



Position on Quality, Safety, and Compliance

Background

A commitment to quality, safety, and compliance is fundamental to Kenvue. Our goal is to meet the high expectations of our customers and consumers and earn their trust by developing high quality, innovative products which are safe, efficacious, and continuously available. By focusing on quality and safety throughout a product's lifecycle, from the early stages of Research and Development, during delivery to customers, and in support of those using our products, we strive to meet our responsibility to put people first.

Our Quality, Safety & Compliance Organization

Our commitment to quality is driven by our Chief Executive Officer, as well as our Chief Operations Officer, Chief Quality Officer, Chief Scientific Officer, and Chief Medical Officer. They are supported by global Quality functions ensuring the quality of our products and that manufacturing standards are met, as well as by a team of Medical Safety professionals who provide a scientific and independent assessment of product safety.

The responsibilities of those teams span throughout all stages of a product lifecycle from research and development phase to commercialization and post-market activities.

All Kenvue employees must contribute to our Kenvue commitment to quality, safety, and compliance, by following laws, regulations and the stringent global Company policies, and procedures we have in place.

Our Position

We maintain our commitment to end-to-end quality excellence and safety across all stages of a product lifecycle through our quality and safety management approach, which is based on the following proactive measures:

- Adherence to Kenvue Quality System Principles;
- Consumer-focused product design;
- Stringent ingredient selection;
- Innovative product development;

- Quality and safety risk management, including continuous monitoring of product safety;
- Process, equipment and product controls including qualification, validation, in-process monitoring, and testing;
- Compliance monitoring through audits and inspections;
- Rigorous procedures for internal communications and notification to management of non-compliance or product concerns;
- Appropriate and timely field action to ensure integrity of marketed products;
- Timely Integration of new acquisitions; and
- Ongoing and consistent enhancement of talent and capabilities through training and education.

Our Policies and Principles: Our Quality System Principles define the requirements that Kenvue must meet to design, make, deliver and monitor the safety of our products, and if needed, take risk minimization actions including in case of quality issues correcting or recalling products from the market. They provide a common foundation for quality and safety systems across Kenvue. The requirements are based on national and international standards such as current Good Manufacturing Practices, International Organization for Standardization (ISO) series, and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Our Quality System Principles apply worldwide, requiring Kenvue to maintain the quality and safety of our products for our customers and to operate in compliance with current regulations while anticipating and preparing for changes in regulations in the future.

Product Design: Quality and safety are built into our products from the very start. Our product design informs the ingredients we use and involves input from our scientific and medical experts to ensure the final product will meet the high bar we have set with our global standards.

Ingredient Selection: All ingredients are carefully selected and must pass stringent safety and quality requirements. We ensure that their quality, purity, and manufacturing meet government regulations, industry standards, and our strict internal policies. In addition, our sourcing and quality assessment teams thoroughly vet our suppliers and only accept vendors that meet our rigorous standards.

Product Development: Beyond design, our products also undergo further development and testing, making sure ingredients are used in the right proportions and any potential issues are addressed before the formula is finalized. Laboratory simulated and home-use tests are also used in the development process and can rely on actual users.

Quality and Safety risk management: Risk management requirements are part of the Kenvue Quality System Principles. They require that quality and safety risks throughout the product lifecycle be identified, assessed, and mitigated or minimized. We are committed to monitoring the safety and quality of our products and have existing systems and appropriate risk minimization strategies in place.

Qualification and Testing: To ensure the final product meets its intended specification, controls are in place. These controls enable consistency and include things like the qualification of equipment used to manufacture products, validation of key equipment and processes, and in-process monitoring to ensure performance meets expectation. Additionally, a testing plan for each product ensures upstream measures are effective.

Compliance monitoring: Kenvue has established an independent audit approach to ensure our facilities and external manufacturing sites operate in compliance with our requirements, as well as global health authority requirements. Our Quality audit program applies to all Kenvue facilities that manufacture, store or distribute product. It also applies to external manufacturers that provide materials, products and services to Kenvue. Through this Quality audit program, we monitor, assess and identify opportunities to continuously improve the effectiveness of our quality systems. Suppliers of Kenvue are audited to ensure compliance to our Quality Agreements and to the regulations under which they operate. The audits are performed by representatives of Kenvue and/or third parties. We monitor product safety information and ensure timely reporting of relevant information to authorities in accordance with legislation.

In addition to our monitoring programs, robust oversight is maintained through appropriate governance which is built into the safety and quality management systems, mandating Kenvue management to review the quality and safety system performance, and to require and oversee improvements where necessary.

Internal communications and notification to management: As part of our Quality System Principles, we maintain Standard Operating Procedures governing notification to management for product safety concerns and quality issues that may arise. We have robust procedures for timely escalation of safety or quality concerns to senior management. This includes additional notification procedures such as external notification to relevant health authorities if required.

Product recall: As required by the Quality System Principles, Kenvue has a formal process to evaluate concerns with the quality of product on the market. The process requires input of leaders from Quality, Medical Safety and Regulatory Affairs. These technical leaders decide, independent of commercial considerations, whether actions need to be taken to correct or recall a product from the market. Consumer safety supersedes any other factor in this decision-making.

Continuous improvement and post-market monitoring for quality complaints and adverse events: We proactively monitor and evaluate our systems, standards, industry landscape and regulatory environment, incorporating changes where necessary to drive continuous improvement. Further, when appropriate, sites develop corrective action plans to systematically improve their quality systems and to prevent a recurrence of any deficiencies.

Once in the hands of our consumers, we are also continuously monitoring our products through consumer feedback and tracking of adverse events, using this information to make refinements and improvements to our products.

Integration of new acquisitions: Consumer safety and product quality are paramount considerations in the Kenvue approach to integrating new acquisitions. We have a well-defined process in place to ensure that when a new business unit joins Kenvue we take

prompt measures to align that quality and safety system to our Kenvue Quality and Safety System framework. Our Quality and Safety teams participate in the due diligence activities during the acquisition process and conduct detailed risk assessments of products, quality and safety systems and processes.

Training and education: Continuous improvement of the skills and capabilities of our team members is essential for ensuring they have the competence needed to perform the requirements of their job in a regulated industry. All Kenvue employees are assigned trainings throughout the year, based on their job responsibilities, and as required by the Kenvue Quality System. This training ensures all associates are knowledgeable of the Current Good Practices (cGxP) requirements for their work.

Health authorities and notified bodies regularly examine these training records during audits. Further, we educate our workforce to develop their skills and capabilities beyond GxP regulatory requirements.

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