MEMORANDUM OF UNDERSTANDING

between

Health Products Regulatory Authority

and

Food Safety Authority of Ireland

CONCERNING COOPERATION IN THE REGULATION OF PUBLIC HEALTH

1. BACKGROUND

The **Food Safety Authority of Ireland ('FSAI')**, established by the Food Safety Authority of Ireland Act, 1998, as amended, and the **Health Products Regulatory Authority ('HPRA')**, established by the Irish Medicines Board Acts 1995 and 2006, as amended, (hereinafter referred to as the "Participants") wish to establish a framework for cooperation in the area of the regulation of public health in Ireland.

2. OBJECTIVES

The objectives of this Memorandum of Understanding ('MOU') are:

a. to promote an understanding between the Participants of each other's regulatory framework, requirements and processes;
b. to facilitate the exchange of information and documentation relating to areas of common interest;
c. to encourage the development of collaborative activities between the Participants; and
d. to enhance the ability of the Participants in the provision of their services relating to or in connection with public health, to meet the needs of the public.

This MOU represents the understanding reached by the Participants, in particular:

a. that each Participant has jurisdiction over different areas of regulation;
b. this MOU is intended to cover areas of common interest or where co-operation will lead to better informed regulation; and
c. each Participant may, in particular circumstances, limit the scope of disclosure of information to the other Participant particularly if the disclosure may be prejudicial to the commercial or other interests of a third party, breach the duty of confidence or privacy, disclose a trade secret, is contrary to the public interest or the interests of the Participant concerned, would be in breach or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by law.

3. DEFINITIONS

In this MOU the following definitions shall apply:

a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

b) "medicinal product" means (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting or modifying pharmacological, immunological or metabolic action, or to making a medical diagnosis.

4. AREA OF COOPERATION

The Participants having reached the above understanding will:

a) establish avenues of communication to facilitate the exchange of information in situations where either Participant comes across information which could be considered relevant to the other Participant's role, including but not limited to:
   i. information obtained by the HPRA in relation to the improper manufacture, supply, sale, use or advertisement of a product which may fall within the definition of food supplement or which may indicate a breach of food or food supplement legislation enforced by the FSAI
   ii. information obtained by the FSAI in relation to the improper manufacture, supply, sale, use, or advertisement of a product which may fall within the definition of a medicinal product or which may indicate a breach of medicinal product legislation enforced by the HPRA;

b) establish avenues of communication with each other to facilitate the exchange of information about their respective fields of regulation and operation of their organisations; and

c) undertake collaborative activities consistent with this MOU.

5. CONFIDENTIALITY

a) HPRA

i. Nothing in this MOU requires the HPRA to release confidential information to the FSAI, except in accordance with law.

ii. Unless otherwise required by law, the HPRA will not disclose any information received from the FSAI under this MOU, except with the written consent of the FSAI. If disclosure is required by law, the HPRA will take all reasonable measures to ensure that the information received from the FSAI will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

iii. Unless otherwise required by law, the HPRA will not use the information disclosed to it under this MOU for any other purpose than the performance of its regulatory activities.

b) FSAI

i. Nothing in this MOU requires the FSAI to release confidential information to the HPRA, except in accordance with law.

ii. Unless otherwise required by law, the FSAI will not disclose any information received from the HPRA under this MOU, except with the written consent of the HPRA. If disclosure is required by law, the FSAI will take all reasonable measures to ensure that the information received from the HPRA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

iii. Unless otherwise required by law, the FSAI will not use the information disclosed to it under this MOU for any other purpose than the performance of its regulatory activities.

6. DATA PROTECTION

Each Participant confirms that any sharing of personal data between them is solely done to the extent necessary for the purpose of performance of their respective regulatory functions and that such personal data as may be shared are protected by each Participant in accordance with all applicable data protection legislation.

7. FINANCIAL ARRANGEMENTS

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

8. VARIATION

Any provision of this MOU may be amended at any time by the mutual consent in writing of the Participants via the respective signatories.

9. STATUS OF MEMORANDUM OF UNDERSTANDING

This MOU reflects the intentions of the Participants. It is not intended to create legal obligations of any nature, either in domestic or international law. The Participants will however observe and give due respect to the confidentiality undertakings which they have expressed in this MOU.

10. EFFECTIVE DATE

This MOU will come into effect upon the date of signature of both signatories and will continue in effect until terminated in accordance with clause 11.

10. AGENCY CONTACT

The liaison officers responsible for the administration of this MOU are:

a) for the HPRA, the person holding the position of Deputy Chief Executive; and

b) for the FSAI, the person holding the position of Director of Risk Management and Regulatory Affairs.

11. TERMINATION

a. Either Participant may, at any time, give written notice of termination to the other Participant. This MOU (excepting clause 5) will terminate six months after the date of receipt of the notice of termination.

b. The termination of this MOU will not affect the confidentiality undertakings expressed by the Participants in this MOU and any commitments given under or as a consequence of this MOU in respect of any arrangement or action taken during the period before the termination takes effect.

Signed in Dublin

on this day of 2018

by Lorraine Nolan, Chief Executive, the Health Products Regulatory Authority

on this day of 2018

by Pamela Byrne, Chief Executive, the Food Safety Authority of Ireland