**REFILL BULK HOUSEHOLD CLEANING PRODUCTS AT POINT OF SALE**

**GOOD FRACTIONATION, STORAGE AND CONTROL PRACTICES - TECHNICAL GUIDELINES**

## GENERAL CONSIDERATIONS:

Household Cleaning products must be safe under normal and predictable conditions of use.

Although these products are low risk, it is necessary to control the operation of fractionation and dispensing/refilling of Cleaning and Home Care products at the point of sale, and must be controlled through a verification of the characteristics of the operation and mainly of the dispensing / fractionation system, in order to guarantee the quality and safety with which they reach the consumer.

This audit should cover aspects related to operating conditions and the controls used for this operation. It is necessary to define unique criteria for the assessment on the fractionation operation and the dispensers of low-risk Household and Home Care products, therefore the Good Practices of the operation and dispensers must be established at the point of sale, which should reflect the essential minimum requirements to ensure the safety and quality of products.

## PURPOSE OF THIS POSITION PAPER

This document aims to provide a guide that considers the requirements to be taken into account in the operations carried out at the point of sale, such as the good use and control of the product dispensers, so that the human, technical and administrative factors (of the fractionation, refill and sales) that may have an influence on their safety and quality, are controlled in order to prevent, reduce and mitigate any deficiency in the traceability, safety and quality of products that may have negative impact on the health and safety of the consumers.

This technical guide gathers the basic elements to be considered by the owners an responsible of the fractionation operation and the dispensers at points of sale to guarantee environmental protection, at the same time the safety of the user and the personnel involved in whole operation.

**PRINCIPLES**:

The correct way to care the refilling operation must be the responsibility of all the personnel involved in defining and controlling the characteristics of the fractionation process and the design and functionality of the dispensers at the point of sale, having as reference the procedures, policies, intentions and guidelines expressed and established by the person in charge the operation and by the management of the company that owns the fractionation operation and / or of the dispensers, and in accordance with the existing regulatory frameworks when applicable. In cases where there are autonomous dispensers, this responsibility will also reach the owners of the operation.

That is why an effective and efficient system for control must be established, documented, implemented and maintained, with the participation of all personnel involved.

The operations must be carried out by competent and trained personnel to comply with the procedures that ensure traceability, quality, safety and security, and the facilities and equipment must be adequate and compatible with the fractionation and retail operation activities.

Those responsible for the operation will provide instructions to ensure that the quality of the products is maintained when they are handled, stored, distributed and sold, performing controls on the operations, equipment, dispensers and on the product delivered to the consumer. Procedures and instructions should be reviewed periodically.

In that sense, the traceability of all processes related to the elaboration, storage, fractionation, and sale must be guaranteed, as well as the correct coding of the product delivered to the consumer, so that there is a univocal relationship between the lot of the finished product in bulk and the batch of the product already fractionated, dispensered and delivered to the consumer.

For aspects related to quality, it is advisable to validate the methodologies used for cleaning and for the control of cross and microbiological contamination.

The fractionation / dispensing processes must be clearly defined, systematically reviewed, and show

that the capabilities of the operation is aligned with defined quality standards.

The critical stages of the fractionation / dispensing processes of bulk product at the point of sale and any significant modification must be validated and controlled.

The fractionation operation must have the appropriate infrastructure and equipment to carry out its activities.

The instructions and procedures should be written in clear and objective language and be applicable to the activities carried out.

Both the storage of the product in bulk and the operation of fractionation / dispensing of the products should minimize any risk that affects their quality and safety.

Complaints about marketed products must be investigated, registered and evaluated, in order to identify the causes of quality issues. Corrective action plan must be taken in relation to products with quality deviations and the measures taken to prevent repetition. For this purpose, there must be written procedures that describe actions and are adopted in case of claims for possible quality deviations, including the need to make a probable product recovery.

**HEALTH, SANITIZATION AND HYGIENE**

Sanitation and hygiene activities must include personnel, facilities, equipment and utensils, fractionation / dispensing systems, materials and containers, cleaning and disinfection products and any other aspect that may constitute a source of contamination for the product. Potential sources of contamination must be eliminated through an adequate sanitation and hygiene program.

In the case of non-autonomous fractionation / dispensing system, where it is necessary to have personnel in the operation, they must be subjected to admission and periodic health exams according to the activities performed, they must also be trained in personal hygiene practices and comply with standards in accordance with internal procedures.

In case of illness or exposed injuries that may adversely affect the quality or safety of the products, packaging materials, finished products in bulk or fractionated products should not be handled until

their condition does not represent a risk to the product.

The company must ensure that a program of hygiene and sanitization of the space and equipment where the fractionation / dispensing operation is carried out, including transferable dispensers. In the dispensing machines the person responsible must have periodic cleaning systems, controls and monitoring, established based on a program that guarantees the quality of the product and its correct and safe use.

