

Contents

Notification	1
Certificates of Free Sale	3
Legislation	4
Product Claims	5
Manufacturers	6
Importation	7
Distribution	7
Retailing	8
Borderline Products	9
Undesirable Effects	9
Frame Formulation	10
Product Information File	10
Safety Assessment	11
Labelling	11
Ingredients	13

Notification

Question: How do I notify the IMB of a cosmetic product being placed on the Irish market?

Answer:

Where a product is manufactured in Ireland or imported into the Community in Ireland, then the Responsible Person (RP) shall notify the Competent Authority of the address of the place of manufacture or of the place of initial importation into the Community of that cosmetic before its first sale or supply in the Community.

Information on the notification procedure can be found in the 'Guide to notification of a cosmetic product' on the IMB website www.imb.ie.

Using the spreadsheets provided, you should register your organisation and status (whether you are a manufacturer, importer or designated RP) as per stage 1 in the guide. The IMB will issue you with an organisation number. You should then notify your products using the spreadsheet as per Stage 2 in the guide.

Question: What charges will apply to the Notifications Process for cosmetic products at IMB?

Answer:

There will be no charge for notifications.

Question: Will IMB issue a 'registration' number to the applicant for each cosmetic file notification, similar to a PA for medicine and CE code for medical devices?

Answer:

There is no premarket approval of cosmetics by the Competent Authority prior to placing cosmetics on the market. The system is not similar to the authorisation of medicines and so there is no number assigned to each cosmetic product notified. The IMB plans to use an online system for cosmetic product notifications. The applicant will need to register the organisation with IMB and we will issue you with an organisation number but not an individual number for each cosmetic product notified.

Question: Is it a requirement to display the company organisation number on the packaging of a cosmetic product?

Answer:

There is no need to display the organisation number on the packaging. This number is for the IMB documentation management system only. We would however require all correspondence to refer to the organisation reference number. Refer to the guide to Notifications for details of the notification process.

Question: As the IMB will build up a database of all Irish manufactured or imported cosmetics, will this database be accessible via the IMB website?

Answer:

This information will not be publicly accessible due to data protection issues associated with making this information available.

Question: Will the notification database be accessible to members of the public?

Answer:

As a registered user of the database you will be able to access your own information only.

Question: Is it necessary to notify a competent authority in more than one EU country?

Answer:

The regulatory framework for cosmetics is such that notification in one member state should allow free movement of cosmetics into other member states once they are already notified in one Member State. However some Member States do impose additional notification requirements regardless of whether or not the product has already been notified in Europe.

The recast of the Cosmetics Directive will come into force in July 2013. This introduces a central notification system via a Cosmetic Product Notification Portal (CPNP). This CPNP will remove the

divergence of national transposition of the Cosmetics Directive and have one centralised system for notifications.

Certificates of Free Sale

Question: How do I apply for a Certificate of Free Sale (CFS) from the IMB for a cosmetic product?

Answer:

Please refer to the IMB guidance document and form 'Guide to applications for certificates of free sale for cosmetics' on the IMB website www.imb.ie.

Question: What charges will apply to CFS applications for cosmetic products at IMB?

Answer:

Applications for CFS will be subject to a fee of €60.95 until Dec 2010. It is envisaged that in 2011 the fee structure will come in line with current charges applied to similar business processes within the organisation (e.g. export license certificates, medical device certificates of free sale). A public consultation will be published in October on the IMB website and the new fee structure for the overall organisation will be available following a review of all responses by the Board.

Question: How many products can we list on Certificate of Free Sale – what is the maximum, and can we add an extra country after new market entry?

Answer:

There is a limit of 300 products per each CFS application. The CFS does not need to be country specific. Duplicate CFS can be requested but will be charged as a new work item.

Question: How many copies per cert can we receive?

Answer:

Four copies of the CFS will be issued per application. Additional copies may be requested at the time of application for a pro rata charge. A charge of €12 per additional certificate requested will be applied.

