Public consultation process on the guide to cosmetic-biocide borderline products

26 September 2011

The Department of Agriculture Fisheries and Food (DAFF) and Irish Medicines Board (IMB) are undertaking a public consultation on the guide to cosmetic-biocide borderline products.

Details of the consultation are given in the consultation information note and comment form below.

Please submit any comments that you may have by 18 October 2011 to Biocides@agriculture.gov.ie

We look forward to your contributions to the process.

IRISH MEDICINES BOARD and DEPARTMENT OF AGRICULTURE FISHERIES AND FOOD

CONSULTATION ON GUIDE TO COSMETIC-BIOCIDE BORDERLINE PRODUCTS

START DATE OF CONSULTATION: **26 September 2011**
CLOSING DATE OF CONSULTATION: **18 October 2011**

INTRODUCTION

The Irish Medicines Board (IMB), as competent authority for cosmetic products and the Department of Agriculture Fisheries and Food (DAFF), as competent authority for biocide products, have prepared joint guidance on the demarcation between products which potentially borderline both of these areas.

Questions on the most appropriate system of regulation that should be applied to such borderline consumer products have been raised by industry at both the European and national level. In recognition of the complexity of this area, the European Commission has recommended that for the classification of consumer products, the relevant competent authorities of Member States should collaborate in the development of their own supplementary guidance to give practical and consistent advice where borderline cases arise. The development of the present 'Guide to cosmetic-biocide borderline products' is the outcome of this collaborative approach to the regulation of such products.

The guide is being made available to stakeholders for consultation with a view to inviting comment and further consideration of its content prior finalisation. The consultation will be open for a period of three weeks commencing from 26 September 2011.

SUMMARY OF PROPOSAL

The IMB and DAFF propose to launch this guidance document to provide information for economic operators placing consumer products on the market which potentially may be classified as borderline cosmetic-biocidal products. The purpose is to provide practical advice for a range of borderline cosmetic-biocidal products currently available on the Irish market. The various factors to be taken into account when considering the system of regulatory control that should be applied to the product including the active substance, excipient composition, method of action, usage instructions, packaging, labelling, literature claims, intended use and presentation, are outlined.

CONSULTATION PROCESS

This consultation is being made available on the IMB and DAFF websites and replies are welcome from all stakeholders. A comment form is provided on the consultation webpage to collate responses and comments.

Please include your comments on these proposals in the table provided and send by e-mail to Biocides@agriculture.gov.ie

or by post to:

Technical Secretariat
Pesticide Registration and Control Division
Department of Agriculture, Fisheries and Food
Backweston Laboratory Complex
Celbridge
Co. Kildare

Comments received will be reviewed and changes made to the proposals as appropriate. If it is necessary to discuss the comments with other stakeholders, the anonymity of the individual or group making the comments will be maintained.

GUIDE TO

COSMETIC BIOCIDE BORDERLINE PRODUCTS

IRISH MEDICINES BOARD

Department of
Agriculture,
Fisheries and Food
An Roinn
Talmhaíochta,
Iascaigh agus Bia

CONTENTS

1. SCOPE

This guide provides assistance with product categorisation for borderline cosmetic-biocide cases. It is recommended that it is read in conjunction with the Commission guidance documents which review categorisation from the perspective of composition and functionality. Further information can be found through accessing documents 1, 2 and 3 which are referenced in section 6.

This guide is not exhaustive and it is important to emphasise that a case-by-case approach is encouraged when determining the appropriate regulatory control to apply to products of this nature. As such, the applicant may be required, to further consult one or more of the Competent Authorities (CAs) involved. In Ireland, the Competent Authority for Biocides is the Department of Agriculture, Fisheries and Food's Pesticide Registration and Control Division (PRCD). The Competent Authority for Cosmetics is the Irish Medicines Board (IMB). Full contact details are provided below in section 7.

2. INTRODUCTION

This guide has been jointly developed by the Irish Medicines Board (IMB) and the Pesticide Registration and Control Division (PRCD) of the Department of Agriculture, Fisheries and Food.

The purpose of this guide is to provide information for companies and persons wishing to place, on the Irish market, consumer products which potentially may fall at the borderline between cosmetic and biocide legislation. In particular, it will assist to determine the applicable legislation and ensure the appropriate regulation of these products.

Borderline issues and questions relating to the most appropriate system of regulation that should be applied to consumer products have been raised by industry at both the European and Member State level. The European Commission, together with the Member States, has developed a number of guidance documents that help provide solutions to some of these cases. It is clearly identified that biocide legislation specifically exempts from its scope products which are defined within the scope of the cosmetic, medicinal and medical device legislation and, are, therefore regulated and controlled by these instruments, unless such products are undoubtedly biocides. The main guidance documents are referenced in section 6 along with additional commentary. However, in recognition of the complexity of this area, the Commission also emphasises that, for the classification of consumer products, Member States should develop their own supplementary guidance to give practical and consistent advice where borderline cases arise.

The purpose of this document is to provide this supplementary guidance. In order to provide practical advice, a range of borderline cosmetic-biocide products currently available on the Irish market at this time (see section 8) are considered. The various factors to be taken into account when considering the system of regulatory control that should be applied to the product including the active substance, excipient composition, method of action, usage instructions, packaging, labelling, literature claims, intended use and presentation, are outlined.

