A·I·S·E

International Association for Soaps, Detergents and Maintenance Products

BULK AND REFILL SALES FOR CONSUMER PRODUCTS

Guidance on safety & regulatory requirements

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Scope of the document

A.I.S.E. recognizes that selling of consumer detergents in bulk or via refill to the general public is a growing trend and that these forms of sales have potential to be positive initiatives from an environmental and sustainability perspective. A common industry position on the topic is needed to ensure that these selling practices do not compromise consumer safety or lead to safety issues at the point of sale for either consumers or for personnel in retailers. Products placed on the market in this way must be fully compliant with safety, classification, labelling and packaging obligations prescribed in applicable EU legislation.

Thus, this document provides a high-level outline of safety and regulatory requirements that should be considered in the execution of bulk and/or refill sales of detergent products (biocides are out of scope). The intention is not to discourage nor to promote the solution, but to provide points of consideration in cases where bulk or refill sale are the selected option. This Guidance is intended for any company placing detergents and maintenance products on the market which are intended for bulk or refill sales.

Although sustainability is an important aspect for bulk/refill sales, it is not considered in this document as lifecycle analysis of products is difficult to generalise and varies significantly on a case-by-case basis (due to difference in container size, distance between point of production and retail etc.). For similar reasons, only high-level recommendations for safe use precautions at the point of sale are provided.

Bulk sale and refill definitions

Bulk sale and refill sale are two different executions, which are defined as follows:

Bulk sale: the sale of a bulk product, be it by purchaser, self-service or in a shop counter, by manual means or by an automatic or semi-automatic equipment.

- "Bulk product: product that is not available to the purchaser prepacked and is just measured or weighed in the shop in the presence of the purchaser"
- When a product is sold in bulk the shop should provide appropriate packaging (wrap paper, bag, box, bottle) or may allow the purchaser to use their own packaging.

Refill sale: the refill in the shop of a reusable packaging. The refill can be done by the purchaser or in a shop counter, manual or automatic or semi-automatic equipment.

- There is a separate category of refill products which consists in the consumer purchasing a pre-packaged product which is used to refill an existing container (e.g. a spray bottle). This type of sale is not in scope of the document.

This document delineates points on safety and responsibility for both bulk and refill sale.

Obligations of the companies and of the retailers selling bulk products and/or refill products

The initiative to sell via refill must be made by the entity that is on the label of the product. As a matter of principle the entity that decides to set up a refill system will need to take responsibility for it. The manufacturer of the detergent will be best placed to take such a decision. We will refer to that entity as the "Detergent Company".

It is for the Detergent Company to determine whether the product they place on the market can be sold in bulk or refill and, if so, under which conditions. It is advisable to reflect the aspects below in contractual arrangements between the Detergent Company and retailers in order to facilitate the transmission of information (e.g. the label) and the product's traceability, and to delineate more specifically their respective roles and responsibilities in this context.

If a retailer unilaterally decides to set up their own refill system, they will be subject to legal implications. The consequences of the development of such a refill system by a retailer are that:

- the retailer will fulfil the definition of a "manufacturer", as he will be a "person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof" (Art. 2 No 10 Detergents Regulation), and will have to be identified on the label as "the party responsible for placing the product on the market" (according to Art. 11 II b Detergents Regulation). The retailer will therefore be fully responsible for the products which are distributed via a refill system that is set up at the retailer's initiative.
- the retailer's initiative may affect the safety of the product, as the product may not have been designed as a refillable product and its safety may not have been assessed for this purpose; and
- such initiative may infringe upon intellectual property rights.

When selling bulk products or refill products the Detergent Company must ensure the appropriate safety assessment is carried out and is reflected in technical/product information conveyed to the retailer.

Therefore, the Detergent Company should:

- provide the retailers with the necessary information and instructions regarding the bulk or refill sale, including for example:
    - how the product can be refilled and under which conditions including any necessary personal protective equipment (PPE).
    - information on the hygiene concept, in particular the hygiene criteria and procedure for staff and for the product filling
    - whether the retailers must inspect the container returned by the consumer for product residue and/or suitability for refilling; if the container is not clean or appears to be unsuitable for refilling, inform the consumer and possibly refuse it;
    - in case of scenario where a consumer brings their own packaging, a retailer must verify that the container brought by the consumer cannot be confused with food packaging;
    - the information to be provided to consumers for each bulk product or refill product, in particular ensuring traceability through correct identification of the batch (see chapter on regulatory requirements);
    - whether the date when the large container was opened needs to be documented; Batch code tracing is an important potential risk that should be agreed on with the retailer.
- consider whether training of the retailers' employees is required and provide it if necessary;
- consider guidance and implementation for cleaning protocols for consumers.

