Collaborative Manufacturer

UNILEVER
COLLABORATIVE
MANUFACTURER
QUALITY
MANUAL

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ABOUT THIS MANUAL

SCOPE

Collaborative manufacturer (referred to as CM), in the context of this manual, refers to a company which is contracted to manufacture Unilever branded goods, which are then sent to a Unilever factory or direct to trade to be sold to customers or consumers in one or more geographic locations.

OUR CM QUALITY FRAMEWORK

The CM Quality Framework encompasses how we :

- Qualify and define contracts with our CMs
- Collaborate and integrate through information transparency
- Collectively monitor and improve our performance

It outlines the procedures to be followed by approved Unilever CM's when preparing Unilever products. It is the responsibility of the CM Management to acquaint all responsible personnel with the details of these procedures and requirements and to make sure that they are carried out.

The provision of this manual, and Unilever's willingness to assist CM's, should not be construed as a waiver of any of the CM's contractual responsibilities. Unilever has the right to inspect the systems in operation at the CM facility to ensure compliance with the requirements laid down in this manual.

The latest version of the Quality Manual will be shared by the Unilever Quality or Procurement first point of contact for the CM via ***QualityOne*** - *the Unilever cloud based system used to manage core quality processes between CM's and Unilever* -. The latest version of the manual should be signed prior to first production and re-signed if any changes arise.

SUPPLIER QUALITY APPROVAL PROCESS (SQA)

As a CM for Unilever, you must conduct a certification audit against globally recognised standards for certifying your Quality Management Systems (QMS), work processes and operating procedures.

By successfully completing the certification audit at your manufacturing site(s), you demonstrate compliance with our ***Supplier Quality Approval Process (SQA)***

A full list of accepted audit standards can be found on the Unilever Supplier Qualification System (USQS). This full list includes the standards that we would '*prefer*' you to use. The *preferred standards* are shown on the 2nd page of the list.

You need to select the appropriate audit standard for your manufacturing facility from USQS.

If the audit protocol has the option for certification, this must be selected. If the audit protocols result in a statement of compliance being issued at the end of the audit process instead of a certificate, this is fully accepted by Unilever.

ISO9001 certification does not provide exemption from our Supplier Quality Approval (SQA) audit requirements.

In addition to the SQA Process, you will also need to comply with Unilever specific requirements through our audit program (see slide "Unilever CM Audit Program")

UNILEVER PREFERRED AUDIT PROTOCOLS (AT THIS TIME)

CM Foods	• GFSI - FSSC 22000 / FSSC 2200 Q - BRC Global Standard For Food Safety - IFS Food - SQF Food Safety Code for Manufacturing edition 8
CM Non-Foods	• BRC Global Standard for Consumer Product • HPC 420 • IFS HPC • ISO 22716 Cosmetics – Good Manufacturing Practices • ISO 13485 Medical devices – Quality Management requirements or regulatory purposes • ISO9001:2015 together with ICH Q7a (Pharma GMP's) and ICH Q9 (Pharma HACCP) or EU 2001/83/EC Directive inspections

We periodically review the list of audit standards we are willing to accept.
To get the entire list of preferred & accepted standards, please reach out to your Quality or Procurement contact.
Please ensure that you only select audit standards from the information provided.

UNILEVER PREFERRED AUDIT COMPANIES

Audits must be performed by licensed audit companies that are certified by the audit standard owner.
We will not accept any certification from an audit company that only holds a “Provisional License”.

We recommend and prefer that you work with one of the following audit companies, however we also, accept certification bodies as long as they exist under certification directories (e.g FSSC, BRCGS directory,...)

Intertek DNV·GL BUREAU VERITAS CONTROLUNION SGS

These audit companies mentioned above, have been selected based on their ability to conduct a wide range of SQA audits and the availability of their auditors around the world. Through USQS, you have the option to allow these companies to contact you directly to clarify any audit details such as auditing costs, schedules, audit formats and duration etc.

You are responsible for all costs related to the audit, close out of non-conformances and certification.

Unilever request to see detailed audit reports from your external audits inclusive of any correction action responses.

