Meeting

Matters Arising: Letter from Council for Responsible Nutrition and background information on the regulation of food supplements

This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

Introduction

1. The Council for Responsible Nutrition, a trade association representing manufacturers and suppliers of food supplements have contacted the COT Secretariat expressing concerns about the minutes from the May 2023 meeting. This relates to an item on novel formulations of supplements and the minutes state that “supplements exist in a “grey space”, Members suggested, where they are claimed to promote some benefit but do not make direct health claims and hence are currently not covered by specific legislation”. The letter from the CRN is attached at Annex A to this paper.

2. Background Information on the regulation of food supplements is given below.

Regulation of food supplements

3. Food supplements are defined in law as 'any food the purpose of which is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination and is sold in dose form'.

4. Food supplements are intended to correct nutritional deficiencies, maintain an adequate intake of certain nutrients, or to support specific

physiological functions.

5. There is no requirement for food supplements to be authorised. If marketed as a food supplement, products must bear the words “food supplement”, and meet supplements labelling requirements, that include details of the daily dose, a warning not to exceed the dose and a warning about storing them out of the reach of children.

6. Food supplements is a complicated policy area with health claims, medicinal claims and safety all sitting with different Government departments. UK food supplements legislation is implemented on a devolved basis. Responsibility for policy lies with the Department of Health and Social Care (DHSC) in England, Welsh Government in Wales, Food Standards Scotland in Scotland and in Northern Ireland the FSA (supplements rules as applied to food business operators) and the Department of Health (population health and messaging, e.g., advice to pregnant women on folic acid supplementation). The FSA leads on food supplement safety across England, Wales and Northern Ireland.

7. Nutrition and health claims in Great Britain are the responsibility of DHSC and there is a register of approved nutrition and health claims, with the UK Nutrition and Health Claims Committee (UKNHCC) reviewing new claims. Claims deemed to be medicinal would be the responsibility of the Medicines and Healthcare Regulatory Agency (MHRA)

8. Food supplements legislation is enforced by local authorities. The FSA as the central competent authority for food and feed receives notifications of food incidents and requests for advice from consumers, local authorities, teams across the FSA, DHSC, MHRA, and many other organisations.

9. The FSA has a policy team which leads on food supplement safety across the FSA, to protect public health, to ensure products are compliant with supplements legislation and that enforcement is carried out consistently and in a targeted manner. The FSA provides risk management advice when products are deemed unsafe (containing excess levels of certain ingredients, or which contain ingredients that are not meant to be present) or are inadequately labelled, which may lead to products being withdrawn or recalled from sale. This is largely on a largely reactive basis.

10. The FSA policy team receives over 200 food supplements enquiries from across England, Wales and Northern Ireland per year on average. These include requests from businesses based abroad who wish to trade in the UK, enquiries

from UK businesses and from local authorities and other agencies reporting incidents or forwarding referrals that sit within the FSA.

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11. The discussion at the May meeting related specifically to the complicated issue of the criteria required for a product to be classified as medicinal, as well as the deciding factors when determining the status of a product (pages 6 and 8 of the MHRA Guide to what is a medicinal product). This allows the sale of products that contained substances with known history of use in traditional medicine that do not meet these criteria, however, make claims of "improvement of wellbeing" to be placed on the market as food supplement, for which currently there is no need for authorisation.

12. Further, there is the additional issue of the status of food supplements active ingredients as novel foods, resulting in the placement of the market of food supplements that contain unauthorised novel foods. Under Retained Regulation (EU) 2015/2283 on Novel Foods, a supplement is considered novel if there is lack of evidence of a significant history of consumption in the UK or EU, prior to 15 May 1997, and it would need to undergo a mandatory pre-market safety assessment and authorisation under the Novel Foods Regulation before they can be legally placed on the market in Great Britain. Additionally, an extract may be novel depending on its composition and whether through consuming it, consumers' exposure to components in the extract is increased compared to the source material. If the product has been modified compared to its recognised use, this may result in a lack of a history of consumption, resulting in it being considered novel.

Questions for the Committee

13. The COT is invited to consider the information presented in the letter from CRN and the supplementary information provided in this paper.

a) Do Members wish to reconsider the wording in the minutes of the May 2023 meeting?

b) Do Members have any questions or comments on the information in this paper?

Secretariat

December 2023