MT.

PART TWO

CONFIDENTIAL FILING

Animal Welfare Matters

Folder: Council Directive of 1976

CLOSED

HOME AFFAIRS

PT1: June 1979

PT2: June 1980

Referred to	Date	Referred to	Date	Referred to	Date	Referred to	Date
~~15.6.90~~							
~~15.1.91~~							
~~29.1.91~~							
~~7.2.91~~							
~~7.5.91~~							
~~24.5.91~~							
~~12.2.92~~							
27.2.92							

PREM 19/3787

Part Closed

HMSO Dd8953031 6/88 C60 GP2265 CCN13412 (3932)

PART

CLOSED

Published Papers

The following published paper(s) enclosed on this file have been removed and destroyed. Copies may be found elsewhere in The National Archives.

Official Journal of the European Commission:
Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC).

Official Journal of the European Commission:
Council Directive of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products (76/768/EEC).

Signed J. Gray Date 29/8/2017

PREM Records Team

Published Papers

The following published paper(s) enclosed on this file have been removed and destroyed. Copies may be found elsewhere on the Internet.

Commission of the European Communities:
SEC(90) 1985 final dated 29 October 1990
Proposal for a Council Directive on the approximation of the laws of the Member States relating to cosmetic products.

A copy of this document can be found in the Archive of European Integration (AEI), hosted by the University Library System of the University of Pittsburgh website.

Signed J. Gray Date 24/8/2017

PREM Records Team

nbpm
- file

cc PM
cc WEC
Political
Press
&
B Wallis

MAFF

Ministry of Agriculture, Fisheries and Food
Whitehall Place, London SW1A 2HH

From the Minister

Dear Colleague

27 February 1992

ANIMAL WELFARE

There is great concern in this country about animal welfare and the Government has given very high priority to ensuring proper standards. We have taken a series of important steps to improve welfare conditions for farm animals in this country, and my objective now is to seek the adoption of the British standards throughout the European Community. The declaration on protection of animals which we secured at Maastricht will ensure that the Community takes full account of animal welfare concerns, and we will make progress on animal welfare a priority for the UK's Presidency of the Community later this year.

I have today issued the enclosed statement which sets out in more detail our plans for taking this issue forward in the Community. I hope this will be helpful to you as an explanation of the Government position and that you will find it useful in responding to any concerns which your constituents and others may express on this important subject.

Yours ever

John Gummer

JOHN GUMMER

MAFF News Release

Ministry of Agriculture, Fisheries & Food, Whitehall Place, London SW1A 2HH. Press Office: 071-270 8973. Out of hours: 071-270 8080. Fax: 071-270 8443.

66/92 27 February 1992

JOHN GUMMER ANNOUNCES NEW INITIATIVE ON ANIMAL WELFARE IN THE EUROPEAN COMMUNITY

John Gummer, Minister of Agriculture, Fisheries and Food, today set out plans for promoting international action on animal welfare.

These would form one of the initiatives of the UK Presidency of the European Community in the second half of this year. Among the priorities would be:

- improved conditions for battery hens;

- further safeguards for live animals during transport;

- higher welfare standards at slaughterhouses.

Mr Gummer said:

"In Britain we have a particular concern for animal welfare which is reflected in the vigorous action the Government has taken to improve the protection of farm animals in this country.

"We have banned the veal crate and are phasing out stall and tether systems for pigs. We have introduced new legislation and codes of practice on livestock markets and slaughter. We have initiated a publicity campaign to raise welfare awareness among farmers and others and have given added impetus to the Welfare Codes by requiring all those attending stock to have received instruction and guidance in the Codes. We have maintained welfare surveillance of farms through the State Veterinary Service and have initiated prosecutions whenever necessary. We are sponsoring a large

body of research to ensure that our welfare policy has a firm scientific basis. We recognise also that farmers' responsibilities extend beyond the protection of their own stock. We have for example, with the Department of the Environment, launched a campaign against illegal poisoning of wildlife with the support of conservation, farming and other organisations.

"In all these policies the UK has led the way in Europe. I now want to ensure that the steps we have taken are extended to the rest of the Community. Standards generally in other Member States lag well behind ours and I want to see them brought up to our level so that animals receive the widest possible protection. This is also essential because unilateral action - while it may give a marketing edge to our producers because of the consumer demand for welfare-friendly products - may also give the opportunity to other countries, producing to lower and cheaper standards, to fill our market. This would please our competitors but would be of no benefit to animal welfare.

"While, therefore, the Government reserves the right to act in this country when exceptional or urgent measures are needed, the main thrust of our policy will be to secure improvements on a Community basis. As the result of a UK initiative, we obtained agreement at the Maastricht summit to an important declaration on the protection of animals. In future all Community legislation on agriculture, the internal market, transport and research will need to take account of animal welfare concerns. We shall also seek to use the forthcoming UK Presidency of the Community to make as much progress as possible on animal welfare.

"The issues to arise this year are expected to include a review of the Battery Hens Directive, where we will be seeking substantial improvements in the current standards for battery hens and new standards for other egg production systems. Further decisions will also be needed on animal transport. The Directive agreed last year provides a

suitable framework and we secured agreement to the maintenance of our safeguards on export of horses, but further decisions are needed on key issues such as maximum intervals between feeding and watering for different livestock species. We will be pressing for these rules to be as close as possible to existing British standards. Similarly on protection of animals at slaughter, on which proposals are awaiting discussion in the Council, we will be pressing for the decisions to be based on the high standards already in operation in this country. We will press for a revision of Community standards on welfare of calves and pigs, where the Council's decisions last year on veal crates and pig stalls and tethers were most unsatisfactory. We will also press for higher standards through wider international bodies such as the Council of Europe and will seek to ensure that all countries trading with the Community operate to equivalent levels of animal welfare.

"In all areas of farm animal welfare we shall continue to benefit from the valuable independent advice of the Farm Animal Welfare Council.

"In areas beyond the protection of farm animals, I am very concerned to ensure that proper welfare controls are exercised on the trade in wildlife, especially wild birds about which there has been great concern. I am in close touch on this with colleagues in the Department of the Environment who are making a major announcement today on the Government's approach to this issue. We will continue to support strongly the United Nations moratorium on large scale pelagic drift nets, and we were successful last year in negotiating a Community regulation to limit the length of drift nets used by EC vessels. These measures are addressing positively the problem of inadvertent netting of dolphins and other species. We will also continue to take a lead in the International Whaling Commission to uphold the moratorium on commercial whaling.

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"The Government will continue to give a very high priority to animal welfare and will take every opportunity to impress on our Community partners the need to pay proper regard to this vital issue."

ANIMAL WELFARE: GOVERNMENT ACHIEVEMENTS

The Agriculture Departments' achievements include

- Negotiation in EC of Directive to protect animals during transport, including retention of national arrangements for horses.

- Regulations to ban veal crates.

- Regulations to phase out close confinement stall and tether systems for pigs.

- New legislation on welfare in livestock markets and on general protection of farm animals.

- New legislation and codes of practice on welfare at slaughter.

- Welfare Codes for farm animals.

- Maintaining support for Farm Animal Welfare Council and implementation of large number of FAWC recommendations.

- Continuing publicity campaign to raise welfare awareness among farmers and others.

- Encouragement of high welfare standards through State Veterinary Service, prosecuting where necessary.

- Tightening controls on import of wild birds, including reduction in consignment sizes.

- Strong support for UN moratorium on use of large scale pelagic drift nets and successful negotiation of EC Regulation to limit length of drift nets used by EC vessels.

- Strong support for IWC moratorium on commercial whaling; action against 'scientific whaling'; pressure for thorough examination of humaneness of whaling methods.

- Development of R & D programme to give welfare policy a firm scientific base.

The Home Office has

- Tightened controls on the use of live animals in biomedical research through the Animals (Scientific Procedures) Act 1986. The legislation is recognised as the toughest of its kind in Europe and the Government has pressed for Community controls to be based on the strong UK safeguards. The Government has continued to encourage alternative procedures wherever possible and is funding an ongoing research programme into ways of reducing or replacing the use of animals in research.

- Given full support to legislation to strengthen the Protection of Animals Act 1911, including increased penalties and stronger powers for Courts to disqualify offenders from having custody of any animal.

- Supported legislation to give stronger protection to wild badgers.

- Supported legislation to strengthen the enforcement of the welfare controls on dog breeding establishments.

- Sponsored amendments to the Veterinary Surgeons Act 1966 to phase out the docking of dogs' tails by unqualified persons.

- Ensured the adoption of the Protection Against Cruel Tethering Act 1988 which created a specific offence of causing unnecessary suffering by the tethering of horses.

- Adopted orders to give added protection to seals following the outbreak of distemper virus among seal colonies in 1988.

- Consolidated the legislation on protection of deer, including the greatly strenthened safeguards introduced in the Deer Act 1980.

The Department of the Environment has

- Tightened controls on protection of wildlife and use of poisons and traps.

- Launched campaign with MAFF against illegal poisoning of wildlife.

- Negotiated an EC Regulation to ban the import of furs from countries which use leg-hold traps.

- Improved standards in British zoos through firm application of the Zoo Licensing Act

- Supported the draft EC Directive to set basic standards for all European zoos.

- As explained in today's separate announcement, launched a major initiative for action to clamp down on abuses in the international trade in wild birds.

