8. Cosmetics and toiletries

Introduction

8.1 In this chapter we consider the Government’s response to the risks posed by the use of bovine material in cosmetics. Cosmetics, as defined by the Cosmetics Products (Safety) Regulations 1996, include:

any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.936

8.2 Cosmetics using bovine materials fell into three categories: (i) products using lightly treated high-risk bovine offals: ‘exotica’; (ii) standard topically applied products using heavily processed bovine by-products; and (iii) implants using bovine collagen.

Exotica

8.3 Concern about a risk of possible BSE contamination focused mainly on those cosmetic products commonly described as ‘exotica’. These included ‘premium priced facial skin care products’ such as certain anti-ageing and anti-wrinkle creams. There was no ban on the use in them of animal material such as ‘cellular extracts’ that was deemed an unacceptable risk in food and medicines, and accordingly proscribed under the food safety and medicines safety legislation. Such material might be only lightly processed or simply chilled. Possible ingredients identified relatively early on were gangliocides extracted from the brain; and placental material, spleen and thymus.937

Standard topical products

8.4 Although never considered a serious risk, questions were also raised about how to ensure the safety of more standard cosmetic products. These included the full range of topically applied cosmetics, ie, creams and toiletries applied to the skin, lips and eyelids, and included soaps, skin creams, shaving sticks and stick deodorants. Many of these used heavily processed bovine by-products such as collagen, elastin, gelatine and tallow derivatives.938

936 L9 tab 7 p. 3
937 S407 Kelly para. 10; YB90/1.00/5.1
938 S407 Kelly para. 10
Collagen implants

8.5 Concern was also expressed about bovine collagen used in implants. Although not mentioned in the highly condensed minutes of the CSM/BSC meeting of 2 November 1988, Dr Pickles’s own note at the time records that this came up at the meeting as an area of concern: ‘Some collagen implants of bovine origin as used by cosmetic clinics are not even licensed.’ Collagen products intended for correction of contour deficiencies of the skin were considered licensable under the Surgical Materials Order SI 1971 No. 1276. DH has told us that although collagen implants might have been used for ‘cosmetic’ reasons, this would have been under medical supervision as they were ‘prescription only’ medicines.

How the issue was handled

8.6 Although specifically identified in the Tyrrell Report in June 1989 as a small-scale user that might not be covered by the regulations and guidelines then in place, the cosmetics industry was not itself the subject of advice or guidance until February 1990.

8.7 In January of that year Mr Richard Roscoe of the Department of Trade and Industry (DTI), the Department with policy responsibility for the safety of cosmetics, had on his own initiative asked DH for advice about the risk from BSE associated with the use of bovine offal in certain cosmetics. DH’s advice was that although the risk of transmission of BSE was remote, it would be prudent to reformulate, or source bovine material from cattle reared outside the British Isles. DTI passed this advice on to the cosmetics industry trade association, the Cosmetics, Toiletries and Perfumery Association (CTPA), which in turn informed its members.

8.8 SEAC considered the use of bovine material in non-food products generally in June 1991. By that time, BSE had been identified in countries other than the UK, and it was suggested that the advice issued to the cosmetics industry in February 1990 should be updated to take this into account. Updated advice was not sent to the CTPA until April 1992.

8.9 One approach that was considered within DH was the introduction of a voluntary ban on bovine materials from countries in which cases of BSE had been reported. Such a ban, if it were to be introduced, would have to be implemented at EU level, so as not to fall foul of European law. The question of BSE and cosmetics was therefore taken forward in the EC Working Party on Cosmetics (ECWPC). Progress at EC/EU level was slow; by the end of October 1994 the Scientific Committee on Cosmetology (SCC) had produced only an interim statement suggesting that material from animals with the potential to transmit infectious agents should not be used in the manufacture of cosmetics. In February 1995 the ECWPC decided that the existing Cosmetics Directive did not need alteration.

939 YB88/11.02/2.1
940 DH01 tab 28
941 IBD1 tab 4 p. 10 para. A1d
942 S471 Roscoe paras 24–30
943 YB90/2.1/7.1
944 YB90/2.01/14.1; YB90/2.8/10.1; YB90/3.00/6.1
945 YB91/6.28/2.1–2.7
946 YB92/4.2/4.1–4.2
947 YB94/10.21/8.1–9.2
948 S483 Payne para. 8
This decision was based in part on assurance by COLIPA, the European cosmetics trade association, that its members were following certain approved basic precautions on a voluntary basis.\textsuperscript{949}

\section*{8.10} When, in March 1996, the EU ban on the export from the UK of bovine products destined for use in cosmetic, medicinal and pharmaceutical products was introduced,\textsuperscript{950} the CTPA conducted a survey of its members and reported that almost all had been using non-UK-sourced bovine material for some time.\textsuperscript{951}

\section*{8.11} In the sections that follow we look first at the regulatory framework on cosmetics safety, which was markedly different from that on either food or medicinal products safety. The sponsoring Department for the industry, which was also responsible for its regulation, was DTI. As we shall see, there was some confusion at various points in the sequence of events about the respective responsibilities of DTI and DH for minimising risks to human health from the production and use of cosmetic products.

\section*{8.12} In the final section of the chapter we review some lessons that emerge from the way BSE was handled.

\section*{Regulatory framework}

\section*{8.13} The regulation of cosmetics is based on the EU Cosmetics Directive (1976), which was implemented in the UK by regulations made under the Consumer Protection Act 1987. Under this system, cosmetic products must meet various safety requirements, but, unlike medicinal products, they do not require a licence.

\section*{8.14} The Cosmetics Directive seeks to ensure the safety of cosmetics and their unhindered trade throughout the EU. In relation to safety, Article 2 provides:

\begin{quote}
Cosmetic products put on the market within the Community must not be liable to cause damage to human health when applied under normal conditions of use.\textsuperscript{952}
\end{quote}

\section*{8.15} Dr Robin Fielder of DH told us that the Cosmetics Directive places the onus on manufacturers and suppliers to ensure that the product is safe for the use intended.\textsuperscript{953}

\section*{8.16} Member States have a duty to ‘take all necessary measures to ensure that only cosmetic products which conform to [the Directive] may be put on the market’.\textsuperscript{954} The Annexes to the Cosmetics Directive list substances that must not be used in cosmetics and substances whose use is regulated. They also contain lists of substances (‘the prescribed lists’) permitted for certain uses (preservatives, colourants, sun screens) and only these substances may be used for those purposes in cosmetic products.\textsuperscript{955} The prescribed lists may be amended following

\textsuperscript{949} S482 Payne para. 8 \\
\textsuperscript{950} L4 tab 7 \\
\textsuperscript{951} S407 Kelly para. 31 \\
\textsuperscript{952} L16 tab 3 p. 2 \\
\textsuperscript{953} S436 Fielder para. 18 \\
\textsuperscript{954} L16 tab 3 Article 3 \\
\textsuperscript{955} S436 Fielder para. 18
consideration by the European Commission’s Cosmetic Products Working Party, which consists of representatives from the Member States and the industry. DTI led for the UK on this with DH also having a role. The final decision is taken by the Committee on the Adaptation to Technical Progress, which is chaired by the Commission and consists of representatives from Member States. Both the Working Party and the Commission have access to the opinions of the Scientific Committee on Cosmetology (SCC), an independent multidisciplinary body of scientists appointed by the Commission to assess the safety of cosmetics ingredients, as well as to advice from their own national scientific advisers.\textsuperscript{956}

8.17 The Cosmetics Directive limits the action individual Member States can take to regulate cosmetics.\textsuperscript{957} If a product complies with the relevant Annex, the UK Government cannot prohibit its use unless, on the basis of a ‘substantiated justification’, it represents a hazard to health.\textsuperscript{958}

8.18 Regulations made, in part, under section 11 of the Consumer Protection Act 1987 give effect to the Cosmetics Directive in UK law. The Cosmetic Products (Safety) Regulations 1984 (made under a predecessor of the Act) were replaced on 1 January 1990 by the Cosmetic Products (Safety) Regulations 1989 (‘the 1989 Regulations’).

8.19 The main provisions of the 1989 Regulations are as follows:\textsuperscript{959}

i. A cosmetic product shall not be liable to cause damage to human health when it is applied under normal conditions of use (reg. 3(1)).

ii. No cosmetic product may contain any substance listed in column 2 of Schedule 1, unless it is only a trace that could not reasonably have been removed during or after manufacture (reg. 4(2)).

iii. A cosmetic product must not contain any substance listed in column 2 of Schedule 2 unless specified requirements in that schedule are satisfied (reg. 4(3)).

iv. The Secretary of State may authorise the use in a cosmetic product of any substance not listed in either schedule 1 or 2 (reg. 5(1)). In giving authorisation the Secretary of State may impose conditions relating to the use of the substance (reg. 5(2)).

v. There are various conditions and standards for labelling and packaging (reg. 6).

8.20 The Consumer Protection Act imposes a general safety requirement on all consumer goods. Section 10 of the Act makes it an offence to supply consumer goods that fail to comply with the general safety requirement. For this purpose, consumer goods fail to comply with the safety requirement if they are not reasonably safe having regard to all the circumstances. ‘Safe’ means that there is no risk (apart from one reduced to a minimum) that the goods will (whether immediately or later) cause death or personal injury to any person.\textsuperscript{960}
8.21 The Cosmetics Directive and the 1989 Regulations left only limited scope for the application of section 10 of the Act. Since the introduction of the General Product Safety Regulations 1994\textsuperscript{961} there has been virtually no scope for its application.

8.22 In practice informal contact and voluntary cooperation played an important part in the regulation of the cosmetics industry.

Enforcement

8.23 DTI had policy responsibility for the safety of cosmetics in the UK. Day-to-day enforcement of safety regulations such as the 1989 Regulations fell to the trading standards departments of local authorities.\textsuperscript{962}

8.24 Supplying consumer goods that failed to comply with the general safety requirement or with certain requirements of safety regulations was an offence and punishable in the courts.\textsuperscript{963}

8.25 In addition, enforcement authorities (which for these purposes meant DTI and the trading standards departments of local authorities) had power to serve a suspension notice prohibiting the person on whom it was served from supplying goods for up to six months; power to apply to the court for a forfeiture order,\textsuperscript{964} and power for an authorised officer of the enforcement authority to enter any premises, inspect any goods, or examine any procedure, or in appropriate circumstances to seize and detain goods.\textsuperscript{965}

8.26 The Secretary of State also had the power to serve a notice on a person prohibiting the person from selling consumer goods if the Secretary of State considered them to be unsafe (a prohibition notice), or requiring the person to publish a warning about such goods (a notice to warn).\textsuperscript{966} However, these powers applied only to the person on whom the notice was served or against whom the order was sought, rather than to a general category of goods, and no power existed to recall products under these provisions.\textsuperscript{967}

8.27 DTI told us that it was unaware of any instance in which these powers had been used in respect of a BSE risk in cosmetics.\textsuperscript{968}

DTI handling of cosmetics

8.28 Within DTI overall responsibility for the safety of cosmetics lay with the Consumer Safety Unit (CSU). Within the CSU, the Chemical Hazards Section (CHS) had day-to-day responsibility for cosmetics.\textsuperscript{969}

8.29 Mr David Jones, a Grade 5 official, was Head of the CSU until 1995. Mr Roscoe, a Grade 7 official, was Head of the CHS from 1983 to 1992, with

\textsuperscript{961} SI 1994/2328
\textsuperscript{962} L9 tab 6 p. 24
\textsuperscript{963} Consumer Protection Act 1987 ss 12; L9 tab 6 pp. 10–11
\textsuperscript{964} Consumer Protection Act 1987 ss 14, 16; L9 tab 6 pp. 12–15
\textsuperscript{965} Consumer Protection Act 1987 ss 29; L9 tab 6 pp. 26–27
\textsuperscript{966} L9 tab 6 p. 11
\textsuperscript{967} DO01 tab 6a paras 8–9
\textsuperscript{968} DO01 tab 6a para. 7
\textsuperscript{969} S471 Roscoe paras 5, 12
specific responsibility for ensuring the safety of cosmetics sold in the UK. He was succeeded by Mr John Walker. Mrs M L Payne, a Higher Executive Officer in the CSU from 1990, was responsible for developing policy on regulation covering chemicals, including ingredients used in cosmetics.

8.30 The CTPA was the peak representative body for the UK cosmetics industry and the channel through which DTI distributed cautionary guidance on BSE to cosmetics manufacturers.

DH’s role in cosmetics safety

8.31 Although DTI had overall regulatory responsibility for cosmetics, DH also played a role as DTI’s adviser on toxicity. The relevant Division in DH was MED TEP (Medical Toxicology Environmental Protection), later evolving into the HEF M (Health Aspects of Environment and Food Medical), which would give advice when necessary.

8.32 Mr Roscoe told us that whenever the CHS was alerted to the presence of a potentially ‘risky’ ingredient in a particular cosmetic product it would refer the matter to DH. Upon receipt of advice from DH, the CHS would then decide on a course of action. According to Mr Roscoe, DTI would always act on this advice ‘unless there were very strong reasons for not doing so’.

8.33 Mr Roscoe also told the Inquiry that he believed that when DH encountered a new risk it was its responsibility to pass on the information to DTI.

8.34 The DH adviser on toxicology over the period of concern was Dr Fielder, who was assisted by Dr Dewhurst (1988–90), Dr Gott (1991–93) and Ms Mulholland (1993–97).