3. LEGISLATION AND DEFINITIONS

The key legal instruments that concern companies manufacturing consumer products and placing such products on the market as biocides, cosmetics, medicinal products and medical devices are listed below.

Cosmetics legislation
- EC Cosmetic Products Directive 76/768/EEC
- European Communities (Cosmetic Products) Regulations, 2004 (SI 870 of 2004), as amended
- Cosmetic Products Regulation (EC) No 1223/2009

Biocides legislation
- EC Biocides Directive 98/8/EC, as amended (S.I. 624 of 2001, as amended)

Medicinal products legislation
- EC Human Medicinal Products Directive 2001/83/EC, as amended
- EC Veterinary Medicinal Products Directive 2001/82/EC, as amended

Medical devices legislation
- EC General Medical Devices Directive – 93/42/EEC (S.I. 252 of 1994)

Legal definitions of products are key in the assignment of the appropriate system of regulatory control. The table below provides the various relevant definitions appropriate to this guidance document as well as providing guidance with respect to those functions that can be used to distinguish borderline consumer products.

It must be noted that these definitions are legally binding and are taken directly from the legislation, however, the product functions do not purport to be the definitive interpretation of the law and/or regulations and are for guidance purposes only. The definitions for human and veterinary medicinal products and medical devices are provided here for the purpose of distinguishing them from biocide and cosmetic products.

Table 1 Definitions for consumer products and their associated primary functions

CONSUMER PRODUCT CATEGORY	DEFINITION	PRIMARY FUNCTION OF THE PRODUCT
Cosmetic product (Article 1 of Directive 76/768/EEC)	A 'cosmetic product' shall mean any substance or preparation intended to be placed 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 mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.	Clean; perfume; correct body odour; change the appearance; protect; keep in good condition;
Biocidal product (Article 1(a) of Directive 98/8/EC)	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render-harmless, prevent the action of or exert a controlling effect on any harmful organism by chemical or biological means.	Antibacterial; antimicrobial; antifungal; viricidal; anti-viral; insecticide; sanitise; hygienically clean; disinfect; kill; repel; deter; destroy; prevent/control the action/spread of; prevent cross-contamination; eliminate; inhibit, preservation, antifouling
Human medicinal product (Article 1(2) of Directive 2001/83/EC)	Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; Or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.	Cure; restore; correct; modify; strengthen; prevent; maintain; protect; stop; heal; control; treat; alleviate; soothe; helps with; clears; anti-inflammatory; anti-septic; antibiotic

CONSUMER PRODUCT CATEGORY	DEFINITION	PRIMARY FUNCTION OF THE PRODUCT
Veterinary medicinal product (animal remedy) (Article 1(2) of Directive 2001/82/EC)	Any substance or combination of substances presented as having properties for treating or preventing disease in animals; or any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.	Cure; restore; correct; modify; strengthen; prevent; maintain; protect; stop; heal; control; treat; alleviate; soothe; helps with; clears; anti-inflammatory; anti-septic; antibiotic
Medical device (Article 1(2)(a) of Directive 93/42/EEC)	Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;	Restore; correct; modify; strengthen; prevent; maintain; protect; stop; heal; control; treat; diagnose; monitor; replace; compensate for;

4. PRODUCT FUNCTIONS, PRODUCT CLAIMS AND THE SUBSTANTIATION OF CLAIMS MADE

With respect to product functions and the naming of products, and the making of claims both the **primary function** and any **secondary function claims** that are made need to be considered when deciding what system of regulatory control is appropriate.

To this end, the PRCD and the IMB have undertaken to provide industry with definitions of primary and secondary functions for consumer products. Since the Biocides Directive does not distinguish between primary and secondary functions, the secondary function definition provided below is applicable only to cosmetic products.

4.1 Primary function definition

The primary function of a consumer product can be described as:

‘The function of a product that has an intended effect when manufactured and placed on the market and where it is known that the product will act to fulfil a described and expected primary task (such as controlling harmful bacteria or moisturising the skin). In such cases, it is expected that the primary or intended function of the product is stated on the front label and the efficacy of the primary function of the product when used to carry out the expressed primary task can be demonstrated’.

(Note: the definition of primary function is not a legal interpretation and is provided for guidance purposes only.)

4.2 Secondary function definition

The secondary function of a cosmetic consumer product can be described as:

‘The function of a product that is inherent to its formulation (i.e. based on an exactly stated ingredient function) and not to its design, or a substantiated property of a product that is appropriate to and acceptable with the purpose served by a cosmetic product. The secondary function can be different from or supplemental to the primary intended purpose of the product when manufactured and placed on the market’.

(Note: the definition of secondary function is not a legal interpretation and is provided for guidance purposes only.)

Therefore, applicants wishing to place cosmetic products on the market that make secondary claims based on ingredient functions and on verified characteristics of the product, in addition to the primary function of the product, must consider the suitability of such secondary claims to the primary functions of a cosmetic product as outlined in table 1. This is because secondary product claims along with the primary function of the product, its mode of action, and how the product is presented and intended to be used are considered critical to the classification of consumer products and, as such, to the regulatory control that should be applied. The intended use of a cosmetic product will also dictate what borderline claims can be made, if any, as per the examples below in section 4.5. Accordingly, label claims may have to be significantly amended in order to comply with the legislation under which the product is being classified. In some cases, for example, depending on the active substance used in the product or the level of active substance in the product, label claim changes may be insufficient and the product may need to be reformulated in order to be classified as a cosmetic.