-END-

CCPL

Northern Ireland Office
Stormont Castle
Belfast BT4 3ST

The Rt Hon John Gummer MP
Minister of Agriculture, Fisheries
and Food
Whitehall Place
LONDON
SW1A 2HH

File
ASpm

17 February 1992

Dear John,

I don't think we can have seen this - with WEC/MA?

ANIMAL WELFARE

Thank you for copying to me your letter of 23 January to Angela Rumbold and Tony Baldry summarising the Government's approach to animal welfare. I understand that at your meeting you agreed the general approach being adopted by the Government.

I fully support the proposals set out in your letter and agree that our strategy on animal welfare should be built upon to encourage our Community partners to give higher priority to this important subject.

Northern Ireland has kept in step with Great Britain on animal welfare and will continue to do so.

I am copying this to the Prime Minister, Douglas Hurd, Kenneth Baker, Michael Heseltine, David Hunt, Ian Lang, Angela Rumbold and Tony Baldry.

Yours ever

Peter

PB

LD/SOFS/8491

610

CC/M

MAFF

Ministry of Agriculture, Fisheries and Food
Whitehall Place, London SW1A 2HH

From the Minister

The Rt Hon Angela Rumbold CBE, MP
Minister of State
Home Office
Queen Anne's Gate
London SW1H 9AT

7th January 1992

16 pm

ANIMAL WELFARE

You have kindly agreed to join Tony Baldry and me on 29 January to discuss the Government's overall approach to animal welfare.

You will be well aware of the immense public and political concern on this issue. It is for example by far the biggest subject dealt with by this Department in terms of correspondence from MPs and the public. We are under pressure to clamp down on all forms of animal abuse both in this country and, where possible, elsewhere through action in the Community and other international organisations. We must do all we can to respond to these concerns.

The Government has a good record in this area. In 1990 I launched an initiative to carry our concern for farm animal welfare into the Community. Some progress has been made (including the important animal welfare declaration agreed at Maastricht) although it is inevitably a hard battle to convince our Community partners to give the matter as high a priority as we do in this country. At home we have continued to develop new legislation and other measures to improve the welfare of farm animals and I know that your Department has also been very active on animal welfare issues.

I would like now to identify ways of maintaining this momentum and to ensure that we have a coherent approach across Government in all policy areas which affect animals.

This is important both because in some areas Departments are dealing with different aspects of the same issue, and because we need to follow a uniform policy of care for animal welfare. I hope therefore that you will be able to contribute ideas within your own areas of responsibility for developing initiatives in this area.

In preparation for the meeting we have prepared the attached paper which lists Government achievements and examples of possible areas for further action. This is intended purely as an aid to discussion and you and Tony will no doubt comment on any points where we may not have given a full picture of Home Office and DOE responsibilities. I hope that after considering these ideas, and any others which emerge, we will be able to agree an action plan for taking forward Government policy on this important subject.

I am copying this to Tony Baldry and also to the Prime Minister, Douglas Hurd, Kenneth Baker, Michael Heseltine, Peter Brooke, David Hunt and Ian Lang.

Yours ever

JOHN GUMMER

ANIMAL WELFARE

(a) GOVERNMENT ACHIEVEMENTS

1. The Agriculture Departments' achievements include

- Negotiation in EC of Directive to protect animals during transport, including retention of national arrangements for horses.

- Ban on veal crates.

- Phase-out of pig stalls and tethers.

- New legislation on welfare in livestock markets and general protection of farm animals.

- New legislation and codes of practice on welfare at slaughter.

- Welfare Codes for farm animals.

- Maintaining support for Farm Animal Welfare Council and good record on implementing FAWC recommendations.

- Continuing publicity campaign to raise welfare awareness among farmers and others.

- Encouragement of high welfare standards through State Veterinary Service, prosecuting where necessary.

- Tightening controls on import of wild birds, including reduction in consignment sizes.

- Strong support for UN moratorium on use of large scale pelagic drift nets and successful negotiation of EC Regulation to limit length of drift nets used by EC vessels.

- Strong support for IWC moratorium on commercial whaling; action against 'scientific whaling'; pressure for thorough examination of humaneness of whaling methods.

- Development of R & D programme to give welfare policy a firm scientific base.

2. The Home Office has

- Tightened controls on animal experiments through the Animals (Scientific Procedures) Act 1986 and encouraged use of alternative testing procedures where possible.

- Introduced the Dangerous Dogs Act (a welfare measure in that it aims to prevent keeping by irresponsible owners).

- Initiated action to ban docking of dogs' tails by non-veterinarians (legislation made by MAFF under Veterinary Surgeons Act).

3. The Department of the Environment has

- Tightened controls on protection of wildlife and use of poisons and traps through the Wildlife and Countryside Act 1981 (as amended).

- With MAFF, launched campaign against illegal poisoning of wildlife.

- Taken powers to restrict trade in species which are unlikely to survive in captivity.

- Jointly with MAFF, written to the EC Commission seeking tighter controls on the wild bird trade.

- Sought to improve standards in zoos, eg in debate over London Zoo.

(b) POSSIBLE FURTHER INITIATIVES

Agriculture Departments

We plan to

- Keep up the pressure for high welfare standards across EC, with proper enforcement.

- Consider with DOE ways of clamping down on unacceptable features of the wild bird trade.

- Implement outstanding FAWC recommendations on slaughter when Parliamentary time permits (unless dealt with through EC).

- Use new powers to make regulations on training of slaughtermen and further codes of practice on welfare of animals at slaughter.

- Maintain support for FAWC and implement recommendations wherever possible.

- Maintain publicity campaigns and support initiatives to promote the marketing of 'welfare friendly' products.

- Continue R & D programme, concentrating on key areas such as welfare problems in intensive farming systems.

Home Office

Possible areas for action may include

- Review of dogs legislation in the light of continuing problems of maltreatment, attacks on humans, strays etc and concern over puppy farming.

- Initiative to improve compliance with animal experiments legislation in EC (it is claimed that experiments are increasingly being conducted in other Member States where controls are laxly enforced). Consideration might also be given to further initiatives to reduce the number of animal experiments.

- Review of Protection of Animals Acts (perhaps by independent body) to consider improvements in protection of captive/domestic animals, possible extension to animals in the wild, and increased penalties.

- Tightening of controls on pet shops and animals in circuses (complaints in these areas seem to be widespread).

Department of the Environment

The DOE could

- Support proposed EC Zoos Directive with a view to extending the reasonable standards in the UK across the Community.

- Use the powers introduced in 1981 to control trade in species which are vulnerable to captivity, or at least give strong support to proposals in EC and in CITES to control trade in such species, with particular reference to trade in wild birds. More radically, the Government could endorse the campaign of the RSPB, RSPCA, EIA and European Parliament for suspending Community trade in wildlife, perhaps with exceptions for genuine breeding programmes for endangered species or where there is a clear conservation benefit. This would be a major change of policy which would receive great public support.

General

The Government should

- Seek to ensure that the Community acts on the Maastricht declaration on animal welfare.

- Seek improvements on an EC basis in all areas where the Community has competence for matters relating to animals.

- Consider in particular how to take forward this initiative in UK Presidency.

- Take every opportunity to promote animal welfare through publicity, speeches etc and to raise the profile of the Government's commitment to animal welfare.

- Maintain close liaison with responsible welfare pressure groups, while condemning the activities of militant groups.

SECRETARY OF STATE FOR THE ENVIRONMENT

2 MARSHAM STREET
LONDON SW1P 3EB
071-276 3000

My ref

Your ref

22 July 1991

The Rt Hon Douglas Hurd CBE MP
Foreign and Commonwealth Office
King Charles Street
LONDON
SW1

Dear Douglas

IMPORT OF CAPTIVE BIRDS

In your minute of 3 June to John Gummer about the import of captive birds you supported EC-wide action and suggested that this would not raise competence problems.

You may be interested to know that we have agreed with the Ministry of Agriculture, Fisheries and Food to make a joint approach to the EC later this year. I do not think, however, that the competence issues are quite as straightforward as your letter suggests. Lawyers and officials here who negotiated the Seals Directive in 1983 advise that it involved no extension of competence. The clubbing of seal pups certainly caused much public concern, but Community action was justified on the basis of a conservation study and the Directive's preamble made no mention of moral or welfare issues.

The question of Community competence for animal welfare has been re-examined since 1983, most recently in relation to the use of leghold traps. Again, action was agreed only on conservation grounds.

I accept nonetheless, that Community competence should not be a problem in this case. Insofar as the study we have commissioned from the Joint Nature Conservation Committee shows that the wildlife trade threatens the conservation of birds, we shall seek appropriate action under the EC CITES Regulation. Insofar as the problem is one of the welfare of animals during transport, MAFF is involved in negotiations on a proposed new regulation.

I am copying this letter to the Prime Minister, Kenneth Baker, John Gummer, Peter Lilley, Lynda Chalker and Sir Robin Butler.

Yours ever

MICHAEL HESELTINE

HOME AFFAIRS: Animal Welfare Pt2

CEQ4

QUEEN ANNE'S GATE [illegible]

5th June 1991

IMPORT OF CAPTIVE BIRDS

You wrote to Michael Heseltine on 7 and 24 May proposing a declaration of intent to work towards a Community agreement to eliminate trade in wild-caught birds. You propose that any agreement to ban such trade should not apply where the trade is shown to have positive conservation benefit.

