

Guidance on Refills and Reuse Models – Key Considerations

July 2022

A decorative graphic in the bottom right corner featuring a large, stylized white swirl shape. Behind this swirl is a photograph of laboratory glassware, including a test tube and several beakers, all containing a vibrant red liquid. The background of the entire page is a light gray.

CTPA Role:

The Cosmetic Toiletry and Perfumery Association (CTPA) is the trade association for the UK cosmetic and personal care industry.

The Association's role is to advise manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK government, and external stakeholders and help promote information to the media on issues relating to the safety of cosmetic products. The CTPA acts as the voice of the UK industry and provides the most up-to-date interpretation of, and guidance on, regulatory matters affecting cosmetic products in the United Kingdom and internationally.

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CTPA supports the transition towards a circular economy and the reuse of packaging for the same purpose for which it was designed, recognised as a key element in the drive towards the overall reduction of packaging and consequential waste.

Why join the CTPA?

CTPA membership gives companies access to experienced regulatory, scientific and technical staff to help them market safe, effective products that provide a wide range of consumer choice both in the UK and overseas.

Membership provides companies with peace of mind with easy access to:

- up-to-date legislative references;
- guidance on compliance;
- confidential one-to-one advice;
- advice on best practice;
- advance knowledge of upcoming changes;
- global updates on key issues;
- media and consumer information; and
- 24/7 online resources accessible worldwide.

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CTPA supports the transition towards a circular economy and the reuse of packaging for the same purpose for which it was designed, recognised as a key element in the drive towards the overall reduction of packaging and consequential waste.

In 2019, in consultation with CTPA committees and working groups, a document outlining the key considerations was compiled to assist members who may be developing such initiatives.

This revision of the 2019 guidance reflects a greater understanding of the topic and its application. The advice takes into consideration the safety, manufacturing, labelling and general requirements under the **UK Cosmetics Regulation**¹ and may not be appropriate for all cosmetic product types or markets outside Great Britain. Reuse and refill should comply with the same regulatory requirements that exist for the introduction on the market of any packaged product.

As we all rethink models of consumption, the trust of consumers and credibility of the industry must be maintained. Therefore, when considering whether to launch a refillable product it may be appropriate to consider the various scenarios before selecting the most suitable with which to move forward.

In addition to determining the environmental benefits of differing models, it is recognised that motivating change to enable the shift in consumer behaviours will be key to the on-going success of such initiatives. Options to build consumer confidence should consider the practicality for the consumer in addition to providing a benefit to consumers beyond sustainability.

There are different models established, such as refill in-store or at home, or returning packaging to a store or from home for refilling and being sold again 'prefilled'. Further information on scenarios and definitions can be found through the **Ellen McArthur Foundation**². In this context, the document below covers the supply of cosmetic and personal care products in formats allowing the filling, directly or indirectly, into previously used and cleaned packaging.

Product Development and Safety Assessment

The refillable nature of the intended product should be incorporated into all stages of product development and Safety Assessment. Formulation chemists, microbiologists and safety assessors will all need to take this vital element into consideration. For example, they will have to decide whether the introduction of water and/or detergents used to clean the packaging to be refilled could impact the integrity and safety of the product or the stability of the formulation. This could lead to the need for a refill-only version of an existing products which may require a different viscosity of preservative mix owing to the increased risk of contamination, which in turn might mean that manufacturing and packaging processes themselves must be reassessed.

Data from additional relevant stability, compatibility and challenge testing will be required to ensure the product's integrity and safety throughout the full lifecycle of the product.

As a multi-disciplinary approach is recommended, if necessary, members are advised to seek expert assistance in each key area. CTPA would also recommend informing your local Trading Standards office of your intentions to show understanding of the key issues.

Packaging and Sustainability

When considering whether to launch a refillable product it may be appropriate to consider the various scenarios available before selecting the most suitable with which to move forward. There should be consideration of the longevity and practicality of a refill/re-use systems and a multi-criteria life cycle analysis conducted to validate the overall environmental benefit. Reusable packaging and refill options should be designed to be deployable at scale and for a sustained period of time to bring significant positive environmental outcomes and maximise the reuses.

To make packaging durable for multiple uses, it may need to be produced more robustly (sometimes referred to as heavy-weighting). However, packaging and packaging waste requirements are designed to ensure that there is no over-use of packing. A heavier bottle will also require additional energy and material to produce and being more solid, may make the product more difficult to dispense.

Whilst more robust packaging may be required to enable sufficient reuse, to determine whether a reusable packaging model is the best option for the environment, consideration should also be given to any additional transportation and cleaning requirements. It is also important that companies consider the mechanism by which the reuse of packaging can be quantified.