The Detergent Company may also provide the retailer with the bulk or refilling station/system and in this case provide instructions on the management of the station/system, notably on its usage (including how to control that it is working well), cleaning and maintenance. If it is an automatic refilling station, the retailer should comply with the specifications of the calibration regulations concerning the labelling of the refilled quantity. If not the quantity must be guaranteed in some other way. The Detergent Company should inspect/audit compliance of the retailer with agreed obligations and requirements. External audits from authorities are in the hands of retailers.

In this case, it will be the responsibility of the retailers:

- to strictly comply with the conditions defined by the Detergent Company; in case of deviation, the retailers' own liability may be engaged due to the contract they have with the Detergent Company; and
- where appropriate, comply with the specifications of the calibration regulations concerning the labelling of the refilled quantity.

Product Safety Assessment

In the case of bulk or refillable detergent products, the Detergent Company should include the following considerations during product development and safety assessment:

- take account of the possible scenario(s) – normal or reasonably foreseeable use, multiple refilling, multiple re-use of the container – depending on the type of product;
- assess the impact of the bulk or refilling process on the product safety and safety of the process; consider all possible contaminations during the process, including traces from cleaning/sanitising process (as defined by the Detergent Company), traces from previous product and risk of microbial contamination;
- Prepare a specific hygiene concept for the entire system of refilling, including the following critical points: adequate product preservation; product residue removal from the container, cleaning of the filling nozzle and/or other key parts of the dispensing machine;
- Define the hygienic/microbial quality management of the product, in close cooperation with a microbiologist at the bulk or refilling station;
- If deemed appropriate, foresee additional challenge tests for the simulation of the entire refilling cycle, which must be carried out under the supervision of a microbiologist;
- If necessary, check whether the addition of water or other kinds of detergents (as residues of the cleaning process) may influence the integrity and safety of the refilled product. It is important in some cases not to mix detergent products;
- Take into account the definition of reusable packaging with regards to age of packaging, number of safe refills as defined in Directive 94/62/EC and apply this as relevant;
- take account of the possible scenario where the consumer brings a different container than that of the original product; if necessary, define acceptability criteria for container type and material and, where applicable, exclude the use of containers which could be confused with food packaging.

Cleaning and sanitation

- With refillable containers, the microbial quality management is extremely important; a key consideration is whether the containers are cleaned and sanitised prior to refill/re-use or whether residue from the previous batch could still be present.
- If the refillable container is washed (and sanitised) the introduction of water may influence the microbial susceptibility of the formulation; therefore, further consideration should be

given to the ability to dry the container to minimise risk; it should also ideally be dried before sanitisation. As sanitization by the consumer is not a common practice, it could be considered to increase the amount of preservative in the formulation to cope with the increased risk.

- Traceability of refillable containers should be considered. Containers having previously contained other kinds of products may leach substances from the original product they contained and are not recommended for refill. This is particularly important if cleaning and sanitation is outsourced to a third party who offers this service for refillable containers from different product categories.
- In case product residue is left behind this may have implications for the safety, stability and/or efficacy of the product. The assessment of the returned container should include the visual cleanliness/dryness to determine which cleaning route is most appropriate before the container is refilled. In this case, the safety assessment should be adapted.
- Consider guidance and implementation for cleaning protocols for consumers

Training of retail staff

- Retail staff should be trained in relation to detergent product refills to minimise safety risks to consumers and themselves. In particular, this training should emphasize the proper implementation of the hygiene concept (e.g. cleaning of hoses; replacement of the larger container, if necessary; visual inspection of the containers to be refilled, etc.) and, where relevant, the (limited) durability of the refills, etc.
- Retail staff should be trained for the technical details of the machine, solving day to day technical difficulties, also day to day technical maintenance, cleaning etc. This may include the implementation of cleaning protocols for the machine at certain intervals by the Retailer staff.

Packaging and sustainability

Sustainability aspects shall be considered with regards to the application of refill or bulk product sale. It is appropriate to consider the various scenarios available before selecting the most suitable system/container/packaging/ process with which to move forward. It is also important to consider the whole product life-cycle when deciding upon a refill model.

