Draft of new regulation of xx.xx.2006 concerning product for cutaneous injection for cosmetic purposes

As laid down by the Norwegian Food Safety Authority xx.xx.2006 pursuant to the Act of 21 December 2005 no. 126 concerning cosmetics and bodycare products etc. § 5 second subsection, § 7 second subsection, § 8, § 9, § 11 second subsection, § 12 first and third subsection, § 13 third subsection, § 14 third subsection, § 15, § 16 sixth subsection, § 19 og § 21, re. regulation of 29 December 2005 no. 1770 concerning delegation of authority to The Norwegian Food Safety Authority pursuant to the Cosmetics Act points 2 and 3.

I

Part I. Introductory decisions

§ 1. *Aim*

The aim of this regulation is to help ensure products for cutaneous injection for cosmetic purposes are safe for humans and animals from the point of view of health.

This regulation shall also promote consumer interests, fair trading, animal welfare, ethics, the environment, food safety and quality.

§ 2. *Scope*

This regulation encompasses all situations associated with developing, producing, importing, processing, distributing, exporting and selling of products for cutaneous injection for cosmetic purposes and health personnel's duty to report any side effects when using such products.

This regulation does not encompass products encompassed by the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc..of cosmetics and bodycare products), pursuant to directive 76/768/EEC (the cosmetics directive), regulation xxxx concerning tattooing products, regulation xxx concerning external healthcare products or regulation xxxx concerning external products for care and marking of animals using chemical substances.

This regulation does not encompass products which are regarded to be medicines or medical equipment pursuant to the applicable decisions on medicines and medical equipment.

In cases of doubt, the inspection authority can decide whether a product is encompassed by this regulation. Should doubt exist as to whether a product should be regarded as a product for cutaneous injection for cosmetic purposes or other product as mentioned in the third subsection, this question will be decided in association with the competent authority in these product areas.

§ 3. *Definitions*

In this regulation the following definitions apply:

1. *Product:* Product for cutaneous injection for cosmetic purposes.
2. *Product for cutaneous injection for cosmetic purposes:* All substances or combination of substances which are meant to be introduced into the skin of humans or animals to change the appearance in ways other than those encompassed by the regulation of xxxxx concerning tattooing products.
3. *Inspection authority:* The Norwegian Food Safety Authority is the inspection authority pursuant to this regulation.

4. *Skin:* Skin includes the epidermis and the dermis or corium
5. *Use:* Use of product which can reasonably be predicted. Purposeful misuse is not included.
6. *Side effect:* A reaction when using the product - stated in appendix I.
7. *Sterility:* A complete absence of living organisms including viruses
8. *Sale*: Possession with the intention to sell, offer for sale, distribute, the sale itself and all other forms of taking possession, with or with out payment being made, including use in salons, etc and for the purposes of advertising.
9. *Business:* Private or public concern or individuals who perform an activity mentioned in § 2 first subsection, apart from private or non-commercial activities.
10. *Ingredients:* Any chemical substance or mixture of such of synthetic or natural origin which is used in products.
11. *Preservative:* Ingredients which are added mainly to hinder the growth of microorganisms.
12. *INCI-name:* A pan-European name of an ingredient as drawn up by the EU Commission (INCI: International Nomenclature Cosmetic Ingredient).
13. *Health personnel:* Personnel defined as health personnel in the Act of 2 July 1999 no. 64 § 3.

Part II. Ban

§ 4. *Ban on products which are not safe from the point of view of health*

It is forbidden to develop, produce, import, distribute, export and sell products which, when used, are not safe for humans or animals from the point of view of health.

