to articles 13 and 13a, such Board shall be composed of

- up to 12 Directors representing the regions, broken down as follows: 5 for Europe, 4 for North America (US 3, Canada 1), 1 for Japan, 1 for Latin America, and 1 for South-East Asia, or as may be decided from time to time by the Board,
- up to five additional Directors possessing the knowledge and experience important to significantly contribute to the industry,
- a Treasurer, who may or may not belong to the aforementioned Directors.

The General Assembly shall confirm the Directors representing the regions/countries from the nominees of such regions/countries; it will elect the Vice-President in accordance with article 13a, and the other directors from the nominees proposed by the President with the support of the Board.

The appointment of a Director is valid for one fiscal year, but is renewable.

Article 12a

All authority not residing with the General Assembly pursuant to these statutes or to any mandatory provision of the law governing the Association shall be with the Board of Directors.

Article 13

The General Assembly shall appoint a President who is ex officio a member of the Board of Directors. His appointment as President is valid for two years.

Article 13a

A Vice-President of the Association is to be elected by the General Assembly at the proposition of the President and approved by the Board.

The Vice-President will assist the President in fulfilling his task. He will replace the President whenever the President is unavailable.

The Vice-President will be elected for a term of office which will expire at the same time as the term of office of the President who has proposed him. At the expiration of the term of the President, the Vice-President must be confirmed President for two years, at which time he will propose a new Vice-President.

If the President retires before the end of his term of office, the Vice-President will replace him as Acting-President until the normal expiration of the term. The Acting-President will then need to be confirmed as President for another two years.

Article 14

The President shall preside over meetings of the General Assembly and the Board of Directors, but he may delegate his powers, except as noted in Art. 16.

The President is responsible to the General Assembly for the functioning of the Association.



Article 14a

A national or regional Director may be represented at a meeting of the Board by a person that has been duly authorized pursuant to a written document mentioning that the person representing the Director has the full power and is entitled to vote and otherwise act on behalf of the represented Director.

Article 15

The Board of Directors will meet at the discretion of the President. A quorum shall consist of two thirds of the members present or represented. Decisions must be adopted by a two thirds majority of the members present or represented, each director having one vote.

Article 16

The President shall have the authority to sign all documents binding the Association without further proof of specific authorization if there are no special proxies. The Association shall be legally bound by the President or the Director General.

General Secretariat

Article 17

The office(s) of the Association shall be located as decided by the Board of Directors. The staff of the General Secretariat is designated by the Board of Directors.

The position of Director General, to direct the General Secretariat, can be created by decision of the General Assembly in accordance with Art. 10, 2nd paragraph. In addition to the responsibility in application of Art. 18, he is also to pursue other activities, such as those defined in his job description.

The Director General is appointed by the Board and is obligated to follow decisions of the General Assembly as well as directives of the Board of Directors. Furthermore, he has to discharge his duties objectively and in agreement with Art. 3 of the statutes. He reports to the President and will cooperate closely with all bodies of the Association as well as with the staff of the General Secretariat.

Article 18

The General Secretariat shall perform the activities and functions with which it has been entrusted by the Board of Directors or by the Internal Rules.

Committees and Task Forces

Article 19

The Board of Directors of the Association is empowered to establish standing Committees and Task Forces as needed in pursuit of its purpose.

Article 20

The members of each standing Committee shall be nominated by the Ordinary Members and approved by the Board of Directors. The President has the power to appoint the members of temporary Committees and Task Forces to pursue a task limited in scope and time.

Each Committee shall have a chairperson elected by its members.

Subscription, Budget, Accounts

Article 21

The members' subscription to the Association shall be determined annually by the General Assembly acting in accordance with Article 10.

Article 22

Each member of the Association shall be liable for the subscription determined by the General Assembly, but shall not be liable individually for the obligations undertaken in the name of the Association.

Article 23

The fiscal year commences on January 1st and ends on December 31st of the same year.

Article 24

The Board of Directors shall submit annually, for the approval of the General Assembly, the accounts of the previous financial year and the budget for the coming fiscal year.

Internal Rules

Article 25

The Association may, subject to the provisions of Article 10, establish Internal Rules which have to be in agreement with the Statutes so as to assure the proper functioning and administration of the Association.