Question: Is applying for a certificate of free sale considered as notification? Can we obtain a Certificate of Free Sale without notification?

Answer:

The notification process is explained in the IMB guidance document to cosmetic product notification: Applying for a CFS will not be considered as notification. The Notification and CFS application processes are considered as two distinct processes by IMB. We will have a cross reference for CFS requests to verify that the products on the CFS have been notified to us (there will be some exceptions to this where product is solely for export markets and is not intended to be placed on the EU market, and so may not be notified).

Question: Can I request a Certificate of free sale for a product 6 to 12 months prior to its launch?

Answer:

CFS may be requested for a cosmetic product due to launch in the future as long as the products will be manufactured in accordance with the legislation and that the declaration of compliance with the regulations has been provided.

Question: Will the CFS be originally signed?

Answer:

Yes these will be signed by an IMB signatory/ Licensing Manager

Question: How much time will IMB need to process a CFS application?

Answer:

CFS will be issued within 3-4 working days following validation of the application (ie completed documentation and payment received)

Question: Who can sign a CFS and how often should I send the Authorized Signature to IMB?

Answer:

Please refer to the IMB guidance document on the issue of CFS:

The procedure involves completing a form with the list of your products to be included on the CFS. At the first request for a CFS a declaration needs to be provided by the organisation that they manufacture in accordance with the legislation and signed by a designated signatory.

Legislation

Question: What legislation governs the manufacture, distribution and importation of cosmetic products into Ireland?

Answer:

As cosmetics legislation differs to other sectoral legislation, reference should be made to a number of legal instruments to ensure the obligations of the manufacturer, importer and distributor are met. There are four principal legal texts listed below for reference:

- **Cosmetics Directive 76/768/EEC**

SI 870 of 2004, European Communities (Cosmetic Products) Regulations, 2004, as amended

- **General Product Safety Directive 2001/95/EC (GPSD)**

SI 199 of 2004, European Communities (General Product Safety) Regulations, 2004

- **Regulation (EC) No 1223/2009** of the European Parliament and of the Council on cosmetic products (Recast)
- **Regulation 765/2008** – Setting out the requirements for accreditation and market surveillance relating to the marketing of products. (part of the New Legislative Framework)

Refer to the Guide to Cosmetics on the IMB website www.imb.ie for further information on the specific legislation impacting cosmetics.

Product Claims

Question: What is meant by the term ‘product claim’ on a cosmetic product?

Answer:

Claims mean any statement regarding the characteristics of a product in the form of text, names, trade marks, pictures and figurative or other signs used in the labelling, putting up for sale and advertising of products

Question: How do I substantiate a label claim?

Answer:

Product claims should not be misleading and should be supported by sound, relevant and clear evidence. Evidence can be based on accepted data, experimental studies conducted in vivo, ex vivo or in vitro. Evidence may consist of one or a combination of these types of evidence as appropriate.

Where a claim is based on scientific research or testing, that work should have been conducted in accordance with best practice (consult independent experts).

Benefits delivered by the product should be consistent with reasonable consumer expectations created by the claims. In evaluating whether claims are appropriate it is essential to consider the overall impression that the average consumer would have in the context of product presentation or advertising.

There is a sub-working group of the Commission looking at developing guidance on appropriate claims for cosmetics. This is in line with the new Regulation 1223/2009/EC for cosmetic products (recast). This guidance is due to be published in July 2016.

Other information on claim substantiation can be found in the ‘Colipa Guidelines for the Evaluation of the Efficacy of Cosmetic products’

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association.html?view=item&id=23>

Question: Can label claims be based on ingredient efficacy?

Answer:

Where claims are based on ingredient efficacy, the RP needs to ensure that the ingredient is stable in the finished product and that its activity is maintained in the product. For ingredient efficacy, the concentration of ingredient in the final product should reflect the levels at which the claims have been substantiated.

Manufacturers

Question: What are the planned inspection programmes for manufacturers?