§ 5. *Ban on products which contain certain substances*

It is forbidden to develop, produce, import, distribute, export and sell products which contain or emit one or more of the following substances:

a) ingredients or combinations of ingredients which are listed in appendix IIa of the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc of cosmetics and bodycare products), re. directive 76/768/EEC,
b) substances which are classified as medicines pursuant to the decisions given in the Medicines Act, with consideration to those exceptions which follow from the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc. of cosmetics and bodycare products),
c) carcinogenic, mutagenic and reprotoxic substances in category 1,2 and 3 pursuant to directive 67/548/EEC,
d) preservatives apart from those listed in appendix II. Appendix II states restrictions on the use of preservatives. It is not permitted to use combinations of these preservatives.

§ 6. *Ban on using non-sterile products*

Products shall be kept in closed and airtight packaging which retains the product's sterility, pursuant to § 3, until use.

Products shall be kept in packaging meant for single use on one person.

It is forbidden to develop, produce, import, distribute, export or sell products which do not meet the requirements in the first and second sub-section.

Products shall be injected or administered with equipment which meets the decisions in the regulation of 6 May 1998 concerning hygiene requirements for hairdressing, skin care, tattooing and ear piercing businesses etc.

§ 7. *Ban on testing on animals*

It is forbidden to test finished products on animals.

It is forbidden to test ingredients or combinations of ingredients in products on animals, unless minor testing of the individual substances contained is permitted pursuant to the regulation of 26 October 1995 no. 871 (General regulation concerning production, import and sale etc of cosmetics and bodycare products) §§ 6a and 6b in accordance with appendix IX, re. 2003/15/EC.

It is forbidden to produce and sell products which have been tested on animals in contravention of this decision.

Part III. Labelling

§ 8. *Location and language*

When selling a product, both the container and the packaging shall have the information mentioned in §§ 9-14 added to them, unless otherwise is stated in this regulation. This information shall be easily visible, easy to read and difficult to remove.

The information mentioned in §§ 9-13 shall be stated in Norwegian or a language which in meaning and spelling resembles Norwegian. The information in § 14 as well as in any general directions for use shall be stated in a language which is easy for the person who is going to use the product to understand.

§ 9. *Name and address*

The company name and complete address, including the telephone number, of the manufacturer and the person in Norway who is responsible for the marketing of the product, shall be stated.

The information may be abbreviated, if the abbreviation makes identifying the business possible.

§ 10. *Contents*

The nominal amount on the day of packaging shall be stated in weight or volume, except for packaging of free samples and packaging of products which are intended to be used once only.

Stating the contents may be omitted for ready-packed items which are usually sold in packs of more than one. If the number of packages can be readily ascertained without breaking open the packaging, or the product is usually sold individually, it is not necessary to state this.

§ 11. *Expiry date*

The product’s expiry date shall be the latest dates an unopened product, or a product which has already been used, is still in accordance with § 4, provided the product is stored under suitable conditions up to these dates.

If necessary, which conditions which must be fulfilled to ensure the product meets the stated expiry date shall be stated.

The expiry dates shall be stated using the words ”an unopened product should be used by...” and ”an opened product should be used by”, followed by the relevant dates or an explanation of where the dates may be found on the packaging.

Stating the date shall consist of month and year, in that order

§ 12. *Special precautions which shall be taken on use*

Special precautions which must be taken to ensure safe use shall be stated by using a directions for use or warning labeling which in each individual case is necessary to ensure safe use.

Products shall be affixed with a declaration which guarantees the contents of the product are sterile, re. § 3.

The information in the first subsection may, because of the product’s size or shape, be stated on a label, attached brochure, ribbon or card which are attached to the product.

§ 13. *Identification labeling*

The consignment’s production number, or other reference which makes it possible to identify production, shall be stated. This information may be stated on the product’s packaging.

§ 14. *Ingredients*

Ingredients

The ingredients shall be stated in the form of a list of such in declining order, according to their weight at the time they were added to the product. The list shall be started with the word ”ingredients” or other definition approved by the inspection authorities. The list may be stated only on the packaging, or on the container if packaging is not used.

If the product’s size or form necessitates it, the ingredient list can be stated on a label, an attached brochure, ribbon or card which is attached to the product. Attention shall be drawn to this by adding a reference to the packaging or container to the ingredients list.