Cosmetics and BSE – a chronology

June 1989

The Interim Report of the Tyrrell Committee

8.35 The Interim Report of the Consultative Committee into Spongiform Encephalopathies (the Tyrrell Report) was submitted to MAFF and DH in June 1989 but not published until the following January. The section of the Report dealing with research propositions drew attention to the possible risk – or at least uncertainties – of transmission of BSE through cosmetics:

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970 S471 Roscoe paras 1, 5
971 S482 Payne para. 1
972 S471 Roscoe para. 15
973 Also known as MED TEH (Medical Toxicology and Environmental Health). We have used MED TEP throughout
974 S436 Fielder para. 1
975 S471 Roscoe para. 15
976 S471 Roscoe para. 18
977 S471 Roscoe paras 26–27
978 S436 Fielder paras 1, 14
Some uncertainty remains as to whether all the possible routes of transmission from bovine (and ovine) tissues to other species have been considered and appropriate action taken. Small scale users of bovine products, such as the cosmetic industry, may not be covered by the present regulations and guidelines.979

8.36 Although cosmetics are specifically mentioned here as an industry that might not be covered by existing regulations or guidelines, no steps were taken to bring this to the attention of DTI, the Department with policy responsibility. It was not until February 1990, following a request for advice from DTI, that the cosmetics industry became the subject of cautionary guidance.

January 1990

MAFF is asked about cosmetics

8.37 In January 1990, Mr Maclean, a Parliamentary Secretary at MAFF, answered a written Parliamentary Question on the use of bovine material by the pharmaceutical and cosmetics industries. His answer, which officials drafted in consultation with DH, said that the returns from the pharmaceuticals industry confirmed that ‘only a small percentage of their products include materials of bovine and other animal origin’ and that he had ‘no comparable information about the cosmetics industry’.980

8.38 Again, we are not aware of any follow-up resulting from this matter being raised.

DTI asks DH for advice on cosmetics

8.39 Mr Roscoe, Head of DTI’s Chemical Hazards Section of the Consumer Safety Unit, told us that he first made the connection between BSE and cosmetics in January 1990 through a conversation with Professor Dayan, of St Bartholomew’s Hospital. From this conversation he learnt that ‘the BSE virus’ was not killed through normal industrial processes. Aware that some cosmetic products included offal, Mr Roscoe sought advice from Dr Fielder, the Section Head of DH’s MED TEP/HEF M.981

DH consideration of Dr Fielder’s letter to Mr Roscoe

8.40 On 26 January Dr Singh, a Senior Medical Officer at MED TEP, sent a minute to Dr Pickles and Mr Love of the Medicines Control Agency (MCA), copied to Dr Fielder, attaching a draft reply to Mr Roscoe’s request for advice.982 The draft stated:

I am replying to your request for advice on the safety of the use of extracts of bovine offal in cosmetics, with respect to BSE. As you are aware there are

979 IBD 1 tab 4 para. A1d
980 YB90/01.22/11.1
981 S471 Roscoe para. 24
982 YB90/1.26/18.1–18.3, YB90/1.00/5.1
a number of cosmetic products on sale in the UK that contain small amounts of such extracts, primarily from spleen and thymus.

Whilst accepting that any risk is likely to be very low, we believe that it would be prudent to take similar action to that already taken by MAFF in the Food Area. Where cosmetic formulations use extracts of bovine offal derived from UK cattle, they should ensure that this is obtained only from animals of under six months of age. Alternatively they should consider the use of material derived from outside the UK.

We accept that the risk of transference by the oral route is likely to be negligible, and that it is even less likely to be transmitted through intact skin. However cut or abraded skin would not offer as effective a barrier, and it would be wise not to use preparations where there is any chance of infection.

We would be grateful if you would transmit these recommendations to industry via the Trade Association CTPA. 983

8.41 In commenting on the draft letter, Dr Pickles expressed concern about permitting the use of bovine offal from British calves under six months of age. 984 She explained why it had been decided that for food consumption calves of this age group did not present a problem, but thought with regard to cosmetics that ‘application to broken skin is getting rather close to parenteral administration. Together with problems of policing the 6 month limit, and the fact that the “benefit” from such material is so dubious, I would prefer to see a complete ban.’ 985 She enclosed a briefing note, 986 along with copies of the Southwood Report (to pass on to DTI) and Tyrrell Report (for Dr Singh’s colleagues).

8.42 Within the MCA Mrs Shersby sent copies of Dr Singh’s draft to Dr Jefferys, Dr Rotblat, Dr Raine, Dr Winship, Dr Purves, Mr Sloggem and Mr Love. She reminded them that the BSE Working Group (BSEWG) had decided at its meeting on 6 September 1989 that its recommendations should not apply to topical products (see Chapter 6). She asked them to ‘address the point about application of topical products to abraded skin, in particular’. 987

8.43 Mr Sloggem’s reply of the same day, 29 January, stated:

The advice from Dr Fielder seems fine to me. There could be a problem with abraded skin providing a route of entry. Spleen and placenta could well have high titres, assuming the analogy with scrapie holds good. Sourcing abroad would seem the sensible thing to do. Some tissues may have higher titres earlier than brain tissue eg gut, hence these are best avoided from British sources. 988

8.44 Dr Jefferys, Dr Adams, Dr Raine and Dr Winship collectively minuted Mrs Shersby on 31 January 1990 expressing concerns about the proposed reply and suggesting a meeting between MED TEP and MCA ‘to discuss overlapping areas
of responsibility, before the reply to DTI is finalised’. They said that no detailed information had been provided on the affected cosmetic products, and therefore informed comment was not possible. They pointed out that the CSM/VPC guidelines ‘were framed in relation to licensed medicinal products where the risk/benefit analysis has been established’. They also asked that the third paragraph be omitted as it would ‘raise new concerns which cannot be scientifically answered.’

February/March 1990

Mr Roscoe advises the CTPA

8.45 The meeting between MED TEP and MCA suggested by Dr Jefferys, Dr Adams, Dr Raine and Dr Winship does not appear to have taken place. However, their concerns, and those of Dr Pickles, were addressed in the modifications to the draft set out by Mrs Shersby in a minute to Dr Singh. Mrs Shersby said:

Following discussions here, we are content that the draft letter will be reworded, as follows: –

Paragraph 1 – to be unchanged

Paragraph 2 – Reference to the use of cattle aged under 6 months is deleted.

Paragraph 3 – Will be replaced by the following: –

‘We accept that the risk of transmission is very remote, but believe that it would be prudent to eliminate any risk from BSE, either by reformulating, so that the products do not contain any extracts of bovine offal, or if incorporation of bovine extracts is retained, material derived from cattle reared outside the UK, Eire and Channel Islands should be used.’

Should problems arise about stating Eire, then the alternative could be . . . ‘cattle reared outside the UK and from countries known to be free from BSE.’ As you are aware our preference is towards material from Australasia.

We are content that the briefing notes used will be those prepared by Dr Pickles.

We may reassess topical preparations in general and with specific relationship to human medicinal products before our next BSE Working Group meeting which is due to be held on 4 July 1990 at 2pm at Market Towers and will let you have an agenda and papers, in case you wish to send an observer along.

8.46 Dr Fielder’s eventual advice to Mr Roscoe, sent on 1 February, was as follows:

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

989 YB90/1.31/14.1
990 YB90/2.1/4.1
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 of 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. 991

8.47 The letter enclosed a copy of the Southwood Report and the background briefing prepared by Dr Pickles headed ‘Presence of Bovine Offals in Cosmetics and Bovine Spongiform Encephalopathy’ 992

8.48 Mr Roscoe immediately wrote to Miss Marion Kelly of the CTPA telling her of DH’s recommendation and requesting that she ask members to follow it. He concluded, ‘Please let me know if you have any trouble persuading [them] to do so.’ 993

The CTPA contacts its members

8.49 The CTPA contacted its members through two channels.

8.50 On 8 February 1990, it issued a circular to its Perfumery Working Group, which was made up of the CTPA members who marketed perfumery and premium skin-care products. 994 Miss Kelly explained to us that the products containing offal extracts would most probably be premium priced facial skin-care products. 995 The circular attached Mr Roscoe’s letter of 1 February 1990.

8.51 The second, and more general, channel the CTPA used to alert its members was through the scientific section of its newsletter, known as the ‘Blue Pages’. The March 1990 ‘Blue Pages’ asked all members marketing products containing ‘bovine extracts’ to tell the CTPA secretariat by 30 March what type of raw materials they used (eg, tallow and gelatine), and in what type of product. 996

8.52 Miss Kelly told us that most of the members of the Perfumery Working Group who manufactured premium facial products did respond to the request for information. On the basis of their responses and the fact that these products were not manufactured in the UK, she said she was satisfied that none of the products concerned contained bovine offal sourced from UK cattle. Unfortunately, the CTPA no longer has its files containing the responses to the request to the general membership via the ‘Blue Pages’. 997
April/May 1990

Dr Pickles drafts paper for SEAC

8.53 For the first meeting of SEAC held on 1 May 1990, Dr Pickles had drafted a paper entitled ‘Routes of Possible Transmission of BSE to Man’. In this draft she referred, among other matters, to the use of bovine spleen and thymus in cosmetics:

These products are said to have ‘anti-ageing’ properties and although supposedly administered only onto intact skin, clearly broken skin could be exposed also. Needless to say, there is no evidence of efficacy. These products are not covered by the Medicines Act.

8.54 She noted that the appropriate trade association had been advised, via DTI, that it would be prudent to exclude bovine tissue or source it from outside the UK, the Republic of Ireland or the Channel Islands. The paper asked whether the Committee was content with the line taken to date on cosmetics.

8.55 In a minute to Mr Lowson dated 23 April 1990, Mr Meldrum commented on Dr Pickles’s draft. In relation to cosmetics he objected to the general proposition that bovine material be sourced outside the British Isles:

At this time there must be some possibility that BSE exists in other countries in either a clinical or sub-clinical form bearing in mind their own scrapie incidence and the trading patterns in cattle and meat and bone meal from the UK to such countries. An answer has to be found that takes cognizance of all these factors and does not simply classify the British Isles as an ‘infected area’. On that basis the paper needs considerable expansion to be helpful to the Tyrrell Committee.

8.56 He suggested the paper be redrafted, then ‘cleared with us’ before being submitted to a later meeting of SEAC.

8.57 Upon receipt of this minute the next day, Mr Lowson faxed it to Dr Pickles, asking her by way of a handwritten note to discuss any revisions with Mr Meldrum. In her reply, Dr Pickles interpreted Mr Meldrum’s comments as an instruction to Mr Lowson not to accept her paper in its current form. She said that in the circumstances there was no alternative but to withdraw the paper from the agenda of the forthcoming SEAC meeting, adding by way of explanation:

... the line taken on cosmetics including sourcing from overseas was based on that given for licensed medicinal products by a group that included Drs Kimberlin, Watson and Will, as well as other MAFF officials. There is no question that the UK is an ‘infected area’: the only question is whether other countries should be included too. The Licensing Authority, quite reasonably in my view, feels they can only insist on sourcing in countries

998 YB90/4.12/1.1–1.4
999 YB90/4.12/1.3
1000 YB90/4.12/1.3–1.4
1001 YB90/4.23/1.1
1002 YB90/4.23/1.1
1003 YB90/4.23/2.1
1004 YB90/4.24/3.1
where there is no evidence of BSE and the veterinary service and reporting system is adequate to detect it were it present. Most manufacturers of mainline pharmaceuticals are not risking having to change sources yet again and so are looking to Australasia. If the CVO thinks he has enough evidence, say concerning the USA, to persuade the CSM, CDSM etc to advise more strongly against sourcing there too, he should present that evidence in a convincing form and in writing. I do not see this as a matter for our group, since there are statutory responsibilities under the Medicines Act. What we should do is ensure consistent advice is given for those borderline products (like these ‘cosmetics’ with medicinal claims) that currently fall outside that Act.1005

8.58 In early May Mr Meldrum wrote again to Mr Lowson. He explained that his remarks were based on concerns about reporting procedures in some countries and the question whether they could diagnose BSE. He further noted that, according to evidence presented at the fourth International Scientific Congress in Fur Animal Production, ‘bovine-scrapie’ might exist in the USA:

...I am only suggesting that more detail and background be provided for the Tyrrell Committee in order that they may come to a balanced view.1006

8.59 The minute was copied to Dr Pickles.

July 1990

The BSEWG considers topical products including cosmetics

8.60 While the withdrawal of Dr Pickles’s paper meant that the approach taken on cosmetics was not formally considered by SEAC, three SEAC members, Dr Tyrrell, Dr Kimberlin and Dr Watson, attended a meeting of the CSM’s BSEWG, which considered topical products. It appears that the presence of this item on the agenda can be traced back to a suggestion by Mrs Shersby the previous January when advising how to respond to Mr Roscoe’s enquiry on BSE (see paragraph 8.45 above).

8.61 A paper entitled ‘Topical Products – Cosmetics and Medicines’, dated June 1990 was prepared by Dr Winship and tabled at this meeting.1007 The paper attached a copy of Dr Fielder’s reply to Mr Roscoe of 1 February 1990. The minutes record the following:

10. Topical Products – Medicines and Cosmetics

10.1 Following a request from the Department of Trade and Industry for advice on the safety of the use of extracts of bovine offal in certain cosmetics, a reply was sent by Dr R J Fielder, Med TEH, Department of Health on 1 February following consultation with Med ISD and the MCA. It is recommended that the products should be reformulated or if the incorporation of bovine extracts is to be retained, material derived from cattle reared in BSE-free areas should be used.