SUPPLIER QUALITY APPROVAL PROCESS (SQA) & DISPENSATION

Your facility may already be certified and meet the Unilever SQA requirements. Before you initiate the SQA process, check if your facility can demonstrate the following:

- A current audit certificate against any of the audit standards accepted by Unilever
- Provided by a licensed audit company
- At least 3 months remaining before the certificate expires
- If the certificate has less than 3 months before expiration, you must be able to demonstrate that recertification is scheduled.

If so, you will be considered SQA-approved once the certificate has been uploaded to USQS and validated by our service provider.

If you cannot demonstrate this, you must select an audit standard and one of the preferred audit companies to perform the required audit or, initiate the re-approval process through USQS.

Any certifications which are due to expire or where a (re)-certification audit is not possible, a dispensation request must be initiated and approved in QualityOne.

The dispensation is subject to demonstrating a clear plan towards attaining the external certification and demonstrating steps to prove that the process is under control and will therefore not introduce any risks. It can be approved for a period of 3 or 6 months (maximum 2 times).

SUPPLIER QUALITY APPROVAL PROCESS (SQA)

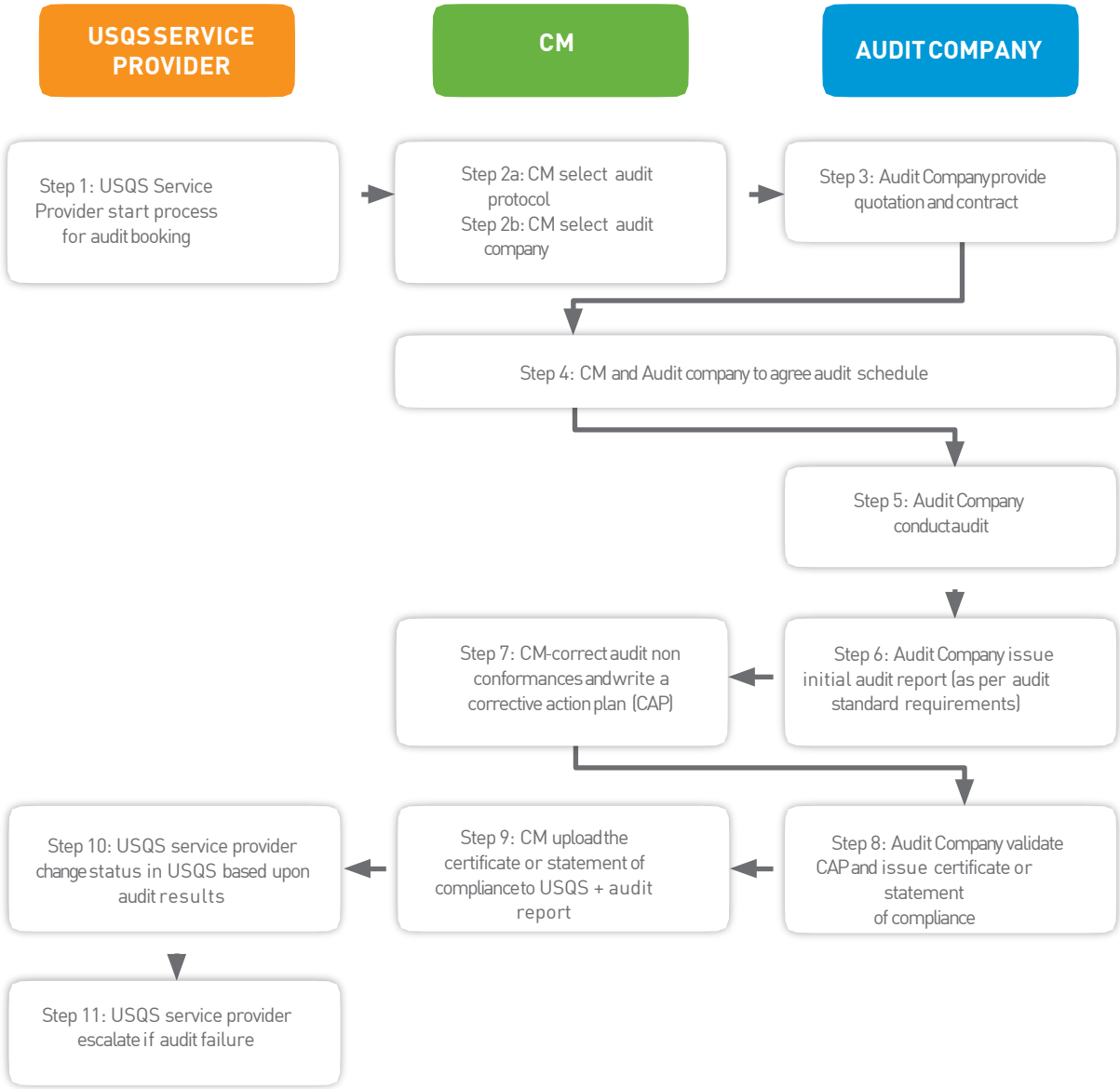
Receipt of the certificate from the appropriate certification body is a confirmation that your facility has met the requirements of the particular scheme your facility has been assessed against.