The following are not regarded to be ingredients:

1. Technical media used to help manufacture the product during production but which are not present in the finished product.
2. Substances which have not been added on purpose, but which are in the product because of pollution.

Part IV. Duties in relation to marketing, notification and information etc..

§ 15. *Misleading marketing*

Labeling and the presentation of, advertising for and other marketing of products shall be correct, give the recipient enough information and not be misleading.

When selling a product, texts, definitions, brands, pictures or other signs which imbue the product with qualities it does not have shall not be used.

§ 16. *Duties regarding notification and information*

The business shall notify the inspection authority immediately if it is suspected that the product is not safe for humans or animals from the point of view of health.

The business shall, when the inspection authority requires it, at no cost give or send in necessary information, samples or results of analyses performed. The inspection authority can decide how the information should be stated, e.g. as far as the form, level of detail etc are concerned.

To facilitate swift and correct medical treatment in cases of acute poisoning, the information mentioned in the first subsection can be given to the Directorate of Health and Social Affairs' Section for Information on Poisoning, provided that such information is only used in this context.

§ 17. *Duty to report*

The Norwegian manufacturer, or importer of a product which is meant to be sold on the Norwegian market, shall on a special report form provide the inspection authority with the following:

1. Name or company name, and the address of the Norwegian producer or importer.
2. Producer and country of production.
3. Name of the relevant product series.

The inspection authority shall immediately be informed if any changes in the information mentioned in point 1 take place.

§ 18. *Statutory reporting of side effects*

Health personnel working at institutions with patients who suspect that a product has led to a side effect as defined in § 3, shall send a report about this to the inspection authority on a separate form.

§ 19. *Dossier*

The Norwegian manufacturer, or importer of a product which is meant to be sold on the Norwegian market, and the person responsible for marketing the product in Norway shall ensure the inspection authority has easy access to the following information, which is to be found at the address stated on the label pursuant to § 9.

1. The qualitative and quantitative composition of the product.

   As far as substances are concerned which are included in the finished product are concerned, identification of such can be limited to the trade name and the supplier's code number for the mixture which has been added to the product. In addition the firm's name and address of the supplier of the mixture shall be stated.
2. The physical/chemical specifications of the raw ingredients and the finished product; this includes stating the raw ingredients chemical purity. The sterilization method shall be stated.
3. The production method in accordance with national or international GPP for the relevant product.
4. Documentation of the safety of using the finished product from the point of view of health. When performing a safety assessment, the ingredients' general toxicological profile, chemical structure and level of exposure shall be taken into consideration. Particular consideration shall be paid to the effects of exposing those parts of the body to the product on which the product is meant to be used. Consideration shall also be paid to the substance's ability to be absorbed by the circulation system and tissue, and to the substance's ability to migrate and be stored in organs other than the skin. Particular

attention shall be paid to those groups of the population for whom the product is meant.

5. Name and address of those persons who are responsible for the documentation which is mentioned in point 4. These persons must have documentary evidence that they are qualified within one or more of the following areas of expertise: toxicology, dermatology, medicine or similar.
6. Existing data on undesirable health effects due to the use of the product.
7. Data from tests performed by the manufacturer, its representatives or suppliers in connection with development or a safety evaluation of the product or its constituent parts.

If the information mentioned in points no. 1 - 7 is not kept at the addressee in Norway, this must be available in either Norwegian or English.

The inspection authority shall be familiar with the dossier address before the product is released onto the Norwegian market.

The inspection authority can decide to make more detailed guidelines to implement the decisions in this section.

§ 20. *Access to premises, duty to assist etc*

The business shall give the inspection authority unimpeded access to the place or premises where activities take place encompassed by this regulation, so that the inspection authority can perform the necessary examinations. Foreign inspectors may also be in attendance on inspections etc when this is necessary to fulfill Norway's international obligations.