1005 YB90/4.24/3.1
1006 YB90/5.2/15.1
1007 YB90/6.0/18.1
10.2 Topical administration of licensed medicinal products containing bovine materials has already been discussed at the BSE Working Group Meeting in September 1989. They were not considered to be a cause for concern at that time and this position is unchanged.

10.3 In view of this more recent concern about the use of bovine offal in cosmetics, it was considered advisable to look into topical use in relation to medicinal products. Such use appears to be confined and the source of the material is Germany. No further action is currently required by the MCA in relation to licensed topical medicinal preparations. 1008

8.62 The issue of bovine materials used by the cosmetics industry did not resurface again until March 1991 (see below).

March to May 1991

SEAC consideration of the use of bovine material in non-food preparations

8.63 On 7 March 1991 a meeting of SEAC was held. After considering a paper on the use of tallow, the Committee asked for a note on the use of bovine material in non-food preparations such as cosmetics.1009 In his list of action points arising out of the meeting Mr Lowson observed that SEAC had asked for a note on ‘the use of bovine materials in cosmetics in particular’ but suggested:

it might make sense to cover all the non-food uses that we can think of (harp strings, tennis rackets etc). I think that all that is required is a factual note about the range of uses, and quantities, together with an assessment of possible risk factors. 1010

8.64 He suggested that this was a job for Dr Pickles.1011

8.65 Dr Pickles was unable to put together a paper before the next SEAC meeting on 10 May 1991 (see Chapter 9). The minutes of this meeting record that steps were to be taken to obtain from the cosmetics industry an indication of whether they used bovine material.1012 This task was allocated to Mr Tom Murray,1013 who had by then taken over from Dr Pickles as joint secretary to SEAC. Dr Pickles continued to attend as an observer.

June 1991

DH contacts the CTPA directly

8.66 Mr Murray evidently enlisted assistance from Mrs Diane Whyte, a Higher Executive Officer within HEF who reported to him. He asked her to ‘make enquiries of the trade organisation representing the cosmetics industry into the use of bovine..."
material’. On 25 June 1991 she informed him that Dr Gott in HEF M had suggested Mr Ian Phillipson in the CTPA as the contact. Dr Gott had also faxed across copies of the correspondence that had taken place with DTI in February 1990. Mrs Whyte continued:

In Mr Phillipson’s absence I spoke to his assistant Mrs Deborah Redborne. She has looked at their file on this subject and can find nothing further to the 1990 correspondence. However she confirmed that the DH advice on bovine material was issued to the cosmetic industry through an article in their trade journal written by Mr Phillipson.

I will speak to Mr Phillipson tomorrow when he returns to check the latest position.

8.67 On 26 June 1991, after speaking with Mr Phillipson, Mrs Whyte sent Mr Murray another minute. Mr Phillipson had told Mrs Whyte that following the receipt of the DTI letter in February 1990 advice was issued to the cosmetics industry through the CTPA Scientific News. Mrs Whyte said:

3. The advice was also discussed at the CTPA European Scientific Committee so international interests have been covered. A copy of the article in the scientific journal is attached for our reference. Mr Phillipson confirmed the advice stands and that the industry has acted on it.

4. The correspondence from DTI did not mention ovine material so this has probably not been covered (if used).

SEAC recommends an update of DTI’s advice

8.68 Two papers were put before the SEAC meeting on 28 June 1991, by Dr Pickles and Mr Murray. Dr Pickles’s paper addressed the uses of bovine material in non-food products generally (see Chapter 9), while Mr Murray’s dealt specifically with cosmetics. After summarising the action taken by the CTPA following the advice of February 1990, Mr Murray’s paper stated:

3. The CTPA claim that their members have received the advice and acted upon it. However, the CTPA has no detailed information on the present use of bovine material, DH cannot therefore be sure all CTPA members have received and adhered to the guidance. Similarly, there is uncertainty about the practices of small scale producers who do not have CTPA membership.

4. No advice has been issued to manufacturers on the use of ovine material and the CTPA has no detailed information on its use.

8.69 The minutes of the meeting record that on consideration of the two papers the Committee thought that although in general no problems arose the following points should be pursued:
– investigate whether any specified bovine offals going for industrial use and hence exempt from sterilisation and staining regulations were likely to end up in products (e.g. cosmetics) which might come into contact with human tissues; and

– remind DTI that as BSE had now been found in other countries their guidance to cosmetic manufacturers should be updated in regard to scrutiny, and importation of prepared cosmetics.1018

July/August 1991

8.70 In early July Mr Lowson circulated a note concerning follow-up to the SEAC meeting on 28 June. Copies of this went to Mr Murray and Dr Pickles. In relation to non-food uses of bovine material, he noted:1019

The Committee were concerned about a number of issues:

– to update the advice from DTI to the cosmetics industry to take account of the existence of BSE in other countries (can Mr Murray please pursue);

– to investigate whether contact lens care products are covered by CSM guidelines (I understand Dr Pickles is pursuing); and

– to find out whether any sbo’s which are exempted from the sterilisation and staining regulations for industrial use might end up in products for human use. Can Mr Lawrence please investigate.

8.71 On 24 July 1991, by way of follow-up, Mr Murray asked Dr Pickles to review the previous advice to DTI and suggest amendments as necessary. He observed: ‘Reference will have to be made to BSE in France and Switzerland and the ingredients from bovines from these countries.’1020

8.72 Dr Pickles replied to Mr Murray’s request the next day. She agreed that the geographical aspects needed updating and observed that the background briefing sent to DTI with Dr Fielder’s letter of 1 February 1990 was not appropriate in that form and not something she had intended to go to DTI in any case. She continued:

The Tyrrell committee remains concerned about excessive contact with specified offal or material derived from them. Apart from abattoir workers, this is the main potential loophole. It could be pointed out that there are potential concerns:

* for workers in the cosmetic industry who may be exposed frequently to these materials, especially if inoculation injuries might occur and

* those who by repeated application particularly to thinned, scarified or diseased skin might absorb material including infective agent that way, also

1018 YB91/6.28/2.7
1019 YB91/7.3/3.1–3.2
1020 YB91/7.24/3.1
* there may still be some strange products administered by injection that are trying to evade the Medicines Act by calling themselves cosmetics. If any of those involve bovine ingredients, they need to comply with the CSM guidelines.1021

8.73 Dr Pickles also noted that the fundamental concerns were ‘well described in previous papers/briefing etc’ and were ‘essentially unchanged from those expressed in the Southwood report’. She said that in addition to writing to DTI, DH should ask to be kept properly informed of any action that followed. It needed reassurance that the message had reached the right people. She questioned whether ‘fringe’ companies were members of trade associations, and, if not, whether information was reaching them, and whether DTI had accepted it was its responsibility to keep such manufacturers informed.1022

8.74 Mrs Whyte drafted a letter to Mr Roscoe along the lines suggested by Dr Pickles.1023 However, it does not appear that any letter was, in the event, sent to Mr Roscoe.

8.75 During August 1991 Mr Lawrence prepared the paper requested by SEAC about whether SBOs exempted from the Meat (Staining and Sterilisation) Regulations for industrial use might end up in products for human use. Evidently, Mr Lawrence consulted Mr Bradley, who had become involved in compiling the list of non-food preparations requested by SEAC in March (see Chapter 9). In a minute to Mr Lawrence dated 5 August 1991 Mr Bradley said:

> I have the feeling we are far too remote from the industry to make meaningful comments. Contacts via DOH/DTI do not inspire me with confidence. I would advise we need to know what bovine materials are really used in cosmetics and for what purposes. We either need to send someone into the industry (as I did for tripe, casings and rennet) or have a closer contact via the trade association. I am not satisfied yet that the industry is ‘in the clear’ and it is us that may shoulder some blame if it is later found ladies are rubbing cow brain or placenta on to their faces. It may not be our job but if we have any responsibility we need to get at the facts. 1024

8.76 Mr Lawrence’s paper was tabled but not discussed at the tenth SEAC meeting on 6 September 1991 (see Chapter 9).1025 In relation to cosmetics the paper stated that placenta was used for its supposed anti-ageing properties, and gangliocides, spleen and thymus might also be used, but there was no firm knowledge on this. It noted that at the SEAC meeting of 28 June it had been agreed that DTI would be reminded that since BSE had been found in other countries, its guidance to cosmetics manufacturers needed to be updated. The paper concluded:

> In view of the legislative controls and the guidance which has been issued to manufacturers of pharmaceuticals it is not considered that products derived from sbos will come into contact with human tissues. Guidance has also been issued in relation to cosmetic use and we have no reason to believe that the major manufacturers have not followed the advice given. However in order
to obtain as definitive a picture as possible it is considered advisable to check
with the trade association to see if this is the case and whether there are small
companies who are not members and may not therefore be aware of the
advice given. A further check could also be made through the abattoir
owners as to the destination of by-products. 1026

October 1991

8.77 On 15 October 1991, Mrs Whyte sent a minute to Dr Wight, who had
succeeded Dr Pickles as coordinator on BSE/CJD matters in DH:

Mr Murray asked me to copy to you our papers on the use of bovine material
in cosmetics in connection with the attached article sent to us by John
Maslin, MAFF. The article appeared in a recent Mail on Sunday supplement
and states that ‘sheep’s placenta and cow’s brain tissue are included in
(cosmetic) treatment products as “fresh cells” and “biological extracts” ’.

We have been looking at the use of bovine material in cosmetics and other
non-food products, and the subject has also been discussed by the Tyrrell
Committee. The Department issued advice to the cosmetics industry, via
DTI, on the use of bovine material in cosmetics in February 1990. This
advice suggested that the use of extracts of bovine offal should be
discontinued. Alternatively material should be imported from cattle reared
outside the UK, Eire and the Channel Islands.

Follow up enquiries of the Industry’s Trade Association indicate that
manufacturers were asked to check with their suppliers the origin of any
bovine material used. However, there is no detailed information on the
present use of bovine material and we cannot be sure that the DH advice has
been widely received or adhered to. Also we do not know about small scale
operators who are not members of the Trade Association.

When this was discussed by the Tyrrell Committee in June, it was agreed that
the DH should consider its earlier advice to DTI with a view to reissuing it.

When you have had a chance to look at the background papers Mr Murray
would like us to get together urgently to consider this further. Perhaps you
can let me know if it is possible for us to meet sometime this week? I look
forward to hearing from you. 1027

8.78 On 31 October 1991, Dr Wight sent to Mr Murray what appears to be an early
draft of the updated advice eventually sent to the CTPA in April the following year:

The Department of Health wishes to reinforce the advice given to the
Cosmetics Industry in February 1990 (ref.)

It is possible that some ruminant-derived materials are being incorporated
into cosmetics or beauty treatments which are then marketed as ‘natural’
products.

1026 SEAC 10/13 para. 7
1027 YB91/10.15/2.1
The particular materials that should not under any circumstances be used in the manufacture of cosmetics or beauty treatments are:

1. bovine (cattle) -derived offals, or proteins derived from these offals. These offals are: brain, spinal cord, spleen, thymus, tonsils, intestines (Bovine Offal (Prohibition) Regulations)

2. ovine (sheep) -derived offals and ovine placenta.

In view of the current uncertainty about the incidence of infection with spongiform encephalopathy agents it is probably advisable that these recommendations apply to the above ruminant-derived materials of any country of origin.1028

8.79 A handwritten note (author unknown) at the bottom of the page states ‘this could go in trade rag(s)’.

November 1991

Consideration of the SBO Regulations

8.80 In early November, when considering the draft SBO amendment regulations, Mr Murray raised a concern about cosmetics. On 6 November 1991, Mrs Whyte sent a minute to Dr Wight explaining Mr Murray’s concerns. She referred to section 2(a)(ii)(b) of the draft regulations which stated that premises used for the manufacture of products other than food or animal feedstuff would be designated as excepted premises. She asked:

Do you know if they are covered by other regulations (ie CSM advice) and what about cosmetic manufacturers? . . .1029

8.81 Miss Jones (Meat Hygiene Division, MAFF) sent a minute seeking ‘urgent advice’ about DH concerns over the draft regulations from Mr Turner of the Legal Section.1030

8.82 Having heard back, Miss Jones wrote to Mr Murray on 25 November 1991:1031

Following discussions with Mr Baker and myself it emerged that you had three areas of concern in relation to the . . . Regulations . . .

Your first point related to the definition of ‘excepted premises’ (Regulation 2). You expressed concern that certain sectors of the cosmetics industry are still using specified bovine offal in the manufacture of their products and you wished to see the definition amended to exclude such premises. Indeed you would prefer to see the Regulations used as a vehicle for introducing a total prohibition on use of SBO in cosmetics and, perhaps, certain other non-food products. While I understand your concern over this issue, our legal advice is that the Food Safety Act 1990 (under which these Regulations are made)
would not be an appropriate means of introducing such a ban. The Act is concerned solely with ensuring that food which reaches the consumer is safe to eat and could not therefore provide a satisfactory basis for action in relation to cosmetics or similar products. In light of this you may wish to consider whether there is other legislation available which would provide a more appropriate basis for taking such action.

8.83 Mr Murray replied on 9 December. He accepted her advice and added:

I have briefly discussed with Robert Lowson the need to control the non-food use of specified offal. He and Dr Tyrrell (Tyrrell Committee) are sympathetic to the suggestion. I will discuss further with Robert how we take forward such action.\textsuperscript{1032}

1992

A questionnaire on cosmetics

8.84 Work continued on the advice to be given to the cosmetics industry. By now the main purpose had changed to a fact-finding exercise. On 28 February, Mrs Whyte sent Dr Wight a suggested set of questions which it was envisaged might ‘determine whether a meeting was needed, with possible guidance issued later’. Mrs Whyte’s suggested questions were as follows:

– How widely was the DH/DTI Guidance issued in February 1990 disseminated to the Trade?

