

**STATEMENT ON CONFIDENTIALITY ARRANGEMENTS BY
THE EUROPEAN FOOD SAFETY AUTHORITY
TO FACILITATE THE SHARING OF NON-PUBLIC INFORMATION
WITH THE
UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The European Food Safety Authority (EFSA) of the European Union (EU) founded under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 which under Article 38 and 39 regulates the dissemination and protection of information, is authorised to share non-public information with the United States Food and Drug Administration, Department of Health and Human Services (FDA/HHS).

EFSA is pleased to facilitate the sharing with FDA/HHS of non-public documents and/or information related to products or substances that are in the field of competence of both EFSA and FDA/HHS.

EFSA understands that some of the information it receives from FDA/HHS may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information.

The term “confidential commercial information” includes information referred to in the US Freedom of Information Act, 5 U.S.C. §552(b)(4).

In the European Union, the basis and grounds for exemptions from public disclosure are laid down in Regulation (EC) No. 1049/2001 of the European Parliament and of the Council regarding public access and include:

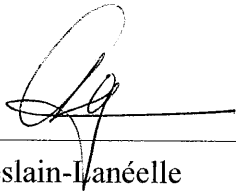
1. Commercial interests of a natural or legal person, including intellectual property;
2. Privacy and integrity of individuals notably as regards protection of personal data;
3. Internal decision-making and preliminary consultations;
4. Court proceedings and legal advice; and
5. The European Union or EFSA’s public interests, international relations, or financial interests.

EFSA notes that it is an essential element of sharing information that confidential information emanating from FDA/HHS be treated as such. EFSA understands that FDA/HHS considers it crucial that this non-public information be protected from disclosure.

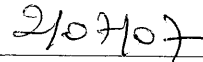
EFSA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives in confidence by FDA/HHS, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No. 1049/2001 and other applicable laws.

EFSA will inform FDA/HHS promptly of any judicial initiative to obtain FDA/HHS-provided non-public information from EFSA. In the event of a court order to disclose FDA/HHS-provided non-public information, EFSA will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

EFSA will promptly inform FDA/HHS of any changes to laws, policies, or procedures that would affect EFSA's ability to honor the commitments in this document.



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Date