The uploaded documentation will be reviewed by the USQS service provider to ensure that the audit matches one of the accepted audit protocols and the documentation has not expired. As soon as the USQS service provider confirms that the audits submitted is in accordance with our audit requirements, you will be considered approved.

Pre-audits or pre-assessment reports, alone, do not demonstrate compliance to the SQA requirements and are therefore not accepted. The certificate or statement of compliance to USQS as well as the audit report with associated findings are expected to be provided.

The basic steps in the SQA process are shown on the next page.

SUPPLIER QUALITY APPROVAL PROCESS (SQA)



Note: Where your input or action is required, you will be contacted by USQS system generated e-mail and given weblinks to directly access the USQS.

Note: The SQA process do not include the assessment of the CMs against our specific Unilever standards (eg. GMP). Those will be covered by our audit program with the respective CMs.

SUPPLIER QUALITY APPROVAL PROCESS (SQA)

Once your facility has been successfully approved, the facility must maintain approved status in order to continue doing business with us. As the audit certification expiration date approaches, you will receive an email alert from USQS to initiate the re-approval process.

Re-approval frequency is prescribed in the audit standard. However, surveillance audits will be a minimum of one per year.

GENERAL INFORMATION

All audit documentation related to SQA will be stored in a secured database managed by a service provider under contract to Unilever.

Only that entity and Unilever personnel are authorized to access the information in the database. Unilever preferred audit companies do not have access to supplier and CM information.

UNILEVER CM AUDIT PROGRAM

In addition to the SQA audit previously described, an Audit Program must be implemented to guarantee the ongoing compliance of the operations against the quality and consumer safety requirements accepted by Unilever. Audit can be carried out – virtually or on site - by a Unilever internal resource or 3rd Party auditor selected by Unilever.

The Audit Program and frequency will depend on the :

- Technology risk
- Product made
- Performance of the manufacturing site

AUDIT PROGRAM	SCOPE	FREQUENCY	AUDIT BY	FORMAT
Vetting Audit *(consumer safety & quality)*	• New CM • New Technology use at the CM	One time	• Unilever internal resources (e.g. Quality, R&D, Engineering) • Approved 3rd Party auditor	• On site
Re-Audit *(consumer safety & quality)*	• Existing CM	1 - 3 years	• Unilever internal resources (e.g. Quality, R&D, Engineering) • Approved 3rd Party auditor	• On site • Virtual
Technical Quality Visit/Surveillance audit *(verification)*	• Existing CM	As needed	• Unilever Quality team • Approved 3rd Party auditor	• On site • Virtual

In addition, it is expected that you will be continuously assessing your compliance against the requirements through self-assessment audits and as part of the agreed improvement activities.

UNILEVER CM AUDIT PROGRAM

The audit must be carried out using a set of auditable standards for CMs and their related checklists.

UNILEVER GENERAL QUALITY STANDARDS

It must contain all the auditable Unilever mandatory requirements, regardless of the goods being produced.

GOOD MANUFACTURING PRACTICES STANDARDS (GMP)

Unilever Product GMP Standards are specific to a family of Unilever products – for example Skin Care, Home Care, Ice Cream etc – and identify key processing and equipment requirements which are essential to enable Unilever's quality and brand requirements to be achieved.
The Standards are confidential and there must be a non-disclosure agreement in place to enable you to have access to these documents.

HYGIENE DESIGN STANDARDS

Hygienic design standards refer to the mechanical design of your manufacturing equipment (for example, pumps, mixers, pipework, valves, drains) and utilities systems (ventilation and air handling, water, steam etc).