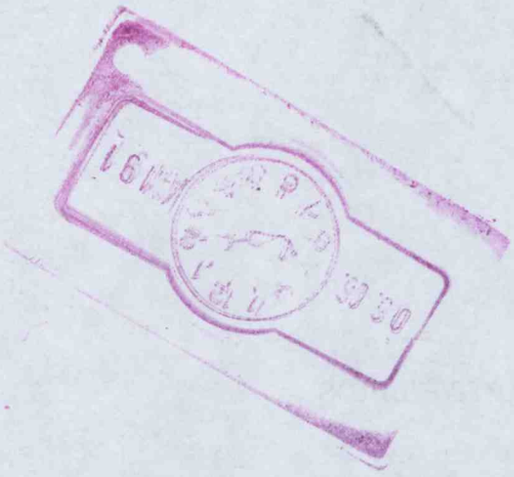
My interest lies in ensuring that any ban would not have the effect of restricting any scientific research carried out under the Animals (Scientific Procedures) Act 1986 which might require the use of wild-caught species. Where the use of certain species of animal is required for research purposes in this country, there may be no alternative to the use of imported wild-caught animals. For example, many non-human primated used in bio-medical research will have been wild-caught abroad and imported into the United Kingdom. A ban on the trade of particular species, which did not make an exception for scientific reasons, could create an unwelcome precedent. If a ban of the type you propose is to be pursued, I would wish exceptions to be made for wild-caught animals for scientific purposes.

Copies of this letter go to the recipients of yours.

The Rt Hon John Gummer MP
Minister of Agriculture, Fisheries & Good
Whitehall Place
LONDON, S.W.1.

HOME AFFAIRS: Animal welfare

pt 2



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MINISTER FOR AGRICULTURE, FISHERIES AND FOOD

Import of Captive Birds

1. Thank you for copying to me your letter of 7 May to Michael Heseltine about the trade in wild birds. I have also seen his reply and your response to that.

2. When you last raised this subject at the end of 1989, I said that, if colleagues considered that a ban was necessary, it was likely to be more effective if it was pursued on an EC-wide basis. This would also avoid the difficulty of unilateral action putting us in breach of our Community obligations.

3. The Department of the Environment were at that point concerned at the possible implications for Community competence. I still believe that the 1983 Directive banning the imports of baby seals skins has set a precedent for Community competence in the field of trade where animal welfare is the primary objective. I therefore continue to see no reason to object on competence grounds to an EC measure, whether for objectives of conservation or welfare.

/4.

4. I am copying this minute to the Prime Minister, the Home Secretary, the Secretaries of State for Trade and Industry, and the Environment, the Minister of State for Overseas Development and Sir Robin Butler.

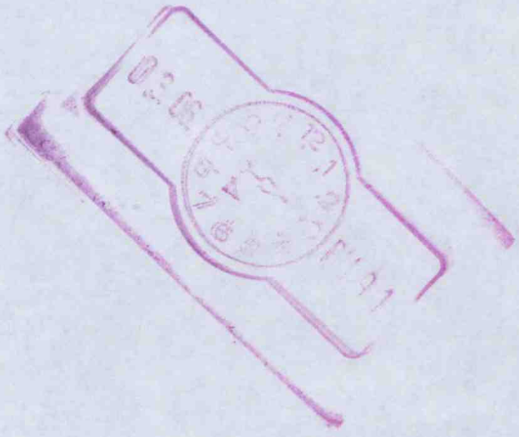
DH

(DOUGLAS HURD)

Foreign and Commonwealth Office

3 June 1991

HONG KONG
: ANNUAL REPORT
PT 2



MAFF

Ministry of Agriculture, Fisheries and Food
Whitehall Place, London SW1A 2HH

From the Minister

The Rt Hon Michael Heseltine MP
Secretary of State for the Environment
2 Marsham Street
London
SW1P 3EB

24 May 1991

Dear Secretary of State

IMPORT OF CAPTIVE BIRDS

Thank you for your letter of 15 May.

I think we must have no delusions about the strength of public concern on this issue. The scientific study which you have established will no doubt provide further detailed information on how the trade affects individual countries and species. We must not however lose sight of the central issue of whether the trade as a whole can be regarded as acceptable. I doubt if we can dispute the evidence brought by the EIA and others on the frequently appalling methods of capture and handling in the countries of origin over which we can have no control. If we are to condone the trade we will be accepting that these practices will continue together with the high mortality levels during transport to this country and in quarantine. It may indeed be shown that continued taking of some species from the wild appears to be sustainable at least in the short term. It will however be very difficult to use this as a justification for continued exploitation when this inevitably produces horrific results of the kind which the current campaign is bringing to public attention.

On issues of animal welfare I have always emphasised the need for action to be taken wherever possible on a Community basis. There have however been instances where I have judged the case for action to be so strong that we should take the initiative by setting high standards first in the UK and then seek their adoption in the Community. This for example is how we are proceeding on the legislation banning the keeping of pigs in close confinement systems. In the case of the bird trade, the Commission's hand would certainly be strengthened in proposing severe restrictions, if they were sure that we would support them in the Council, together with other Member States who we would

/hope would then...

hope would then fall into line. This is why I have suggested both that you could look again at using the powers available under the Endangered Species Act, and that the UK could declare its clear intention to work towards a Community agreement to end the trade except where there are shown to be positive benefits for conservation.

I am copying this as before.

Yours sincerely

JOHN GUMMER

Approved by the Minister and signed in his absence.

Home Affairs: Animal Welfare PTC

SECRETARY OF STATE FOR THE ENVIRONMENT

CC MA

2 MARSHAM STREET
LONDON SW1P 3EB
071-276 3000

My ref:

Your ref:

The Rt Hon John Gummer MP
Minister of Agriculture, Fisheries and Food
Whitehall Place
London SW1A 2HH

15 May 1991

1) Stephen
To see

Dear Minister,

2. nbm
Withi
15/5

IMPORT OF CAPTIVE BIRDS

Thank you for your letter of 7 May about bird imports.

There has, of course, already been extensive contact between our Departments on this. We welcome your support for the study into the conservation implications of trade in wildlife. Tony Baldry announced this initiative on 9 May and I am enclosing copies of his Parliamentary Answer and letter to colleagues.

Tony also met RSPB representatives the same day. They welcomed our initiative and did not suggest that there was a need for action within a shorter time-frame. They recognise the importance of acting on a sound scientific basis and of concerted international action.

I am copying this letter to the recipients of yours.

Yours sincerely

Philip Ward

MICHAEL HESELTINE
Approved by Secretary of State
signed in his absence

DEPARTMENT OF THE ENVIRONMENT
2 MARSHAM STREET LONDON SW1P 3EB
071-276 3000

My ref :

Your ref :

10.5.91

Dear Colleague

TRADE IN WILDLIFE

As you may know, there is growing concern about the effects of trade in wildlife on the survival of some species. In particular, statistics published by the Ministry of Agriculture, Fisheries and Food on mortalities in imported birds have caused some anxiety. I thought you would like to know about the action the Government is taking to investigate whether further import controls are needed.

The UK was one of the first signatories of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). 110 countries are now party to the Convention, which regulates trade in about 30,000 plant and 2,500 animal species. CITES is the primary instrument for preventing the over-exploitation of wildlife by trade, although we have not hesitated to introduce stricter measures in this country and the European Community when necessary. My Department acts as the UK Management Authority for CITES, with advice from two Scientific Authorities, the Joint Nature Conservation Committee of the three territorial conservation agencies and the Royal Botanic Gardens, Kew. We must act on facts and on the most accurate interpretation of them using the best scientific information available.

I have therefore asked the two Scientific Authorities to undertake a wide-ranging study in preparation for the conference next year of the parties to CITES. The terms of reference for the study are:

- To review the evidence as to whether trade in wild-taken plants and animals is compatible with maintaining species at a satisfactory conservation status.

- Insofar as trade in general is not shown to be inimical to that status, to make recommendations to be taken into account in considering proposed changes to the Appendices to the Convention on International Trade in Endangered Species".

The JNCC and Kew intend to complete the study by the end of July.

I can assure you that the Government remains fully committed to ensuring that trade in wild life is controlled so that it does not threaten the survival of any species. We intend to remain in the forefront of promoting and supporting any necessary changes to CITES and complementary measures in this country and the European Community to further conservation.

Yours ever
Tony.

JM

HOUSE OF COMMONS

Mr Steve Norris (Con - Epping Forest):

183 To ask the Secretary of State for the Environment, what steps he is taking to ensure that international trade in wildlife does not threaten the survival of species.

MR BALDRY

This Government has always been active in ensuring that trade in wildlife is controlled so that it does not threaten the survival of any species. Because of growing concern about the effects of trade on some wildlife populations, we have asked our scientific advisors - the Royal Botanic Gardens at Kew and the Joint Nature Conservation Committee - to undertake a wide-ranging study. They will review the evidence as to whether the trade in wild-taken plants and animals is compatible with maintaining species at satisfactory levels. Following this review, they will make recommendations to be taken into account when considering proposals to change current controls under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

The UK was one of the founder members of CITES, which is based on the principle that wildlife should be used only at levels which can be sustained. We have always been in the forefront of promoting and supporting necessary changes to the Convention and complementary measures in this country and the European Community. The study - which is to be completed by the end of July - will make a significant contribution to the conservation of wildlife by ensuring that Government action continues to be based on a sound scientific foundation.