Amendments to the Statutes and Dissolution

Article 26

The text of any proposed amendment to the Statutes shall accompany the notice of a meeting of the General Assembly which will consider the matter in accordance with Article 10.

Article 27

The Association is dissolved when it is insolvent or when the Board of Directors can no longer be constituted according to the Statutes. In the event that the Association is dissolved, the available assets shall be entirely attributed to an organization of public interest that pursues similar purposes to the Association. In no case shall its assets be returned to the founders or to the members, nor used for their benefit, in part or whole, in any manner whatsoever, unless as provided above.

General Rule

Article 28

Any subject not contained in the present Statutes will be settled according to the provisions of Swiss law.



IFRA (The Association) Internal Rules

General Secretariat

- 1 Details concerning the duties of the staff and members of the General Secretariat are defined in job descriptions, which will be regularly revised and updated, as necessary.
- 2 The Executive Director will attend meetings of the Board of Directors and of Committees in an advisory capacity. He shall report regularly to the President on his own activities.
- 3 The Scientific Director is a member of the General Secretariat and attends the meetings of the Board. He reports to the Executive Director and, as requested, to the Board of Directors. As separately defined in a job description, the Scientific Director is responsible for all scientific, technical and regulatory items in detail.
- 4 The Secretary General will attend the meetings of the Board of Directors and of the Committees in an advisory capacity. He shall report regularly to the Executive Director on his own activities and on those of the Committees of Experts. He reports to the Board of Directors as requested.
- 5 The members of the General Secretariat may be engaged in other activities in the field of professional organizations with the consent of the President.
- 6 The Executive Director and the staff of the General Secretariat are bound to secrecy.
- 7 The General Secretariat shall be responsible for the functioning of the Association. It shall prepare the agenda and working documents for all the meetings of the General Assembly, the Board of Directors and Committees. All such documents will be copied to the members and individuals entitled to receive them.
The General Secretariat shall send the agenda and working documents at least thirty days before the date of any meeting, to all persons entitled to attend these meetings, with copies to the Member Associations. When necessary, this time-limit may be reduced to eight days.
- 8 The General Secretariat shall draw up the minutes of meetings held by the General Assembly, the Board of Directors and Committees, a copy of which will be forwarded to the members of the Association.

Committees and Task Forces

- 9 The Committees and Task Forces established in accordance with the statutes are empowered to draft their own by-laws. These become definitive only after approval by the Board of Directors.

Extraordinary budgets

- 10 Extraordinary budgets may be established for special activities determined by the General Assembly. These budgets, each one referring to a particular activity, can extend over several financial years, in order to cover the whole period of activity. These budgets must be presented at the same time as the proposal to assure their financing.



APPENDIX 4 TO THE IFRA CODE OF PRACTICE

Community Relations

1. Assistance to Physicians

Fragrance manufacturers shall cooperate with and give full assistance to physicians in attempting to discover the causative agents of clinical dermatitis or other adverse reactions in individual patients (see also last paragraph of item 3 in this document).

2. Claims and Advertising

Fragrance manufacturers shall have justification for all claims made in connection with a fragrance material.

3. Intellectual Property and Formula Disclosure

IFRA recognizes the importance to the fragrance industry of the protection of intellectual property, including particularly fragrance formulae. Fragrances are complex mixtures of natural and synthetic raw materials. The creation of a fragrance requires the commitment of significant financial and human resources to identify the most appropriate fragrance ingredients and to combine them in a way that produces the intended effects. This process is very time-consuming and requires significant expertise and creativity. Each fragrance formula is unique: it is both an invention and a work of art and deserves intellectual property protection.

Trade Secret Protection

Patent and copyright protection is generally unavailable for fragrance formulae. As a result, to the extent that a fragrance manufacturer elects to protect (i.e., maintain confidential) and not disclose its formulae, the manufacturer should take appropriate steps, both with respect to its relations with third parties and also within the creating company itself, to protect its formulae. This would include, but is not limited to, restricting formula access to a small group of individuals within the company who have a demonstrated need to know. A fragrance manufacturer may justify confidential treatment by the high creation costs and by the unfairness that would arise were its formulae able to be copied by others. Confidentiality of a fragrance formula thus preserves the uniqueness of the fragrance - often the principal distinguishing feature of the product in which it is used - for the customer for which it was created.