The documents and the related checklists will be housed in QualityOne.
If unsuccessful at meeting the requirements, you must formulate a corrective action plan to rectify any issues and be reassessed. If investment is required as part of the corrective action plan, meaning that some actions cannot be implemented immediately, Unilever will need to know the timeline for implementation.

UNILEVER CM AUDIT PROGRAM

The table displays the minimum standards considered in the audit program. The list is not exhaustive and must be read as guidance. The standards selection will be agreed, in advance, between Unilever and the CM. The documents are accessible in QualityOne during the audit preparation.
In situations where specific equipment is required to successfully produce Unilever products, we will also provide equipment specification information.

AUDIT PROGRAM	UNILEVER GENERAL QUALITY STANDARDS	GOOD MANUFACTURING PRACTICES	HYGIENE DESIGN
Vetting Audit	• Personnel Hygiene & Employee facilities • Internal Non-Conformance Management • Cleaning & Disinfection • Allergen Management • Change Management • Foreign Matter Management & Control • Pest Management + local Unilever requirements in specific geography	• Dedicated Product GMP(s)	• Hygienic Engineering & Maintenance
Re-Audit			
Technical Quality Visit/Surveillance audit	• "Keep Consumer Safe" requirements		

As a final component of certification and standards compliance, certain products in Unilever's portfolio may require you to be able to demonstrate and maintain very specific capabilities to support product performance claims. Examples include Halal certification, Kosher certification, GMO-free, Vegan, Gluten free, etc. These claims will be identified in the product specification and you must be able to provide certification documentation to enable manufacturing to start.

CROSS CONTAMINATION

A robust and reliable cross contamination program is an essential part of your manufacturing controls. The CM must manufacture, store the products and store the components only at an approved site, unless the prior written consent of Unilever is obtained.

The principle mechanism for contaminant risk management within manufacturing is the use of risk management tools such as Allergen Management Process, HACCP and/or FMEA. Hazards to consider are Microbiological, Foreign Matter, Chemical, Biological and Allergens.

Understanding the risks correctly, input from a cross functional team and even across companies are needed:

- Include when needed Unilever in a risk assessment to prevent assumptions regarding our risks
- Understand your allergen risks and the potential worst case allergen cross contamination for all semi/finished product made. Where applicable, cross contamination data must be provided to Unilever
- Work to understand how cross contamination can be reduced, and if possible, eliminated
- Work within Unilever specifications and guidelines
- Create cleaning matrix requirements for production runs. These must factor in allergen cross contamination
- Take the Supplier Alerts and Consumer Complaints as an opportunity to verify “it could happen to me; how do I prevent?"

Unilever must be informed of any :

- Changes in process or formulations that change the cross-contamination risk, whether it is microbiology, chemical or allergen in nature;
- Foreign matter contamination of product;

As any of these could lead to marketplace incident.

SPECIFICATION AGREEMENT

The specification defines all the properties and conditions of which you have to ensure:

- Consumer safety requirements
- Product performance requirements
- Appearance & sensory requirements as described in our Consumer Relevant Quality Standards (CRQS)
- Materials, ingredients and primary packaging requirements
- Processing parameters, bill of materials, order of addition
- Shelf life & “best before” date
- Secondary packaging
- Pallet pattern and pallet quality requirements
- Storage and transportation requirements

The product specification will be provided by Unilever or the CM. In either case, the specification must be signed prior to the first production and if specification changes occur.

Certain properties are defined as being “critical” for either consumer safety or quality performance reasons. You must confirm conformance for these critical properties for each production lot delivered to us by providing a Certificate Of Analysis (COA) or Certificate Of Conformance (COC), unless otherwise agreed.

RETAINED SAMPLES AND MANUFACTURING RECORDS

FINISHED PRODUCT RETAINED SAMPLES

You must retain finished product samples from each lot delivered to Unilever. These retained samples must be labelled and stored under the proper conditions. A sufficient* quantity of samples must be retained. Finished product samples must be retained for a time period equal to the Unilever-defined shelf life of the product + 25% or the time period denoted by local regulations or GMP requirements (whichever is longer). The shelf life of the product is defined in the specification agreement.

RAW MATERIAL RETAINED SAMPLES

You must also retain a sufficient* quantity of samples of the raw material lots used (unless approved under exception by Unilever, for highly perishable raw materials). These retained samples must be labelled and stored under the proper conditions. These samples must be retained for a time period equal to the maximum shelf life of the material +25% or the time period denoted by local regulations or GMP requirements (whichever is longer). The maximum shelf life is defined by the material supplier.

