



IFRA Recommendations for Good Operating Practice

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.

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.

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.

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.

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.

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.

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.

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.

Health and the Environmental Protection on Manufacturing Sites

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.

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.

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.

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.