Consumer Product Manufacturer Requests for Fragrance Composition Data

From time to time customers or other third parties may request information about the composition of fragrance formulae. As examples, these requests may be made because of (a) a wish to evaluate specific aspects of the fragrance composition, or one or more ingredients in the formula, or (b) a need to respond to enquiries of others, including governments, the media, physicians and consumers. Each fragrance manufacturer must determine individually how to respond to requests for formula information and, if information is provided, what the nature and scope of that information will be and whether it will be provided with or without the execution by the receiving party of a confidentiality agreement. As an example, for disclosures involving only information required by the user under applicable legislation (such as Safety Declarations or Material Safety Data Sheets), or simply an acknowledgment of the presence of specific ingredients, the manufacturer may choose to provide the requested information without asking the user to execute a confidentiality agreement. On the other hand, for disclosures that contain more detailed information about



the composition of fragrance formulae (for example, banded formula data/concentration ranges or acknowledgement of the presence of IFRA restricted ingredients, as well as safety-related information about such materials), the manufacturer may elect to require the recipient to execute a confidentiality agreement.

Manufacturer Disclosures to Governments and for Medical Reasons

Disclosures to governmental bodies and for medical reasons sometimes present different issues. Governmental bodies and medical professionals seeking information about fragrances generally focus on their presence and/or levels in consumer products. Although each fragrance manufacturer must make its own decision as to how to respond to such requests, it is IFRA policy that:

- a) The fragrance manufacturer, in cooperation with the consumer product manufacturer, make such disclosures of information as are required under applicable legislation and regulation, or as are appropriate under the circumstances to satisfy government bodies that fragrance ingredients in finished products are safe for the consumer and the environment.
- b) The fragrance manufacturer, in cooperation with the consumer product manufacturer, respond promptly to requests for information from physicians treating patients who are suspected of having suffered adverse reaction to products containing fragrances.



APPENDIX 5 TO THE IFRA CODE OF PRACTICE

Safety Evaluation of Fragrance Materials

Ingredient Evaluation

Fragrance ingredients that deviate from generally accepted quality standards or that are not covered in section 4.2 of the Code of Practice should be used only after satisfactory evaluation according to the requirements set forth in this Annex.

The IFRA Scientific Committee will collect and make available to RIFM data that are relevant for the safety evaluation of fragrance ingredients. This may include ingredient volume of use, ingredient use level in fragrance compositions, as well as data from the scientific literature, results of testing programs made available by the originators of such programs, and validated reports of adverse reactions to fragrance materials.

Safety data for all fragrance ingredients that are commercially available and offered for sale as such must be submitted by the ingredient manufacturer to RIFM for inclusion in the Fragrance Ingredient Database. Manufacturers must provide all available information on specifications, use and use levels as well as copies of test reports and other safety related information for examination by the REXPAN. In particular, when fragrance manufacturers have evidence that warrants creation or modification of a Standard, they shall inform IFRA and supply the data to RIFM.

Nature of Human Health and Environmental Effects Evaluation

In evaluating a fragrance ingredient, consideration should be given to possible effects on the skin, including skin irritation and sensitization, with special attention paid to the effect of sunlight, should the ingredient absorb ultra-violet radiation.

Systemic toxicity should be considered in relation to the quantities of fragrance material used and likelihood of entry into the body.

The safety evaluation of the ingredients requires the review of consumer exposure information and supporting safety data. An important component in establishing priorities, applicable to a thorough safety assessment, is a survey of the total usage of individual fragrance ingredients. IFRA generally carries out a worldwide survey of fragrance ingredient usage every three to five years. This survey is conducted by requests made to all suppliers or compounders of fragrance materials on record, whether members of IFRA member associations or not.

Also critical to a thorough safety assessment of individual fragrance ingredients are data on levels, and routes of exposure of consumers, to individual fragrance ingredients. These data are determined from a collaborative effort of IFRA and various cosmetic companies or trade associations, with the data being analyzed and summarized in documents prepared by IFRA.

All data collected as described above are communicated routinely to RIFM, for consideration by REXPAN.

If there are inadequate data from the sources mentioned above, a toxicological program must be designed, which includes dermatological and systemic endpoints as described in the RIFM "Criteria Document" (see below).

Possible environmental effects should be considered in the assessment of substances' use.



IFRA Standards

As a result of safety assessments, the usage of certain fragrance ingredients has been restricted and these restrictions are set forth in IFRA Standards (see [Appendix 8](#)).