MANUFACTURING RECORDS AND FINISHED PRODUCT TEST RESULTS

Manufacturing records for each batch of finished product must be retained for a time period equal to the Unilever-defined shelf life of the product + 25%. The shelf life of the product is defined in the specification agreement. Manufacturing records include processing data and factory floor log sheets, laboratory analytical data, materials consumed, cleaning records, HACCP records etc.

However, this retention time could be up to 7 years depending on requirements of external certification or local regulatory requirements.

sufficient*: usually refer as two rounds of full parameter testing or the minimum amount of test doable mandated by law (whichever is stricter)

PRODUCT QUALITY VERIFICATION

Unilever may require you to deliver a set of finished product samples to a Unilever approved laboratory or (any laboratories certify ISO 17025 with accreditation for the analysis of the product matrices in scope) for verification testing. The frequency of the verification and the scope of products from the portfolio to be tested will be determined by each Unilever market. This could be based on the following:

- Market assessment of product and CM risk
- Local regulatory requirements
- Manufacturing non-compliance data

Verification testing may include a set of analysis versus the agreed specification, utilizing the agreed test methods. This may include, but is not limited to, testing of microbiological, chemical, physical and sensorial parameters testing.

REGULATORY VERIFICATION

In certain countries in which Unilever operates, local legislation requires product claims verification to be provided. Alternatively, where finished goods are being shipped across international boundaries, importing countries invariably require analytical documentation and country of origin certification as part of the importation process.

In most cases, to meet these requirements, you will be asked to provide a certificate of analysis (COA) for each lot of finished products.

In these instances, the regulatory requirements will be identified as part of our commercial agreement.

CONTAMINANTS MANAGEMENT PROGRAM

Where materials are not sourced from Unilever-approved suppliers, you must have a contaminants' monitoring plan.

You must demonstrate you have a risk assessment process in place for the assessment of potential contaminant and are periodically monitoring your portfolio for their presence. This assessment should include (but is not limited to):

- Nitrates, pesticides, veterinary drugs
- Environmental contaminants (dioxins, heavy metals, PAHs, PCBs)
  natural toxins (biogenic amines, mycotoxins)
- process-derived contaminants (chloroform, ethyl carbamate, 3-mcpd, PAHs)
- Storage contaminants (fumigants), GMOs, food preservation (irradiation, sulphur dioxide, nitrites)
  adulteration (illegal dyes, melamine)
- Other organic contaminants (formaldehyde, nicotine, mineral oil, pentachlorophenol)

The external laboratories you use for contaminant testing must have the correct capabilities and are accredited for the analysis of each specific contaminant (ISO 17025 with accreditation for the analysis of the product matrices in scope)

Contaminant monitoring plans must be part of the quality agreement that is signed by Unilever and your representative. The results of your testing program must be shared with Unilever annually at a minimum. Occasionally, due to emerging risk, Unilever may ask you to conduct/ask your suppliers to conduct additional testing for certain parameters for raw materials. These should be handled on a 'case-by-case' basis.

If requested by Unilever, you must provide the overview of your risk assessment and potentially the results to a contaminants test.

CHANGE NOTIFICATION

Any proposed changes such as materials, ingredients and their sourcing, changes to processing or packaging equipment, processing parameters or manufacturing location that will potentially affect the quality and/or safety of finished goods must be shared with Unilever in advance of the proposed change. Such notification should be given in advance so that Unilever has opportunity to consider the proposed change and evaluate potential effects prior to implementation. You must receive written consent from Unilever before implementing the changes.
Any agreed changes must be reflected in the specification.

Alternatively, Unilever will inform and agree with the CM if there is any change in the component, specifications, or process for the product prior implementation of the changes.

QUALITY PERFORMANCE MONITORING

Unilever uses a standard set of Quality performance measures to monitor the performance of our manufacturing network. Product quality is measured from incoming raw and pack materials, at the point of manufacture, at the point of sale and during our consumers' experience.

For example, when we receive any consumer or customer complaints or identify issues related to any of the products you have manufactured, we will alert you to these complaints and may request that you complete an investigation within an agreed timeline.