– What about companies/outlets not members of Trade Association?

– Were any other organisations included in this exercise?

– Was there any feedback on the 1990 Guidance?

– Was there any check on what was happening at that time?

– Has there been any subsequent check on the use of bovine material in cosmetics?

– Is there a list of suppliers of bovine material for use in the production of these products?

– If not, how easy/difficult would it be to produce?

– What is the geographical source of this material?

– Do you know the scale of usage of bovine material?

– Do you know what type of bovine material is used?
– Is there a list of products of which bovine material is an ingredient, no matter how small in quantity?

– Are any products made in the UK and exported, and if so to where?

– Are any products imported to the UK which use bovine material in their preparation?

– Are there likely to be other beauty products other than cosmetics or toiletries which use bovine material?

– Have there been any products rejected or discontinued because of the type of bovine material used in their preparation?

– Have you received any enquiries from the industry on the safety of bovine material?

– Have you received any enquiries from the public or consumer associations on the use of bovine material in cosmetics?

– Have you received any queries, from any source, on cosmetics and related products and BSE?

Once we have agreed the questions to be put to the CTPA we can write to them fairly quickly. I will copy any correspondence to MAFF to keep them informed of our action. I look forward to hearing from you.1033

8.85 By 1 April 1992, Mrs Whyte had completed a draft letter to the CTPA. She sent this and the questionnaire to be cleared by Mr Murray. In her cover minute she noted that the contents of the questionnaire had been agreed by Dr Wight.1034

8.86 The next day, having incorporated amendments suggested by Dr Fielder, Mrs Whyte sent the letter and the questionnaire to Mr Phillipson of the CTPA. We set the letter out in full:

I am writing further to our discussion last year about the Tyrrell Committee which was looking at the use of bovine material in non-food products in the light of the problem with Bovine Spongiform Encephalopathy (BSE).

You will recall I was enquiring about the action taken by the Cosmetics Industry following the issue of Departmental advice on 1 February 1990, on the safe use of extracts of bovine offal in certain products, such as skin products claimed to have ‘anti-aging’ properties. At the time you confirmed that this advice had been disseminated to the Cosmetics Industry through the ‘CTPA Scientific News’ and the CTPA European Scientific Committee.

As it is some time since the Departmental advice was issued it is possible that some ruminant-derived materials are again being incorporated into cosmetics or beauty treatments which are then marketed as ‘natural’ products. As an example, an article on ‘natural beauty products’ has
appeared in a Sunday supplement which stated that ‘sheep’s placenta and cows’ brain tissue are included in (cosmetic) treatment products as “fresh cells” and “biological extracts”. This is exactly the type of use and product about which the Tyrrell Committee was concerned. The particular materials which should not, under any circumstances, be used in the manufacture of cosmetics or beauty treatments are:

1. Bovine (cattle)-derived offals, or proteins derived from these offals, such as: brain, spinal cord, spleen, thymus, tonsils, intestines. These are the specified offals covered by the Bovine Offal (Prohibition) Regulations 1989.

Ovine (sheep)-derived offals and ovine placenta.

In an attempt to gauge the extent to which bovine and ovine material may be used in the production of cosmetics and beauty products it would be helpful to have some basic information relating to this subject. This is set out in the attached questionnaire and I would be grateful if you could complete the form as fully as possible and return it to me by 24 April.1035

**The CTPA’s response**

**8.87** Miss Kelly of the CTPA told Mrs Whyte that she could not obtain answers to the questionnaire by 24 April 1992, as the cosmetics in question were manufactured by companies all over the world.1036 She added:

> On the basis of our knowledge that these substances are used in relatively few products and that these products have a relatively small turnover we have assumed that the number of companies supplying the ingredients would, for economic reasons, be fairly limited . . .

> If you would like us to try to get answers to all your questions it would be most helpful if you could identify, on a worldwide basis, the sources which would be of concern to you . . . The work involved in following this up will be considerable and if there are geographical areas which are considered to be ‘clean’ in relation to BSE the task may be manageable.1037

**8.88** Having seen Miss Kelly’s response, Dr Wight sent a minute to Mr Murray.1038 She pointed out that feedback had not been received from all of the companies notified at the time:

> We can only assume they heeded the advice. Non-member companies may still be unaware of previous advice, assuming that they make these type of products (which given the target market Ms Kelly describes may perhaps be unlikely). Do we have any way of estimating this likelihood (through CTPA or DTI?) or the extent of non-membership?1039

**8.89** She went on to note that they knew France and Switzerland had some BSE cases and therefore it would be appropriate to update the 1990 advice to include
these countries as an unacceptable source for bovine material. She also observed that the manufacturing country was not always the same as the source country of raw material. Therefore the message should be conveyed that ‘these products should not contain sbo’s or other ruminant offal/placenta materials at all, as we do not [know] how the ruminant SE situation could develop globally’.1040

May 1992

The CTPA asks its membership for further information

8.90 In May 1992 the CTPA contacted its membership through its scientific newsletter, the ‘Blue Pages’. We set out the reference to BSE use in full:

Use of Bovine and Ovine Material in Cosmetic Products.

We have received an enquiry from the Department of Health about the use of the above materials in cosmetic products. In particular the following ingredients were specified.

Bovine (cattle)-derived offals, or proteins derived from these offals, such as: brain, spinal cord, spleen, thymus, tonsils, intestines. These are the specified offals covered by the Bovine Offal (Prohibition) Regulations 1989.

Ovine (sheep)-derived offals and ovine placenta.

Attention is drawn to the Bovine Offal (Prohibition) Regulations 1989 and members using these ingredients are asked to contact Ian Phillipson at CTPA as soon as possible.1041

8.91 Miss Kelly of the CTPA told us that there was no positive response to the newsletter request and that this indicated to the CTPA that members were not using these products.1042

July 1992

DH prepares updated advice for the CTPA

8.92 In early July 1992, a draft of a further letter to the CTPA giving updated advice on the BSE issue was prepared by Mrs Whyte and circulated to Dr Wight and Dr Fielder for comment. In her cover minute Mrs Whyte suggested that the advice would be difficult for the CTPA to enforce, particularly as it did not know about smaller manufacturers not covered by the Association.1043 The draft letter explained:

Since February 1990 epidemiological information on BSE has increased, and it is evident that BSE cases have occurred outside the UK including France, Switzerland, the Falklands and Oman. As trade in feedstuffs and

1040 YB92/4.24/1.1
1041 YB92/5.00/3.1–3.2
1042 S407 Kelly para. 7
1043 YB92/7.1/6.1
Cattle is international; it is possible that BSE cases could occur in other countries. Therefore it is difficult to give precise advice on where bovine material for inclusion in cosmetics can be safely sourced.

... Your Association may think it prudent to advise your members that bovine materials generally, including {DN: specified bovine offals, other offals and ?} placenta etc, should not be used in cosmetics whether or not they are sourced from countries with reported cases of BSE. This would ensure that the public is not exposed to the admittedly very remote risk of exposure to BSE infected material {DN: or any other SE agent?}, in some cosmetics.1044

A warning of possible European involvement

8.93 On 6 July, Dr Fielder replied to Mrs Whyte, pointing out that the situation was now somewhat more complicated than when the CTPA was asked only to give advice on the source of bovine material. If what was wanted was a voluntary ban on bovine materials, regardless of their country of origin, action would have to be taken at the European level to amend the Cosmetics Directive. He set out the reasons why:

... Cosmetics products marketed in the EC are covered by the Cosmetics Directive which is implemented in the UK by DTI's Cosmetic Products Safety Regulations. We (HEF(M)2) advise DTI on the toxicity of chemicals used in cosmetics and have regular meetings with DTI/CTPA prior to attending meetings of the EC Working Group on Cosmetics which is the forum for discussing all aspects of the Cosmetics Directive, and for agreeing alterations in the ‘permitted lists’ of ingredients or the prohibited list.

... Even if we seek a voluntary ban on bovine material in cosmetic products marketed in the UK, we are likely to be challenged at the EC level with regard to barriers to trade, unless we then take our case to the EC Working Group on Cosmetics and argue for a ban throughout Europe. This could be accomplished by the inclusion of ‘bovine material’ in Annex II of the Directive (ie the prohibited list). We would however need to have a strong enough case to convince the other EC Member States (or sufficient to give us a weighted majority when it came to a vote!). In practice the matter is likely to be referred in the first instance to the CECs Scientific Committee on Cosmetology (SCC) for an opinion. This is the Committee of experts established under the terms of the Cosmetics Directive to advise on all aspects of the safety of cosmetics. Dr Ian White (consultant dermatologist from St Thomas) and I are the UK members.

... It is particularly pertinent in this instance for us to seek action at the European Level since (in addition to our Cosmetics Directive obligations) the concern is very predominately with companies from outside the UK, in particular France.1045

8.94 Dr Fielder suggested they have a meeting to discuss the issue. He also suggested involving DTI’s Consumer Safety Division to agree a line, before meeting with the CTPA.1046

1044 YB92/7.01/6.2–6.3
1045 YB92/7.6/9.1
8.95 Dr Wight agreed with this suggestion. She identified some discussion points:

2. Firstly, we on the SE side have a rather scanty knowledge of the cosmetics industry. It would be helpful if you could provide any background information on the trade.

As part of this, what about current controls – regulations and otherwise – governing the use of raw materials, with respect to microbiological rather than chemical safety, and how is the safety of the production process and the end product monitored?

3. Is it possible to compare any trade controls with controls used in the drug industry?

4. How do our controls relate to EC requirements and how, if necessary, are these enforced?

5. Do you have any idea as to what sort of products are likely to be a problem with bovine/ruminant derived materials and is it possible to have details of the handling of these materials in the production process? Would any of the likely compounds be for non-topical use?

6. We recognise that we are discussing theoretical rather than proven risks, which makes deciding on a course of action more difficult, particularly if any action would have repercussions in the EC.

While we feel there is a need to update the previous DH advice, we need to think how this might best be done, and how it can reach all parts of the trade effectively. 1047

8.96 It was agreed that the best way to proceed would be to hold a meeting involving DTI/CSU, the CTPA and a team of MAFF/DH experts to give advice on BSE. The earliest date that this could be arranged was for September 1992. 1048

8.97 Mr Lowson, who was sent a copy of the draft letter inviting the CTPA to the meeting, recommended that Mr Bradley attend as the MAFF representative. 1049

September 1992

Meeting between DH, MAFF, DTI and the CTPA

8.98 The meeting on 21 September 1992 was attended by Dr Wight and Dr Fielder (DH), Mrs Payne, an HEO from the CSU in DTI, Mr Bradley and Mr Dixon (MAFF), Miss Kelly (CTPA) as well as representatives from three of the larger cosmetics manufacturers: Proctor & Gamble, L’Oréal, and Unilever. 1050

8.99 Dr Wight began the meeting by stating that its purpose was:
to reappraise the situation with respect to BSE and the use of bovine and other materials derived from animal origin in cosmetics manufacture. The situation, both in the UK and worldwide, had changed since the CTPA last issued advice to their members in February 1990 with respect to the risks associated with the use of bovine offals.

8.100 Mr Bradley confirmed that BSE had by now spread to the Republic of Ireland, Northern Ireland, France, Switzerland, Denmark, Oman and the Falklands.

8.101 Miss Kelly advised the meeting that the cosmetics of concern could be divided into two categories: 10 per cent expensive ‘exotica’ containing materials like cerebrocides and placenta, and 90 per cent ‘routine’ products, many based on collagen, elastin or gelatine. The main producers of ‘exotica’ were French and American companies; the final products were very expensive and the manufacturers were in a position to ensure the safety of their products by sourcing from countries, such as Australia, where no BSE or scrapie had been identified. French manufacturers were about to agree with their Department of Health to discontinue using placental material.

8.102 The CTPA believed that small UK companies would most probably be relying on vegetable materials. They were not thought likely to be incorporating materials of concern and the same could be said for producers who were not members of the CTPA.

8.103 There was discussion of the risks associated with gelatine and tallow. As far as tallow was concerned, Mr Bradley observed that it should be derived from the rendering of protein and fat waste from cattle only after SBO had been removed. In general, the extraction processes used meant that there was not a problem. The CTPA was told that DH would inform it of the results of MAFF/DH discussions on gelatine.

8.104 Miss Kelly told us that the use of gelatine in cosmetics was rare and mostly confined to pharmaceutical grade.

8.105 DH and MAFF felt that a list of cosmetics incorporating the discussed materials would be useful to aid estimation of their frequency and extent of use when considering any associated risks. Dr Wight’s minute of the meeting notes that this list was to be followed up with the CTPA.