The design of hosepapes, tanks, seals, product dispensing tanks and others, must have a system of removable parts and easy access for adequate localized cleaning.

You cannot eat, drink, chew, smoke in areas that may adversely influence the quality of the products.

Before starting a fractionation and dispensing process, verify that the clothing, equipment and workplaces are clean and suitable for use.

The deposit areas must ensure the storage conditions of the finished product in bulk as well as the packaging material that is delivered to the consumers.

If there are rejected materials or products, they must be stored separately and properly identified as “rejected”.

The storage must be carried out with due order and safety, avoiding possible mixtures in its control and dispatch, as well as accidents in its handling.

Visitors or untrained people will only be able to access the fractionation / dispensing areas avoiding direct contact with the product being fractioned. In case of involuntary contact with the product, the operator must follow the guidelines indicated for each situation.

**DOCUMENTATION and REGISTERS**

The company must establish a documentation and monitoring system according to its equipment and product structure. The data must be registered in such a way that they offer information security, contemplating the recording of any modification and must be available during the established retention period.

A record of the fractioning operation of each finished product in bulk must be kept containing:

- Product name and / or internal code
- Split product batch and bulk product batch
- Relevant observations
- Main equipment used (such as: scales, fractionation systems / dispensers etc)
- Controls carried out and responsible for its execution showing results obtained.

Also, for:

- Receipt of materials
- Identification of bulk products and packaging materials, approved or rejected
- Suppliers
- Cleaning and sanitation activities
- Storage and dispatch
- Cleaning, Calibration and maintenance of equipment and dispensers
- Pest control, contemplating methods and materials used and deactivation of empty containers
- Emergency measures in case of spills of substances or with other danger potential
- Inventory of assets, supplies and stock controls

**FRACTIONATION / PACKAGING AND LABELING**

In order to minimize risks, allow for suitable cleaning/maintenance and avoid cross-contamination, the company must have established procedures for safety and physical facilities in fractionation / dispensed areas, they must be orderly and rational, be arranged according to a continuous flow of distribution that allows to control and guarantee the safety of the products there divided / packaged and delivered.

The areas must be of size compatible with the volume of operations carried out and with the necessary identifications.

The refill containers must comply with the standards for filling, they must be free of dirt or water, they must be the same product that was to be filled. Any refill container that does not meet these refill standards must be removed from the refill circuit as waste.

All equipment in disuse or with defects must be properly identified.

**WASTE MANAGEMENT**

There must be written waste management procedures in accordance with current legislation, which must be previously known to the technical managers and the owner.

Waste management and disposal should not impact operations or product quality and should be recorded and monitored frequently.

**QUALITY CONTROLS**

The responsible person in charge of the fractionation operation must have the following documentation:

- Certificate of analysis provided by the bulk product manufacturer.

- Certificate of Notification / Sanitary Registration (when applicable)

- Product safety sheet with precautions for handling

The documents must include:

- Name and / or coding

- Lot and name of manufacturer / supplier

Packaging materials must comply with the specifications or be material compatible with the product. The material must be examined in relation to physical, visible and critical defects, taking into account the characteristics of the required packaging material.

**IDENTIFICATION LABELS**

Labels or identification systems for fractionated / dispensed products must contain:

- Product name

- Identification of the responsible / owner of the product in the country

- Identification of the responsible / holder of the fractionation process in this point of sale

- Instructions or mode of use

- List of ingredients, which should indicate all those ingredients of toxicological importance that may present risks to the consumer, the use of common names, trade names, functions, brands or by family of ingredients for the rest of the ingredients will be allowed.

- batch number, item or fractionation series

- When applicable, according to the characteristics and use of the product:

a) Precautions and / or warnings (such as: keep out of reach of children, read the label carefully, number of toxicological center or center of attention to the consumer, etc)

b) Storage conditions

- Nominal or net content (This may be included in the label and / or in any type of document that accompanies the dispensed/ refilled product).

NOTES:
- The information that is relevant only for the Health Authority and not for the consumer will be available in the companies themselves and / or at the time of the notification / records of the presentations, and this information is excluded from the product labels.
- The classification (1) and labeling are based on the RISK of the product, avoiding any classification based on the intrinsic danger of the components of that same final product.
The use of other complementary means of dissemination of the required mandatory information (such as: additional labels, stickers, QR code, chips, radio frequency identifier, or brochures) will be allowed, the product owner being responsible for ensuring that consumers and Authorities access through these means unequivocally, securely and easily to this mandatory & relevant information. Through this labeling, the traceability of the product refilled container must be ensured, and in the case of printed media they must be indelible, in contrast and legible.

(1) Note: For the classification of product risk, the possibility of performing a risk analysis is accepted, not only by extreme pH criteria, but also through the use of internationally recognized safety tests available, such as : use validated in vitro models, use alternative approaches (information available worldwide, bridge principles and use of relevant historical data), in order to minimize the generation of unnecessary evidence.