Any claims around the environmental benefit of a reuse model must be backed by robust evidence, such as a full Life Cycle Assessment or Product Environmental Footprint (PEF) to demonstrate a reduced environmental footprint covering the whole reuse life cycle. [A Product Environmental Footprint (PEF) is a methodology by the European Commission's Joint Research Centre (JRC) based on Life Cycle Assessment.]

An assessment should be made for how many times the packaging can be safely re-used before the need to discard/recycle the pack and how it can be determined when this stage is reached. This should include a recognition that for some brands and consumers, acceptance of a battered and worn pack would be greater than for others. Companies should report and track not just sales but repeat purchases to substantiate claims, and understand consumers habits to help build engagement. Ultimately, the packaging will end up as waste so should use materials, and be designed to be recycled at the end of its use.

1. Refills in Store

Definition: The consumer returns to store with the original packaging to be refilled in store from 'service packaging' – that is a larger capacity container from which product is drawn for refilling.

Cleaning and Sanitisation

With refillable packaging the microbial quality management and compliance with GMP should be revisited. Special consideration should be given to whether the used consumer packaging will need to be cleaned and sanitised prior to re-use as residue from the previous batch could still be present.

Any residue from the previous fill will have implications for the safety and/or efficacy of the product. An assessment of the returned packaging should include the visual cleanliness/dryness to determine which cleaning/sanitisation route, as per the scenarios below, is most appropriate before the pack is refilled. This assessment will be more difficult for opaque packaging.

Scenarios:

1. The container is cleaned/rinsed and dried by the consumer before returning to store for assessment and refilling.
2. The container is returned to the store for cleaning (in-store or at a different facility such as the original manufacturing site) and re-use by a subsequent consumer, sometimes referred to as **(return on-the-go)**
3. The container is cleaned in store and the same container refilled and returned to the same consumer.
4. The container is assessed in store before a decision about which of the options above is most appropriate.

Water is a significant risk for promoting microbial growth, with real impacts in terms of the microbial integrity, and therefore safety of products. The introduction of water to the packaging could influence the microbial susceptibility of the formulation when in use by the consumer after refilling. Further consideration should be given to the ability to dry the container to minimise risk.

Advice may be obtained on whether an unwashed bottle may pose less risk than a poorly washed bottle. This may be the case with oil-based products where rinsing with water alone may not be effective at removing product residue but could leave water behind.

Certain parts of the pack, for instance, lids, may be prone to retaining residue and therefore might be handled separately either for external cleaning and sanitising before returning to the store, or by removing the component for recycling separately.

It may be necessary to increase the amount of preservative in the formulation to cope with the increased potential for contamination. This will need to be balanced with the regulatory restrictions in place around maximum concentrations and consumer expectation to use alternative or minimum preservation.

Clear instructions should be provided on the procedure for obtaining a refill and whether the consumer needs to wash/dry the bottle before re-use. Further instructions should be supplied about what containers will be considered for refilling, for example, only using the containers specified (as originally sold as part of the product) or any bottle the consumer provides.

Additional facilities may be required 'back-of-store', for instance to hold refill specific stock, and refill hoppers. This should include suitable cleaning and drying facilities.

Good Manufacturing Practice and Filling Instructions

To maintain compliance with Good Manufacturing Practice (GMP) throughout the processes (transportation, cleaning, sanitising, filling etc) it is recommended that the procedures the retailer will use for filling and any additional strategies necessary to minimise risk, are fully defined by the Responsible Person (RP) and followed by staff with this being documented in the Product Information File (PIF). This will also necessitate additional and continual training at store level.

Production of refillable formats may lead to changes in company operations, facilities, production lines and equipment, and therefore additional consideration should be given to microbiological controls, procedure validation and mapping the differing risk areas within a site, potentially including within the retail environment.

In the case of a consumer-operated system, unambiguous instruction should be provided with guidance on hand if necessary.

Compliance with Weights and Measures

The **UK Weights and Measures (Packaged Goods) Regulations 2006**³ applies only to products that are pre-packaged without the purchaser present. Therefore, the average fill system and, in particular, the e mark, cannot be applied to products filled in store in the presence of the purchaser. The minimum fill system should be applied to these products and be accompanied by regular and systematic checking of the equipment and procedures to ensure the minimum declared fill is being achieved. CTPA would advise consulting Trading Standards Officers to explore the most appropriate options whilst ensuring obligations for content marking are met.

The ability to control stock accurately will need to be carefully considered, as in-house systems may not recognise stock bought in as Stock-Taking Units (SKUs) but sold in differing quantities. This would be particularly significant when a consumer is able to fill any quantity they wish to purchase.