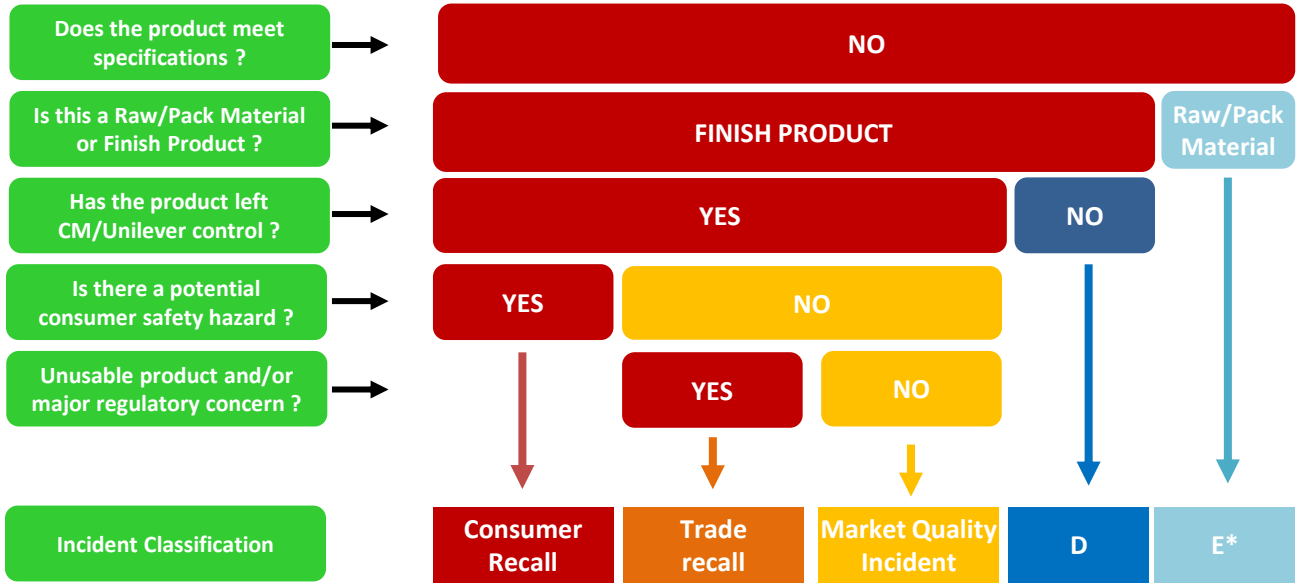
You may be requested to review processing records, provide copies of manufacturing, maintenance or cleaning records, or conduct further analysis on retained product samples.

QUALITY INCIDENT CLASSIFICATION

Unilever has a simple Quality incident framework to classify all product non-conformances according to the severity of the incident and where the incident was identified. In the event of a quality failure, if all of the non-conforming product is contained within our distribution network or within your manufacturing facility, it is classified as a D incident for finish product and E incident for raw/pack material.

Otherwise, if it has been shipped into our customers' networks or has reached our consumers and there is a potential consumer safety concerns, it is classified as a marketplace incident. Marketplace incidents are categorized in three tiers according to the action taken on the market – Consumer recall, Trade recall, Market Quality Incident.

Unilever has incident management procedures which cover how we handle marketplace incidents and D incidents within our supply chain. These procedures are covered in the next section.



*Note: E incidents are not in scope for CMs and apply to raw/pack material suppliers

MARKETPLACE INCIDENT MANAGEMENT & REPORTING

When defective product is identified in the marketplace, Unilever follows very rigorous incident management and reporting procedures. Your response to a potential marketplace incident must take the highest priority within your organization.

Marketplace incidents can be identified in one of two ways:

- Unilever receive information from consumers or customers alerting us to a problem, or
- A failure at one of your suppliers, within your manufacturing process or in your distribution system is identified

For the first scenario, you will be contacted by your Unilever Quality first point of contact (referred to as FPoC) or by the Quality manager in the country/business unit affected. You will be asked to initiate an investigation and, depending on the severity of the quality defect, potentially activate your traceability and product recall systems and form a crisis response team. All information must pass through the designated Unilever contact and must not be circulated via any other routes.