Standards that impose a quantitative limit on the use of fragrance materials are expressed as a maximum concentration of fragrance material in the consumer product. This implies knowledge of (a) the concentration of the restricted fragrance material in the compound and (b) the concentration of the compound in the final consumer product. It is therefore essential that fragrance suppliers inform manufacturers of consumer products, who use or intend to use a fragrance compound, that due to the presence of a restricted ingredient, the compound should only be used up to a specified maximum concentration or in well-defined applications. Unless otherwise specified, “concentrations” are expressed in weight-weight percent.

Guideline for Communicating IFRA Status

Whenever the IFRA status of a fragrance compound is communicated (see also [Appendix 8](#) for the IFRA Standards), the following aspects should be considered:

- the identification of the supplier;
- the identification of the fragrance compound;
- the intended application in consumer products;
- a (realistic) use concentration for the intended application;
- a written statement that the fragrance complies with the requirements of the Code including the Standards for the specified application and use concentration;
- the maximum use concentration allowed by IFRA;
- a date-specific reference to the version of the IFRA Code and Standards at the time the statement is made;
- the comment that the use of a higher concentration or a different product application will require another safety evaluation; and
- the date of assessment.

In order to effectively apply the Code to the manufacture and handling of all fragrance materials, fragrance manufacturers should take all measures to assure that any fragrance compound offered for sale is in full compliance with the requirements of the Code and all applicable Standards. In cases where an Amendment to the Code of Practice (and the therein contained Standard) changes the status of a fragrance compound, it is the responsibility of the manufacturer to inform the fragrance purchaser of the change and to provide all information relevant to the user’s determination of the conditions under which the material(s) can be used in full compliance with the Code and the applicable new or revised Standard. If required, the manufacturer should offer the purchasing party an alternative fragrance compound that complies with the new or revised Standard.



Guidance Documents

The following guidance documents relate to the specifics for human health and environmental effects evaluations as well as to IFRA procedures on how to provide estimates of consumer exposure to fragrance ingredients:

1. Human Health Evaluation

Evaluation of the potential effects of fragrance materials on the skin, for irritation and sensitization, as well as sunlight-mediated effects, systemic toxicity, etc., should utilize the Human Health Criteria Document which has been published as “Criteria for development of a database for safety evaluation of fragrance ingredients”, R.A. Ford, B. Domeyer, O. Easterday, K. Maier, and J. Middleton, *Regulatory Toxicology and Pharmacology*, 31: 166-181 (2000).

2. Environmental Effects

A methodology for conducting a preliminary aquatic risk assessment for fragrance materials can be found in the Environmental Framework Document which has been published as “A framework for prioritizing fragrance materials for aquatic risk assessment”, D.T. Salvito, R.J. Senna, and T.W. Federle, *Environmental Toxicology and Chemistry*, 21(3): 1301-1308 (2002).

3. Safety Assessment of Fragrance Materials

A description of the process applied for fragrance material safety evaluation by the RIFM Expert Panel has been published as “The safety assessment of fragrance materials”, D.R. Bickers, P. Calow, H.A. Greim, J. M. Hanifin, A. E. Rogers, J.H. Saurat, I.G. Sipes, R.L. Smith and H. Tagami, *Regulatory Toxicology and Pharmacology*, 37: 218-273 (2003).

4. Exposure Assessment

A description on how fragrance industry’s procedures for estimating exposure to fragrance ingredients through different routes and leading to different potential endpoints has been published as “Consumer exposure to Fragrance Ingredients: Providing Estimates for Safety Evaluation”, P.A. Cadby, W.R. Troy, and M.G.H. Vey, *Regulatory Toxicology and Pharmacology*, 36: 246-252 (2002).



APPENDIX 6 TO THE IFRA CODE OF PRACTICE

IFRA Recommendations for Good Operating Practice

1 Basic Approach

The following paragraphs formulate basic recommendations for good operating practice by the fragrance industry. The application of these recommendations does not relieve individual manufacturers from the obligation to comply with all national or international regulations that pertain to their operations.

2 Basic Principles of Good Manufacturing Practice

2.1 Personnel

Any fragrance materials manufacturing center should employ personnel with adequate levels of technical and practical training and with the authority and responsibility, to ensure and maintain the identity, purity and quality of the products manufactured.