4.3 Biocides labelling

The labelling applied to biocides must comply with the requirements set out in either the Dangerous Preparations Directive 99/45/EC (until 1 June 2015) or Commission Regulation (EC) No 1272/2008 (also known as the CLP Regulation). Additionally, biocidal products must also comply with the specific requirements set out under Article 20 of the Biocides Directive 98/8/EC. The Biocides Directive does not distinguish between the primary or secondary function of a biocidal product. Instead, the definition of what a biocidal product is concerns the intention of the product to have a biocidal effect or action as manufactured and placed on the market for use. That is, if the intention of the manufacturer is to place a product on the market that has a biocidal action as a primary function then the product is a biocidal product. It is reasonable to expect that an intended biocidal action would be reflected in a relevant label claim, but it does not necessitate a label claim for a product to be considered a biocide. In the absence of a biocidal label claim, some other relevant matter in the context of the product (e.g. primary function, mode of action, active substance concentration, presentation of the product, usage instructions, efficacy data etc.) would be required to justify a conclusion that it was ‘intended’ to be biocidal.

4.4 Cosmetics labelling and secondary claims

The labelling applied to cosmetic products must comply with the requirements set out in the European Communities (Cosmetic Products) Regulations, 2004 (SI 870 of 2004), as amended. It is generally accepted that cosmetic products can make secondary claims, and that more than one secondary claim can be made, because the ingredients used in a cosmetic product can have additional functions that are not necessarily related to the primary function. Secondary claims that are permitted for use on cosmetic products should be in-line with the secondary function definition provided above in section 4.2. Furthermore, any secondary claims that are made should not imply that the cosmetic product has characteristics that it does not have. As such, secondary claims can be based on:

- The usual function(s) of ingredients as listed in the inventory of ingredients employed in cosmetic products established under article 5a of the Cosmetics Directive 76/768/EEC, provided that ingredient is acceptable for use in a cosmetic product and the function claimed is appropriate to the cosmetic product type it is being applied to.

- Or to a substantiated property of the cosmetic product, again, provided the secondary claim being made is appropriate to a cosmetic product

Companies and persons wishing to place cosmetic products on the market must ensure that any secondary claim(s) made is relevant to, and consistent with, that particular product and that the intended use of the cosmetic product will also dictate what secondary claim(s) can be made. To this end, it will not be acceptable for particular cosmetic product types to make any secondary biocidal or other borderline claims. In addition, the secondary claim(s) made and the intended use of the cosmetic product will also dictate the prominence of this claim on the labelling. Accordingly, secondary function claims, particularly those that are borderline in nature, should not be given equal prominence with the primary function claim on the product packaging. This principle should also apply to text applied to the back and other parts of the packaging of cosmetic products. As such, careful consideration needs to be given to the naming of cosmetic products and the location of claims.

4.5 Examples of primary and secondary claims

When making secondary claims, care should be exercised so that the consumer product is presented in a manner that clearly identifies its primary function and any secondary function claims that are made should not confuse this.

It has been agreed (see document 3 section 6) that the activities of protecting or keeping-in-good condition, which are primary functions of cosmetic products, cannot be interpreted as being synonymous with the following activities:

- Prevention of disease
- Protection from contamination
- Protection from infection

If the above descriptors are the primary functions of a product then the product falls into the borderline area with medicines, medical devices or biocides and is no longer classified as a cosmetic product. In addition, the above descriptors are not permitted as secondary claims on any cosmetic product. The following examples serve to distinguish the use of primary and secondary function claims.

Example 1

- If the primary or secondary function of a ‘hand wash’ product is to ‘wash’ or ‘clean’ the hands whilst also moisturising them, then such a consumer product can be controlled via the cosmetics regulatory system. The intention served by such a product should be inherent from its name, if not clear from how the product is presented, and its primary and secondary labelling claims. Biocidal secondary claims are not acceptable on cosmetic hand wash products because it is not the intention of such products to provide for anything other than a visual or physical clean with or without hand moisturisation.

Example 2

- If the primary or secondary function of a ‘hand wash’ product is to act as an ‘antibacterial hand wash’ and/or ‘kill 99.9% of bacteria’ etc., then such a consumer product should be controlled via the biocides regulatory system. Claims such as ‘antibacterial’ and ‘kill’ are not in line with the purpose served by a cosmetic product. If such a product was to be marketed as a cosmetic product, the product label should not make the above claims or any other biocidal claims, and the product must not have been designed to have such an effect. In addition, before such a product could be classified as a cosmetic product other factors such as active substance and excipient composition, method of action, the intended use, the products usage instructions and how the product is presented must be considered.

4.6 Substantiation of cosmetic product claims

Companies intending to market cosmetic products are reminded of their obligations under Article 11 of S.I. No. 870/2004 European Communities (Cosmetic Products) Regulations, 2004, to ensure that claims made and signs used on their packaging are not misleading. Furthermore, any claims made must be capable of being substantiated as per Article 12(1)(g) of S.I. No. 870/2004 European Communities (Cosmetic Products) Regulations, 2004.