Labelling for the Consumer

All Article 19 mandatory labelling is applicable to the product, including the batch identifier relevant to each refill (if different from the original batch). Article 19 also requires the 'Best Before End' date (BBE) or the Period After Opening (PAO) to be labelled on pack where applicable to the refilled product. This information must be communicated to the consumer and, if relevant, should replace the information supplied with the original filled container or previous refill. It should also be remembered that the mandatory labelling provided under Article 19 must be indelible.

Labels may need to be produced to be applied in store over/replacing existing labels so that all Article 19 information, relevant to the filled batch, is visible on the product container. These labels will need to be durable for use but easily removable for when the bottles are cleaned and refilled. This label must then not ultimately hinder the final recyclability of the packaging.

Please consider that in a multi-product refill environment, in addition to cross-contamination considerations under GMP, additional allergen labelling might be required to highlight the risk of contamination from other products handled within the same facility.

Period After Opening (PAO)

In the UK, products that remain durable for 30 months or less are required to be labelled with a date of minimum durability, indicated by a 'best used before the end of' or an hour-glass symbol. A product that remains durable for more than 30 months may be required to be labelled with a PAO if, after its opening, the deterioration of the product may lead to harm to the consumer. The date of minimum durability is communicated as an indication to the user that once opened the product will not deteriorate to cause harm to human health within that time period. By deterioration to cause harm to human health we usually mean microbial contamination at an unacceptable level.

In calculating the durability of a refillable product, a full understanding of the operational details will be required to assess at which point the product is considered 'open'.

Labelling of 'Service Packaging'

CTPA identified two regulatory scenarios that can be applicable to the product required in store for refilling consumers' packaging. It is ultimately a company decision to decide which scenario is best suited, depending on how the model is implemented.

Scenario 1. The product in the store container/dispenser (prior to filling the consumer pack) could not be considered a finished cosmetic and should be labelled according to the requirements of the GB Classification, Labelling and Packaging (CLP) Regulations.

Supplying bulk product will also mean that a Safety Data Sheet needs to be made available to the store and specific handling considerations included for instance for transferring product between containers and filling machines.

Scenario 2. The product supplied for refilling in-store could be considered a finished cosmetic product (for instance, a large hospitality size pack).

The UK Cosmetic Products Enforcement Regulations 2013⁴ states that *‘Where cosmetic products are not pre-packaged or are packaged at the point of sale at the purchaser’s request, information required to be provided in accordance with Article 19(1) (which provides for labelling) of the UK Cosmetics Regulation must appear on the container in which the product is exposed for supply or on a notice in immediate proximity to that container’.*

Therefore, the Article 19 information, as required under the UK Cosmetics Regulation, must be supplied on or in proximity of the refilling station, as well as provided to the consumer on the refilled pack.

If companies decide this scenario best applies, CTPA would still advise the RP to supply a Safety Data Sheet to the store together with specific handling considerations, for instance to transfer product between containers and filling machines.

Prefill vs Refill

Operationally, an alternative model to refilling in-store is the provision of a new product in reused, suitably cleaned packaging where the product has been filled into a separately collected container, at the original factory or another contracted establishment.

In addition to the guidance around refill above, a move to this format would require consideration of the impact, including environmental, of used, returning packaging being transported to a facility for cleaning and sanitisation before refilling.

2. Refills at Home

Definition: The consumer purchases a refill (e.g. pouch) to decant into an existing bottle at home.

In addition to the considerations outlined above:

- The development of appropriately sustainable lightweight packaging. Options for consideration include a large format from which the refill can be dispensed over time into the ‘mother’ packaging or a lightweight insert compatible with the ‘mother’ packaging.
- The container in which the refill formulation is supplied (e.g. laminated pouch instead of plastic bottle) may use a different packaging material than was originally assessed for stability, compatibility and microbiology. Data should be supplied to the safety assessor regarding the new packaging material as well as for the product in its reusable container. It should also be noted that laminates can adsorb preservatives in some circumstances, meaning that the preservative level may decrease during storage.
- The safety assessment should consider the potential for misuse or misunderstanding of the refill nature of the product; consumers may decide to use their own, potentially unsuitable packaging.
- For products with a PAO, the durability will need to be assessed to determine suitability for decanting months after originally purchased.

- The refill container (such as a pouch) will need to fully comply with Article 19 mandatory labelling. Under the UK Cosmetics Regulation, this information is required to be supplied with the product when it is made available. However, should a consumer report a problem with the refill product but no longer have the refill pouch/container, consideration will need to be given to how the potentially faulty batch will be traced.
- In addition to the Article 19 mandatory labelling, clear instructions should be provided on to the use of a specified container, cleaning and drying the container, including where necessary advice on removing/replacing caps, pumps or more awkward components, filling and advice on the potential for cross contamination.