H. AFFAIRS: Animal welfare Names

PT2

MAFF

Ministry of Agriculture, Fisheries and Food
Whitehall Place, London SW1A 2HH

From the Minister

The Rt Hon Michael Heseltine MP
Secretary of State for the Environment
2 Marsham Street
LONDON
SW1P 3EB

7 May 1991

Dear Michael

IMPORT OF CAPTIVE BIRDS

You will know that conservation and animal welfare organisations are planning shortly to mount a new campaign against the trade in wildlife and captive birds in particular.

You have already taken a welcome initiative in seeking scientific advice on the validity of the 'sustainable use' principle which has been quoted as an argument in favour of wildlife trade. I believe though we must go much further in tackling the problems and respond positively now to the mounting concern on this issue. The RSPB's 900,000 members for example will be looking for Government action and it will clearly not be sufficient to defend the status quo.

MAFF's studies of mortality in imported birds in 1988 and 1989 showed that around 13% died during transport or in post-import quarantine. My Department is doing all it can within its powers to improve standards and minimise the animal welfare problems and the risks of spreading disease. There is however much concern over the range of species which are permitted to be imported, over which I have no control. I have for example just received a Parliamentary Question asking for details of mortality in imported hummingbirds. I will have to give the information that of these birds imported in 1988 and 1989 half died during transport or in quarantine. I would like to go further and say that the Government has decided not to permit the import of hummingbirds (and other highly vulnerable species) on the grounds that they are unsuitable for trade and captivity. This would however depend on your willingness to use the powers which Parliament specifically gave to the Secretary of State for this purpose in 1981.

Discussions will no doubt continue on the wider aspects of the trade. It is of course for you to judge the conservation arguments. I for my part see much merit in a declaration of intent to work towards a Community agreement to eliminate trade in wild-caught specimens except in cases where such trade is shown to have positive conservation benefits.

I am copying this letter to the Prime Minister, Douglas Hurd, Kenneth Baker, Peter Lilley, Lynda Chalker and Sir Robin Butler.

Yours ever

JOHN GUMMER

EXPLANATORY MEMORANDUM

1. Directive 76/768 was intended to approximate the laws of the Member States relating to cosmetic products in order that those products might move freely within the Community market (legal basis Article 100 of the EEC Treaty).

Articles 7 and 8 of the Directive introduced the clauses of free movement and exclusive admission respectively with a view to complete harmonization of this sector at Community level. Such a goal could not be attained without harmonizing the safety conditions of cosmetics and the information to be supplied to the user. The following degree of protection was therefore introduced:

- the manufacturer was
  - made responsible for the safety of these products (Article 2);
  - obliged - to comply with the lists of authorized (280 colouring agents, preservatives and UV filters), restricted (50) and prohibited (400) substances annexed to the Directive (Articles 4 and 5);
    - indicate on the packaging and the label of the product five obligatory pieces of information relating to the manufacturer or the person responsible for marketing, the nominal content, the date of minimum durability, particular precautions to be observed in use and the reference for identifying the goods (Article 6);

- no pre-marketing procedure (such as registration, notification or authorization) was required.

Member States could also:

- for purposes of prompt and appropriate medical treatment in the event of difficulties, require that adequate and sufficient information regarding substances contained in cosmetic products be made available to the competent authority (Article 7(3));
- if a product represented a hazard to health, provisionally prohibit the marketing of that product in its territory or subject it to special conditions (Article 12).

Lastly, a regulatory Committee was set up to adapt the annexes to the Directive to scientific and technical progress (Article 10).

Ten years after these rules were implemented, the Commission started looking into the expediency of revising the instrument referred to above in the face of persisting barriers to intra-Community trade.

Talks were held with national experts, manufacturers, consumers, scientists and animal protection groups.

2. After the second round of talks it was apparent that if national laws on cosmetics were to be harmonized Directive 76/768 would have to be amended as follows:

A. Stipulation of the information on the identity, quality, safety and efficacy of the cosmetic product to be kept available by the manufacturer in the event of a check by the competent authority. This information should not constitute a precondition for marketing, whether directly or indirectly, and should be made available only to the monitoring authority in the place of manufacture or of initial importation into Community territory.

In addition, it should be stipulated that the relevant competent authority should be apprised of the place of manufacture, for monitoring reasons, and of information necessary in the event of poisoning, for medical reasons.

B. Transparency regarding the ingredients used in cosmetic products. Given that:
- the manufacturer is responsible for the safety of the cosmetic product (Article 2 of Directive 76/768);
- the manufacturer is free to place his product on the market without any preconditions;
- each monitoring authority in the Member State of marketing should recognize the checks carried out by its opposite numbers in the Member State of manufacture where the information referred to at A is available;
- the user should be in a position to know the content and purpose of a product for economic reasons and to allow for individual allergies,

it is vital that the packaging of a cosmetic product indicate the ingredients used in it and its function;

C. Drawing-up of an inventory of the ingredients used in cosmetics. This should enable the Commission to assess all issues relating to the use of cosmetics;

D. A more watertight and consistent definition of cosmetics by removing the words "exclusively or principally" and "in order to" from Article 1(1). The present definition is as follows:
"A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body

(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 principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours."

The following amendments are proposed:

1. Deletion of the words "exclusively or principally". These adverbs indicate that the recognized functions of cosmetic products are of an exclusive or principal nature. This suggests that there are also functions of an accessory nature. The latter are not defined, however, which gives rise to a state of legal ambiguity as to the scope of the said definition. Deletion of these adverbs would turn the present definition into an exhaustive list and put a limit on the possible functions of the cosmetic product.
2. Deletion of "in order to" and addition of "and/or" between the last two functions. Use of the words "in order to" creates two categories of function: principal functions (cleaning, perfuming, protecting) and secondary functions (keeping in good condition, changing appearance, correcting body odours). The need to associate a secondary function with a principal function gives riseto a contradiction with regard to Article 1(2), which refers to the indicative list of products to be considered as cosmetic products. This means that products intended exclusively to embellish or colour (so as to change appearance), such as foundation or certain hair care products, do not fall within the scope of the present definition, since their "secondary" use cannot be associated with any of the principal uses. Thus the proposal to delete the words "in order to" is intended to turn the two groups of the present definition into six individual functions, whether or not cumulative;

E. A more consistent formulation of Article 2 by deleting the words "be liable to" and adding the words "and reasonably foreseeable". Article 2 is currently worded as follows:

"Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use."

The following amendments are proposed:

1. Deletion of the words "be liable to". The present wording ("liable to cause damage") weakens the need for cosmetic products not to cause damage to human health. It is inconsistent to accept a greater degree of risk to human health in the sale of cosmetic products than in the marketing of medicinal products intended to act upon a pathological condition. Council Directive 65/65/EEC of 26 January 1965 on proprietary medicinal products[1] does not employ this watered-down wording, but lays down in Article 5(1) that marketing authorization is to be refused "if it proves that the proprietary medicinal product is harmful in the normal conditions of use."

In addition, the proposed new measures, such as the compilation of an inventory of ingredients, stipulation of the information to be kept available for the monitoring authority and notification of the place of manufacture will provide a sufficient guarantee of harmlessness; thus the watering-down of the clause on the non-toxicity of cosmetics is inconsistent with the new measures giving it effect.

2. Addition of the words "or reasonably foreseeable" after the word "normal" in Article 2 so as to provide greater protection for the consumer, particularly where the cosmetic product is applied to areas close to those initially foreseen. This is already provided for in the seventh recital of the Directive.

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1 OJ No 22, 9.2.1965.

The proposal for a Council directive on general product safety (COM(89) 162 final) takes the same approach in defining "unacceptable risk" in Article 2;

F. Extending application of the Article 10 procedure to cover the amendment of Annexes I and VIII to the Directive, so that they can be adapted more rapidly to technological progress. It should be noted that Annex I is merely illustrative and cannot take precedence over the abovementioned Directive 65/65/EEC.

Annex I to the Directive, which sets out an illustrative list by category of cosmetic products, serves as a guideline for placing a product in the category of medicinal or cosmetic products. Given the possible overlaps between the preventive and/or physiological aspects of the definitions of medicinal and cosmetic products, it was deemed necessary to add an illustrative list of cosmetics.

There can be no overlap between medicinal and cosmetic products since the interests protected by the legislation governing medicinal products are of a higher order. Directive 65/65 introduced a system of prohibition based on the authorization, prior to marketing, of all pharmaceutical products. Directive 76/768 introduced a system to prevent abuse by establishing a list of admissible substances; cosmetic products are not subject to any procedure prior to marketing.

Directive 65/65 therefore takes precedence over Directive 76/768; Directive 76/768 can only give an indication (area of application, six functions, list in Annex I) of what might be a cosmetic product since in the last resort a product will be considered medicinal if, owing to its form and/or composition (substances used and their concentration), it is subject to a marketing authorization procedure ensuring safety, quality and efficacy.