8.106 The meeting concluded that concrete advice might well not be feasible and guidance would probably need to focus on enabling the industry to formulate questions for their suppliers when obtaining source material. The CVL offered to act as a contact point to assist in formulating the relevant questions and to provide answers where possible. The CTPA indicated that it would consider the information that had been put forward at the meeting and then reach its own conclusions on what advice to give on which materials could be used. Miss Kelly felt that the safest and most logical course would probably be to advise against the

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1051 YB92/9.23/1.2
1052 YB92/9.23/1.3–1.4
1053 YB92/9.23/1.3
1054 YB92/9.23/1.3
1055 S407 Kelly para. 15
1056 YB92/10.1/2.3
1057 S407 Kelly para. 12
inclusion of animal offals altogether. It was agreed that the advice that the CTPA would issue to its members would be subject to consultation and agreement with DH and MAFF.\footnote{S407 Kelly para. 13, 14}

8.107 Dr Wight told us that, although there was ongoing discussion after the meeting, she could not recall whether the consultation and agreement referred to took place.\footnote{T71 Wight p. 105}

8.108 After the meeting Mrs Payne telephoned Dr Fielder.\footnote{S482A Payne para. 3} She told us that she and Dr Fielder:

\[\ldots\text{recalled that the CTPA had mentioned that the French cosmetics industry would be discussing the issue of bovine materials in cosmetics with their Ministry of Health and that this could lead to the industry producing Europe-wide guidelines, in consultation with COLIPA, the European cosmetics trade association. We agreed that we should ensure that whatever the outcome of the meeting in France, UK industry should be issued with guidelines, the content of which would need to be agreed by experts in MAFF and DoH before being circulated to the industry. Dr Fielder said he would let Dr Wight know what we had decided.}\footnote{S482A Payne para. 4}

8.109 After speaking to Dr Fielder, Mrs Payne contacted Miss Kelly at the CTPA to check whether she had received any feedback from the French cosmetics industry and if any progress had been made in drafting the industry’s guidelines. She was told that the French Ministry of Health had expressed concern to its industry over the use of bovine material in cosmetics. In view of this, the CTPA had agreed with its French counterparts that they should jointly draft guidelines for the use of both their industries. They also agreed to discuss the provision of guidelines with other cosmetics trade associations in Europe. She was advised further that COLIPA would be hosting a meeting to facilitate the latter and, in the meantime, Miss Kelly would be raising the issue of guidelines with the CTPA. Mrs Payne was later informed by Miss Kelly that the CTPA Council had agreed that draft guidelines should be prepared for the UK industry and that these would be drafted jointly with the French industry, drawing on advice from MAFF and DH.\footnote{S482A Payne paras 5, 6}

8.110 The agreed draft of the minutes of the 21 September meeting was circulated by Dr Wight on 1 October 1992, together with a suggestion that Mr Bradley, Dr Fielder and anyone else who was interested could get together to discuss the CTPA proposals for advice when they arrived.\footnote{YB92/10.01/2.1–2.3} Dr Wight also requested Mrs Whyte to ask Dr Fielder to get in touch with the French authorities for feedback on their discussions with their Health Ministry.\footnote{YB92/9.23/1.1}

8.111 On 30 September 1992, Miss Kelly wrote to Dr Wight. The letter followed up on the request made at the 21 September meeting by MAFF and DH for a list of cosmetics incorporating bovine materials:
Following our meeting on 21 September I have contacted the company which promotes a range of products based on cerebrosides. I understand that materials of bovine origin are now being replaced by a synthetic alternative and that this change will be completed by early 1993.

I have not yet received a report from the French Federation about their meeting with the French Ministry of Health, I am writing again today to move this along. In relation to materials such as tallow, collagen, etc which are widely used in the UK I have asked one company to prepare a brief outline for each ingredient, including the treatments used in its preparation and any ‘best practice’ advice.1065

October 1992

DTI and DH attend a meeting of the EC Working Party on Cosmetics

8.112 As outlined in the section on regulation and enforcement in this chapter, the EC Working Party on Cosmetics (ECWPC) was the forum through which the Cosmetics Directive could be amended. On 2 October 1992, Mrs Payne attended a meeting of the ECWPC together with representatives from DH.1066 At the meeting the Italian delegation raised the question of whether there might be contamination by the BSE agent in medicinal products based on animal extracts. They asked the Commission for an assessment of the categories of cosmetic products that contained animal extracts – principally based on brain or marrow – so that they could be withdrawn from the market. The Italians felt that products applied to the mucous membrane or around the eyes were the most dangerous and it was agreed that they would provide the Commission with all their documentation on the matter.1067

8.113 In late October Mr Phillipson wrote to Mrs Whyte. He said that the subject of BSE and cosmetics and the production of guidelines for members was ‘now the subject of discussion among our sister associations in the EEC and the matter will be discussed at a technical committee of our European association in Brussels in the middle of November. Following this it is hoped that guidelines will be produced for use by European industry.’1068

November 1992

8.114 In early November Mr Murray sent Mr Phillipson’s letter to Dr Fielder. He commented that the development of guidance at an EC level was promising as it ‘should avoid the impression the problem is one for only the UK cosmetics industry’. He qualified this with two concerns:1069

Firstly, we must ensure the content of the guidance is accurate and does not unduly single out the UK for restrictions. Secondly, on timing I hope the exercise will not drag on for an overlong period when the guidance needs to go out as soon as possible.

1065 YB92/9.30/3.1
1066 YB92/10.02/4.2
1067 YB92/10.02.4.2
1068 YB92/11.4/3.2
1069 YB92/11.4/3.1
Can I leave it to you to be proactive in tracking developments on the guidance, copying papers to me for information and comments as appropriate. I will in turn ensure HEF(M) (Dr Wight) and MAFF colleagues are fully involved in any action we think necessary at Government level.

8.115 On 17 November 1992, Dr Wight sent Mr Murray and Mrs Whyte a draft letter which she proposed to send to the CTPA. The draft letter echoed Mr Murray’s satisfaction that the matter was being taken up at European level, as well as his concern that the matter should not be delayed. It also reported that SEAC had reaffirmed its view that tallow was not a high-risk product, and that gelatine was also felt not to pose a risk. None the less, it remained advisable for the purchasing company to ensure SBOs were not used in the production process.1070

8.116 Dr Wight’s letter was sent to Mr Phillipson in early December.1071

1993

8.117 In early January 1993, Dr Fielder wrote to Dr Wight enclosing a copy of the Italian proposals to the Commission of the European Communities (CEC) on medicinal products. He stated that at a ‘quick look’ the proposals seemed ‘reasonable in principle as a basis [for the] consideration of cosmetic products’ and he understood that the CTPA had no major problems with this approach.1072

The ECWPC refers the matter to the Scientific Committee on Cosmetology

8.118 On 22 January 1993, another meeting of the ECWPC was held.1073 Dr Gott, who attended the meeting on behalf of DH, reported that while the subject of BSE was raised, no decisions were taken, as most Member States wanted more time to consider the issues. He explained that most Member States were clearly unprepared for detailed discussion and essentially only the French and the English had a grasp of the problem.1074

8.119 The French Higher Council of Public Hygiene was reported to have recommended that bovine material used in the manufacture of cosmetics be supplied from countries free of epidemic, providing the following conditions were met:1075

i. Veterinary surveys were held;

ii. Consumption of meat flour [MBM] was controlled;

iii. Material was class IV or sourced from animals under six months old; and

iv. Ovine material was limited to certain classes, provided that the processes used could deactivate infectious agents.

1070 YB92/11.17/6.1–6.2
1071 YB92/12.4/1.1
1072 YB93/1/7.3.1
1073 YB93/02.04/1.1–1.3
1074 YB93/2.04/1.1
1075 YB93/2.4/1.3
8.120 It was decided that the matter would be referred to the SCC. As explained in
the section on regulation in this chapter the SCC provided scientific, in particular
toxicological, advice on matters relating to the Cosmetics Directive. The UK
offered to send any recent advice from SEAC to aid the SCC’s deliberations.\textsuperscript{1076}

March 1993

8.121 By 17 March 1993, an English translation of the French proposals from their
Higher Council of Public Hygiene became available. Dr Fielder told Dr Wight in a
minute that he and the CTPA felt the proposals were satisfactory and should be
supported at the May 1993 meeting of the Cosmetics Working Group.\textsuperscript{1077} In the
event, however, the topic was not discussed at the May 1993 meeting of ECWPC.

8.122 Miss Kelly told us that the CTPA prepared general guidelines for its
members around this time.\textsuperscript{1078} We have a copy of the guidelines dated 22 March
1994.\textsuperscript{1079} It seems likely a first draft may have been produced in 1993 and final
guidelines in March 1994.

June/July 1993

MAFF seeks an update on EC discussions

8.123 On 22 June 1993, Mr Howard (Animal Health Division MAFF) asked
Dr Wight and Mr Bradley for an update on the EC position. He referred to a
discussion between Dr Wight, Mr Bradley and Mr Maslin on the progress of the
proposed guidelines before SEAC’s April meeting:

\[Y\]ou undertook to establish the timetable for EC discussions and on that
basis decided not to raise the matter at that meeting. Mr Maslin made the
point that the Committee should be involved at some point and that this
should be before any decision by the EC.\textsuperscript{1080}

8.124 Mr Howard asked whether discussions about the proposed guidelines were
under way in Brussels and, if so, whether the issue should be raised at or before the
next SEAC meeting.

8.125 Mr Bradley replied to Mr Howard the next day. He said he had had no direct
contact with the EC on timetabling and no knowledge that Dr Wight was formally
asked to do this. He said he had spoken to Dr Wight with the following outcome:

1. She will send me a paper on the subject from Italy.
2. A previous translation of a paper from France was forwarded and
   suggested changes made. This was copied to Mr Lowson on 26 March with
   a minute from me.
3. Overall Dr Wight does not see any serious problems.
4. The matter is being dealt with she told me by a technical sub-group of the Consumer Group in DGXI. It is regarded as low priority and is moving very slowly.\textsuperscript{1081}

\textbf{8.126} The same day Dr Wight asked Dr Fielder, by means of a handwritten note, whether he had any information about the progress of the discussions with the EC, or what the UK trade was doing.\textsuperscript{1082}

\textbf{8.127} Dr Fielder updated the position regarding the EC discussions for Dr Wight in early July. He said the matter had been referred to the SCC, one of whose members had been asked to prepare a draft opinion:

4. . . .This should have been discussed at the meeting on 25 June, but a document sent to the CEC in early June must have got misplaced as it was not circulated. It will now be discussed at an SCC meeting on 15 October.

5. This topic will thus not be discussed by the EC Working Party on Cosmetics until its meeting in early 1994 (there are only 2 or at most 3 meetings a year). If agreement is reached at that meeting proposals will be included in a draft Commission Directive, adapting the Cosmetics Directive to technical progress which will be voted on in mid-1994. Such adaptations are only made on a yearly basis and if discussion is not concluded at the Working Group meeting in January/February 1994 the item may be deferred until the 1995 adaptation directive.

6. Thus at best the BSE proposals may be adopted by a Commission Directive in mid 1994 (with implementation by member states in National Legislation in 1995)

7. As I have said earlier the EC pathway is relatively slow. It is not because a particularly low priority is being put on this particular area (ie bovine material) as suggested in Mr Bradley’s minute of 23 June. It is an inherent property of the procedures used and the limited number of meetings available. The advantage is that agreements are binding on all member states.

8. If it is considered that the urgency of this area requires the UK to take unilateral action (I hope that is not the case) the way forward should I believe be to try and obtain some ‘voluntary’ action under the auspices of the CTPA. We could ask them to consider providing guidance to member companies through their Newsletter etc. I do not believe that we should (or need) to ask DTI to take unilateral regulatory action pre-empting the conclusions of the EC discussions in this area. At present CTPA prefer to await the results of the EC discussions, but will be supporting (through the European Trade Association COLIPA) in principle the French proposals.

9. We will need to arrange a meeting with CTPA if we believe the urgency of the situation requires unilateral action.\textsuperscript{1083}
On 6 July 1993, Dr Wight replied to Mr Howard’s minute of 22 June 1993 sending copies to Mr Bradley, Mr Eddy, Mr Lister and Dr Fielder. She said that the matter was progressing rather slowly at EC level because of the procedures necessary and the limited numbers of meetings available to the relevant Committee. Dr Wight indicated that the topic was likely to be discussed by the ECWPC at the beginning of 1994, and that following a favourable outcome of these discussions, adaptations would be made as necessary to the Cosmetics Directive and then adopted later in the year. She said she did not perceive any great urgency on the issue:

We seem to be in general agreement on measures to minimise risk with the CTPA . . . who in turn would prefer to support European proposals rather than see any unilateral UK action at this stage.\textsuperscript{1084}

Dr Wight told us that although any change to the Directive was not envisaged until later in 1994, she did not perceive this as a danger to public health that needed to be dealt with swiftly:

I think that the minute makes it clear that there was a feeling – I do not know, I was not involved in any negotiations after the initial discussions with the industry on any sort of legislative basis either in the UK or in Europe. But I think the – my understanding, from colleagues who were involved, was that they would rather progress it on sort of all fronts through Europe rather than the UK acting independently. But there was the guidance that was being drawn up.