Regulatory requirements

The Detergent Company is responsible to make the full label and any information available to the Retailer as required by the legal frameworks applicable. This document summarises labelling and packaging obligations of the three main regulations applicable to detergents and maintenance products:

- CLP Regulation (EC) No 1272/2008 (as amended)
- Detergent Regulation (EC) No 648/2004 (as amended)
- Biocidal Products Regulation (BPR) (EC) 528/2012 (as amended), considered here for the purpose of labelling

For the execution of bulk and refill sale, currently, four generic scenarios are foreseen. These examples seek to support identification of the key changes that impact the regulatory obligations, without being prescriptive regarding execution. Regardless of which of the four different scenarios is enacted, product traceability to identify any issue / request coming from Authorities or consumers must be ensured.

1. **Same SKU/product but change in batch**
   Consumer buys the exact same product (same company, brand and name) via a refill or bulk sale. Thus, the only change will be those to consider in a batch to batch change.
2. **Different SKU/product, but same product type/same company**
   Consumer buys the same product type (e.g. a laundry detergent) from the same manufacturer, however it is not the same product as before (e.g. different fragrance).
3. **Different SKU/product, but same product type/different company**
   Consumer buys the same product type (e.g. a laundry detergent, automatic dish wash) but from two different manufacturers.
4. **Different product types/from different companies**
   Consumer buys completely different product type, from a different company via bulk or refill sale (e.g. using a laundry detergent package to buy fabric conditioner).

For each of these four scenarios, the company will have to consider the legal requirements and how to manage the change in variables to ensure legal compliance of each product.

Change management of variables

The CLP Regulation prescribes several criteria that need to be considered and accommodated within any execution of bulk and/or refill sale. Specifically:

- product identifier and unique formula identifier (UFI)
- mixture classification (physical, human health and/or environmental hazards)
- change in composition

Other variables to consider will be related to the labelling and packaging requirements applicable to detergent and maintenance products. A brief outline of these is provided for guidance in the next section.

Labelling and packaging requirements:

CLP, BPR and the Detergent Regulation impose labelling and packaging requirements that must be addressed in the scenarios outlined above. Measures should be put in place to ensure that packaging and labelling is appropriate and accurate for both bulk and refill sale.

CLP – Labelling

CLP requires that the following elements are provided on the physical on-pack label

- For hazard – pictogram(s), signal word and hazard statement(s)
- For precaution – precautionary statement(s)
- Disclosure of certain ingredients according to CLP requirements
- Other mandatory label elements (Unique Formula Identifier (UFI), EUH-statements, etc.)

Labelling information must be provided in the official language(s) of the Member State where the product is placed on the market (unless otherwise provided).

CLP – Packaging
Packaging must be able to fulfil its function and thus should not be subject to decay through (chemical) reactions with the mixture it contains. This is especially important, since the packaging used in bulk or refill sale is expected to be reused and thus will be in contact with the detergent products for much longer, compared to packaging that is only filled on one occasion.

Product classification may also trigger special rules on packaging, covering the use of:

- child-resistant fastenings (CRF)
- tactile warnings of danger (TWD):

In cases where bulk or refill sale are the selected option, certain aspects need to be managed in cases of CRF and TWD. Companies placing products on the market which require CRF or TWD must enact solutions that ensure the hazards that oblige the use of these measures are fully managed over time e.g. ensuring CRF maintaining effectiveness over the multi-use life cycle, or that mixtures requiring TWD are never filled in non-compliant packaging.

If on-going compliance with TWD or CRF obligations cannot be ensured via bulk or refill sale, then sale via these routes is not advisable. In particular in these cases the safety of the refill process will also be an issue.

Note: Special packaging rules also apply to liquid consumer laundry detergents in single use soluble packaging. These requirements are independent of hazard classification. For more detailed information on Child Resistant Fastenings (CRF) and Tactile Warnings of Danger (TWD) refer to DUCC Factsheets on CRF & TWD.

Detergent Regulation – Labelling
Without prejudice to CLP, the Detergent Regulation requires the following on pack:

- Information on dosage instructions/ instructions for use
- Ingredient list by family and percentage range
- Allergenic fragrances
- Preservation agents
- A web address that leads the consumer to the list of ingredients online

This document provides only a high-level outline of the on-pack labelling requirements of the Detergent Regulation. For more detailed information on the Detergent Regulation requirements refer to A.I.S.E. Guidance on the Implementation of the Detergent Regulation.

BPR – Labelling
In addition, and without prejudice to CLP and the Detergent Regulation, labelling according to BPR should also be considered for detergent and maintenance products:

- Ingredient disclosure (every active substance and its concentration and any nanomaterials)

- *Refer to BPR (EC) 528/2012 art. 69 for a more detailed understanding of the requirements.* Note: Depending on country specific legislation, other information may need to be provided instead of and/or on top of the information listed above.