As such, if marketing a cosmetic product with a secondary claim, the responsible person must ensure that the consumer is not mislead into believing that the product has characteristics which it does not have and the product should not be presented in a manner that gives the impression that it is a substitute for a medicinal or biocidal product. Otherwise the product is a medicinal or biocidal product.

Claims made with respect to the product being a ‘natural’ antibacterial or antimicrobial etc. due to the presence of natural essences or extracts does not bring the product outside of the control of the biocides, medicinal products or medical devices regulations. The use of the term ‘natural’ does not eliminate potential risk and does not negate a consumer product from being the subject of regulatory control.

5. DUAL FUNCTION PRODUCTS

If during the manufacture of a product, substances are added as part of the formulation to have an additional intended effect, then these cannot be considered as conferring a secondary function, since the addition is intended to be functional in the product and have a deliberate effect (or primary function). If this means that the product has an additional primary function it should be considered as a dual function product and, as such, may require dual governance.

In general, however, it should be noted that a product cannot be a cosmetic product and a biocidal product at the same time (see document 3 section 6). In such cases, dual function products are to be considered in Ireland under the legislation that provides the higher level of human and environmental protection. Nonetheless, in certain cases, dual regulatory governance of such a consumer product might be required. For example, a sun block product with insect repellent activity has two primary functions, a cosmetic function with respect to sun protection and a biocidal function with respect to keeping insects away. Due to the critical nature of sun block products to public health, and the need to frequently apply these products, the increased exposure of the consumer to the biocidal active substance will need to be considered as will the protection afforded from the sun. In this regard, both the PRCD and the IMB will have a governance role (see section 8.8).

6. DETERMINATION OF CONSUMER PRODUCT BORDERLINES AND DELIBERATION ON BORDERLINE CONSUMER PRODUCT CASES

The determination of clear borderlines between the key pieces of legislation governing biocide, cosmetic and other consumer products is crucial for the correct and appropriate implementation of these systems of regulation.

However, a company or person intending to market a consumer product in Ireland must carefully consider under which legislative area the product is covered. A number of factors should be considered by applicants wishing to place a product on the market, which include:

- The intended use of the product (i.e. its primary function) and its mode of action;
- The label claims being made on the product and their acceptability, position and prominence on the label (front and/or back);
- The active substance(s) used in the product (i.e. function);
- The concentration of the active substance(s) contained in the product;
- The level of efficacy of the active substance in the product;
- The ingredients used and the concentrations they are used at.

Consideration of the above factors will aid an applicant to identify and place their product under the correct regulatory system. If in doubt as to which piece of legislation covers the product, please contact the regulatory organisation(s) where the potential borderline exists between two pieces of legislation (i.e. PRCD and IMB in this case).

The key guidance manuals published by the European Commission, the Pesticide Registration and Control Division of the Department of Agriculture, Fisheries and Food and the Irish Medicines Board to assist with the classification of consumer products falling within the scope of the biocides, cosmetics, medicinal products and medical devices legislation are referenced below.

The European Commission's guidance manuals (1 – 3 below) are broken down in terms of examples of product type. These are reviewed primarily with respect to composition, method of action and the appropriate system of regulation assigned on the basis of these factors. It is clearly identified that biocide legislation specifically exempts from its scope products which are defined and within scope of the cosmetic, medicinal product, veterinary medicinal product or medical device legislation and are, therefore, regulated and controlled by these instruments.

1. Manual of Decisions:
   http://ec.europa.eu/environment/biocides/manual.htm
2. Borderline Documents:
   http://ec.europa.eu/environment/biocides/borderline.htm
3. Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal products and Directive 76/768/EEC concerning Cosmetic products:
   http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/borderline-products/index_en.htm
4. IMB guide to the definition of a human medicine:
   http://www.imb.ie/EN/Publications/Medicines/Classification-of-Medicines/Guide-to-the-Definition-of-a-Human-Medicine.aspx?page=1&year=0&categoryid=&letter=&q=
5. IMB guide to cosmetics:
   http://www.imb.ie/EN/Publications/Publications.aspx?pagecategoryid=200
6. IMB guidance note 1: about the medical devices department of the IMB:
   http://www.imb.ie/EN/Publications/Publications.aspx?year=0&page=10&categoryid=&letter=&q=&pagecategoryID=202
7. IMB guide to the definition of an animal remedy and the classification process:
   http://www.imb.ie/EN/Publications/Publications.aspx?year=0&page=3&categoryid=&letter=&q=&pagecategoryID=6133

The IMB offers a classification service for products which are on the borderline of human medicines and other products such as cosmetics and medical devices. Where there is a product borderline issue, the relevant national CAs for the relevant legislations decide, through consultation, which area of the legislation a particular product falls. Where there are divergent views concerning a particular product between national CAs and/or the person responsible for placing the product on the market, it is considered the responsibility of the latter to assist the CAs in providing appropriate justification for the system of regulatory control to be applied.

In Ireland, borderline issues will be examined on a case-by-case basis and examples of some currently relevant cosmetic-biocide cases are given in section 8 below. More borderline product examples will be added in due course as considered appropriate.

7. USEFUL CONTACT POINTS

For queries relating to Veterinary Medicines/Human Medicines/Cosmetics/Medical Devices/IMB Classification Committee please contact the IMB using the contact details below.