Answer:

We do not plan on putting a formal inspection programme in place during the first year of operation. Before we engage in a formal inspection programme we would like to hold another information day to coincide with the implementation of the recast of the Cosmetics Directive (Regulation 1223/2009). We would envisage, however, that as part of the market surveillance programme that we will request documentation from manufacturers to verify the Product Information File, including the Safety Assessment, as part of a desk review.

Question: How do I obtain a GMP certificate?

Answer:

ISO 22716 GMP is intended to be a self declaration of conformance to the standard – and certification of compliance to this standard by Competent Authorities is not required. It is envisaged that Competent Authorities would carry out an assessment to the standard but certification is not part of this assessment.

Question: My cosmetic products are handmade, how will the GMP certification affect me?

Answer:

For handmade products, the same standards apply in terms of compliance with the legislative requirements. Manufacturing of your products will need to be in compliance with the GMP standard IS EN 22716 (or demonstrate proof of equivalence) from 2013. Compliance to this standard should be a self-declaration by the manufacturer as certification to this standard is not a requirement.

Question: For Pharmaceutical manufacturers that are also involved in cosmetic product manufacturer, what parodies are there between the ISO 22716 GMP standard and the pharmaceutical guideline on GMP compliance?

Answer:

Pharmaceutical GMP and the ISO standard are similar in the scope of GMP but the difference is in the level of detail. If you apply the same principles of Pharmaceutical GMP to your cosmetic manufacture then you will likely be in conformity with the ISO 22716 standard. In terms of the specifics of ISO 22716, these are to be determined by the RP themselves and there is reference to the term 'as appropriate' throughout the standard. You must justify what is appropriate by looking

at the risks associated with your product. This differs to Pharmaceutical GMP which is more prescriptive.

Importation

Question: What information must I obtain from the manufacturer when importing a cosmetic product into the EU?

Answer:

As an importer of cosmetic product from outside the EU you are considered a responsible person. As such you must ensure that the product you are importing complies with the cosmetic legislation. You will be required to keep the Product Information File accessible to the Competent Authority at your address specified on the label of the products you import. You should have a technical agreement with the manufacturer or supplier of all cosmetics products imported.

Question: If I am importing a product from another EU country am I the responsible person?

Answer:

If you are placing a cosmetic product on the Irish market and the product has already been notified to another EU member state then you will not be considered the Responsible Person (RP), unless you are acting as the designated RP by agreement with the supplier/ manufacturer. However, you will be required to have access to the Product Information File (PIF) if required.

Distribution

Question: Will an inspection programme be put in place by the IMB for distribution of cosmetic products?

Answer:

The distributor obligations for cosmetics include traceability requirements; labelling requirements and cooperation with authorities in the event of a product presenting a risk to consumers. Bearing this in mind the focus of the inspections programme will more likely be in the context of market surveillance activities e.g. labelling review, record keeping etc and also where traceability may be considered sub-standard, the need for an inspection of the distributor's practices will be examined.

Question: What oversight does the IMB have in relation to logistics and supply chain?

Answer:

As a distributor you are required to keep up to date records on your suppliers and customers. Distributors should have technical agreements in place with suppliers and a distributor should be capable of gaining access to the Product Information File as necessary.

Question: How do I go about establishing technical agreements with my suppliers?

Answer:

A technical agreement between a distributor of cosmetic products and their supplier should include but is not limited to:

- Relationship of parties
- Distributor sales, service and storage facilities
- Product traceability
- Responsibilities in terms of recall/withdrawal procedures
- Location of the responsible person (and Product Information File) for each product supplied
- Packaging Requirements
- Inspection and Acceptance criteria

Question: What are the storage requirements for wholesaling of cosmetic products?

Answer:

Cosmetic products should be stored appropriately according to a written procedure outlining receipt and checking of deliveries, storage and withdrawal from saleable stock. A quality system should enable any defective product to be found and there should be an effective recall procedure. Records should be kept including records of clients' orders, returned products and recall plans.