G. Mentioning the need not to carry out unnecessary experiments on animals when assessing the safety for human health of the ingredients contained in the cosmetic product and the finished product.

Proposal for a

COUNCIL DIRECTIVE

amending for the sixth time Directive 76/768/EEC
on the approximation of the laws of the Member States
relating to cosmetic products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas legal ambiguities in Council Directive 76/768/EEC(1), as last amended by Directive 89/679/EEC(2), particularly in Articles 1 and 2, should be removed;

Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered with a view to the assessment of all issues relating to their use and of the resulting action at Community level with a view particularly to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of this data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas this inventory is indicative and is not intended to constitute a definitive list of substances used in cosmetic products;

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(1) OJ No L 262, 27.9.1976, p. 169.

(2) OJ No L 398, 30.12.1989, p. 25.

Whereas greater transparency is needed regarding the ingredients employed in cosmetics if the latter are to be placed on the market without any prior procedure and in order to obtain the necessary information on the finished product solely at the place of manufacture or of initial importation into the Community and provide better information to the consumer; whereas such transparency should be attained by indicating the product's function and by indicating the ingredients used in a cosmetic product on its packaging; whereas where for practical reasons it is impossible to indicate the ingredients and any warnings regarding use on the container or the packaging, such indications should be given on an enclosed leaflet with a suitable symbol;

Whereas, with regard to the finished cosmetic product, it should be made clear which information is to be made available to the monitoring authorities of the place of manufacture or of initial importation into the Community market; whereas this information should include all the necessary elements relating to identity, quality, safety for human health and the claimed effects of the cosmetic product;

Whereas the competent authority should be apprised of the place of manufacture, for reasons of monitoring, and of the information needed for rapid and appropriate medical treatment in case of difficulties;

Whereas the Commission should be authorized to amend Annexes I and VIII to Directive 76/768/EEC, in view of their illustrative and technical natures;

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product must take account of the requirements of Council Directive 86/609/EEC[1] regarding the protection of animals used for experimental and other scientific purposes, and in particular Article 7(2) thereof,

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(1) OJ No L 358, 18.12.1986, p. 1.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as follows:

(1) Article 1(1) is replaced by the following:

"1. A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view to cleaning them, perfuming them, protecting them, keeping them in good condition, changing their appearance and/or correcting body odours."

(2) Article 2 is replaced by the following:

"Article 2

"Cosmetic products put on the market within the Community must not cause damage to human health when they are applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of every communication made in this regard by the manufacturer or his authorised agent or by all others responsible for placing these products on the Community market."

(3) The following Article is inserted:

"Article 5a

1. Not later than 31 December 1993, the Commission shall, on the basis in particular of information supplied by the Member States, compile an inventory of ingredients employed in cosmetic products.

For the purposes of this Article "cosmetic ingredient" means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

2. The inventory shall contain information on:
- the identity of the ingredient, in particular its chemical name and, where appropriate, the EINECS, CAS and Colour Index numbers;
- the function(s) of the ingredient in the final product;
- where appropriate, restrictions and conditions of use and warnings which must be printed on the label.

3. The Commission shall publish the inventory and shall update it periodically. The inventory is indicative and does not constitute a list of the substances authorised for use in cosmetic products or an exhaustive list of substances used in these products.

(4) In Article 6(1), the introductory phrase is replaced by the following:

"Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering, except for the information mentioned in (g) hereafter which may be indicated on the packaging alone:".

(5) Article 6(d) is replaced by the following:

"(d) particular precautions to be observed in use, and especially those listed in the column "Conditions of use and warnings which must be printed on the label" in Annexes III, IV, VI and VII, which must appear on the container and packaging as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, this information must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the information specified.".

(6) The following points (f) and (g) are added to Article 6(1):

"(f) the function of the product, unless it is clear from the description of the product;

(g) A list of ingredients in descending order of weight at the time they are added. This list shall be preceded by an appropriate indication including the word "ingredients". Where this is impossible for practical reasons, the ingredients must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the ingredients specified. Perfume and aromatic compositions and their raw materials shall be referred to by the word "perfume". Ingredients of a concentration of less than 1% may be listed in any order after those of a concentration of more than 1%. Colouring agents may be listed in any order after the other ingredients.

In accordance with the Article 10 procedure, the Commission shall, no later than 31 December 1993, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.".

(7) Article 7(2) is replaced by the following:

"2. They may, however, require that the particulars provided for in Article 6(1)(b), (c) and (d) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6(1) (f) and (g) be expressed in a language easily understood by the consumer. To this end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.".

(8) Article 7(3) is replaced by the following:

"3. Furthermore, a Member State may require, for purposes of prompt and appropriate medical treatment in the event of difficulties, that the qualitative and quantitative formula of the product be made available to the competent authority, which shall ensure that this formula is used only for the purposes of such treatment.

Member States shall designate that competent authority and send details thereof to the Commission, which shall publish this information in the Official Journal of the European Communities."

(9) The following Article is inserted:

"Article 7a

1. The manufacturer or his agent, provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall, for control purposes, keep the following information readily available to the competent authorities of the Member State concerned at the place of manufacture or, in the case of importation from a non-member country, at the place of initial importation into Community territory:

(a) the qualitative and quantitative formula of the product;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purety and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned;

(d) assessment of the safety for human health of the finished product. To this end, the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure. Should the same product be manufactured at several places on Community territory, the manufacturer may choose a single place of manufacture where this information will be kept available. With regard to this, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1993 and shall inform the Commission thereof forthwith.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels ,

For the Council

(e) the name and address of the qualified person or persons responsible for the assessment referred to at (d). This person must have received university training in the field of natural sciences;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where this is justified by the nature of the product.

2. The assessment of the safety for human health referred to in paragraph 1.(d) of this Article shall be carried out in accordance with the principles of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.[1]

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent national authority of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish this information in the Official Journal of the European Communities.

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1 OJ No L 15, 17.1.1987, p. 29.

(10) Article 8(2) is replaced by the following:

"2. The amendments necessary for adapting to technical progress the Annexes to this Directive and the common nomenclature of ingredients used in cosmetic products shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee on Cosmetology.".

(11) The Annex is added as Annex VIII.

Article 2

1. Member States shall take all necessary measures to ensure that from 1 January 1997 neither manufacturers nor importers established within the Community place on the market products which fail to comply with the provisions of this Directive.

2. Member States shall take all necessary measures to ensure that the products referred to in paragraph 1 cannot be sold or disposed of to the ultimate consumer after 31 December 1997.

ANNEX

"Annex VIII

Home Affairs:
Animal Welfare
Matters
Pt 2

cc PM

10 DOWNING STREET

LONDON SW1A 2AA

From the Private Secretary

7 February 1991

Dear Martin

ANIMAL TESTING FOR COSMETICS

The Prime Minister was most grateful for the information provided about the Commission's proposals and the approach to them that we have so far taken in Brussels. The Prime Minister's view is that, while animal testing may be necessary for advances in medicine, there is no obvious justification for any animal testing for cosmetics: if a chemical is of a sufficient potential hazard to warrant animal testing it has no business being in cosmetics.

The Prime Minister has noted that the Commission have now published their revised proposals. He would be grateful if more thought could be given to how we can further improve this aspect of the Commission's proposals before they go to the Council of Ministers. It might usefully be taken at EQO in the near future.

We spoke separately about the draft reply you are kindly preparing to the people who raised this subject with the Prime Minister.

I am copying this letter to Christopher Prentice (Foreign and Commonwealth Office), Heather Wilkinson (Home Office), Stephen Alcock (Department of Health), Sonia Phippard and Brian Bender (Cabinet Office).

Yours ever

Dominic C

Dominic Morris

Martin Stanley, Esq.,
Department of Trade and Industry

DOMINIC MORRIS

1 February 1991

EC COSMETICS DIRECTIVE

The DTI letter does not add much to the sum of knowledge, and to appreciate this you may care to glance at the attached earlier papers. In particular, the letter gives no hint of where things go from here.

On the one hand it is noted that the Commission has not yet published its final proposals. On the other it asserts that we have actually secured certain objectives on animal testing. Moreover, what it is said has been secured is really quite vague - no testing of new ingredients if "clearly unnecessary": who is to be judge of that? And "keeping the increase in animal testing to the absolute minimum"; and no testing of existing ingredients unless taxocologists are "worried" about them. Who is it, one is led to ask, that makes a living from testing and has a vested interest in as much of it as possible?

It is also rather surprising to be told that there are various ingredients around that are so nasty that there is no option but to test them on animals. I wonder how the Body Shop manages!

Another area where I think the DTI line is uncertain is on full ingredient labelling. They seem to be opposed to this although it is now pretty well an absolute requirement for food. In America it is quite normal (and instructive to see just what goes into shampoo and toothpaste). I don't see why we shouldn't be urging it here. The arguments were not properly rehearsed in last year's EQO paper.

I do not think the DTI response is adequate as a response to the Prime Minister on the representations he received. I suggest you invite the Cabinet Office to ensure that the matter is brought back to EQO at a very early date, so that all the issues can be properly aired and the UK line worked out.