Irish Medicines Board (IMB)

Phone: +353 1 6764971
+353 1 6764976
Fax: +353 1 6767836
E-mail: imb@imb.ie
Website: http://www.imb.ie/EN/Medicines/Human-Medicines.aspx
http://www.imb.ie/EN/Veterinary-Medicines.aspx
http://www.imb.ie/EN/Cosmetics.aspx
http://www.imb.ie/EN/Medical-Devices.aspx
http://www.imb.ie/EN/Medicines/Classification-of-Medicines.aspx

For queries relating to Biocides, please contact the Department of Agriculture, Fisheries and Food using the contact details below:

Department of Agriculture, Fisheries and Food,
Pesticide Registration and Control Division (PRCD)

Phone: +353 1 6157552
Fax: +353 1 6157575
E-mail: Biocides@agriculture.gov.ie
Website: http://www.pcs.agriculture.gov.ie/biocides.htm

8. SPECIFIC COSMETIC-BIOCIDE BORDERLINE PRODUCT CASES

This section provides some practical examples of cosmetic-biocide borderline cases that are currently on the market in Ireland. In a number of the examples presented below, there are also other borderline cases to consider between cosmetics and human medicines.

Each sub-section below offers information on where such products can be placed within the legislative frameworks and the tables provide guidance based on product primary and secondary labelled claims.

However, it should be noted that changing a claim on a product or removal of a claim, does not necessarily exempt it from being considered within the scope of another piece of legislation, such as medicines or biocides. Changing or removal of a claim for a product may require its reformulation, depending on the type and level of the active substance(s) in the product. In cases where the intention of the product is biocidal or medicinal, then 'such products should not be considered as cosmetics' since biocides or medicines cannot, by definition, be cosmetics.

8.1 Mouthwashes and toothpastes

It is considered that these products can potentially be classified as a cosmetic, medicinal product or medical device based on composition, mode of action, labelling claims made and how the product is presented. This is because products used on mucous membranes and, in this case, the mouth, are generally not considered as biocides.

Where the product is marketed only on the basis of protecting and keeping the teeth and oral cavity in good condition with claims of providing a cleaning, freshening and/or protective effect for the purpose of guarding against plaque formation and mouth odour, it is considered consistent with the definition and function of a cosmetic product (see table 1 in section 3).
Where such products are marketed with claims of antiseptic action or claims to repair or restore, prevent or treat gum disease, prevent or fight the formation of cavities, these are considered consistent with claims of a therapeutic effect and/or disease prevention. As such, these products would be considered medicinal products.

The table below provides guidance with respect to the classification of mouthwash and toothpaste products based on the claims made (the list is not exhaustive).

Table 2 Classification of mouthwash and toothpaste products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Protect teeth; protects teeth and gums; helps protect teeth from decay; protect tooth enamel	Cosmetic – protection function in line with the definition of a cosmetic
Keep teeth and gums in good condition	Cosmetic – function of keeping in good condition is in line with the definition of a cosmetic
Assists in protecting against cavity formation; Assists in guarding against cavities	Cosmetic - protection function in line with the definition of a cosmetic

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Assists in preventing teeth and gum problems	Cosmetic – function of preventing here is in line with the purpose of a cosmetic in that the product is protecting the teeth and gums and, as such, keeping them in good condition which is the purpose of a cosmetics product
Kills bacteria/kills up to 99.9% of bacteria	Biocide – use of the word 'kill' and the claim of a '99.9%' bacterial kill are strong biocidal claims.
Antiviral and words having the same meaning	Biocide – use of the word 'antiviral' is medicinal or biocidal in nature and generally associated with products used to treat disease, prevent infection or to control the spread of germs.
Antifungal and words having the same meaning	Biocide - use of the word 'antifungal' is medicinal or biocidal in nature and generally associated with products used to treat disease, prevent infection or to control the spread of mould.
Strengthen teeth against decay/strengthen tooth enamel	Medicinal Product or Medical Device depending on mode of action – use of the words 'strengthening tooth enamel or strengthening teeth against decay' implies a medicinal action.
Maintain healthy teeth and gums	Medicinal Product - care should be taken with claims of acting by directly maintaining the health of gums and teeth, as this may imply a medicinal action.
Repair and/or restore	Medicinal Product or Medical Device depending on mode of action - for oral care products use of the words 'repair' and/or 'restore' teeth or gums implies medicinal action.
Reduces cavities; fights cavities	Medicinal Product - the word cavity is considered a disease state, and so in this case, the use of the words 'reduce' and 'fights' is a medicinal claim and associated with the provision of a treatment, modifying or correcting

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
	effect against tooth disease.
Re-mineralises the tooth/enamel or re-calcifies/re-harden enamel	Medicinal Product - use of the words ‘re-mineralise(s)’ and/or ‘re-calcifies’ is a medicinal claim since it is associated with the provision of a modifying, correcting or healing effect.
Fights teeth and gum problems	Medicinal Product - use of the word ‘fight(s)’ in this context implies a medicinal action.
Antiseptic	Medicinal Product - antiseptic is a medicinal claim and the function of an antiseptic product is to prevent or control sepsis/infection.
Protects against gum disease	Medicinal Product or Medical Device depending on mode of action

8.2 Shaving gels

These products can be marketed as cosmetics where the main function of the product is to protect and keep the skin in good condition whilst cleaning and changing its appearance, and this is consistent with the definition and function of a cosmetic (see table 1 in section 2). For example, claims which make use of the verb ‘prevent’, such as ‘helps prevent dry and tight skin’ and ‘helps prevent skin redness associated with shaving’ are acceptable here because moist loose skin is needed for a comfortable shave and shaving itself can lead to skin redness. It is also considered appropriate to use the descriptor ‘protect’ as well.

