Position on quality, safety and compliance

Background

Our commitment to quality, safety, and compliance is fundamental to Kenvue. Our aim is to meet the high expectations of our customers and consumers, earning their trust by developing high-quality, innovative products that are safe, efficacious, widely accessible and in compliance with applicable regulations around the world. By focusing on quality and safety throughout a product's lifecycle – from the early stages of research and development, through delivery to customers, product use, and to the product's end of life in market– we strive to meet our responsibility to put people first.

Our goal is to achieve end-to-end quality excellence and safety across all stages of a product lifecycle through our quality and safety management approach.

Our Quality, Safety & Compliance Organization

Our commitment to safety, quality and compliance is driven by our Chief Executive Officer and our Kenvue Leadership Team. They are supported by global Quality and Medical functions, ensuring the quality and safety of our products and confirming they meet manufacturing standards. Our Medical Safety professionals provide scientific and independent product safety assessments through all stages of a product lifecycle. 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.

Our Position

Our commitment to end-to-end quality excellence and safety is based on the following proactive measures:

- Adherence to Kenvue Quality System Principles
- Consumer-focused and innovative product design and development
- Stringent ingredient selection
- Process, equipment and product controls including qualification, validation, in-process monitoring, and testing
- Rigorous procedures for internal communications and notification to management of non-compliance, product concerns and compliance matters
- Continuous monitoring of product quality and safety and mitigation of identified risks
- Appropriate and timely field actions to ensure safety and integrity of our products
- Compliance monitoring through key performance indicators and audits
- Timely Integration of new acquisitions
- Ongoing, 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 and in the event 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 regulations and international standards such as our 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 around the globe, requiring Kenvue to maintain the quality and safety of our products for all who use them, and to operate in compliance with current regulations as well as anticipating and preparing for changes in regulations in the future.

The ISO 9000 family consists of the world's best-known standard for QMS, including ISO 9001, along with a set of supporting standards on quality management, all published by ISO/TC 176 and its subcommittees. Five of our sites have individual ISO 9001 certifications including Pomezia, Italy; Eastern Cape, South Africa; Bangkok, Thailand; Beijing, China; and Sezanne, France.

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

Our objective is to ensure that the quality, purity and manufacturing of our products meet international, national and local government regulations and industry standards, as well as our internal policies.

To achieve the product quality and safety expected by our consumers and required by international standards, we adhere to the below process:

- **Product Design:** We aim to build efficacious, quality products from the very start. Our product design influences the ingredients we use and involves input from our scientific and medical experts to ensure the final product meets global standards.
- **Ingredient Selection:** All ingredients are carefully selected, tested and must pass safety and quality requirements that comply with international, national and local government regulations, industry standards, as well as our internal policies. In addition, our sourcing and quality assessment teams evaluate our raw material suppliers and contract manufacturers, ensuring we only work with vendors that meet our safety and quality standards.
- **Product Development:** Beyond design, our products also undergo further development and testing to make sure ingredients are used in the right proportions and that any potential issues are addressed before formula finalization.

Laboratory-simulated, clinical studies and home-use tests are used in the development process to assess the product properties and user experience.

- **Qualification & testing:** Appropriate controls are in place to ensure the final products meet intended specifications. These controls enable consistency and include things like the qualification of equipment and instruments used in manufacturing, process validation, and in-process monitoring to guarantee performance meets expectation. Additionally, testing requirements used for each product are in place to provide effective upstream measures.
- **Upholding global standards:** The safety of everyone who touches our products is our first and greatest responsibility. Technical teams conduct safety evaluations on our products before we bring them to the marketplace, ensuring they comply with applicable regulatory requirements everywhere we do business. We work with regulatory agencies worldwide, including but not limited to the U.S. Food and Drug Administration (FDA), the European Medicines Agency, the World Health Organization (WHO), and Health Canada, confirming our products meet high standards.
- **Quality compliance monitoring:** Our Kenvue team has established processes for key performance indicators monitoring and an independent audit approach to ensure our facilities, external manufacturing sites, and internal functions operate in compliance with our requirements, quality agreements as well as global and local health authority requirements. Our Quality Audit Program applies to all Kenvue facilities that develop, manufacture, store or distribute products. It also applies to suppliers and external manufacturers that provide materials, products and services to Kenvue. Through the Quality Audit Program, we continuously monitor, assess and identify opportunities to improve the effectiveness of our quality systems. In addition to our monitoring programs and audits, product quality and safety oversight is maintained through appropriate governance. The safety and quality management system (QMS) requires Kenvue management to review the quality and safety systems performance, and to provide oversight for improvements where necessary.

Our facilities and functions are also subjected to inspections by Health Authorities and Notified Bodies globally.

- **Continuous post-market monitoring for quality complaints and adverse events:** Once in the hands of our consumers, we continue to monitor our products through consumer feedback and tracking of adverse events, product complaints and scientific publications. We then use this information to assess product safety, manage risks, make refinements and improvements to our products. The Medical Safety Council – comprised of senior leaders from Medical Safety, Regulatory and Quality – ensures robust product safety assessments and decisions on the need for risk minimization and overall improvements.
  Regulatory authorities and consumers are informed about new risks and their mitigation. Kenvue ensures the most up to date information is included in our packaging, labelling and monographs.
- **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 recalls:** As required by the Quality System Principles, Kenvue has a formal process to evaluate concerns with the quality of products 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.
- **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 when a new business unit joins Kenvue, we take prompt measures to align their quality and safety systems to our Kenvue Quality and Safety System framework. Our Quality and Safety teams participate in 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 confirming 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 inspections. We also educate our workforce to develop their skills and capabilities beyond GxP regulatory requirements.

Continuous improvement

We proactively monitor and evaluate our systems, standards, industry landscape and regulatory environment, incorporating changes where necessary to drive continuous improvement. When appropriate, sites develop corrective action plans to systematically improve their quality systems and to prevent a recurrence of any deficiencies.