Question: What are the traceability requirements?

Answer:

Deliveries should be examined at receipt and batch number or unique identifier recorded. A written procedure should be in place to enable any defective product to be found and there should be an effective recall procedure.

Question: Who do I contact if I suspect a cosmetic product may be counterfeit?

Answer:

If you are suspicious that a cosmetic product may have been counterfeited please contact IMB at cosmetics@imb.ie

Retailing

Question: As a retailer of cosmetic products what checks must I carry out to ensure that cosmetics comply with the legislation?

Answer:

As a retailer you are expected to exercise due diligence in accepting product from your supplier. A technical agreement should be in place with suppliers. Labelling requirements can easily be reviewed, see 'What information must appear on the labelling of a cosmetic product?'. If you suspect that a product does not conform to the cosmetics legislation please contact IMB at cosmetics@imb.ie

Borderline Products

Question: How do I determine if my product is classed as a cosmetic product in Ireland?

Answer:

You may submit a sample of your product to the IMB Classification Committee for an opinion on the product classification. This classification procedure is subject to a fee. See guidance on submitting a classification request to the IMB at the following link: <http://www.imb.ie/EN/Publications/Medicines/Classification-of-Medicines/Request-for-classification-of-a-human-medicine.aspx?page=1&year=0&categoryid=43&letter=&q=>

Undesirable Effects

Question: How do I handle data on undesirable effects reported to me?

Answer:

As responsible person you are required to investigate and maintain data on undesirable effects reported to you. This involves setting out a procedure for customer complaints to record the receipt and gathering of data on undesirable effects. You are required to investigate all undesirable effects reported to you and carry out a risk assessment. All data must be maintained in the Product Information File (PIF). The safety of the product should be reviewed on a regular basis. To that end, undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and taken into account in the next safety assessment of the product. This information should be made available to the competent authority and members of the public on request. Any product posing a risk to consumers must be reported to IMB at cosmetics@imb.ie

Industry guidance has been provided in the Colipa Guidelines on the Management of Undesirable Event Reports

<http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=62>

The EU Commission is also drawing up guidance on reporting of Serious Undesirable Effects in accordance with the recast Regulation 1223/2009.

Question: How can I make data on undesirable effects & product composition available to members of the public?

Answer:

A guidance document has been published by the European Commission 'Composition and undesirable effects of cosmetic products to be made easily accessible to the public - practical implementation of article 7a(1)(h) 2nd paragraph of Council directive 76/768/EEC' http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guide_access_info_en.pdf

A website has been set up by industry to aid in making this information easily accessible to the public. <http://www.european-cosmetics.info/site/index.cfm?SID=14075>

Question: Who do I notify if an undesirable effect is reported to me?

Answer:

Please report data on undesirable effects posing a risk to consumers to cosmetics@imb.ie to include:

1. Product identification – brand, model, type number and photograph of the presentation
2. Description of the effect – number of incidents that have occurred
3. Traceability – batch number or unique identifier, number of batches affected.
4. Market Action taken

Frame Formulation

Question: How do I submit a frame formulation for my cosmetic product?

Answer:

Frame formulations are completed in accordance with the Colipa guide for frame formulation: <http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=22>

Please note that this guidance is being revised in accordance with the recast regulation 1223/2009.

For more information on submission of frame formulations for cosmetic products please refer to the poison information centre <http://www.poisons.ie/>

Product Information File

Question: What is a product information file?

Answer:

The product information file (PIF) must be held by the responsible person for all cosmetic products for which he is responsible at the address specified on the label. It must be made available at the request of the competent authority. The PIF includes:

- Qualitative & Quantitative composition

- Physico-chemical & microbiological specifications of raw materials and finished product
- Method of manufacture complying with GMP
- Assessment of the safety for human health of finished product
- Data on undesirable effects
- Proof of the effect claimed

Safety Assessment

Question: What information is required for a safety assessment?

