ANNEX V

ANNEX III

ACAF/00/12

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

Fourth ACAF Meeting 4 May 2000 - information paper

PROCEDURES FOR MARKETING HERBAL AND HOMEOPATHIC PRODUCTS AND FUNCTIONAL FOODS FOR HUMAN CONSUMPTION

Secretariat April 2000

PROCEDURES FOR MARKETING HERBAL AND HOMEOPATHIC PRODUCTS AND FUNCTIONAL FOODS FOR HUMAN CONSUMPTION

Introduction

1. At the third ACAF meeting on 2 March members discussed briefly the use of herbs and homeopathic additives in animal feed. It was thought that information on the use of these sort of products for human consumption would help inform the debate and the Secretariat was requested to prepare an information paper. The purpose of this paper is to outline existing legislation affecting and controls over the marketing of herbal and homeopathic products and functional foods for human consumption. A separate paper has been prepared by the Veterinary Medicines Directorate on animal feed aspects as ACAF/00/18.

Homeopathic and Herbal Supplements

2. Homeopathic and herbal products used for human consumption are usually described as 'food supplements' or 'dietary supplements'. While most products described as such are regulated as foods, some are classified as medicines.

Medicines

3. Products for which claims are made for the treatment or prevention of disease, or which are administered to restore, correct or modify physiological functions, fall within the definition of a medicine and are subject to the requirements of the Medicines for Human Use (Marketing Authorisation etc.) Regulations 1994, the Medicines Act 1968 and Medicines Directive 65/65/EEC. Such products normally require a marketing authorisation (i.e. a licence) before they can be sold or supplied.

Foods

4. Those supplements which are considered to be foods are normally subject to the general provisions of the Food Safety Act 1990, and subsidiary legislation (see below). There is no requirement in this legislation for supplements to be approved or notified prior to their being put on the market and the responsibility for ensuring that they comply with the law rests with the importer or distributor. However, if a supplement contains any substance that has not been consumed to a significant degree in the European Community prior to May 1997, it will be subject to the requirements of the EC Novel Food and Novel Food Ingredients Regulations (258/97). This regulation is enforced in the UK by the Novel Foods and Novel Food Ingredients Regulations 1997 (SI 1997 No. 1335).

These regulations require that novel foods or novel ingredients in foods are subject to an EC wide pre-market safety assessment.

5. The Food Safety Act makes it an offence to sell food which is:

   i) injurious to health

   ii) not of the nature, substance and quality demanded

   iii) unfit for human consumption

   iv) misleadingly or falsely labelled.

6. Dietary supplements are also subject to the general provisions of the Food Labelling Regulations 1996 (SI 1996 No 1499) except for the general nutrition labelling requirements. There are specific requirements that must be met if a vitamin or mineral claim is made. These are listed in Schedule 6, part 2, paragraphs 4 and 5. General claims and descriptions are also subject to the Trade Descriptions Act 1968.

Functional Foods

Definition of a functional food

7. The link between diet and health is now well established and this has resulted in the development and launch of an increasing number of products that claim to provide a specific health benefit. The term "health claim", and specific criteria for individual health claims, are not defined in law. However, for working purposes, the Food Standards Agency consider that health claims are any statement, suggestion or implication in food labelling or advertising that a food carries a specific benefit, but not including nutrition claims nor medicinal claims. Health claims include claims which refer to nutrient function (e.g. "contains calcium for healthy teeth and bones") and to recommended dietary practice (e.g. "use as part of low sodium diet").

Legislative control

8. Manufacturers must comply with the general provisions of the Food Safety Act 1990 and the Food Labelling Regulations 1996 (as amended). The Act prohibits false or misleading claims and the Regulations contain more detailed rules. These detailed rules prohibit claims that a food has the property of preventing, treating or curing a human disease or any reference to such a property. Claims which relate to the effect of a food, or its components, on the body (e.g. "can aid digestion") are generally permitted provided they are true and not misleading. Local authorities are responsible

for the enforcement of these rules. Like most other types of foods, foods carrying health claims/functional foods are not required to be approved or licensed unless they are genetically modified or are "novel."

Voluntary control

9. It is generally agreed internationally that specific regulation of health claims is desirable both to protect consumers and to promote fair trade. In the UK a self regulatory Code of Practice On Health Claims, which will define good practice and establish a system for the validation of claims, is being developed. The Code which is being developed by the Joint Health Claims Initiative (JHCI), an alliance between industry, consumer groups and law enforcement bodies, is expected to be published in the autumn. The JHCI will be administered by the Leatherhead Food Research Association and funded by industry. Decisions will be taken by a Council with tripartite representation advised by an expert panel. The Council which will establish a list of acceptable 'generic' claims available for use by all companies and assess the validity of proposed new product specific claims.

International Control

10. International agreement is considered the most appropriate way forward to ensure products on our shelves follow a common standard. The Codex Alimentarius programme on food standards (jointly sponsored by the World Health Organisation and the Food and Agriculture Organisation) is developing definitions, conditions for use and scientific criteria for the validation of health claims, and the UK are urging the European Commission to use areas of consensus reached in this forum as the basis for Community policy. In its White Paper on Food Safety, the Commission indicated that it intends to develop rules for health claims, including functional and nutrient content claims; discussions on these issues are at a very early stage, and the Commission is not expected to issue draft proposals before July 2001.

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