大江生醫股份有限公司
限用與禁用物質政策
TCI Co., Ltd. — Restricted Substances Policy

一、政策聲明

1. Policy Statement

大江生醫致力於管理產品生命週期各階段對消費者健康與安全的影響，涵蓋研發、原料採購、製造、標示、使用至廢棄階段，並持續降低對消費者之潛在健康與安全風險。

TCI Co., Ltd. is committed to managing consumer health and safety impacts throughout the product lifecycle, from research and development, raw material sourcing, manufacturing, and labeling to product use and end-of-life, while continuously reducing potential health and safety risks to consumers.

二、適用範圍

2. Scope of Applicability

本政策適用於本公司研發、採購及生產之原料、包裝材料與成品，以及供應本公司原料、物料之供應商及代工廠。

This policy applies to the raw materials, packaging materials, and finished products researched, procured, and manufactured by TCI Co., Ltd., as well as to suppliers of raw materials and packaging materials and to subcontract manufacturers supplying the Company.

三、遵循法規

3. Regulatory Compliance

本公司產品檢測標準對齊主要國際法規及客戶要求，包括：

TCI Co., Ltd.'s testing standards are aligned with major international regulations and customer requirements, including:

- 歐盟 REACH 法規 — **避免使用 REACH 候選清單（依 ECHA 最新公告）所列之高度關注物質（SVHC）**
- EU REACH — **avoiding the use of Substances of Very High Concern (SVHCs) on the REACH Candidate List, as published and updated by ECHA**
- 歐盟化粧品法規 (EC) No 1223/2009
- EU Cosmetics Regulation (EC) No 1223/2009
- 各銷售市場（歐洲、美國、台灣、中國、東南亞等）當地食品、保健食品與化粧品法規
- Local food, health supplement, and cosmetics regulations in all sales markets, including Europe, the United States, Taiwan, China, and Southeast Asia etc.
- 歐盟 RoHS 指令 — 參照其所列限用物質，作為原物料及包裝材料有害物質管控之參考基準
- EU RoHS Directive — referencing its restricted substances as a benchmark for hazardous substance control in raw materials and packaging materials
- 歐盟包裝與包裝廢棄物法規（PPWR）
- EU Packaging and Packaging Waste Regulation (PPWR)
- 各銷售市場之全氟及多氟烷基物質（PFAS）相關限制 — 詳見第六條
- Restrictions on per- and polyfluoroalkyl substances (PFAS) in all sales markets — see Section 6

四、供應商義務

4. Supplier Obligations

1. 提供原料規格書、原產地證明及分析證明書（COA）。
   Provide raw material specifications, certificates of origin, and Certificates of Analysis (COAs).
2. 原料須接受重金屬、微生物及農藥殘留檢測。
   Raw materials are subject to testing for heavy metals, microorganisms, and pesticide residues.
3. 提供安全資料表（SDS）。
   Provide Safety Data Sheets (SDS).
4. 依《供應商行為準則》落實危險物質標示與安全操作程序。
   Implement hazardous materials labeling and safe operating procedures in accordance with the Supplier Code of Conduct.
5. 依本公司供應商評鑑管理程序接受初評、風險分級、永續審查、年度複評及稽核。
   Undergo initial evaluation, risk rating, sustainability review, annual re-evaluation, and audits in accordance with the Company's Supplier Evaluation Management Procedure.
6. 包裝材料供應商應提供符合適用包裝法規要求之符合性聲明或第三方檢測報告。
   Packaging material suppliers shall provide declarations of conformity or third-party test reports demonstrating compliance with the applicable packaging regulations.

五、內部管理機制

5. Internal Management

- 依 HACCP 建立關鍵管制點（CCP），實施 GMP、過敏原管理與無塵室管控。
- Establish Critical Control Points (CCPs) in accordance with HACCP requirements, and implement GMP, allergen management, and cleanroom controls.
- 依《品質風險管理程序》與《驗證管理程序》管理全生命週期產品品質風險。
- Manage product quality risks throughout the product lifecycle in accordance with the Quality Risk Management Procedure and the Validation Management Procedure.
- 維持 HACCP、ISO 22000、GMP 等關鍵品質與食品／化粧品安全認證之有效性。
- Maintain the continued validity of key quality and food/cosmetics safety certifications, including HACCP, ISO 22000, and GMP.
- 目標：產品因品質或安全問題之召回件數為零、重大消費者健康安全事件為零。
- Targets: zero product recalls due to quality or safety issues, and zero major consumer health and safety incidents.

六、**PFAS** 管理

6. PFAS Management

- 本公司之原料、配方及包裝材料不得刻意添加 PFAS。
- PFAS shall not be intentionally added to the Company's raw materials, formulations, or packaging materials.
- 食品接觸包裝符合各銷售市場適用法規所定之 PFAS 限值。
- Food contact packaging complies with the PFAS limits laid down by the regulations applicable in each sales market.

- 持續追蹤歐盟及美國各州 PFAS 相關法規之發展，並據以調整管控措施。
- Continuously monitor developments in PFAS-related regulations in the EU and in individual US states, and adjust control measures accordingly.
- 供應商應提供 PFAS 未刻意添加聲明，必要時提供第三方檢測報告。
- Suppliers shall provide declarations that PFAS are not intentionally added and, where necessary, third-party test reports.

七、清單更新與替代

7. List Review and Substitution

本公司每年檢視限用與禁用物質清單，依國際法規修訂、客戶要求及科學證據更新，並對已列管物質評估可行替代方案。

The Company reviews its restricted and prohibited substances list annually, updating it in line with international regulatory amendments, customer requirements, and scientific evidence, and evaluates feasible alternatives for listed substances.

八、違規處理

8. Non-compliance

發現原料或產品含有限用或禁用物質時，啟動客戶申訴處理程序（七個工作日內回覆），必要時執行產品召回及召回演練，並要求供應商提出矯正措施。

Where restricted or prohibited substances are identified in raw materials or products, the Company initiates the Customer Complaint Handling Procedure with a response provided within seven working days, conducts product recalls and recall drills where necessary, and requires suppliers to submit corrective actions.

九、相關文件

9. Related Documents

- 大江生醫集團供應商行為準則
- TCI Group Supplier Code of Conduct
- 供應商評鑑管理程序
- Supplier Evaluation Management Procedure
- 品質風險管理程序
- Quality Risk Management Procedure
- 驗證管理程序
- Validation Management Procedure
- 客戶申訴處理程序
- Customer Complaint Handling Procedure