Doc 25

Dr E Wight

From: Dr Fielder HEF4

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cc: Dr R Skinner
Mr M Skinner
Ms Mulhill
Also issued to DTI (Marion Payne CIV)

USE OF BOVINE MATERIAL IN COSMETICS

I agreed to update you on the position regarding the use of bovine material in cosmetics.

As you know this is an on-going area which has proved slow to progress at the regulatory level, since we are department on decisions being taken on the Cosmetics Directive by the EC Working Party on Cosmetics (DTI lead and we provide support relating to the health effect of chemicals). They in turn are dependent on receiving expert advice from the CECs Scientific Committee on Cosmetology (SCC) established under the terms of the Cosmetics Directive to advise on safety issues.

There are 2 types of product under consideration, and which we discussed in detail with the Cosmetic, Toiletry and Perfumery Association (CTPA) in 1991-3.

There were a few 'up-market' products sold as 'anti-aging' skin creams and containing bovine extracts of particular concern (spleen, thymus, perhaps placentas). These were invariably produced by French, US or Swiss companies and used material that was not sourced in the UK, Eire or the Channel Islands. The 2nd type of ingredient was the widely used materials gelatin, tallow, and proteins such as collagen, keratin and elastin. These materials will have been prepared using heat or acid treatment and are of low concern.

The issue was raised by the UK at a meeting of the EU Working Party on Cosmetics in 1993 and referred to the SCC. They were provided with data from the French and German authorities.

Since this area is covered by an EU Directive (implemented in the UK by the DTIs Cosmetic Products Safety Regulations) we would have difficulty in taking any unilateral regulatory action. However, industry (CTPA) issued guidelines to all member companies in 1992 and 1994 on the use of bovine and ovine extracts in cosmetics products. This was essentially based on advice originally produced by the French government and was particularly concerned with the source and processing of the bovine products (copy attached).

At the end of 1994 the SCC issued a statement on this issue namely 'since animal extracts may be contaminated with the causative agent of BSE, materials with the potential of transmitting such agents should not be used in cosmetics!

This was considered at a meeting of the EU Working Party on Cosmetics in February 1995 when the Commission stated that it was unclear whether such a statement could be used as a basis for any alteration of the cosmetics directive but added that the SCC were working on more detailed proposals (based on original proposals made by Professor Dony (Belgium) and in line with the French proposals from their Senior Health Council, which we consider generally acceptable, and more complex proposals from Germany.

The SCC have not provided any further report to date.

The situation is still therefore that there are no regulatory controls on the use of bovine products in cosmetics but the UK trade association has issued guidance to all members (based on original proposals by the French government). At the EU level the matter is being considered by the Scientific Committee on Cosmetology who advise on scientific aspect of the Cosmetics Directive (76/768/EEC).

I hope this is of some help.

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PROCEDURES WHICH REMOVE OR INACTIVATE AGENTS CAUSING SPONGIFORM ENCEPHALOPATHIES

Removal and inactivation procedures contribute to the reduction of the risk of infection. Their effectiveness in removing infectivity during a given production process must be tested and validated using appropriate model systems (presently: animal infection experiments).

Whereas none of the following procedures may guarantee complete inactivation of the infectious agents, the efficiency of the first three methods on this list is considered greatly superior to that of the remaining ones:

- autoclaving at appropriate conditions (recommended parameters are 134–138°C for 18 minutes for porous-load autoclaving, and 132°C for one hour for gravity-displacement autoclaving);
- treatment with sodium hydroxide (preferably: 1 N solution, for 1 h at 20°C);
- treatment with sodium hypochlorite (preferably: solution containing at least 2% available chlorine, for 1 h at 20°C);
- autoclaving at shorter times and/or lower temperatures than those given above;
- extraction by organic solvents (use the organic phase);
- removal of protein by precipitation, ultracentrifugation or absorption;
- preparation of filtrates by passage through 10-nm-filters;
- passage through appropriate chromatographic columns (before reusing treat columns for 4 h with at least 0.1 N sodium hydroxide);
- treatment with 6M urea (6).

RELATIVE SCRAPIE INFECTIVITY TITRES IN TISSUES AND BODY FLUIDS FROM NATURALLY INFECTED SHEEP AND GOATS WITH CLINICAL SCRAPIE(*)

CATEGORY I	
High infectivity	brain, spinal cord, (eye)
CATEGORY II	
Medium infectivity	ileum, lymph nodes, proximal colon, spleen, tonsil, (dura mater, pineal gland, placenta), cerebrospinal fluid, pituitary, adrenal
CATEGORY III	
Low infectivity	distal colon, nasal mucosa, sciatic nerve, bone marrow, liver, lung, pancreas, thymus
CATEGORY IV	
No detectable infectivity (**)	blood clot, faeces, heart, kidney, mammary gland, milk, ovary, saliva, salivary gland, seminal vesicle, serum, skeletal muscle, testis, thyroid, uterus, foetal tissue, (bile, bone, cartilaginous tissue, connective tissue, hair, skin, urine)

(*) Tissues in brackets were not titrated in the original studies[1-3], but their relative infectivity is indicated by other data on spongiform encephalopathies. Materials not listed may be classified by analogy to those mentioned on the basis of their composition.

(**) No infectivity was transmitted in bioassays involving inoculation of up to 5 mg tissue into rodent brains.

GUIDELINES ON THE USE OF BOVINE AND OVINE EXTRACTS IN COSMETIC PRODUCTS

Outbreaks of Bovine Spongiform Encephalopathy (BSE) in animals have raised questions in the scientific world as to its role in the origin of the related human condition, Creutzfeld-Jacob disease, although transmission has not been demonstrated by the oral or cutaneous route. Additionally, the question of a species barrier limits direct transmission.

Experience with BSE has shown that a rare disease can spread under certain conditions, and it is necessary to take general precautions.

Although cosmetic products are generally applied on healthy skin, the Council considers that the risk of infection from cosmetic products on broken skin is of the same order of magnitude, for the same infecting dose, as the risk from ingestion. For example, in animal models with sub acute Spongiform Encephalopathies, in order to obtain an equivalent effect to one unit by the intracerberal route, it needs 25,000 by the sub-cutaneous route and 40,000 by the oral route.

Tallow, used mainly in toilet soaps and hard soaps, is produced as part of the rendering process of animal tissue. Tallows are filtered at the rendering plant to remove protein and other impurities and then subjected before use to further processing (eg, tallow used in cosmetics such as lipstick undergos a process of 250°C/30 minutes at 50 atmospheres - enough to destroy the BSE agent). This means that tallow is not a risk for human or animal health, a view endorsed by the World Health Organisation.

The Association recommends that for use in cosmetic products, bovine extracts can be supplied by countries exempt from outbreaks of BSE (or where only sporadic outbreaks are known) on condition that these countries have veterinary control with effective veterinary surveillance, and that the consumption of feed supplements is controlled and regulated.

In the absence of such a guarantee, the following can be used:

(a) Either bovine or ovine extracts conforming to class IV of the WHO,

(b) Bovine and ovine extracts from animals less than 6 months old.

(c) Bovine and ovine extracts conforming to classes I, II and III of the WHO, on condition that the supplier uses processes known to inactivate or reduce infection, such as those given by the WHO for the protection of public health concerning BSE, or other valid procedures.

Attached: WHO classification system.

Procedures which remove or inactivate agents causing spongiform encephalopathies.

IMP/bjh
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