In order to avoid contamination of a fragrance material or its packaging, all personnel involved in their manufacture and handling should practice good personal hygiene and be free from skin disorders or infections.

2.2 Premises and Sanitation

All manufacturing areas should be clean and orderly. Written procedures should be in place defining the areas to be cleaned, cleaning frequency, appropriate cleaning equipment and materials, and personnel responsible for cleaning operations.

Eating, smoking and unhygienic practices should not be permitted in compounding and packaging areas.

Sufficient clean and well-ventilated toilet facilities, including facilities for hand washing and changing of clothes should be available near the working areas for the use of manufacturing personnel.

Access to all manufacturing areas should be restricted to authorized personnel.

2.3 Quality Assurance

Predefined properties of all fragrance ingredients and finished products should be monitored and controlled by a quality control department directed by a qualified person reporting to management and independent of other departments. This department should operate according to defined procedures, with the responsibility and authority to approve or reject the evaluated materials.

The laboratory facilities available to the quality control department should be staffed and equipped commensurate with the requirements of effective quality control.

Quality assurance procedures should define in sufficient detail the taking of samples, including the quantities, tests to be performed, sample retention, and the schedule for release of the results. QA samples should be uniquely labeled, with reference to the date and batch number. Samples should be stored under suitable conditions for future reference.

The quality assurance department should maintain adequate records regarding the specification and test results of each batch.

The quality assurance organization and procedures should enable management or outside monitoring agencies to check regularly whether all instructions and procedures involved in any stage of manufacturing and quality control are being strictly followed.

2.4 Fragrance Ingredients: Quality Control and Storage

All ingredients to be used in fragrance compounding or to be sold should be properly sampled, tested for compliance with organoleptic and analytical specifications and released by the quality control department via defined procedures.

For all ingredients and products, records should be kept permitting identification of the batch, the production history or origin, and defining dates for the various control steps, including release by the quality assurance department.

During the period between their arrival from the supplier or from the production center and their use in fragrance compounding or shipment to the customer, all fragrance ingredients should be stored under conditions compatible with their physical and chemical properties.

Ingredients that have been rejected for any reason should be designated accordingly, quarantined either physically or electronically, and treated in accordance with the nature of the rejection.

2.5 Manufacturing Operations

All manufacturing systems should be supervised and operated by qualified personnel, trained according to defined procedures in unit operations.

For all manufacturing equipment and utensils, adequate cleaning instructions should be available as well as qualified personnel responsible for the proper execution of these instructions and for the cleanliness of the equipment prior to its use.

All manufacturing equipment should be designed and maintained to make it suitable for its intended use.

All manufacturing equipment should be installed in the production premises in positions facilitating cleaning and maintenance and minimizing contamination during its use.

Weighing and measuring equipment used in production and quality control should be calibrated and checked for accuracy at suitable intervals by appropriate methods.

The contents of all vessels and containers used in manufacture and storage between manufacturing stages should be identified by conspicuously placed and clearly legible labels, bearing the name and/or identification code of the processed materials and the necessary batch identification data.

In the case of continuous operations, batch records per se may not be possible. Instead, a continuously updated file or automated data collection can be used to permit without delay a review of the production history of the contents of any particular container.

Manufacturing records should be kept providing a complete record of the manufacturing history of each batch of a fragrance material, showing that it has been manufactured according to the relevant process documentation and that its properties have been measured and controlled in accordance with relevant specifications.

A separate batch manufacturing record should be prepared for each batch containing the name of the product, the date of manufacture, the batch identification code, the weight, as well as information regarding the types of packaging materials or containers. The record should identify the person and/or equipment responsible for the production batch.

For each batch meeting the requirements of the relevant specifications, a quality control report should be made, duly authorized by the person responsible for quality assurance.

2.6 Packaging and Labeling

In selecting, handling and control of all packaging materials, proper attention should be given to their condition, cleanliness and suitability for the product they contain.

All packages and containers of finished products should be identified by labels complying with applicable legislation and mentioning the name, code and batch number of the product, its weight, and any special storage and handling instructions.

2.7 Record Pertaining to Quality Assurance and Distribution

All quality assurance records should be retained for a period in accordance with applicable legislation, but in any event at least for three years.