JM

JOHN MILLS

jm110

dti

the department for Enterprise

The Rt. Hon. Peter Lilley MP
Secretary of State for Trade and Industry

Dominic Morris Esq
Private Secretary to the
Prime Minister
10 Downing Street
LONDON
SW1A 2AA

Department of Trade and Industry

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Enquiries
071-215 5000

Telex 8811074/5 DTHQ G
Fax 071-222 2629

Direct line 071 215 4440
Our ref JW1190
Your ref
Date 29 January 1991

Dear Dominic,

As you know your letter of 10 January to Stephen Alcock about the implications for animal testing of the proposed Sixth Amendment to the EC Cosmetics Directive has been passed to this Department since we are responsible for the safety of cosmetics sold to the public and for negotiating amendments to the Directive. For their part the Home Office are responsible, under the Animals (Scientific Procedures) Act 1986 for ensuring that experiments on animals are necessary and as humane as possible.

In the United Kingdom the safety of cosmetics is secured by the Cosmetic Products (Safety) Regulations, made under the Consumer Protection Act 1987, which implement the Directive. The Regulations operate by prescribing ingredients that must not be used in cosmetics, those that may be used but with restrictions and warning labelling, and in the case of more hazardous categories of ingredient, colourants, preservatives and ultra-violet filters, approved or "positive" lists of the only ingredients that may be used. They also make the general prescription that cosmetics must be safe in normal use, as does section 10 of the Act itself.

The European Commission are proposing a Sixth Amendment to the Directive designed to tighten up safety requirements in order to enable a number of Member States to abolish various non-tariff barriers to trade imposed to secure the safety of cosmetics sold in their countries. The Commission have not as yet published their final proposals.

As originally drafted, the proposals implied considerably more testing on animals and in particular testing on the ingredients of cruelty free products. The cruelty free lobby

dti

the department for Enterprise

reacted strongly to this, particularly that section with an interest in promoting the sale of cruelty free produces.

However, with the help of lobbying by the cruelty free lobby, the United Kingdom have succeeded in persuading the European Community to keep the increase in animal testing required by the Sixth Amendment to the absolute minimum.

In particular we have secured that existing ingredients do not have to be tested on animals unless toxicologists are worried about them, and that new ingredients do not have to be tested on animals if this is clearly unnecessary, as in the case of bland "natural" ingredients.

In the case of the two further "positive" lists, our toxicologists advise us that these categories of ingredient - hair dyes and anti-oxidants - are potentially particularly hazardous and do need to be tested on animals before they are used on human beings.

The European Community have however also undertaken to avoid animal testing where other alternatives are available, and to avoid duplication of animal testing.

That said, there are unfortunately as yet no adequate alternative methods for testing for acute toxicity or carcinogenicity, though the industry are working on it. So very often the only way in which suppliers can at the moment ensure that their products are completely safe is by testing the ingredients on animals. Final products themselves are not normally tested on animals.

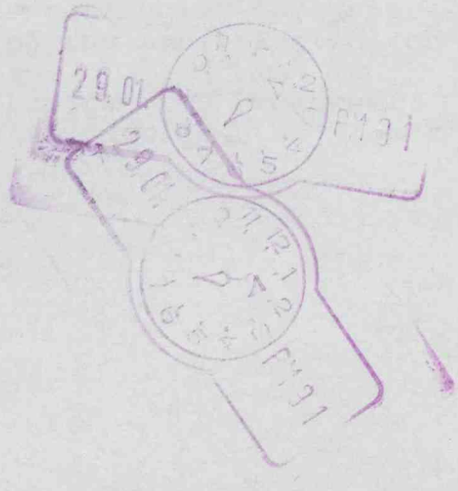
I hope that this is helpful.

Yours ever

Phil Bennett

PHIL BENNETT
Assistant Private Secretary

Recycled Paper



From: THE PRIVATE SECRETARY

r28/1

29/1

GR
Pl. chase DTI.
Dm

HOME OFFICE
QUEEN ANNE'S GATE
LONDON SW1H 9AT

25 January 1991

Dear Dominic

Thank you for your letter of 10 January about animal testing for cosmetics. As we discussed on the telephone, this is a matter on which DTI takes the lead.

When we spoke, I offered to let you have some background on the Animals (Scientific Procedures) Act 1986. The annex to this letter gives a concise account of the way the Act operates and the controls which are exercised over licence holders. The introduction of the 1986 Act greatly stepped up the controls on the use of animals, whilst at the same time permitting valuable biomedical research to continue.

These controls ensure that no more pain or suffering is caused than can be justified on scientific grounds. It is forbidden to cause any animal severe and enduring pain, whatever the purpose of the work. In fact, in a substantial number of cases, only very minor pain or suffering is allowed and a large number of procedures involve no more pain than that caused by the extraction of a blood sample.

Another consequence of the 1986 Act is that the Home Office has established a research scheme to grant-aid research to reduce the number and severity of experiments using animals.

Yours

Heather

MISS H J WILKINSON

Dominic Morris Esq
10 Downing Street
London SW1

APPENDIX

General system of control under the Animals (Scientific Procedures) Act 1986

Introduction

1. The Animals (Scientific Procedures) Act 1986 replaced the Cruelty to Animals Act 1876 with a new and more rigorous system of controls on scientific work on living animals, including the need for both the researcher and the project to be separately licensed, stringent safeguards on pain and suffering, and general requirements to ensure the care and welfare of animals.

Scope of the Act

2. The Act provides for the licensing of experimental and other scientific procedures carried out on "protected animals", which may cause pain, suffering, distress or lasting harm. Such work is referred to in the Act as a "regulated procedure". "Protected animals" are defined in the Act as all living vertebrate animals except man and the definition extends to foetal, larval or embryonic forms which have reached specified stages in their development. Under the Act an animal is regarded as "living" until the permanent cessation of circulation or complete destruction of its brain. Procedures carried out on decerebrate animals are subject to the controls.

3. The Act not only encompasses work covered by the 1876 Act but extends to some work not previously controlled. Such work includes, in particular, some breeding of animals with genetic defects; production of antisera and other blood products; the maintenance and passage of tumours and parasites; and the administration for a scientific purpose of an anaesthetic, analgesic, tranquilliser or other drug to dull perception. Killing an animal requires licence authority in certain circumstances.

4. The controls do not extend to procedures applied to animals in the course of recognised veterinary agricultural, or animal husbandry practice; procedures for identification of animals for scientific purposes if this causes no more than momentary pain or distress and no lasting harm; or clinical tests on animals for evaluating a veterinary product under authority of an Animal Test Certificate (Medicines Act 1968).

Project and Personal Licences

5. Two kinds of licence are required for all scientific work controlled by the Act. The procedures must be part of a programme of work authorised by a **project licence** and the person applying the regulated procedures must hold a **personal licence**. No work may be done unless the **procedure**, the **animals** used and the **place** where the work is done are specifically authorised in both project and personal licences.

6. A **project licence** is granted where the Home Secretary considers that the use of living animals in a programme of work for a purpose permitted by the Act is justified, and the methods proposed appropriate. In deciding whether and on what terms to authorise the project, he is required to weigh the likely adverse effects on the animals used against the benefit likely to accrue from the work. He must also be satisfied that the applicant has adequately considered the feasibility of using alternative methods not involving living animals. The holder of a project licence undertakes overall responsibility for the scientific direction and control of the work.

7. The **personal licence** is the Home Secretary's endorsement of the holder's competence and suitability to carry out specified procedures on specified animals. Applicants, who must be over 18, are required to give details of their qualifications, training and experience. Those who have not previously held a Home Office licence need the endorsement of a sponsor (normally someone in a senior position at the applicant's place of work).

Designation of premises

8. Except where otherwise authorised in a project licence (e.g. for field work at a specified place and time), any place where work is carried out under the Act must be designated as a scientific procedure establishment. From January 1990 establishments which breed certain types of animal (mouse, rat, guinea-pig, hamster, rabbit, dog, cat and primate) for use in scientific procedures ('breeding establishments'), and establishments which obtain such animals from elsewhere and supply them to laboratories ('supplying establishments'), must also be designated by a certificate. Designated establishments are inspected by the Home Office Inspectorate, and are required to nominate a person to be responsible for the day-to-day care of animals, and a veterinary surgeon to advise on their health and welfare.

Fees

9. The Act empowers the Home Secretary to charge fees to the holders of certificates of designated establishments. The fees charged are proportional to the number of personal licensees.

Assessment of Applications

10. All applications for authority under the Act are considered by the Home Office Inspectorate, who recommend whether and on what terms the application should be granted. The Home Secretary may also seek the opinion of an external assessor on part or all of an application, if he thinks it is necessary, for example because the area of research is highly specialised or the techniques involved novel. The assessor will be an expert from an appropriate branch of the biological sciences. The applicant is always informed if it is proposed to consult an assessor. The final decision about any application for authority under the Act rests with the Home Secretary.

11. Applications may also be referred for advice to the Animal Procedures Committee (see paragraph 18 below). All project licence applications for work on cosmetics are referred to the Committee and, for the present, applications for project licences for work on conscious animals involving tobacco products and also for training in microsurgery.

Conditions of Licences and Certificates

12. The Home Secretary may include appropriate conditions in any personal licence, any project licence, or any certificate designating an establishment as a scientific procedure, breeding or supplying establishment. Certain conditions are referred to in the Act itself, in particular conditions in personal licences requiring precautions to be taken to prevent or minimise suffering by animals used in procedures, and requiring any animal in severe pain or severe distress which cannot be alleviated to be humanely killed immediately. Conditions are also included in all project licences regulating the source of animals used in work under the Act. Special restrictions apply to the sources of cats and dogs.