Other requirements/voluntary schemes

In addition to requirements under chemical control legislation, other legislative requirements or voluntary industry initiatives may need to be considered:

- Legislation regarding metrology of these products, Council Directive 76/211/EEC[1], may be applicable, as may other laws related to product delivery.
- Inclusion of brand information
- Use of industry voluntary logos on-pack (Charter, A.I.S.E. safe use icons). The manufacturer should ensure the logos are applicable also to refill products.
- Consideration of guidance coming from national, regional or local authorities in the execution of bulk sales is advised. Due to national requirements, or the opinions of national authorities, utilization of bulk/refill sales should be assessed at Member State level. This could include the exclusion of sale of specific product categories.

[1] Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products

Examples of Refill Sale Executions and Considerations:

There can be different executions of bulk and refill sale. Here are some examples, in particular of refill sale with considerations on the possible learnings of these executions for inspiration of best practices.

Example 1:
A company who provides pre-labelled packaging to consumers. This pre-labelled packaging would then be attached to a specialized machine for the container to be filled with new detergent. The machine in question would only recognize the special packaging of the company. This avoids spillage of product also when the product is being filled and allows for the labelling to remain correct, as long as the formula and the classification of the ingredients do not change to the extent a label change is required.

Example 2:
The idea of a label being printed and attached to product packaging at the point of sale (inspired by executions in other industry sectors – e.g. food, paints). This execution is positive as it is a practical, easily implementable way to ensure consumers always have the correct label. However, if a consumer simply attaches a new label to the same packaging repeatedly, this could lead to a pack filled with different labels where the correct information would be difficult to identify in case of accident. It is advised that the problem of confusing information on the packaging must be avoided, e.g. through checks of the proper labelling after every refill at retail level.

Example 3:
An A.I.S.E. member company provided the following learnings of points that when included in a refill sale led to positive execution:

- Fully automated refill station
- Empty bottle taken from the shelf or consumer brings an already used and cleaned bottle
- Scan the Barcode of the back label – the respective nozzle will be activated
- Place the product under the nozzle and press start – automatic filling process starts
- Batch code – expiration date will be printed out on a sticker
- Place sticker on the back label
- Pay at the cashier – Cashier places a sticker indicating that bottle is paid – bottle can be reused in future without additional payment
- Inclusion of several safety measures: splash protections on nozzles, lockable doors for child safety, CLP declaration behind every nozzle, eye rinsing equipment, personal protective equipment, proper ventilation etc.
- The sticker contains UFI, net and gross weight of the filled products. If the formula is changed it is communicated via a sticker (e.g. - only if something is added in the original ingredient declaration, addition or deletion of an allergen etc.)

Example 4:
Company implements instructions on the label on how to properly clean the containers before refilling, for optimal safety and hygienic standards. Then, to avoid impact due to human error of retail staff or unavailability of the staff, some companies have installed the inspection criteria at the machine level.

Example 5:

With regards to a good example of supply chain communication, A.I.S.E. raises an initiative in the professional sector: the SUMIs. These are tools which offer companies supplying to the industrial and professional cleaning industry a standardized way to communicate Operational Conditions and Risk Management Measures (OC/RMM), in simple and clear two-page documents, using consumer friendly messaging and pictograms. This is a learning that could be applied from the professional sector, to communicate key information to stakeholders e.g. retailers.



A summary of key aspects to consider is below :

Packaging	The use of inappropriate bottle/container for the bulk sale of detergents (e.g. of old food or drink containers) must be avoided, in line with legal requirements (Art. 35 (2) CLP, Art. 69 (1) BPR and Directive 87/357/EEC). It is recommended that packaging used in bulk refill sale is empty, clean and dry before having new products decanted into it.
Appropriate handling ● Avoid contact with damaged skin ● Important not to mix products ● Keep away from children	
Consideration for retail staff	In general, for products which meet the criteria for classification as “hazardous”, a Safety Data Sheet (SDS) needs to be supplied. Usually for consumer products only distributors or retail shops selling the product need to be provided with an SDS. In case a product needs to be handled (e.g. decanted) by retail staff, they should have access to an SDS and information for safe use. It is key to ensure that retail or maintenance personnel are properly trained to handle the products safely in case of bulk/ refill sale through filling stations.
Hygiene practices	Execution should ensure hygiene/microbial quality across the life cycle of products subject to bulk and refill sale. This may require identifying aspects of the execution that could lead to a hygiene risk (e.g. packaging cleanliness, use of appropriate dilution solvent) and taking preventative measures.