3 Health and the Environmental Protection on Manufacturing Sites

3.1 Field of Application

This section applies to the manufacture and handling of all fragrance materials, including storage, production and plant design. It may require revision if future developments in the industry make it necessary.

The application of this section does not exempt individual manufacturers from the obligation to comply with all national or international regulations, which are relevant to their operations.

3.2 Basic Principles

The protection of health in the workplace and the protection of the environment are of primary concern to the fragrance industry. This section expresses a determination to protect human health and the environment from adverse effects.

Risks to human health and the environment shall be minimized by taking all appropriate precautions and actions which are practicable, compatible with operational requirements and consistent with local conditions and national regulations. Measures taken should be appropriate to the degree of risk involved.

Free exchange of information on health and environmental subjects among individual companies is encouraged.

3.3 Health Protection

All personnel involved in the manufacture and handling of fragrance materials should be protected from health hazards of a physical nature (e.g. noise, radiation, vibration) or chemical effects of gases, vapors or dusts.

Efforts should be made to eliminate or minimize exposure to health hazards by taking those precautions, which are necessary in the light of experience, feasible according to the state of technology and appropriate to the operating conditions.

Priority should be given to technical measures and improvements such as closed systems, the use of less hazardous materials, source venting and general ventilation.

If technical and organizational measures are not sufficiently effective, personal protective clothing and equipment should be worn such as respiratory protection (face mask, breathing apparatus, etc), eye and ear protection (safety glasses, face visor, ear plugs, etc.), hand and body protection (gloves, suit, apron, shoes, etc.).

Specific information and instructions on required protective measures should be provided to personnel in order to avoid health hazards in the workplace.

Companies should periodically audit any of their workplaces which have potential health hazards, with regard to health protection performance. If necessary, exposure-monitoring surveys should be carried out.

Where law requires no safety data sheets, recommendations on storage and handling should nevertheless be provided to customers.

3.4 Environmental Protection

The environment should be protected from adverse effects by appropriate organizational and technical measures. Pollution affecting water, air, soil and public health should be avoided.

Emissions, which can have an adverse effect on the environment, should be identified, assessed and, if necessary, reduced.

Provision should be made to avoid accidental discharges into the environment, which could pose a risk to health of personnel or the general public, or could have adverse effects on the environment.

Awareness of environmental protection should be developed among all personnel handling materials and they should be instructed on emergency procedures in case of accidental discharge.

Recommendations should be provided to customers on storage and handling precautions in those cases where this is required to protect the environment.

3.4.1 Water Protection

Technical and administrative measures should be taken to make sure that discharged wastewater complies with the legal requirements relevant to the receiver (water stream, public or private sewer or treatment plant).

Provision should be made to avoid discharging polluting materials into surface water drains.

3.4.2 Air Protection

The emission of inorganic or organic materials into the atmosphere must be kept within the levels specified in national regulations.

Technical and administrative measures should be taken to avoid the accidental discharge into the atmosphere of quantities of materials hazardous to health or to the environment.

3.4.3 Soil and Ground Water Protection

The soil should be protected from adverse contamination by inorganic or organic materials.

Technical and administrative measures should be taken to avoid contamination of groundwater arising from soil contamination.

3.4.4 Waste Disposal

Priority should be given to reducing the quantity of waste material produced and to recycling it as feedstock, to using it for energy production or for other purposes.

Chemical wastes shall be disposed of according to local, national or international legal requirements. Only officially approved disposal sites shall be used.

The most appropriate disposal methods should be selected for each waste so as to ensure adequate protection of the public and the environment. Currently, incineration is to be preferred to land filling, wherever possible.

Appropriate waste management methods should be applied. Adequate records of all disposed wastes should be kept. Landfill disposal records should be held indefinitely.

APPENDIX 7 TO THE IFRA CODE OF PRACTICE

Definitions

Batch: A specific quantity of material of homogeneous composition that can be unambiguously identified, manufactured in a single operation or a series of operations according to a well-defined process.

Batch number: A unique combination of letters and/or numbers printed, stamped or written on labels or packaging materials, which uniquely identifies a batch and which permits the tracing and review of all stages of its production history.

Environment: Water, air and soil and their inter-relationship as well as relationship between them and any living organisms.

Fragrance compound: A blend of fragrance ingredients, representing a specific fragrance formula. Throughout the IFRA Code of Practice this definition is taken to include flavor compounds in oral care products, in so far as their effects on skin and mucous membrane are concerned.