Representations against Refusal of Applications, etc

13. A person whose application for authority under the Act is refused, or whose licence or certificate is to be revoked or varied other than at his own request, has the right to make representations to an independent legally qualified adviser appointed by the Home Secretary. The adviser will consider any representations made and the Home Secretary will take into account the adviser's recommendation.

Additional Controls

14. The Act contains a number of additional controls. These include restrictions on the use of animals in more than one series of procedures; a requirement to kill an animal suffering at the conclusion of a series of procedures; and restrictions on the use of neuromuscular blocking agents. Other controls prevent the performance of procedures as an exhibition to the general public or for live showing on television; empower an Inspector to require the destruction of an animal which he considers to be suffering excessively; penalise the provision of false information in support of an application; and prohibit the improper disclosure of information obtained in confidence by a person exercising functions under the Act.

The Inspectorate

15. The Act gives statutory recognition to the Home Office Inspectorate and describes the Inspectors' duties. Inspectors hold either medical or veterinary qualifications. They are available to give advice and assistance to licensees and other personnel.

16. Inspectors consider in detail applications for licences and advise the Home Secretary how to ensure that only properly justified work is licensed. Inspectors also carry out visits, mainly without notice, to establishments designated under the Act to ensure that its controls and the terms and conditions of licences issued under it are being observed.

17. In order to take account of the demands of the new system of control the format for recording the work of Inspectors was changed from 1 January 1989. During 1989 Inspectors made 2,775 visits to establishments. 2,510 visits were for the purpose of inspection or assessment of research projects. 265 visits were for the purposes of maintaining scientific or professional skills, representing the Home Office or furthering Home Office policy. The change has necessarily involved a loss of comparability with figures for visits to departments published in Table 30 of the 1988 statistics but the figures for 1989 are broadly equivalent to a total of 6,681 visits to departments consisting of 6,416 within designated establishments and 265 elsewhere.

The Animal Procedures Committee

18. The Act established the Animal Procedures Committee which has the duty of advising the Home Secretary on matters concerned with the Act. The Act prescribes the composition of the Committee. The Committee is required in its consideration of any matter to have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures. The Committee makes an annual report to the Home Secretary which is laid before Parliament and published.

Guidance, Codes of Practice and Statistics

19. The Act requires the Home Secretary to publish and lay before Parliament guidance on the operation of the controls, codes of practice as to the care and accommodation of animals and their use in scientific procedures, and annual statistics. A *Code of Practice for the Housing and Care of Animals used in Scientific Procedures (1989; HC 107)* and *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (1990; HC 182)* have both been published. The Guidance sets out in detail how the controls of the Act are applied.

Infringements

20. It is an offence under the Act to carry out regulated procedures without proper authority from the Secretary of State. The Act also creates certain other offences: for example failure to comply with an Inspector's requirement that a protected animal be humanely killed forthwith if it is undergoing excessive suffering. A licence holder is required to observe the conditions of his licence, as described in paragraph 12 above, whether or not failure to do so is a criminal offence.

21. Fourteen cases of infringement of the Act or licence conditions were dealt with in 1989. In one case the person's licence was revoked. Admonishments were given in the remaining 13 cases and in a number of cases additional conditions were imposed on the relevant licences to ensure that any recurrence was unlikely. [Paragraph 20 of Appendix A to the 1988 Statistics recorded that there had been nineteen cases of infringement, one of which was reported to the Director of Public Prosecutions. The figures should have been twenty cases of which two were referred to the Director of Public Prosecutions.]

DOMINIC MORRIS

GR/CF

Pub w PPS pl.

15 January 1991

ANIMAL TESTING FOR COSMETICS

Your letter of 10 January to the Department of Health about the representations made to the Prime Minister.

DTI is in fact in the lead (the Consumer Safety Unit). I have sent a copy of your letter to Mike Gillespie in the Cabinet Office who will ensure proper co-ordination.

I raised queries on this with DTI almost a year ago. They were proposing to agree to a Commission proposal that "limited" animal testing would be required for "basic safety data" for all "new ingredients". This was accompanied by considerable ambiguity as to the position regarding existing ingredients. DTI replied to the effect that the Commission was rethinking its ideas, and I believe the issue has been relatively dormant since. But if DTI have conceded anything on this they will have some explaining to do. There has been no EQO discussion.

Please let me have a copy of the advice you receive.

JOHN MILLS

jm63

APC(90)14

ANIMAL PROCEDURES COMMITTEE

SAFETY TESTING OF COSMETICS ON ANIMALS: THE LEGAL POSITION

Note by the Department of Trade and Industry

The basic position

Although there is no specific requirement in EC or UK law to test cosmetics on animals, animal testing is implicit in the way the EC regime operates and essential in practice to comply with EC and UK legislation.

The legal position before 1978

2 Before the implementation of the European Community Cosmetics Directive cosmetics were regulated by the Sale of Goods Act 1893, as amended, which required goods to be of mechantable quality. Under the Common Law manufacturers were liable for the sale of unsafe products.

The EC Cosmetics Directive

3 The Cosmetics Directive 76/768/EEC, as amended, (copy attached), seeks to ensure the safety of cosmetics throughout the Community and ensure free trade in cosmetics. It operates by prescribing lists of ingredients that must not be used in cosmetics; lists of those that may be used but with restrictions and warning labelling; and in the case of those classes of ingredients likely to pose more of a hazard, colourants, preservatives and ultra-violet filters, "positive" or approved lists of the only ingredients that may be used. The Directive also prescribes the catch-all that all cosmetics must be safe in normal use.

EC practice

4 In practice this means that animal testing is required. Before ingredients are put on the positive lists, the toxicologists in the EC Scientific Committee on Cosmetology require a full range of safety data, some requiring animal testing including testing for teratogenicity and carcinogenicity. In the case of other ingredients, they may require animal testing to ensure that a new ingredient is safe to use, or to review the safety of an existing ingredient that has come under suspicion. A copy is appended of the SCC's Guidelines. More generally, in most cases the only way of meeting the general requirement that cosmetics must be safe in normal use is by means of animal testing.

5 Since the Directive is intended to remove barriers to trade within the EC, Member States are not permitted to prescribe additional warning labelling or labelling such as "tested on animals" or "not tested on animals" to that prescribed by the Directive.

UK Law

6 In the UK the Cosmetics Directive and the amendments made to it are implemented by the Cosmetic Products (Safety) Regulations 1989, (copy appended) which are made under section 11 of the Consumer Protection Act 1987 and section 2(2) of the European Communities Act 1972.

7 The Regulations include the prescription that cosmetics must be safe in normal use. This is in fact equivalent to the general provision in section 10 of the Act which prescribes that all consumer products must be as safe as the purchaser is entitled to expect (the "general safety requirement"), (extract appended).

8 In addition to this, section 2 of the Act (extract appended) provides that the producer is strictly liable for any harm done to the public by a consumer product, even it is not his fault, subject to a number of defences of which the 'development risks' or 'state of the art' defence is the most important. In practice this means that if there is any doubt about a product's safety the producer may have to test the ingredients or, much less frequently, the product itself before he puts it on the market. In order to protect himself from potential liability, the producer may consider that it is necessary to test some cosmetics on animals.

Other international constraints

9 Outside the EEC, the most important restrictions are those of Japan, which tends to put up non-tariff barriers to trade on an ad-hoc basis; and of the United States which tends to ban cosmetics without, in our view, adequate justification.

DTI/CSU

April 1990

ANIMAL PROCEDURES COMMITTEE
COSMETICS SAFETY TESTING ON ANIMALS
NOTE OF A MEETING HELD ON 3 MAY 1990 AT THE HOME OFFICE, LONDON

PRESENT

Animals Procedures Committee

Lord Nathan (Chair)
Dr Balls
Mr Bernard
Mr Ewbank
Dr Hampson
Mr Hollands
Sir Andrew Huxley
Dr Newbould
Professor Pilkington
Lord Soulsby
Professor Spyer
Professor Venables
Mr Marriage (Secretary)

Department of Trade and Industry

Mr Roscoe
Ms Payne

Department of Health

Dr Fielder

Home Office

Mr Johnson
Mr Edmundson

Home Office Inspectorate

Dr Watt
Dr Anderson

Cosmetics, Toiletries and Perfumery Association

Mr Sharpe
Miss Kelly
Dr Clark
(Unilever)
Mr Piccionni
(Beauty Without Cruelty)

Body Shop International

Dr Puri
Ms Adams

1.1 The meeting was held to enable the Committee to apprise itself more fully of the issues surrounding the safety testing of cosmetics on animals. This note records the main points to have arisen from the presentations made by representatives of the Department of Trade and Industry, the Department of Health, The Cosmetic, Toiletries and Perfumery Association and the Body Shop International.

General

2.1 It was noted that in the UK cosmetics testing on animals accounts for only about 0.5% of the total number of procedures for all purposes and 6.6% of all procedures for safety evaluation.

2.2 The Committee noted the wide definition of cosmetics which, following EC practice, encompasses not only beauty preparations but also toiletries such as soap, toothpastes and shampoos and products, such as 'Swarfega', which are undoubtedly not considered by the public to be cosmetics.