Table 3 Classification of shaving gel products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Reduces shaving rash/skin burn due to shaving	Cosmetic - function of reducing here is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin which is the purpose of a cosmetic product
Soothes skin whilst shaving	Cosmetic – function in line with the definition of a cosmetic in that the product is protecting the skin

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Reduces skin redness due to shaving	Cosmetic - function of reducing here is in line with the definition of a cosmetic in that the product is protecting the skin from the effects of shaving and, as such, protecting the skin which is the purpose of a cosmetic product
Shave cream/gel that kills 99.9% of facial bacteria	Biocide - the claim of a 99.9% kill of bacteria would render the product a biocide.
Reduces skin inflammation; Calms inflamed skin	Medicinal Product - The claim reduces/calms skin inflammation is considered a medicinal claim because inflammation is a biological response and, as such, the product is acting as a treatment.

8.3 Deodorants

In general, antiperspirant and deodorant products are classified as cosmetics.

Nonetheless, such products should not be marketed with antibacterial or any other biocidal claims otherwise they will be classified as biocides because the product would be considered as functioning to kill/deter the bacteria which act on sweat and this is consistent with the definition and function of a biocide (see table 1 in section 3). Furthermore, any claims made should be in-line with the function of such a product which is to perfume and correct/mask body odours of the under-arm, body or foot. Concerning anti-perspirants, such products should not be marketed for use in hyperhidrosis (excessive sweating), which is a medical condition.

Table 4 Classification of deodorant products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Correct body odour; Mask body odour	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odour and perfuming the body.
Protects against sweat; Masks sweat	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odours.

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Reduces the signs of sweating;	Cosmetic – function in line with the definition of purpose of a cosmetic product with respect to changing their appearance and correcting body odour.
Minimise the effects of sweating	Cosmetic – function in line with the definition and purpose of a cosmetic product with respect to correcting body odour and perfuming.
Eliminate bacteria	Biocide – eliminate bacteria is a biocidal claim and so the product would be considered a biocide.
Antimicrobial	Biocide - antimicrobial is generally considered a biocidal claim and it is not the purpose of a deodorant to control micro-organisms.
Antibacterial	Biocide - antibacterial is a biocidal claim and it is not the purpose of a deodorant to control bacteria.
Antifungal	Biocide - antifungal is a biocidal claim and it is not the purpose of a deodorant to control mould.
Prevent body odour	Medicinal Product - the use of the phrase ‘prevent body odour’ implies a physiological or physical effect is being exerted on the process of hidrosis.
Prevent sweat gland functioning/ sweat gland treatment	Medicinal Product - this is considered a medicinal claim because the intention of the product is to have a controlling, modifying or correcting effect on a physiological function, or the sweat gland.
Prevents hyperhidrosis	Medicinal Product –the reference to hyperhidrosis is a medical condition.

8.4 Anti-dandruff shampoo

These products can be classified as cosmetic or medicinal based on composition, mode of action and labelling claims made.

Where the product is marketed only on the basis of protecting and keeping the scalp in good condition then this is considered consistent with the definition and function of a cosmetic product (see table 1 in section 3). For example, if the product is marketed with a claim such as ‘rejuvenates’, ‘re-invigorates’ and ‘restores’ tired limp hair then this is acceptable because tired/limp hair is not necessarily associated with illness, and is in line with the function of a cosmetic to freshen and improve/enhance the appearance. Other uses of these words will be deliberated on a case-by-case basis.

If the product is marketed for use when dandruff is caused by a medical condition or infestation due to a fungus or lice, the product may be considered as medicinal. As such, anti-dandruff products when marketed with secondary claims should not give the impression that it is functioning to treat or prevent a fungal infection or that its mode of action functions to cease the formation of dandruff. The impression given should be that the use of the anti-dandruff product with any labelled secondary claims is to keep the scalp and hair in good condition.

Table 5 Classification of anti-dandruff products based on labelled claims.

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Protects the scalp	Cosmetic – the function of protection is in line with the definition and purpose served by such a cosmetic product which is to protect and keep the scalp in good condition.
Protects scalp/head from the effects of dandruff*	Cosmetic – the function is in line with the purpose of a cosmetic to protect and keep-in-good condition.
Protects the scalp from dryness*	Cosmetic - the function is in line with the purpose of a cosmetic to protect and keep-in-good condition.
Keep the scalp in good condition	Cosmetic – the function is in line with the definition and purpose served by a cosmetic product.
Immediate protection	Cosmetic – the protection function is in line with the definition of a cosmetic
Immediate results	Cosmetic – the function is in line with the purpose of a cosmetic to enhance the appearance

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Soothes itchy scalp associated with dandruff Soothes itchy scalp Soothes your scalp/head (should we take this out or include it as a cosmetic claim)	Medicinal Product - the use of the phrase 'soothes itchy scalp associated with dandruff' is considered a medicinal claim because the intention of the product is to have a modifying or correcting effect on the scalp e.g. due to redness or inflammation.
All day itch relief	Medicinal Product - This is considered a medicinal claim because the intention of the product is to treat irritation associated with an itchy scalp.
Relieves dry scalp and itch	Medicinal Product - The use of the word 'relieves' is considered medicinal because the intention of the product is to treat the symptoms associated with a dry and/or itchy scalp.
Restore your scalp to health	Medicinal Product - it is not the intention of a cosmetic product to restore health. The use of the word 'restore' implies that the intention of the product is to cure, correct for or heal ill-health.
Immediate relief	Medicinal Product - the implication is that the product is intended to treat, alleviate or control symptoms such as scalp inflammation caused by dandruff.