Existing fragrance compound (see also "New submission"): A compound currently sold for use or already the subject of evaluation for performance in a defined consumer product. Explanatory note: the period of time permitted to achieve compliance with a new or revised Standard (see section 3.2 of the Code) applies only to that compound in that defined consumer product.

Fragrance ingredient: Any basic substance used in the manufacture of fragrance materials for its odorous, odor-enhancing or blending properties. Fragrance ingredients may be obtained by chemical synthesis from synthetic, fossil or natural raw materials or by physical operations from natural sources. The class comprises aroma chemicals, essential oils, natural extracts, distillates and isolates, oleoresins, etc.

Fragrance material: An individual fragrance ingredient or a fragrance compound.

Manufacturing: All operations involved in the production of a fragrance material including processing, compounding, packaging and labeling.

New submission (see also "Existing fragrance compound"): Any fragrance, new or existing, which does not fall within the definition of an existing fragrance compound.

Quality: Conformity of a fragrance material with its olfactory, physical and chemical specifications and conformity of its production and control with the basic standards of good manufacturing practice.

Recommendation: Guidance offered by IFRA in case the manufacturers have no internal rules [See [Appendix 6](#) to the Code].

Standard: Mandatory restriction to the usage of a fragrance ingredient following a safety assessment by the REXPAN. (In this meaning the word starts with a capital "S").

Waste: Any unavoidable material, resulting from an industrial process, which must be disposed of.





APPENDIX 8 TO THE IFRA CODE OF PRACTICE

IFRA Standards

1. Introduction to the IFRA Standards

2. IFRA Standards

1. Introduction to the IFRA Standards

Standards that impose a quantitative limit on the use of fragrance ingredients are expressed as a maximum concentration of fragrance material in the consumer product.

(For communication of the IFRA status of fragrance materials/compounds, see [Appendix 5.](#))

From the 40th Amendment on, the Standards limiting ingredients due to sensitization will be based on the Quantitative Risk Assessment for dermal sensitizers (QRA). The QRA methodology for fragrance ingredients is a refined risk assessment approach for dermal sensitizers, which identifies individual limitations for 11 specific product categories (based on similar Safety Assessment Factors and exposure). As such, it is a step forward compared to the existing risk management strategies, under which the limit of each specific fragrance ingredient identified as an allergen varies according to potency, but is the same across all product types. More information on how the QRA works in detail is available from IFRA or RIFM.

Note on Phototoxic Ingredients

If combinations of phototoxic fragrance ingredients are used, their levels of use must be reduced accordingly. The sum of the concentrations of all phototoxic fragrance ingredients, expressed as a percent of their recommended maximum level in the consumer product, shall not exceed the level of restriction imposed by a single phototoxic ingredient.

Note on Contributions from Other Sources

Prohibited Substances

An IFRA Standard may ban the use of a substance when it is intended to be used as such in a fragrance mixture. However, this does not necessarily exclude the use of a fragrance material (natural or synthetic) which contains the same substance, provided, in the judgment of the RIFM Expert Panel, that there are sufficient data supporting the use of the fragrance material, and that it is not being used to provide an alternative source of the banned substance.

One source of prohibited substances is the small amounts of organic solvents that are carried over into a synthetic fragrance ingredient during the manufacturing process. There are specific steps within a synthetic pathway that are designed to remove these small amounts of solvents, but these are inevitably not completely successful in removing every trace of these substances. These processes may result in extremely low, technically unavoidable traces of substances in the final synthetic chemical. Where feasible IFRA develops guidance regarding maximum accepted limits for these substances, which are based on current limits of quantitation that have been reviewed and approved by the RIFM Expert Panel. A second source is certain essential oils from which the banned substance cannot be removed. If the RIFM Expert Panel finds that the presence of the banned substance in either material, a synthetic chemical or an essential oil, cannot be supported, the latter material will itself be prohibited from use.



Restricted Substances

Standards that set maximum use concentrations for specific fragrance substances in final consumer products shall apply regardless of whether the restricted substance is added directly or indirectly. Unless there is an adequate scientific basis for allowing specific exemptions to be mentioned in the Standard, these limits shall apply to the total concentration of the substance arising from both direct addition and from indirect addition (e.g., as a constituent of natural materials or of complex synthetic ingredients). Those contributions from other sources must be taken into account in the calculation of the levels of the restricted substance; these are contained in the Annex I to the IFRA Standards.