Answer:

The safety assessment should contain information on:

- the toxicological profile
- the level of exposure
- special exposures –children, mucous membranes
- the chemical structure

The European Commission have published the following guidance document to aid in the assessment of safety of your cosmetic product.

SCCP safety testing guidelines 6th Revision
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf

Question: Where can I find a contract laboratory that can carry out a safety assessment on my behalf?

Answer:

As the regulator, IMB cannot recommend a laboratory. Industry associations may be able to assist in referrals for the names and address of laboratories conducting the testing you require. Please ensure that any laboratory you use to conduct these tests is GLP accredited. The name, address and qualifications of the safety assessor must be maintained in the Product Information file (PIF).

Labelling

Question: What information must appear on the labelling of a cosmetic product?

Answer:

There are 9 requirements for the labelling of a cosmetic product:

1. Name and address of the Responsible Person (EU address)

2. Nominal weight / volume
3. Date of minimum durability or Period after opening
4. Precautions for use
5. Professional use only (*if applicable*)
6. Batch number for traceability
7. Product function
8. List of ingredients
9. A suitable language

Question: What does the open jar symbol mean?

Answer:

The open jar symbol or Period After Opening (PAO) indicates the period of time after opening for which the product is considered safe. It is accompanied by a number and the letter 'm' to indicate how long the product will last once opened. For example 12M indicates that the product is suitable for use for up to 12 months after opening. Data to support the PAO must be held in the Product Information File.

Question: My product is for single use only, does it require the open jar symbol?

Answer:

Single use only products do not require a period after opening date if a date of minimum durability of greater than 30 months has been substantiated. Guidance to exemptions from the period after opening is available at http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/wd-04-entr-cos_28_rev_version_adoptee20040419_en.pdf

Question: How do I know whether to use the date of minimum durability or the period after opening symbol on my cosmetic product?

Answer:

The date of minimum durability is similar to a best before date on food products. You must prove with stability data that your product is stable for the duration indicated by the date of minimum durability. Guidance on how to conduct a stability study is given in the SCCP safety testing guidelines 6th Revision http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf The date of minimum durability is only mandatory where the minimum durability is less than 30 months. Once the date of minimum durability is shown to be greater than 30 months by way of stability data, and then the PAO application applies.

A guidance document on justifying the period after opening is found at http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/wd-04-entr-cos_28_rev_version_adoptee20040419_en.pdf

Question: What precautions must appear on the labelling for my product?

Answer:

Precautions relating to undesirable effects or results from the safety assessment may be presented on the labelling. It is mandatory to label your cosmetic product with precautions listed in the Annexes to the Cosmetics Directive. These precautions refer to the product's ingredients, if your product contains a substances listed in Annex III to VI of the directive then the necessary precautions must appear on the label. You can use the CosIng Database to search for ingredients and reference data. <http://ec.europa.eu/consumers/cosmetics/cosing/>

Ingredients

Question: What ingredients are not allowed in cosmetic products?

Answer:

Ingredients listed in Annex II of the cosmetics directive 76/768/EC are not permitted in cosmetics products. Annex III lists restrictions on certain ingredients to their field of application, composition and precautions of use. Annex IV listed the colouring agents that are allowed for use in cosmetics. Annex V lists the preservatives allowed for use in cosmetics. Annex VI lists the UV filters allowed in cosmetics products.

A list of all the annexes to the cosmetics directive is available on the European commission website: <http://ec.europa.eu/consumers/cosmetics/cosing/>

Question: What is the INCI nomenclature?

Answer:

INCI is the International Nomenclature of Cosmetics Ingredients. The INCI name should appear on the ingredient list. See the CosIng database for INCI names <http://ec.europa.eu/consumers/cosmetics/cosing/>

Question: Must I comply with REACH legislation?

Answer:

For information on REACH legislation, please refer to the Health and Safety Authority. Their website is <http://www.hsa.ie/eng/Topics/Chemicals/>