. . . we had brought it to the attention of the industry that the industry were taking steps through their own channels to communicate that to their members, I think that is fair to say that over and above that I did not see that there was a pressing need.\textsuperscript{1085}

1994

February to April

In February 1994, the ECWPC held another meeting. At this meeting the German delegation called for measures to ban the use of bovine-derived substances in cosmetics, as had been done with medicinal products. The Commission pointed out that the SCC was investigating the problem.\textsuperscript{1086}

The Germans issue their own guidelines

On 30 March 1994, at a special meeting of the EC Health Council, all Member States except Germany supported the UK and Commission view that existing measures to control BSE and protect public health were sufficient. The German Health Minister expressed dissatisfaction with the outcome and issued a
statement reserving Germany’s right to unilateral action.\textsuperscript{1087} Among Germany’s proposed restrictions was:

4. The issuing of recommendations to producers of cosmetics, based on the existing recommendations for the production of medicines. Such a measure is necessary since the theoretical risk of BSE transmission by cosmetics is on a par with that in the case of medicines for external use.\textsuperscript{1088}

\textbf{8.132} In April, Mr Stelchens (EC Agriculture Commissioner) announced in a press release that the Commission was developing guidelines for the manufacture of cosmetics in order to supplement those already adopted for medicinal products.\textsuperscript{1089}

\textbf{May 1994}

\textbf{The CTPA releases guidelines}

\textbf{8.133} The CTPA released its own updated, voluntary guidelines to members in May 1994.\textsuperscript{1090} These drew upon WHO guidelines for inactivating spongiform encephalopathies as well as its four categories of relative scrapie infectivity titres.\textsuperscript{1091} Dr Wight told us that she could not recall whether the guidelines were issued in consultation with DH and MAFF, as had been agreed at the meeting on 21 September 1992.\textsuperscript{1092}

\textbf{8.134} The CTPA guidelines stated that, although cosmetics were generally applied to healthy skin, the risk of infection from application to broken skin was of the ‘same order of magnitude, for the same infecting dose, as the risk from ingestion’. However, tallow, used in soap and lipstick, was not considered to be a risk. The CTPA recommended that bovine ingredients could be sourced from countries free from BSE (or where only sporadic outbreaks were known), on condition that these countries had effective veterinary surveillance and the consumption of feed supplements was strictly controlled. In the absence of this guarantee the following bovine ingredients could be used:

i. Bovine or ovine extracts conforming to class IV of WHO classification;

ii. Bovine and ovine extracts from animals less than six months old; and

iii. Bovine and ovine extracts from animals classified as I, II or III of WHO classification, on condition that suppliers used processes known to inactivate or reduce infection, such as those recommended by WHO for the protection of public health concerning BSE, or other valid procedures.\textsuperscript{1093}

\textbf{July–November 1994}

\textbf{8.135} On 15 July 1994, following reports that the French and Germans were calling for a European ban on British beef, Mrs Payne alerted Mr John Walker, now head of the Chemical Safety Section in DTI, that it was possible France and Germany
might again question the safety of UK cosmetic products at the next meeting of the ECWPC (scheduled for 9 September 1994): 1094

3. Although there is no proof that ‘mad cow’ disease can be transmitted to humans if, in the unlikely event, the French and Germans call for a ban on UK cosmetics the effect would be that soap manufacturers will need to source from UK herds which are certified ‘BSE-free’ or import bovine extracts (see point 4). The other alternative is to replace bovine extracts with other comparable ingredients, for example coconut oil. Small firms which cannot adapt quickly and have low liquidity, will go under. As for manufacturers of ‘exotica’ products, they are virtually all based in France or Japan.

4. If it is possible for humans to contract ‘mad cow’ disease from cosmetics, the risk is greater from ‘exotica’ products because, unlike soap ingredients, the ingredients are not subject to repeated boiling and some are just merely chilled. MAFF have advised the CTPA that the only safe source is Australasia. Along with other European countries, France and Germany have imported from the UK infected feedstuff and live cattle. There have been reports of BSE outbreaks in Germany and France and even in the USA, a prime market for Jersey cattle. The Germans claim that they have ‘cured’ their infected cattle by bathing them in a special dip they have developed but MAFF say there is no magic German cure. The French are masters at suppressing bad news. However, their higher scientific committee has issued ‘approved BSE guidelines’ for French industry to follow. These guidelines cover, amongst other things, cosmetic products and are based on guidelines issued by MAFF. The French have not credited MAFF at all and are touting their guidelines around the Commission.

8.136 On 9 September 1994, the ECWPC met to discuss SCC reports on the safety of cosmetic ingredients. Mr Walker and Miss Mulholland, HEF(M), who worked for Dr Fielder, attended. Mr Walker’s note of the meeting, dated 12 September 1994, records:

The Germans sought a Community approach on the issue of using animal derived ingredients from stock containing BSE. The SCC chair Mr Kemper said SCC had had a look at the matter and said BSE-containing animal products were undesirable in cosmetics, but there was still a problem about data. 1095

8.137 The German proposals on the control of animal products were submitted to the SCC in October 1994.

The SCC issues advice on BSE and Cosmetics

8.138 On 21 October 1994, the SCC issued an interim statement advising ‘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’. 1096
8.139 On 25 November 1994, Miss Mulholland minuted Dr Wight that the German proposals for control of animal products had been submitted to the SCC but were ‘not very enthusiastically received as they were felt to be impractical and unwieldy’. Miss Mulholland went on: 1097

Nothing very much has happened since then. At the last SCC meeting (October), as we understand it, a statement was made to the effect that materials derived from animals should not contain transmissible agents. However, this does not seem to have translated into concrete proposals. The discussion became rather confused with the issue of the use of human material (ie placenta) in cosmetics. The French have recently introduced domestic legislation with this intention and the SCC (and member states) support this. It is thought that proposals on both subjects will be forthcoming but it is unclear how long this might take.

1995

ECWPC decides no amendment to Cosmetics Directive is necessary

8.140 The ECWPC met again on 16 February 1995. 1098 Mrs Payne of DTI attended, along with representatives of DH. 1099 The Working Party concluded that there was no need to amend the Cosmetics Directive to ban the use of bovine material. It was influenced by COLIPA’s assurance that its members used only materials sourced:

i. from BSE-free herds; or

ii. from animals less than 12 months old; or

iii. from body parts for which the WHO confirmed no risk of infectivity; and

iv. from bovine material subjected to heat or acid treatment to remove any possible risk.

8.141 The Working Party considered the opinion issued by the SCC on 21 October 1994 to be too general to be used as a basis upon which to alter the Cosmetics Directive. 1101 The Working Party noted that the SCC was working on more detailed proposals and therefore no decision was made at this meeting. 1102 The possibility of a future amendment was not completely ruled out. 1103

1996

8.142 Commission Decision 96/239/EC came into force on 27 March 1996. This
banned the export from the UK of bovine products, including those destined for use in cosmetic, medicinal or pharmaceutical products.\footnote{L4 tab 7}

8.143 Miss Kelly told us that, following this Decision, the CTPA immediately asked members again for details of bovine-derived ingredients used. The results of the survey confirmed the following:

a) Tallow derivatives were the only ingredients of overriding importance, these being widely used and not easily replaced by non-animal derived materials. The usage of any other bovine derived ingredients was very limited.

b) Major ingredient suppliers were already supplying materials of non-UK-bovine origin. In a telephone conversation with one supplier I was told that the German industry had, for some time, been requiring that ingredients supplied to them should be of non-UK-bovine origin.\footnote{S407 Kelly para. 31}

8.144 Further to this, Miss Kelly told us that by 1996 almost all the CTPA’s members ‘were able to \textit{certify} that their bovine derived material was sourced from outside the UK. Those who could not obtain such certification were in the process of resourcing that material. Most of the UK industries had sourced material from two major suppliers who assured them that their tallow derivatives and gelatin met UK guidelines’.\footnote{S407 Kelly para. 33}

1997/98

8.145 Although outside the period covered by the Inquiry, it is of interest to note the Cosmetics Directive was subsequently amended by Commission Directive 97/1/EC on 10 January 1997 to prohibit the use in cosmetics of:

- Bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom.\footnote{L16 tab 12}

8.146 The Cosmetics Directive was further amended by Commission Directive 98/16/EC on 5 March 1998 to prohibit the use in cosmetics of:\footnote{L16 tab 13}

(a) the skull, including the brain and eyes, tonsils and spinal cord of:

- bovine animals aged 12 months,

- ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum;

(b) the spleens of ovine and caprine animals and ingredients derived therefrom.
However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:

– Transesterification or Hydrolysis at at least: 200°C, 40 bars (40,000 hPa) for 20 minutes (glycerol and fatty acids and esters);

– Saponification with NaOH 12 M (glycerol and soap);

– Batch process: at 95°C for three hours, or

– Continuous process: at 140°C, two bars (2000 hPa) for eight minutes or equivalent conditions.

Discussion

8.147 Cosmetic and medicinal products shared many characteristics in terms of exposing humans to potential risk from BSE. For that reason there was some read across in considering them in relation to BSE.

8.148 A general difficulty for those concerned with human risk was lack of knowledge of what ingredients were actually used in cosmetics, and where they were sourced. We look at this below. Responsibility for the safety of cosmetics sold in the UK and for their regulation lay not with MAFF or DH but with DTI, although DTI relied on DH toxicological expertise. The immediate and obvious first step for MAFF and DH, therefore, was to alert and advise DTI. Thereafter, those producing or overseeing the safety of cosmetic products needed to be kept up to date on the evolving understanding of BSE as a disease and to be in a position to take appropriate measures to block possible channels of transmission to humans.

8.149 We considered three questions on cosmetic products:

– Was DTI promptly and adequately informed?

– Did DTI on being informed take appropriate initial action?

– Was effective action taken thereafter?

We discuss each of these below.

Was DTI promptly and adequately informed?

8.150 Once the Tyrrell Committee had submitted its interim report in June 1989, the question of potential human risk via cosmetics clearly lay on the table. Whatever might be involved in setting up a study of the fate of all bovine and ovine tissues (a proposal we discuss separately in the next chapter), the Report had specifically identified cosmetics as an area that had not been ‘considered and appropriate action taken’. DTI needed to be alerted to this. However, no information was passed to DTI until it sought this itself in early 1990.

8.151 Mr Roscoe, head of chemical safety section in DTI at the time, told us he would have expected DH to contact him when it first became aware of the BSE risk
for cosmetics.\footnote{S471 Roscoe para. 26} We put this to Dr Pickles. She told us her initial view in 1988 was that ‘the risk of BSE to humans from non-parenteral routes of transmission through licensed medicinal products was so slight that effectively it could be disregarded’ and that the CSM/BSEWG at its meeting the following November considered no action on unlicensed topical products was warranted.\footnote{S115D Pickles para. 2}

8.152 We thought this was an unsatisfactory explanation. First, it did not address the need to alert the Department with policy responsibility and knowledge about the topic. Secondly, it seemed to us that an informed judgement could not be reached without knowing the nature of the products involved. Indeed MCA officials were to make that very point in January 1990. Dr Pickles could not be expected to possess this knowledge as a basis for deciding that DTI need not be informed. When we explored the matter further with her at an oral hearing along with the apparent shift in her degree of concern by January 1990, as evinced in her advice to Dr Singh, she said that she gradually began to learn more during 1989:

DR PICKLES: Obviously I have been trying to work out what changed in the year between the initial view we had, I think with expert advice, that we did not need to be concerned about cosmetics, and writing this. I suspect we probably did learn about some of the ingredients in cosmetics, that, you know, thymus and some of the SBOs were used in cosmetics. So if we had gone to DTI, we would have found that out earlier. You are quite right on this.

The other thing that obviously happened during this time period was the offal ban was being brought in and new scientific evidence was coming through in any case about BSE. And I think just generally the atmosphere was shifting and changing. I mean if you ask me why this could not have been said six months earlier, I would find it very difficult to answer.\footnote{T116 pp. 88–89}

8.153 An admirable feature of Dr Pickles’s involvement in the BSE story was her many prompt initiatives to ensure that all those who should be thinking about issues were alerted to them and carrying action forward. Sadly, in the particular case of informing DTI in 1989, Homer nodded. She acknowledged to us that had she informed them, DTI could have addressed the issues six months earlier than they did. She should have done so; but this lapse is minor in comparison with the commendable action taken by her in many other respects.

8.154 We explored whether Mr Lowson, Dr Pickles’s MAFF counterpart in handling BSE and joint customer for the findings in the Tyrrell Report, shared with her the responsibility to inform DTI, or should have ensured DH did so. When we asked him about this he replied:

I am quite sure I at that time would have had the most hazy notion of the DTI’s involvement in the cosmetics industry . . . this was a report delivered to both Departments. The question of any risk or any exposure to the agent associated with cosmetics is clearly a human health matter and, therefore, something where one would expect other Departments to take the lead, particularly the Department of Health.\footnote{T127 pp. 106–107}
8.155 This too was an unsatisfactory explanation. The *Tyrrell Report* was commissioned jointly by MAFF and DH to take a comprehensive view of animal and human health research needs on BSE, and submitted to them jointly. They each had policy interests in its package of recommendations. MAFF took the lead in negotiating how research monies might be found and in the briefing for publication. There is no question in our minds that MAFF had at least equal responsibility with DH, which included ensuring that matters on which recommendations were made were properly followed up as a basis for developing effective policies.

8.156 Did this administrative responsibility lie with Mr Lowson as head of Animal Health Division? We think it did, although others took the lead within the Department in reviewing how a specific programme of research on the recommendations might be drawn up and funded. Action on cosmetics at this stage was a straightforward matter of notifying DTI. We acknowledge that Mr Lowson was new to the Division and had been plunged into handling many novel and pressing issues. His evidence has made plain that he lacks a clear recollection of events surrounding the recommendations made in the Report. No doubt at that stage he relied heavily on his staff in dealing with some matters.

8.157 However, in so doing, he did not thereby relinquish responsibility as head of Division for ensuring policy matters raised in the Report were properly assessed and followed up.

8.158 So far as alerting DTI was concerned, his previous experience should have meant he was well versed in the conventions and processes for informing sponsoring Departments about ‘official’ recommendations impinging on their field of responsibility. Mr Lowson could not recall any discussion or agreement between himself and DH about who would carry matters forward on cosmetics. He quoted to us minutes passing in DH in January 1990 about the DTI query to it as evidence that he did not need to take such action, but these were irrelevant to the period up to then. In the draft Parliamentary Answer he saw in January 1990, to which he drew our attention, the sentence ‘I have no comparable information about the cosmetic industry’ should have jangled warning bells rather than reassured Mr Lowson.