The Annex I to the IFRA Standards provides indicative levels of restricted substances in a non-exhaustive list of various fragrance ingredients (of complex composition, including essential oils). These indicative levels should be taken into account when determining the compliance of a fragrance compound under its conditions of use. However, if analysis has shown that the level of the limited substance in a specific fragrance ingredient is not the same as the indicative level given in the Annex I, then this level can be used instead of the indicative level.

Fragrance manufacturers are invited:

1. To also use for the purpose of calculation additional information they may have on levels of the restricted substances in any other essential oil, extract, etc used as fragrance ingredients, but not already mentioned in the Annex I to the IFRA Standards;
2. To provide to IFRA-RIFM information on those substances and levels.

Note on Aerosol Products (Skin Contact)

When calculating fragrance ingredient concentration in pressurized aerosols, to determine compliance to an IFRA Standard, the propellant should not be taken into account.

Note on Oral Care Products¹

In the case of oral care flavors/fragrances, with the implementation of the Quantitative Risk Assessment approach, the IFRA Standards are applied to skin effects only; the aspect of safety through ingestion is managed by the International Organization of Flavor Industries (IOFI, see its Code of Practice).

Note on Non-Skin Contact Products

For non-skin contact consumer products, a Standard may allow higher limits for some restricted ingredients. In this case also, users should be informed that the fragrance compound should only be used in these specific types of products. It should be noted that as the Quantitative Risk Assessment approach is implemented for dermal sensitization, these consumer product types are placed into categories.

¹ Mouthwash and toothpaste are the principal oral care products currently identified in the respective category resulting from the QRA. Exposure limits for these products are established to reduce the risk of peri-oral skin sensitization and, as such, are not related to considerations of safe levels for ingestion. The safety of flavor/fragrance materials, present in products intended to be orally ingested, is outside the scope of IFRA's risk assessment process. In the latter cases, salivary dilution and short/variable contact time in the oral cavity would suggest a different risk assessment approach for ingested flavor/fragrance substances.



For the purpose of complying with Standards that are not based on the QRA, the following consumer products are considered as non-skin contact products:

- Solid substrate air fresheners
- Plug-in air fresheners
- Membrane delivery air fresheners
- Insecticides (mosquito coil, paper and electrical)
- Toilet blocks
- Joss sticks and candles
- Plastic articles (excluding children's toys)*
- Fuels / Petrol
- Paint.

In contrast, the products listed below may involve some skin contact and are excluded from the category of non-skin contact products:

- Household cleaning products
- Aerosols
- Detergents
- Shoe polishes
- Pot-pourri
- Carpet powders
- Liquid refills for air fresheners when not in an enclosed cartridge
- Ingredients of perfume kits
- Fragrance compounds for cosmetic kits
- Scent strips
- Children's toys*.

Those specific definitions of skin and non-skin contact products will not be valid anymore once all IFRA Standards based on sensitization have been re-issued as QRA Standards.

* All children's toys that carry a fragrance, like any other fragranced product, should follow the Standards and general guidelines as contained in the IFRA Code of Practice.

Further, certain toy categories may require additional careful consideration because of the likelihood of mouth contact. Following the criteria established by the toy industry, these include 1) toys for children under 3 years of age; 2) any toy designed and intended to go into the mouth; and/or 3) those toys for which such a mouth contact is reasonably foreseeable.

Due to the possibility of ingestion of small amounts of fragrance ingredients (if oral exposure is foreseeable), materials present in the fragrance compound for use in these toy categories must be approved for use in food, meaning that all ingredients should be listed as having "no safety concern" by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and/or listed as Generally Recognized As Safe (GRAS) in accordance with the US Federal Food, Drug, and Cosmetic Act.



2. IFRA Standards

The IFRA Standards, the list of Standards, the list of Other Materials² and the Annex 1 to the IFRA Standards³ are stand-alone documents and subject to regular changes. They can be downloaded from the IFRA website or obtained from the IFRA Secretariat (see [Appendix 1](#) to the Code of Practice for contact information).

2 The list of other materials is the list of materials that should not be used until additional data is available to support their use.

3 The Annex 1 to the IFRA Standards is a list of indicative maximum levels of the limited substances in different fragrance materials.