3. Dilution at Home

Definition: The consumer purchases a concentrated or dry product which needs to be mixed with a specified quantity of (tap) water at home. The diluted product is designed to be stored in a pre-determined reusable container larger than the concentrated purchase.

The option to provide a concentrated product for dilution at home, into a reusable container, offers the opportunity to reduce the impact of packaging, the use of water, and consequently transportation.

However, as per Article 3 of the UK Cosmetics Regulation, all cosmetics have to be safe. Therefore, CTPA advises that both the concentrate product and the diluted product are tested for stability, compatibility and microbiology and assessed as safe by a qualified safety assessor, who should consider all possible foreseeable scenarios, including a consumer believing that a more concentrated product would be more beneficial. Ingredients may have upper limits for use under the UK Cosmetics Regulation which might impact on the levels in the concentrate and when diluted correctly or not.

Directions for use must be very clear with prominent warnings about not using the product undiluted.

As dilution accuracy will be dependent on the consumer understanding any consequences of trying to make a product more, or less dilute, packaging can be designed, for instance, indicating correct dilution level, or by not enabling access to the concentrated product. It might be possible to supply the concentrated product with a specific container, which may indicate the level up to which water has to be added. However, the company should not exclude from their safety considerations that the consumer may opt to use a random bottle they have at home, which is not clean, sanitised or designed to be compatible with the formulation.

This format of dilution at home to create a cosmetic product is likely to be treated as a cosmetic kit, where components (concentrate and water) are mixed following clear instructions. In this case, the Cosmetics Regulation applies. However, if there are no clear instructions for obtaining the finished cosmetic product, CLP Regulation will apply to the concentrated product.

Just as the previous formats, microbial quality management and hygiene remain extremely important. If re-using packaging (either that which is supplied by the RP or chosen by the consumer) a key consideration remains whether the old packaging will be cleaned and sanitised prior to re-use, whether residue from the previous batch could still be present or whether a new pack will be used.

The level of preservative should be compliant and appropriate within the final product (diluted) even if the product is not fully diluted, tap water (softened, naturally hard or soft) is used to dilute the product and that the container is not sterilized.

References

¹ Regulation (EC) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

² Reuse – rethinking packaging (ellenmacarthurfoundation.org)

³ Weights and Measures (Packaged Goods) Regulations 2006, as amended by Schedule 11 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

⁴ UK Cosmetic Products Enforcement Regulations 2013, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Further Reading

SPICE, the Sustainable Packaging Initiative for Cosmetics – Guidance which references multiple use packaging with definitions, methodological requirements, study cases and other information on reuse/refill/rechargeable packaging and take back systems. <https://open-spice.com/publications/>

SOFW, a specialist journal for the cosmetic, personal care, home care and fragrance industry – Guidance on the Essential Aspects of Filling Stations for Cosmetic Products in the Retail Trade. (<https://www.sofw.com/en/hikashop-menu-for-categories-listing/product/1210-essential-aspects-of-filling-stations-for-cosmetic-products-in-the-retail-trade>)

Ellen MacArthur Foundation, which works to accelerate the transition to a circular economy provides a framework to understand reuse models by providing definitions, identifying benefits of reuse and providing examples. (<https://ellenmacarthurfoundation.org/reuse-rethinking-packaging>)

The On-Pack Recycling Label Scheme (OPRL) – provides a set of principles which would form best practice for refill. (<https://www.oprl.org.uk/refill/>)

The Institute of Grocery Distribution (IGD) – Report ‘How to Help Consumers Adopt Reusable Packaging’ which outlines opportunities to help adoption of, and necessary behaviour change around reuse models. (<https://www.igd.com/articles/article-viewer/t/how-to-help-consumers-adopt-reusable-packaging/i/29147>)

UK Government Guidance Note UK Packaging (Essential Requirements) Regulations. (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/460891/BIS-15-460-packaging-essential-requirements-regulations-gov-guidance-notes.pdf)

For further information on Environmental claims, please refer to CTPA Environmental and Green Claims Guidance and the Competition and Markets Authority (CMA) Guidance on Environmental Claims on Goods and Services. (<https://www.ctpa.org.uk/file.php?fileid=3802>)

For any advice on carrying out refilling activities in the EU and Northern Ireland, please refer to the Cosmetics Europe Cosmetic Products that are Refillable at Points of Sale: Guidance Document (<https://www.ctpa.org.uk/file.php?fileid=4218>)

FEBEA, The French Cosmetics Association – GMP Guidelines for Cosmetic Products Manufactured/Packaged In-store (<https://www.ctpa.org.uk/file.php?fileid=4217>)