* The acceptability of these claims will depend on how the product is presented.

8.5 Hand and body cleaning wash-off products: soaps, foams and liquids

Such products should be evaluated on the basis of a number of factors, such as, how the product is presented, the mode of action, labelling claims and composition.

The majority of products in this category are likely to be classified as cosmetics where the function of the product is primarily to cleanse or clean. Such products should not be marketed with any claims of biocidal activity or specific effects of reducing cross-contamination. General non-biocidal secondary claims can be made in the context of protecting the skin and these should be due to verified properties of the product's formulation and not due to a specific biocidal ingredient. Any claims made should be verifiable under the conditions of use of the product i.e. whilst washing the hands using the product and water.

Where the product is considered to function by having a controlling effect on harmful organisms through biocidal action in order to prevent cross-contamination, or claims to this effect, it should be classified as biocidal.

Where the product is considered to function by treating or preventing disease or skin conditions, it should be considered as medicinal.

Table 6 Classification of hand and body wash off products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Physically clean/visually clean	Cosmetic – the function is in line with the definition and purpose of a cosmetic product with respect to cleaning and improving the appearance of the hands or body.
Daily use, suitable for dry, and sensitive skin	Cosmetic – function in line with the use of a cosmetic product to clean and freshen the hands or body without acting as an irritant.
Unique antibacterial formulation	Biocide – claim infers that the product is a biocide as it is formulated to achieve an antibacterial effect.
Germ Kill/Kills 99.9% of bacteria	Biocide – function is not in line with the definition or purpose of a cosmetic hand or body wash of product. The statements ‘kill’ and ’99.9% bacterial kill’ are strong biocidal claims.
Antibacterial	Biocide - antibacterial is a biocidal claim and it is not the purpose of a cosmetic cleaning product to control bacteria.
Natural antibacterial	Biocide - antibacterial is a biocidal claim irrespective of whether it is achieved by natural extracts.
Hygienically clean	Biocide - this claim is interpreted as the product functioning as a preventative measure to reduce the incidence and spread of contaminants or disease causing agents and is, as such, acting as a biocide.
Daily care, suitable for dry, sensitive, and	Medicinal Product - the product is

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
itchy skin	intended to act as a hand and body wash which are generally used on a daily basis and, as such, the use of the descriptor 'daily care' implies that the product is functioning as a treatment for dry, sensitive and itchy skin which renders it medicinal.
Antiseptic	Medicinal Product - antiseptic is a medicinal claim and the function of an antiseptic product is to prevent or control sepsis/infection.

8.6 Hand and body gels, other leave on products and hand and body wipes

These products can be classified as cosmetic, biocidal or medicinal depending on their function, composition, mode of action and labelling claims. If such products claim to have an 'antibacterial' or similar effect then the main function of the product is to act as a biocide.

Where the product is to be marketed as a cosmetic product, it should not make any claims of having a biocidal action or specific effects of reducing cross-contamination. General non-biocidal secondary claims can be made in the context of protecting the skin and these should be due to verified properties of the product's formulation and not due to a specific biocidal ingredient. In such cases, any claims made should be verifiable under the conditions of use of the product. Such products when marketed as a cosmetic should also not give the impression that it is a substitute for a medicinal product.

Product labelling must clearly state precautions to be taken by the consumer with respect to using gels or lotions that are not washed off the hands or body.

Table 7 Classification of hand and body leave-on cleaning products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Hand cleaner	Cosmetic – the function is in line with the definition and purpose served by a cosmetic product.
Physically clean/visually clean	Cosmetic – the function is in line with the definition and purpose of a cosmetic product with respect to

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
	cleaning and improving the appearance of the hands or body.
Antibacterial	Biocide - antibacterial is a biocidal claim and it is not the purpose of a cosmetic cleaning product to control bacteria.
Kills a wide range of germs	Biocide - it is not the function of a cosmetic to kill germs. Based on the claim the product is acting as a biocide.
Kill bacteria	Biocide - it is not the function of a cosmetic to kill bacteria. Based on the claim the product is acting as a biocide.
Antiviral	Biocide - antibacterial is a biocidal claim and it is not the purpose of a cosmetic cleaning product to control viruses.
Kills viruses Virokill	Biocide - it is not the function of a cosmetic to kill viruses. Based on the claim the product is acting as a biocide.
Hand/body sanitizer	Biocide - it is not the function of a cosmetic to sanitize. Based on the claim the product is acting as a biocide.
Disinfection of hands/other body parts	Biocide – disinfection is not a function of a cosmetic product. Based on the claim the product is acting as a biocide.
Hygienically clean	Biocide - this claim is interpreted as the product functioning as a preventative measure to reduce the incidence and spread of disease and is, as such, acting as a biocide.
Antiseptic	Medicinal Product - antiseptic is a medicinal claim and the function of an antiseptic product is to prevent or control sepsis/infection.

