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Your reference
Our reference

1 February 1990

Mr R Roscoe
Consumer Affairs
Department of Trade and Industry
13-18 Victoria Street
London SW1

Dear Richard

USE OF BOVINE OFFAL IN COSMETICS

I am replying to your request for advice on the safety of the use of extracts of bovine offal in certain cosmetics, such as skin products claimed to have 'anti-ageing' properties with respect to bovine spongiform encephalopathy (BSE). As you are aware there are a number of cosmetic products on sale in the UK that contain small amounts of such extracts, primarily from spleen and thymus.

We accept that the risk of transmission is likely to be remote, but believe that it would be prudent to eliminate any risk by reformulating such products. Alternatively if the incorporation of bovine extracts is retained, material derived from cattle reared outside the UK, Eire or the Channel Islands should be used.

We would be grateful if you would transmit these recommendations to industry via the Trade Association CTPA.

I attach background briefing prepared by medical colleagues from those sections most involved with consideration of BSE in DH, together with a copy of the Southwood report.

Please let me know if you need any further information.

Yours sincerely

R. J. Fielder

DR R J FIELDER

Enclosure

Y 90/2.1/7.1

BACKGROUND BRIEFINGPresence of Bovine Offals in Cosmetics and Bovine Spongiform Encephalopathy

(1) Extracts of bovine spleen and thymus are present at between ca 0.1 and 5% in certain cosmetic preparations, for example certain products claimed to delay the signs of ageing of skin. The concern about the increasing incidence of BSE in cattle in the UK has made it necessary to reconsider the safety of such products.

The disease

BSE is a progressive neurological disorder in cattle, which results from infection with an "unconventional viral" agent. The first case was described in cows in 1986. By 19 January 1990 there had been 9436 confirmed cases in the UK on 5474 farms. There are no confirmed cases outside the British Isles, apart from a case in a cow recently exported from England. BSE is one of a family of spongiform encephalopathies which also include scrapie in sheep and kuru and Creutzfeldt Jakob disease (CJD) in man. The infection which leads to BSE appears to have been introduced into cattle from the contaminated feeding stuff, meat and bone meal, made partly from sheep offal: scrapie is endemic in sheep in the UK.

The causative agents of these diseases are thought to be unconventional transmissible agents (referred to variously as prions, virinos, filamentous viruses or slow viruses). They are extremely resistant to most denaturing processes eg heat, UV, high salt concentration, formalin and alkylating agents. The current DH guideline for treating items used on CJD patients is a temperature of 134-138 C (at 2 atmospheres) held for 18 minutes. They are also not removed by normal microbiological filters. It is thus unlikely that the mild processing techniques used to obtain the extracts used in cosmetics would remove the causative agents.

(2) Government action to date includes:

a. An expert working party was set up under Sir Richard Southwood and reported in February 1989. All their recommendations have been acted upon.

b. The disease has been made notifiable in cattle.

c. All suspect animals are slaughtered and carcasses destroyed (50% compensation policy but 100% if diagnosis not confirmed); milk from such animals is also destroyed.

d. Sale or supply of animal protein from ruminants for feeding to ruminants prohibited - hopefully to prevent any new infections in cattle. This has had a major effect on the rendering industry.

e. Another committee was set up under Dr David Tyrrell to report on research needs. An interim report was published in January 1990 together with an announcement about additional funding. Much research work into the disease is currently in progress and additional studies are being planned.

f. Regulations in November 1989 introduced a ban on various

bovine offal for human consumption, going wider than the Southwood recommendations which were for such a ban to affect baby food only.

g. The Medicines Control Agency have gathered information from pharmaceutical companies about use of bovine ingredients in parenteral pharmaceuticals and issued interim guidelines. Many biological products and vaccines use such ingredients. The MCA are considering whether action on specific products is appropriate.

h. The Health and Safety Executive (HSE) is reviewing its guidance to those who come into direct contact with bovine "risk" tissues. A press release for those who handle BSE carcasses has been issued and one for abattoir workers is in preparation. The HSE are also discussing risks from BSE exposure with the veterinary profession.

i. All UK^c cases of CJD will be monitored in a study to be conducted by Dr R G Will in Edinburgh, funded by the Department of Health: this should allow detection of any spread of infection to hummans, although this possibility is considered remote.

(3) Current live issues

Research: Dr Tyrell's interim report identified a large research programme classed as high priority. Almost all of this research falls to MAFF (Central Veterinary Labs) or the AFRC, although the MRC also has an interest. Substantial money has been made available for this work but research will be laborious and results will come slowly.

Food: There has been constant pressure on MAFF about the supposed risk to humans from eating beef and beef products. Infected animals who are incubating the disease but do not show any abnormalities cannot be detected at present and will be entering the human food chain. The offal ban removes the highest "risk" tissues. Some critics may not be satisfied by this. However, others may argue the action to date is over the top, not demanded by the experts, and illogical since scrapie-infected sheep can still be eaten and doing so for the last 200 years has not caused harm to humans. We expect BSE agent to be resistant to irradiation as applied to food, as well as relatively resistant to cooking.

Other animals: There is no evidence that animals other than cattle (and domesticated deer) have been or could be affected by BSE, other than experimentally, but there are pressures to extend the ruminant protein ban: at present pigs and poultry receive this sort of feed. Such action, as well as being hard to justify scientifically, would increase costs for the industry and cause perhaps insurmountable problems for abattoirs, who would find renderers no longer willing to accept offal. Many 1000's of tons of offal need to be disposed of daily.

Compensation: This has been set at 50% for BSE, although for some other diseases it is higher. Some critics believe this encourages evasion, with cows affected minimally being sent for human consumption. Even the current level of compensation is proving expensive for MAFF.

Exports: Some foreign countries have banned British exports of semen, embryos and livestock. The EC now no longer accepts live cattle over 6 months of age. The Germans are creating difficulties over beef exports too. The EC are also considering making BSE

notifiable and banning ruminant protein feeding to ruminants, as we have done here. At present, British meat and bone meal can still be exported and might spread infection overseas (MAFF claim importers have been warned that it is not regarded suitable for feeding to ruminants).

Human transmission: There are some in the media and even the medical profession who are trying to make connections between BSE and the human disorder CJD. There is no evidence of any association nor would we expect any cases by now even were BSE to be transmissible to humans. Dr Wills' study (see 2i above) will monitor the situation for the next decade or two.