March 2006

APPENDIX 5

ASEAN Cosmetic Directive

Frequently Asked Questions on Cosmetic Product Notification

1. What should I do if I intend to import or manufacture a cosmetic product for local sale?

The company or person responsible for placing the cosmetic products in the market must notify the regulatory authority responsible for cosmetics of each Member State where the product will be marketed, of the place of manufacture or of initial importation before the product is placed in the market, using the Product Notification Form prescribed by the regulatory authority. The product can only be marketed after notification has been sent to the regulatory authority and acknowledgement has been received. Member countries shall endeavour to ensure that notifications will receive acknowledgement within three working days.

2. After filing a product notification and receiving an acknowledgement (e.g. notification number) from the regulatory authority, does it mean that the product has been approved for sale by the authority?

Acceptance of a product notification does not constitute, in any way, an agreement that the product meets all the regulatory requirements. The company or person responsible for placing the product in the market has to ensure that each consignment of the product meets the requirements of the Directive and will not cause damage to human health under normal or reasonably foreseeable conditions of use. The ASEAN Cosmetic Directive shifts from a pre-market approval system, to a post-marketing surveillance system. The Regulatory Authority will carry out a range of post-marketing monitoring and surveillance activities to ensure compliance with the Directive.

3. If my product has been notified to an ASEAN Member Country, is it exempted from notification to another ASEAN country in which I intend to market the product?

No, the authority of each country where the product is going to be marketed has to be informed individually. If you intend to market the product in 3 ASEAN Member Countries, you will have to notify the regulatory authority of the respective 3 ASEAN Member Countries.

4. If the cosmetic product is meant <u>solely</u> for export or re-export, must notification be filed with the regulatory authority?

Cosmetic products that are imported solely for direct re-export or locally manufactured solely for export are exempted from product notification requirement, as they will not impact the safety of local consumers, but the company should maintain proper records and documents. These records should

be open to inspection by the regulatory authorities at any time when required. However, if you export the products to market in an ASEAN Member Country, notification in that ASEAN Member Country is required.
Country specific requirements for manufacturers or importers of cosmetic products meant solely for export or re-export must be complied with.

5. Are samples including Hotel's sample, and professionally used cosmetic exempted from notification and the requirements of ACD ?

All product samples must be notified to the authority and comply with all the requirements of the ACD

6. Does each individual shade of a range of a cosmetic product or a palette of colours require a separate product notification?

No. A single notification can be made for a range of cosmetic products or a palette of colours. However, if required by the regulatory authority, full ingredient listing (one can use "may contain" to list the colorants used in each product in the palette) and the percentage of restricted substances will have to be declared for each colour in the range or palette. Please refer to the Guidelines on filing a notification to the regulatory authority.

Please note that you will have to file a new notification for colours added to an existing range or palette that are not included in the initial notification.

7. Can a company that is not registered to operate business in the ASEAN Member Country where the product will be marketed, file the product notification?

No, only a company registered to operate business in the ASEAN Member Country where the product will be marketed can file a product notification.

8. What are the supporting documents to be submitted with a product notification?

The following documents should be submitted with the notification:

- Full ingredient listing (as per labeling requirements) and the percentage of restricted ingredients appearing in the annexes of the Directive, if required by regulatory authority;
- Clear & legible colour photographs or draft drawing/artwork of the product labels, package inserts, inner and outer cartons, if required by regulatory authority;
- Copy of the Business Licence of the registrant or company responsible for placing the product in the market, to be submitted once, if required by regulatory authority;

- Letter of authorization from the product owner or manufacturer, if required by regulatory authority;

9. If there are any changes in the information submitted in a product notification, do I have to file a new product notification?

It will depend on the types of changes involved, as indicated in the table below:

Types of Change	**Product Notification**
Brand name	New
Company change due to change of distribution rights	New
Product types	New
Product presentation(single product, palettes in a range, etc)	Amendment
Intended use	New
Product name	New
Formulation	New
Manufacturer and or assembler (name and/or address)	New
Name and/or address of company without change of distribution rights	Amendment
Person representing company	Amendment
Pack sizes, packaging materials, labels.	Amendment, but not applicable if the information need not be submitted in Product Notification Form.