2.3 It was also noted that most testing is of cosmetics ingredients rather than of finished products, although figures collected by the Inspectorate for the APC suggest that the split is less marked than the industry representatives at the meeting believed. The figures show that 60% of testing is of ingredients and 40% of finished products. Of the latter some 80-90% is of toiletries. It was pointed out that the main reason for testing finished products is that a specific concern has arisen about the safety of a particular product despite the prior testing of its ingredients.

2.4 The issue of cosmetics testing has become a marketing consideration between companies and is connected to consumers' increasing awareness of 'green' matters. However while many consumers may wish to have cosmetics which have not been animal tested they nevertheless wish them to be safe, innovative and efficacious. It was pointed out that these desires are not necessarily compatible.

The legal position

3.1 It was noted that while there is no specific requirement in UK or EC law that cosmetics should be safety tested on animals it is implicit in the EC regime and the way regulatory authorities work. The EC Cosmetics Directive 76/768/EEC seeks, inter alia, to ensure the safety of cosmetics throughout the EC by a number of means (as outlined in paragraph 3 of APC (90)14).

3.2 The approach of the Directive is to concentrate on ingredients of most concern, with other compounds being investigated only if these give rise to concern about some specific aspect. New compounds require prior approval before inclusion in the permitted lists and hence before they can be incorporated in complete products. A package of toxicity data covering acute and repeated dose effects, irritancy and sensitisation, mutagenicity and, if absorbed significantly through the skin, teratogenicity are generally regarded as the minimum necessary. Most of these data are obtained from animal testing as, in general, acceptable alternatives are not yet available. An exception is in the mutagenicity area, although animal testing may still be required to eliminate metagenesis as a hazard.

3.3 In the UK the Cosmetics Directive as amended is implemented by the Cosmetics Products (Safety) Regulations 1989 made under the Consumer Protection Act 1987. The 1987 Act makes a producer liable in civil and in some cases in criminal law for the safety of his product. In practice if there is any doubt about a product's safety the producer may have to test the ingredients or the product before it is put on the market. This may involve animal testing.

3.5 The EC Scientific Committee on Cosmetology which makes recommendations to the EC Working Group on Cosmetics does not specify the tests which need to be carried out although it promotes harmonisation in test methods by reference to those in Annex V to the EC Dangerous Substance Directive.

These are used in most areas by EC Member States and are essentially in line with OECD test methods. Harmonisation of methods has led to the acceptance of test data in different countries and reduced the needless duplication of studies. There are also established procedures for reviewing these guidelines.

3.6 It was pointed out that as the EC Cosmetics Directive was also concerned with ensuring free trade in cosmetics, any ban on cosmetics tested on animals would have to be the result of agreement within the Community. Similarly it was not open to a Member State to prescribe that products be labelled that they have, or as the case may be, have not been tested on animals.

3.7 The possibility also remains that even if new substances did not need to be tested for cosmetic purposes, there would still be a need for animal testing to meet normal health and safety requirements.

'Not Animal Tested' Claims

4.1 It was noted that it is probably impossible to say with any certainty that an ingredient has not, at some time, been tested on animals. Even where ingredients may not have been tested for use in cosmetics they may well have been tested on animals for another use, for example, for use in the chemical or food industry.

4.2 Some companies only use substances tested before the original 1976 EC Directive. These substances may however still have been tested on animals prior to 1976. It was noted however that in connection with ingredients tested many years go cruelty-free claims could be misleading as the controls on animal procedures then was less than those currently in force.

4.3 Some companies only use ingredients which have not been tested within a rolling 5 year period up to the present. However as it can often take 5 years to obtain approval for the positive listing of a substance the delay is in practice not too

onerous. Companies which adopt this approach can benefit from the results of animal tests while claiming to be opposed to it. On the other hand it was argued by some that a refusal to use substances tested on animals in the past 5 years can provide a means whereby suppliers of raw materials can be encouraged to develop materials whose safety has been assessed by non-animal tested means.

4.4 Further it is not always clear on whose behalf a cruelty-free claim is being made. The producer/retailer may claim not to have tested either the finished product or the ingredients. However his supplier or a contract house may have carried out the necessary animal testing in effect vicariously.

4.5 The Committee's attention was drawn to the concept of 'severability'. 'Cruelty-free' claims often centre on the testing or lack of it which a company has sanctioned or carried out on ingredients rather than on the finished products over which it can be said to have complete control for all intents and purposes. It was pointed out that it could be considered somewhat unrealistic of companies to seek to dissociate themselves from the wider scientific, legislative and safety context of which the substances they use are a part. Such companies use published safety data obtained from animal testing by or on behalf of other companies while seeking to distance themselves from such testing.

4.6 It was also pointed out in relation to the development of alternatives, that their validation relies on the use of existing data obtained from animal testing.

4.7 The Committee was informed that the value of animal testing was limited. As animals do not blush like humans, erythema cannot be observed. Animal skin is shaved before use which changes the skin characteristics and hair growth during the test period creates difficulties. <u>In vivo</u> human testing was a better predictor.

Proposed Sixth Amendment To EC Directive

5.1 It was explained that the proposed amendments have come from the European Commission as an attempt to strengthen the Directive following breaches of it by some Member States. The proposed changes are intended to remove the legal ambiguities in the definition of cosmetics; to achieve free movement of cosmetic products within the Community; to improve the protection of public health; and to increase the information available to the consumer.

5.2 The amendment as proposed implies a substantial increase in animal testing, in the main, because it would require suppliers to submit some animal toxicity data on the current 8,000 ingredients to enable them to be included on the proposed inventory of ingredients. As this information is available on only a few ingredients, a considerable amount of further testing on animals could be required.

5.3 It was noted that while the United Kingdom's counter-proposals which would not result in significantly greater animal testing were believed to be gaining support, it remained to be seen whether the Commission's proposals would be eventually changed satisfactorily as ultimately the decision lies with the Council of Ministers.

Development of Alternatives to Animal Testing

6.1 It was pointed out that the cosmetics industry itself fully recognised that the way forward lies in developing validated and legally acceptable alternatives so that consumers can have innovative ingredients with less allergenic potential which have not been animal tested. While reductions in animal testing had been achieved, further progress was desired. To this end industry has already invested substantial funds, manpower and other resources into the development of alternative testing methods. It was noted that the decision to carry out animal tests was often taken at the highest level within companies only after careful consideration had been given to the need for such tests, including whether the

improvements sought in the product were sufficient to justify the testing involved.

6.2 It was explained that the process of reducing and replacing the use of animals in safety assessment however is a long-term process in which animal testing will gradually be replaced with a battery of in vitro screening methods before testing on humans. A principal constraint is the need to have alternative methods satisfactorily validated.

6.3 It was also noted that the industry was looking at ways of having more regular sharing of test data in the United Kingdom and between countries where this would not be commercially disadvantageous. Such exchanges of information already takes place for substances which after testing have been shown to be unsafe.

Public Perception and Presentation

7.1 It was noted that it was easier for those opposed to cosmetics testing on animals to capture the public's sympathy. As far as industry is concerned the case for animal testing required more detailed exposition, and was a longer term undertaking. The first step lay in seeking to make the case to opinion formers, before presenting the case to the public.

Home Office
30 May 1990

ANIMAL TESTING FILE

25/1

VLS

C:/Animal.VLS

cc HO

10 DOWNING STREET
LONDON SW1A 2AA

From the Private Secretary

10 January 1991

Animal Testing for Cosmetics

Over the Christmas break representations were made to the Prime Minister about animal testing for cosmetics, and in particular the proposed amendment to EC Directive 76/768. As we understand it, there is a requirement to test any new raw materials for cosmetics and toiletries; and that the Commission are likely to publish very shortly "positive lists" where animal testing on raw materials is mandatory. The position on testing for cosmetics and toiletries remains unclear.

The Prime Minister would be grateful for a short note setting out what our position is on these matters and the extent to which we are seeking to influence other EC countries against unnecessary animal testing.

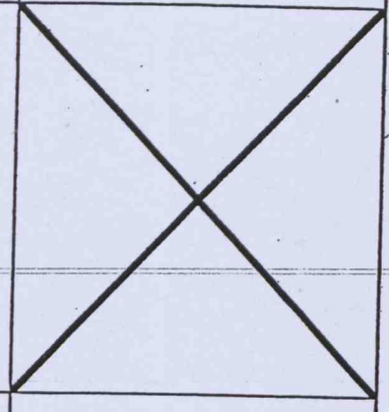
I am not sure whether this subject falls primarily to you or to the Home Office. I am copying this letter therefore, with a similar request if appropriate, to Heather Wilkinson.

DOMINIC MORRIS

Stephen Alcock, Esq.,
Department of Health.

To DH 18/1

The National Archives

DEPARTMENT/SERIES PREM 19 PIECE/ITEM 3787 (one piece/item number)	Date and sign
Extract details: Turnbull to Butler dated 15 June 1990	
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PART 1 ends:-

PAB to HO. 25.9.86

PART 2 begins:-

S. PHIPPARD to AT. 13.6.90


Grey Scale #13
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A 1 2 3 4 5 6 M 8 9 10 11 12 13 14 15 B 17 18 19