In the second scenario, once a quality failure is identified and a potential marketplace incident is recognized, it is essential that you contact your designated Unilever (FPoC) immediately. If this person is not available, you should contact their appointed back up. If unable to reach Unilever in this way, please reach out to your Procurement contact. Unilever personnel will then respond to the information you provide and initiate the incident management process if appropriate.

Unilever personnel will handle the reporting of the incident and lessons learned in QualityOne and any external communications. Detailed investigation of the incident must include the use of root cause analysis methodology to ensure that the cause of the incident has been correctly identified (with sufficient details). The target for completion of investigation and lessons learned is 2 weeks for incidents where consumer or trade recall was required and 3 weeks for other market quality incidents – unless otherwise agreed with Unilever Quality team.

The escalation/incident management process in your organization must be describe in a set of procedures and include the above requirements for the Unilever products.

EMERGENCY CONTACT INFORMATION

Marketplace incident management is dependent on clear, direct and timely communication.
It is essential that emergency contact information in your organization is kept up to date in QualityOne and that you only use the designated Unilever points (FPoC) when dealing with potential incidents.

For each manufacturing site, you must provide a (FPoC) and at least one alternative person who will act as the emergency contacts in the event of a marketplace incident to ensure the incident management process can be activated in a timely fashion. For each emergency contact, you must provide mobile and work telephone numbers and email addresses.

Unilever will also provide their (FPoC) information as well as at least one alternative contact.

D INCIDENT MANAGEMENT & REPORTING

A robust and reliable Quality incident management system is an essential part of your manufacturing controls. A key part of the external audit, Unilever audit protocol and certification process will require you to demonstrate the ability to identify, control and segregate any defective materials, formulations or finished products within your manufacturing process, on the packing floor or in the warehouse.

If defective products are identified during manufacturing or after a production run has been completed & all the defective products is still within your control, this is defined, by Unilever, as a D incident.

All defective finished formulation, consumer units, customer units or palletized units must immediately be identified, segregated.

Ideally, you will have both visual controls (labels, placards, colour coding etc) and system controls in place to ensure this defective product cannot be released for shipment to Unilever.

Any D incident related to Unilever product must be reported by the CM in QualityOne.

EXCEPTION MANAGEMENT & REPORTING

At times, you may produce goods which deviate from the agreed product specifications.

In this instance, you must inform Unilever of the deviation so we can evaluate whether we can accept the deviation or not.

You will be requested to :

- Provide all the details about the product affected (eg. materials, finish good, artwork, spot buying)
- Complete the necessary investigations
- Implement all acknowledged corrective actions to avoid reoccurence.

The Exception must be reported in Quality One.

PERFORMANCE MEASUREMENT & FOCUSED IMPROVEMENT

We have a performance improvement culture which requires a relentless focus on loss elimination. Improvement goals are set with a zero-based vision and mindset – zero incidents, zero defects, zero losses. The quality information generated through the performance monitoring and reporting process forms the basis for identifying improvement opportunities and loss elimination projects.

QUALITY PERFORMANCE REVIEW

It is expected that Quality Performance Reviews will be periodically organized to monitor progress on key indicators and focused improvement projects.
Product quality data from any available system in Unilever or the CM must be used to set the baseline and reduction target (e.g. Incident, Exception, Product complaint, Audit finding..)

FOCUS IMPROVEMENT PROJECT

To protect Unilever brand and keep our consumer safe, any causes of incidents such as – cross packing of product, artwork errors, product contamination, wrong material, incorrect block and release - will require focused improvements.
Any project should be managed through a formal approach using continuous improvement tools (e.g. Kaizen, PDCA, FMEA, 6 sigma, etc.). A good practice would be to nominate a project leader and ensure visibility of progress and performance improvement across your leadership team.

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Author Contacts	Cedric Huet
Evaluator	Denise Webley
Approver	Matthias John; Tracy Burton

Revision History			
Issue Date	Revision Number	Updated By	Reason for Update
January 2016	01	Nurul-Firdaus Ahmad	First issue
December 2016	02	Joisce Cunha	Specific 3PM manual created, Product Verification update, Retain&Samples record update
February 2017	03	Joisce Cunha	Approver name changed
August 2017	04	Lieselotte Roozeveld	Overall update
April 2018	05	Katie Gleave	Terminology change from 3rd Party Manufacturer to Manufacturing Partner
August 2022	06	Cedric Huet	Overall update