8.159 We consider that, jointly with Dr Pickles, Mr Lowson ought to have promptly ensured that what the Report said on cosmetics was drawn to the attention of DTI. The failure to do so contributed to several months’ delay in the start of action to secure the safety of cosmetic products.

**Did DTI on being informed take appropriate action?**

8.160 The powers available to DTI to take action against the BSE threat, once it was seized of the problem, were limited.

8.161 As in the pharmaceutical industry, cosmetic product manufacturers had their own closely guarded formulae. Unlike the pharmaceutical industry, however, there were no statutory licensing, testing or inspection requirements covering safety, potency or efficacy, and no associated databases held in Departments about what was being used. DTI had poor leverage to require firms to provide such information or to change their ingredients.

1113 YB90/1.18/10.1–10.2
8.162 The cosmetics industry also differed from the food industry, in that it was not protected and governed by controls designed to eliminate suspect animal raw material at source. The lack of this protection was something the industry raised in 1992 and is discussed below. Indeed, a feature of the SBO regulations was that they specifically contained provisions exempting material sent to non-food manufacturers. Even where a cosmetics manufacturer wished to ensure that ingredients such as the tallow he was using had not originated from SBO, this might be difficult to achieve.

8.163 DTI, as noted earlier, did have powers to put a prohibition notice on individual products or to forbid the use of listed ingredients. However, the former required proof of harm and was of only limited application, while the latter involved securing agreement at EU level – an extremely slow process with an intangible human risk such as BSE, as we have seen.

8.164 On learning about the possible risk from BSE, therefore, the only realistic course open to DTI was to persuade the industry to take voluntary action and to seek to assure itself, so far as feasible, that this was being done.

8.165 We do not consider any criticism attaches to DTI for failing to take action prior to January 1990. As we have noted, it was unaware of the Tyrrell Report, still under wraps within MAFF walls. We consider Mr Roscoe, head of the DTI Chemical Hazards Section, is entitled to register the significance of the possible connection between BSE and cosmetics in the light of his conversation with Professor Dayan and for thereafter himself taking up the matter with DH. Had he not done so, further months might have been lost.

8.166 We also think Mr Roscoe deserves credit for promptly contacting the cosmetics industry’s trade association, the CTPA, as soon as he had Dr Fielder’s advice. The CTPA had noted the Parliamentary Answer referred to above and also acted commendably promptly in writing to its Perfumery Working Group, asking members to confirm that if they used any bovine offal extracts they would ensure these were from cattle reared outside the British Isles. This was followed up by a newsletter in March to all members asking whether they used bovine material and what products it was used for.

8.167 This was a valuable initiative and the most significant single action taken to address the risk to cosmetics. However, DTI, DH and MAFF all needed to know the outcome. This did not happen. Moreover, although it was the major trade association of which all mainstream manufacturers were members, CTPA did not cover the whole of the industry. Mr Roscoe referred in a statement to 90 per cent coverage. DTI had no list of firms outside the CTPA, and thus lacked the means to inform them other than through a general press release.

8.168 Mr Roscoe told us he considered that a press notice as an alternative way of alerting non-member companies would have been a ‘blunt instrument’ that would only have risked attracting irresponsible media coverage. In the light of the DH advice that the risk was remote, this would have caused unnecessary panic. For similar reasons, Mr David Jones, Head of the CSU at DTI, has supported this view. We accept this was a reasonable judgement.

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1114 S471B Roscoe para. 8
1115 S471A Roscoe para. 6
1116 SS19 Jones para. 15
8.169 However, the alternative was to make special efforts to identify non-members of the CTPA. This was not done. Mr Roscoe stated:

There were so many small manufacturers making cosmetic products, that in my view it would be impossible to compile a list of manufacturers who are not members of the CTPA . . . I do not know of anybody who has compiled a list of manufacturers who were not members of the CTPA.1117

8.170 By way of testing this proposition, we consulted the Dun & Bradstreet publication Key British Enterprises, a trade directory. It took only a few hours’ work to extract a list of cosmetics companies who were not members of the CPTA. We think it was unfortunate that Mr Roscoe did not explore the option of doing something similar. Such a list might have been useful to the Department for other purposes.

8.171 When we asked him about this, Mr Roscoe said:

At the time I was unaware of the existence of the Dun and Bradstreet publication ‘Key British Enterprises’. Had I been aware of its existence I might well have consulted it and endeavoured to make contact with those manufacturers who were there listed who were not members of the CTPA. However I was not particularly worried since I had been advised that the risk was, in any event, likely to be remote; I had warned 90% of the industry through the CTPA, including all of those we knew had been using bovine material.1118

8.172 His reference to known users of bovine products concerned a DTI investigation a couple of years earlier into extravagant claims of skin regeneration through such material.

8.173 We noted from Mr Roscoe’s evidence that the over-simplified and apparently reassuring message ‘the risk is remote’ influenced perceptions in this part of Whitehall as elsewhere. DH had not indicated that any special efforts were needed, or called for reports about the outcome. Indeed, as we have seen, MAFF and DH at this stage had given little thought to cosmetics as a possible pathway of infection.

8.174 None the less, the thrust of Dr Fielder’s advice to DTI was clear. It would be prudent to eliminate the risk by reformulating products or sourcing outside the British Isles and these recommendations should be transmitted to the industry. This kind of guidance is not lightly given by Government. Indeed, as we discuss below, its implications were to cause Mr Meldrum some concern in April 1990 when he registered the contents of Dr Pickles’s draft paper to SEAC (see paragraphs 8.193–8.194). We consider that on a matter that justified issuing national guidance about switching away from UK materials it was unfortunate that Mr Roscoe did not endeavour to identify and contact firms outside the CTPA. It was indeed, as he said, a ‘flaw in the system . . . that we could not reach all manufacturers’.1119

1117 S471 Roscoe paras 47, 48
1118 S471B Roscoe para. 8
1119 S471 Roscoe para. 24
8.175 We believe that DTI should regularly check that an up-to-date communication system is in place with each of the industries it sponsors to enable it to contact and advise all those who need to know in the event of future questions arising over the safety of an ingredient or process in general use.

What happened next

8.176 We now turn to consider some shortcomings in the way matters were handled thereafter. We do not suggest that individuals should be criticised in relation to these. Some of them had wider causes and some are clear only with the benefit of hindsight. However, they raised some general questions over the way cosmetics safety was administered and we revert to these at the end of this chapter.

8.177 The most striking feature of the handling of the BSE risk to cosmetics after 1990 was its erratic and leisurely pace. We considered the reasons for this.

The causes of delays and diversions

8.178 We saw four main causes.

(1) *The risk was perceived as remote, and action therefore not urgent.*

8.179 As in other areas, a simplistic reading of the Southwood findings diluted the response. It was not appreciated that the Southwood Report was not intended to be definitive. As Sir Richard Southwood told us, the members of the working party thought their report was a statement of the position at the time. They hoped that there would be enough research done and enough new discoveries that it would soon be out of date. Indeed, this was emphasised in the Report itself. We believe that had those concerned had a different understanding about the expert advice on risk, this would have influenced the urgency with which various matters were addressed. They would not have allowed the best to become the enemy of the good.

(2) *The differences between the statutory regime on cosmetics and those on food and medicines provided a poorer repertoire of possible responses.*

8.180 The SBO regulations screened out suspect ingredients from food, but did not do so for cosmetics. Nor, as was the case for medicines under the Medicines Act, did the Consumer Protection Act or relevant regulations impose any licensing requirement on cosmetics. There was no ready way of identifying immediately all relevant manufacturers and products. The Secretary of State had powers, for example, to obtain information and to prohibit the supply of unsafe goods on an individual basis, but there were different criteria and statutory powers from those that applied to food and medicines. Relevant European legislation limited the action that could be taken.

(3) *Since cosmetics were largely EU ‘occupied territory’ UK action had to interact with EU requirements.*

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1120 T106 p. 12
1121 IBD1 tab 2 p. (i)
8.181 Even with a sense of urgency, it would have been difficult to secure swift action on an EU-wide basis. Cosmetics were an internationally traded product and largely ‘occupied territory’ under Community legislation. International negotiations are by their nature far more protracted than decision-taking within an individual country, particularly where the problem being addressed principally concerns only one Member State. As a long-term strategy it made good sense for the UK to seek EU-wide action since cosmetics were so widely sourced and traded. But what was also needed was to ensure that matters were satisfactorily carried forward on an interim basis within the UK while the issues edged through the toils of EU committees.

(4) *There was confusion about who was holding the ring.*

8.182 As we have discussed earlier, there was initial delay in informing DTI. Thereafter there was to be further confusion about what fell to DH and DTI respectively to do. Effective management of the situation to ensure the safety of cosmetics using bovine products and negotiation in the EU required shared perceptions and good working relations between DTI and the cosmetics industry it sponsored. It also required good communication and policy coordination between DTI, DH and MAFF. Somebody, to use an apt phrase adopted by Mr Roscoe, needed to hold the ring in managing the various interests. This proved to be a weakness as events unrolled.

8.183 Mr Roscoe told us that throughout his time on cosmetics safety:

> I kept complete control of events taking place between the Department of Health, the industry and DTI.

> I ‘held the ring’ between my advisers at the Department of Health and the members of the cosmetics industry.\(^ {1122} \)

8.184 However, the fact was that DH engaged in direct action about BSE with the trade association without informing DTI. When Mr Roscoe moved to new duties in February 1992, his role on cosmetics safety was inherited by his HEO, Mrs Payne. She told us her first involvement with BSE was when the CTPA invited her to its meeting with DH and MAFF in September 1992.\(^ {1123} \) She carried the Departmental lead in international negotiations, working closely with Dr Fielder, but so far as cosmetics safety within the UK was concerned her actions indicate that she did not see her role as keeping ‘complete control of events’. Indeed, such an approach in dealing with far more senior officers in other Departments, as well as a well-organised trade association, might have been a difficult one for her to pursue.

8.185 If DTI was not doing so, who then was holding the ring? Was it DH and if so who was responsible? Dr Fielder clearly had an important continuing function throughout the whole story, and was UK expert representative in EC discussions. He received copies of most of the papers and on at least two occasions he offered important handling advice to Dr Wight and Mr Murray. However, his job was as professional adviser to DTI and his colleagues. He did not hold the administrative lead.

\(^ {1122} \) S471A Roscoe paras 4, 5
\(^ {1123} \) S482 Payne para. 3
8.186 Dr Pickles, who had been energetically chivvying action forward on BSE generally, moved to different duties in 1991 and her role on BSE was divided between Mr Murray and Dr Wight. Mr Murray was the DH half of the joint secretariat of SEAC, and in that capacity was asked by Mr Lowson and then by Dr Pickles to follow up SEAC concerns with DTI on the administrative network and ensure they reported back. His HEO, Mrs Whyte, who was active in promoting the action that then ensued, told us she had a purely executive role, taking all her instructions from Mr Murray and Dr Wight.1124

8.187 Dr Wight inherited Dr Pickles’s general coordinating role on BSE and human health in September 1991. She told us: ‘I took the DH lead on drawing BSE to the attention of the cosmetics industry.’1125 However, her understanding, as she came, brand new, from her previous post as a hospital registrar to take up the BSE job in DH, was that all the significant action on BSE had by now been taken and her role was principally a watching brief.1126 We noted that most of her contributions were responses to requests for comments from Mr Murray’s team.

8.188 We were led to the conclusion that the policy responsibility within DH for carrying matters purposefully forward from summer 1991 onwards to ensure the rapid elimination of bovine materials in cosmetics was ill-defined. Insofar as there was a moving spirit, it was at a relatively junior level in the form of Mrs Whyte, who showed considerable perseverance in her attempts to bring to fruition the matters she was asked to pursue.

Consequences for the course of events after 1991

8.189 We considered how these four factors operated at critical points and opportunities for handling policy on cosmetics and BSE between 1991 and 1996.

Following up the guidance

8.190 Things got off to a prompt start. Once DTI had issued its guidance, Dr Pickles did not let the grass grow under her feet in preparing a draft discussion paper for SEAC’s first meeting on 1 May 1990.

8.191 However, her draft fell foul of Mr Meldrum’s opposition to what appeared to him to be encouragement to SEAC to regard the British Isles as an ‘infected area’; a situation he was striving to avoid both on cattle and on meat and bonemeal. As she pointed out, her draft reflected the fact that such advice had already been given on medicinal products and that the cosmetics advice mirrored this. No doubt Mr Meldrum acted from the best of motives, but his intervention was unhelpful and resulted in delay. Not surprisingly and quite properly, Dr Pickles withdrew her paper until the differences between them could be sorted out and consistent advice offered. This is perhaps an example of allowing desire for perfection to hinder the taking of any action.

8.192 We discuss in Volume 10 Mr Meldrum’s general concern about trade implications for the UK.

1124 S545 Whyte paras 69, 15, 49
1125 S192 Wight para. 49
1126 S192 Wight para. 11
8.193 The original momentum having been lost, another year was to pass before, in March 1991, SEAC itself called for a paper on cosmetics following its discussion about tallow – widely used in products applied to the skin. However, we noted that a paper on cosmetics and topical products was discussed by BSEWG in July 1990 and that the SEAC Chairman, Dr Tyrrell, and two other members of his Committee were present for this. Since this paper indicated DTI had been informed and taken action, it was understandable that SEAC was not moved to seek a general discussion itself for some time thereafter.