8.7 Face washes

These products can be classified as cosmetic, biocidal or medicinal based on composition and labelling claims made. For example, a product marketed with a claim to 'alleviate skin dryness' might be acceptable as a cosmetic depending on how the product was presented.

Such products can be marketed on the basis of protecting and keeping the facial area in good condition but no biocidal claims or other borderline claims can be made.

If the product is marketed for use, on the basis of its antimicrobial action, for the treatment and/or prevention of disease or a skin condition it is classified as a medicinal product.

Table 8 Classification of face wash products based on labelled claims

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
Keeps the skin in good condition	Cosmetic – the function claimed is in line with the definition and purpose served by a cosmetic.
Assists in protecting against blemish formation; Enhance/improve the appearance of the facial area	Cosmetic – the function to assist in protecting against blemishes is in line with the purpose of keeping the skin in good condition and enhancing the appearance.
Assists in protecting against blackheads	Cosmetic – the function to assist in protecting against blackheads is in line with the purpose of keeping the skin in good condition.
Protects the skin against excess oil	Cosmetic – the function to protect is in line with the definition of a cosmetic and with the purpose of keeping the skin in good condition.
Protect the skin	Cosmetic – the function to protect is in line with the definition of a cosmetic.
Cleansing wash/scrub; Protecting wash/scrub	Cosmetic - the function to protect is in line with the definition of a cosmetic and with the purpose of keeping the skin in good condition.
Fights the causes of spots	Medicinal Product - The claim is considered to be medicinal because the

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
	implication is that the product is acting as a cure, treatment or preventative of an infection/skin condition.
Fights the bacteria that cause spots	Medicinal Product - the claim is considered to be medicinal because the implication is that the product is acting as a cure, treatment or preventative for an infection/skin condition.
Reduces redness and spot size	Medicinal Product - the implication is that the product is intended to control, stop or help with inflammation and treat infection and as such is acting as a medicinal product.
Helps prevent new spots from forming	Medicinal Product - the claim implies that the purpose of the product is to have a correcting or modifying effect on the skin in order to prevent or stop spot formation/infection and so should be classified as a medicinal product.
Controls the oil balance of your facial skin	Medicinal Product - the claim implies that the intention of the product is to act as a treatment for a skin condition or provide a correcting, controlling or modifying effect on facial oil production and, as such, is a medicinal claim.
Supports the skin's renewal process	Medicinal Product - the claim implies that the intention of the product is to have a restorative effect or to maintain natural skin physiological processes or correct for a skin condition and, as such, is a medicinal claim.
Treatment wash Treatment scrub	Medicinal Product – treatment in this context is not a function served by a cosmetic. The claim implies that the intention of the product is to act as a treatment for a skin condition and, as such, is a medicinal product or medical device.
Prevents spots and pimples	Medicinal Product - not a function served by a cosmetic. The claim

LABELLED PRIMARY AND/OR SECONDARY CLAIM	PRODUCT CLASSIFICATION
	implies that the intention of the product is to act as a treatment for a skin condition and, as such, is a medicinal claim.
Antiseptic	Medicinal Product - antiseptic is a medicinal claim and the function of an antiseptic product is to prevent or control sepsis/infection.

8.8 Sun block with insect repellent

In general, these products can be marketed as biocides or cosmetics depending on their composition, the biocidal active substance, and their method and frequency of use. Sun block is normally applied frequently (~ every 60 min) on all exposed areas of the skin while insect repellent is normally applied sparingly (~ 2 times per day) on certain locations of the body e.g. around the wrists, ankles and neck. The high frequency of use of such combination products as a cosmetic could result in the product being toxic to the user. Depending on the biocidal substance and how the product is to be used, the product should most likely be marketed as a biocide. In this circumstance, any claim with respect to the sun protecting effect of the product should be modified in the context of the lower frequency of application. The possibility of dual governance will need to be considered given the criticality of sun block products, in order to ensure all areas have been addressed from a safety perspective.

This would also apply to other sun block products claiming repellent effects for other harmful organisms such as jellyfish.

IMB and DAFF Draft Guide to Cosmetic-Biocide Borderline products
Public Consultation Comment Form

Clause	Section heading	Comment
1	Scope	
2.	Introduction	
3.	Legislation and Definitions	
4.	Product functions, product claims and substantiation of claims made	
4.1	Primary function definition	
4.2	Secondary function definition	
4.3	Biocides labelling	
4.4	Cosmetics labelling and secondary claims	
4.5	Examples of primary and secondary claims	
4.6	Substantiation of cosmetic product claims	
5	Dual function products	
6	Determination of consumer product borderlines and deliberation on borderline consumer product cases	

7	Useful contact points	
8	Specific cosmetic-biocide borderline product cases	
8.1	Mouthwashes and toothpastes	
8.2	Shaving gels	
8.3	Deodorants	
8.4	Anti-dandruff shampoo	
8.5	Hand and body cleaning wash off products: soaps, foams and liquids	
8.6	Hand and body gels, other leave on products and hand and body wipes	
8.7	Face washes	
8.8	Sun block with insect repellent	
General		