8.194 In fact, unknown to it, DTI had taken no further action after sending guidance to the CTPA on DH’s advice. It had done all that DH had advised and believed that no more was required of it given that the risk was remote. It did not learn of the more recent developments until August 1992.

8.195 DTI officials’ illusion was fostered by a DH misapprehension about roles that had the effect of keeping them in the dark. DH, unknown to DTI, was dealing directly with the trade association, the CTPA, rather than via Mr Roscoe and his team as the Department responsible for oversight and regulation of cosmetic safety. This was contrary to the usual Whitehall practice, which exists for sound reasons.

Getting sidetracked

8.196 A further twist was that the action on cosmetics within DH became sidetracked in autumn 1991. Following the SEAC meeting in June 1991 Dr Pickles had given Mr Murray prompt advice, raising among other issues the continuing SEAC concern about excessive contact with SBOs, the risk to workers in the cosmetics industry and the need for DTI to accept responsibility for contacting companies who were not members of trade associations. She advised that DTI should be asked to keep DH properly informed about action taken and suggested that Mr Murray’s Division should write to DTI. A draft letter to Mr Roscoe was prepared by 1 August for Mr Murray’s signature covering all the points raised by SEAC and Dr Pickles. Had it been sent, it might not only have carried matters forward, taking account of the EC dimension, but might also have paved the way to a better information base than exists today about what was actually happening in the industry.

8.197 It appears that the letter was never sent. Instead Dr Wight, newly arrived in the Department, was sent Mr Murray’s papers about the SEAC concerns in mid-October, and invited to discuss them urgently.1127 Shortly after, she suggested a robust form of words about not using bovine or ovine tissues such as brain, spinal cord, spleen, thymus, tonsils and intestines. They ‘should not under any circumstances be used in the manufacture of cosmetics or beauty treatments’.1128

8.198 At some point around then, there was a shift in handling plans within DH and a detailed questionnaire was drawn up to send to the CTPA. The proposal now was that, depending on the outcome, a meeting with the CTPA might be arranged and, if need be, guidance would be considered later.

8.199 The letter eventually sent to the CTPA in April 1992 made no reference to the emergence of BSE in other countries. There was no mention of the SEAC

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1127 YB91/10.15/2.1
1128 YB91/10.31/8.1
request or of Dr Pickles’s points, and it spatchcocked Dr Wight’s forthright warning against using bovine and ovine tissues together with a polite request to CTPA to supply the information covered by the questionnaire. This, it said, would be helpful basic information in ‘an attempt to gauge the extent’ of usage. It asked for a reply within three weeks.\textsuperscript{1129}

8.200 Admireable though the aim of getting basic information might have been, it struck us as a job for DTI. Timely discussion with it about the DH proposed approach might not only have alerted officials there to the concerns in SEAC, DH and MAFF, but might also have elicited their views about the realism of expecting the CTPA to supply DH with the wealth of confidential detail sought at three weeks’ notice, if indeed at all.

8.201 Not surprisingly the DH request received a cool response. The letter failed to elicit the desired information. There was no statutory reason for the industry to provide such material, and the situation was not being painted as one where it was in the industry’s own interests to do so. Moreover, the questionnaire appears to have diverted attention away from the strictures in the letter against the use of bovine materials. These were not quoted by CTPA in its bulletin for its members in May. Instead the bulletin simply reported a DH ‘enquiry’ about the use of a list of ingredients and asked firms using them to contact the CTPA.

8.202 Consultation with DTI might also have identified rather sooner the need to handle the situation in its EC context. That in turn might have led to earlier processing through the EC committee system, where it missed at least one time slot. The EC context does not appear to have been taken on board until Dr Fielder’s intervention in July 1992, when he saw the draft guidance that Mrs Whyte was struggling to get agreed within DH. He suggested a meeting with DTI to agree a line before meeting with the CTPA. Dr Wight spoke truly when she observed in responses ‘we on the SE (spongiform encephalopathy) side have a rather scanty knowledge of the cosmetics industry’.\textsuperscript{1130}

**Holding the ring and the EC minuet**

8.203 When, eventually, on 21 September 1992 a meeting about BSE and cosmetics took place between the CTPA, DH, DTI and MAFF, confusion about where the lead lay still reigned. Whose meeting was it? Mrs Payne’s statement indicates she thought it was called by the CTPA.\textsuperscript{1131} Certainly the somewhat tentatively worded letter from DH proposing the meeting gave the clear impression that the CTPA was the arbiter of whether and when it might take place.\textsuperscript{1132}

8.204 The minutes produced by Dr Wight do not indicate who chaired the meeting or who was perceived to be calling the shots.\textsuperscript{1133} Not only were three divisions of DH and DTI at the table, apparently on an equal footing, but also MAFF, who suggested that firms should come to them direct to get advice on questions to ask their suppliers.

\textsuperscript{1129} YB92/4.2/4.1
\textsuperscript{1130} YB92/7.23/2.1
\textsuperscript{1131} S482 Payne para. 3
\textsuperscript{1132} YB92/08.14/1.2
\textsuperscript{1133} YB92/9.23/1.2–1.3
8.205 None the less, it is clear this was an important and useful meeting, if long overdue. It provided the first substantive information exchange between all the Departments involved and the industry. It identified issues to be pursued, such as the safety of tallow and gelatine.

8.206 It appeared to us from the minutes and subsequent events that this was the point where de facto the trade association took over the holding of the ring. It was left with them to provide a list of cosmetics at risk. It was also left with them to decide whether and when to issue guidance. This was a somewhat unusual approach for Departments to accept on a matter of public safety. It differed from the approach to other forms of advice on BSE where there was a possible risk to human and animal health.

8.207 Moreover, shortly afterwards, the centre of gravity for considering guidance moved to the EC arena, and the CTPA became a major party to the negotiations along with the EC cosmetic trade association, COLIPA. A protracted minuet between all concerned ensued at European level.

8.208 Although it had been agreed at the September meeting that the CTPA advice would be subject to consultation and agreement with DH and MAFF, Dr Wight told us that she could not recall whether this happened.\(^{1134}\) Mrs Payne said that she was told the CTPA Council subsequently agreed it would draft joint guidelines with the French industry, drawing on advice from MAFF and DH.\(^{1135}\) Dr Wight later wrote to the CTPA commending its action but adding the concern that it should not be delayed. She also relayed SEAC advice that tallow and gelatine did not pose high risks.\(^{1136}\) None the less, she indicated that it would be advisable for the purchasing company to ensure SBOs were not used in the production process. She did not suggest how this might be achieved.

8.209 When we asked Dr Wight about her role during this period she told us she ‘was not involved in any negotiations’.\(^{1137}\) Her understanding from ‘colleagues who were involved, was that they would rather process it on . . . all fronts through Europe rather than the UK acting independently’.\(^{1138}\) It is not clear precisely which colleagues she had in mind – though we infer this must have been Dr Fielder and Mr Murray – or where she thought the last word on this lay. Having brought matters to the attention of the industry she considered it was up to it and there was no pressing need for her to do more.\(^{1139}\)

8.210 It seems to us that Dr Fielder’s minute of July 1992 rightly warning about the need to work within the Cosmetics Directive had the unfortunate effect of derailing Mrs Whyte’s efforts to get guidance out. Had the matter been viewed as urgent, the process need not have been derailed. We accept that Dr Fielder’s words of caution were sound, and that they were pointing up an obvious flaw in the way matters were being handled. In his minute a year later he pointed out that, given the slow international progress, there were other ways of getting guidance out if the matter were urgent. Indeed, that had been indicated by the CTPA at the September meeting; but, as we have seen, the matter was not viewed as urgent. The risk was believed to be remote.

\(^{1134}\) T71 p. 105
\(^{1135}\) S482A Payne para. 6
\(^{1136}\) YB92/12.4/1.1
\(^{1137}\) T71 p. 106
\(^{1138}\) T71 p. 106
\(^{1139}\) T71 p. 107
8.211 In the event the CTPA did not issue its own guidelines until May 1994, almost three years after the original SEAC advice.

The consequences

8.212 We have considered the consequences of the three-year delay in getting out what was a relatively straightforward update of guidance, albeit to safeguard against a remote risk. It appeared to us that nothing was gained by the delay in terms of better advice and better protection for consumers on the BSE risk. The guidelines the CTPA eventually issued drew heavily on 1991 WHO guidelines, which themselves stemmed from earlier UK guidelines on medicinal products. Most of the information they contained and that firms needed to know could have been issued far earlier. Certainly they could have been advised as SEAC proposed about the need to respond to the emergence of BSE in other countries.

8.213 Instead, it was left to manufacturers to use up stocks and to decide at leisure whether and when to reformulate their products. They were not informed about the strictures in Mrs Whyte’s letter of April 1992. There was little or no pressure on them to act. Was it relevant that the CTPA was effectively taking the lead on progress, working with its international partners in COLIPA? We think it was. We do not criticise the trade association. The general message was that the risk was remote. It had stepped into the gap left by the fragmented Departmental leadership. Departmental correspondence on BSE was now taking place with the CTPA through at least four channels: Mrs Whyte, Dr Wight, Dr Fielder and Mrs Payne. At the meeting on 22 September 1992, it was proposed that it should also deal directly with yet another party, the CVL, on what questions to ask its suppliers.

8.214 Much of what the CTPA did appears sensible and useful. Miss Kelly told us its efforts were vindicated because none of its members used suspect UK material after 1996. Even taking that as gospel, it still leaves unanswered the same questions as arose on medicines: how long did production runs continue? On what scale? What happened to stocks? Would earlier warning have led to action being taken sooner to eliminate them?

8.215 Trade associations do not exist to serve the public interest or to recommend actions that impose costs on their industry. Their duty is to the members who pay their subscriptions. It is not satisfactory to expect them to conduct public business or to reflect wider considerations outside those of their own industry. Nor can they be expected to collect information and offer views from firms who are not their members. With hindsight it seems to us that had there been a clearer and earlier lead from Whitehall, rather than a tacit agreement to let the CTPA make the running, not only would updated guidance have been issued to UK firms much sooner than in May 1994, but the issues might have figured sooner on the agenda of the EC Cosmetics Working Party. It was unfortunate that the DH efforts to get information through a questionnaire backfired and contributed to the delays.
General conclusions

8.216 For an industry as unregulated as the cosmetics industry, whose products were used so widely in relation to skin and eyes, the issue of guidance was particularly important. No other realistic approach was available. The issue of guidance in 1990 as a result of Mr Roscoe’s inquiries, and getting the trade association on board, was a crucial first step which we welcome.

8.217 However, it was only the first step. In what followed we identified three general lessons. First, there needed to be clear collective understanding about what mattered and who was responsible for taking the lead, both interdepartmentally and within DH, in following matters up. In that process it was important not to delegate responsibility to relatively junior levels when clout was needed to make things happen. This was not the course that events took. The outcome was that opportunities were missed, sometimes because of gaps in understanding about the processes.

8.218 Second, the best should not be allowed to become the enemy of the good. Without the pressure of a timetable, this was allowed to happen. Enthusiasm for an elaborate questionnaire led to delay on other action. Time was allowed to drift by while drafts were worked on. The perception that by waiting for the EC directive a more comprehensive outcome would be achieved was allowed to block interim action.

8.219 Third, a striking moral of this tale is that it is not a good idea to leave the sponsor Department for an industry outside a process in which it would normally have been taking the lead.

8.220 In considering these shortcomings and associated delays in moving matters forward, we asked ourselves whether they prolonged any risks to humans from cosmetics.

8.221 It appears that the types of product that might pose the most serious risk – the exotica – were quickly identified. The manufacturers who were trade association members were alerted immediately, though others, if there were any, were not. We noted from the CTPA’s letter of 30 September 1992 that a range of products still included brain material and that they would not be phased out until 1993.

8.222 We were reassured by what we were told on the licensing of collagen implants. On the generality of products the only concerns raised from time to time were about gelatine and tallow. These products are widely used in food and medicine preparation as well as in cosmetic products. It appeared to us that appropriate steps were taken in the light of knowledge at the time and the advice of SEAC to ensure that these did not pose risks.

8.223 A problem for us in assessing all this was the basic and continuing absence of information about what products were on offer and what precisely they contained. Little information on these, other than the purely anecdotal, was amassed by DTI and DH. Infectivity studies were not carried out. No direct action was taken comparable to Mr Bradley’s first-hand investigation in respect of tripe, casings and rennet. We do not know where they were sourced or in what conditions they were
harvested. The CTPA assurances without any supporting data are all that are available, since it has disposed of the details it collected at the time.

**8.224** Thus it is impossible to know today whether the delays we have described in this chapter significantly protracted the period in which people were exposed to such products either because manufacture continued or because existing stocks were not withdrawn.

**8.225** We recognise the reasons why so little information exists today in DTI on these matters. However, it seems to us unfortunate that so little is apparently known about the basic constituents of widely used products of an industry with so many features in common with the pharmaceutical industry. If this information gap still persists, we suggest that it might be reviewed.

**8.226** We also believe attention should be given to the absence of effective statutory powers to destroy at source slaughterhouse materials for human non-food use, such as cosmetics, that are deemed too dangerous to be used for food or medicinal purposes. We noted that this question was raised by the CTPA and that it exercised both DH and MAFF.

**8.227** These matters stretch well beyond our remit. However, it appears to us, as it did to the Tyrrell Committee, that cosmetics were indeed a potential pathway for pathogens, and that not enough was known about this. Future occasions could arise when, as with BSE, there needs to be a means of turning off the tap at source, rather than catching droplets downstream. Consideration might usefully be given to what powers and processes would assist this.