The business shall at no cost provide the premises, inventory, help and devices necessary so that inspection can be performed and otherwise help the inspection to be performed.

Part V. Administrative decisions

§ 21. *Inspection and decisions*

The Norwegian Food Safety Authority performs inspection and may make the decisions necessary to forbid development, production, import, processing, distribution, export and sale of a product, and decisions to sequestrate, destroy and close down the business.

The Norwegian Food Safety Authority can instruct the person responsible for the business to cover the actual costs associated with the sequestration, destruction and closing down of the business.

If the instructions are not followed, if it is unknown who is responsible or if it is necessary to take action swiftly, The Norwegian Food Safety Authority can implement the measures mentioned in the first subsection. The measures can be performed at the person responsible's cost. Monies owed are grounds for execution.

§ 22. *Dispensation*

The Norwegian Food Safety Authority may in special cases grant dispensations from this regulation, provided this is not in conflict with Norway's international obligations, including the EEA agreement.

§ 23. *Penalties*

Deliberate or careless breach of this regulation, or of decisions made pursuant to it, are punishable pursuant to the Cosmetics Act § 21.

II

§ 24. *Coming into force*

This regulation comes into force 1.1. 2007.

APPENDIX I: REACTIONS WHICH ARE RECKONED TO BE SIDE EFFECTS, PURSUANT TO § 3:

1. Allergic contact eczema
2. Toxic/irritative contact eczema
3. Eczema, unspecified
4. Photoallergic contact eczema
5. Phototoxic contact eczema
~~7.~~6. Hyperpigmentation
~~8.~~7. Hypopigmentation
~~9.~~8. Urticaria
~~10.~~9. Central nervous system side effects
~~18.~~10. Misc.

APPENDIX II: PRESERVATIVES PERMITTED IN PRODUCTS PURSUANT TO THIS REGULATION WITH STATED HIGHEST CONCENTRATION IN FINISHED PRODUCT AS WELL AS STATUTORY DIRECTIONS FOR USE AND WARNING LABELLING. COMBINATIONS OF THESE PRESERVATIVES ARE NOT PERMITTED, RE. § 5

Substance or substance group	Highest permitted concentration in finished product	Statutory directions for use and warning labeling
Ammonium(C12-C22)trimethyl-ammonium bromide and chloride (including cetrimonium bromide) CAS-no. 57-09-0	0.1%	
5-Amino-1,3-di(2-ethylhexyl)-5-methyl-n-hexahydropyrimidine (Hexetidine) CAS-no. 141-94-6 INCI: Hexetidine	0.1%	
Benzoic acid and its salts and esters CAS-no. 65-85-0 INCI: Benzoic Acid	0.5% (acid)	
Benzyl alcohol CAS-no. 100-51-6 INCI: Benzyl Alcohol	1 %	
2-Benzyl-4-chlorphenol (Chlorophene) CAS-no. 120-32-1 INCI: Chlorophene	0.2%	
1,6-Bis(4-amidinophenoxy)-n-hexane and its salts (including isethionate and 4-hydroxybenzoate) (Hexamidine) CAS-no. 3811-75-4 INCI: Hexamidine	0.1%	
1,3-Bis(hydroxymethyl)-5,5-dimethylhydantoin CAS-no. 6440-58-0 INCI: DMDM Hydantoin	0.6%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05%.
1-[(1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-1-yl]-1,3-di(hydroxymethyl)urea CAS-no. 78491-02-8 INCI: Diazolidinyl urea	0.5%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05%.
3,3'-Dibromo-5,5'-dichloro-2,2'-dihydroxy-diphenylmethane (Bromo Chlorophene) CAS-no. 15435-29-7 INCI: Bromo Chlorophene	0.1%	
3,3' - Dibromo - 4,4'-hexamethylenedioxy-benzamidine (dibromohexamidine) and its saltS including isethionate	0.1%	
2,4-Dichlorobenzyl Alcohol CAS-no. 1777-82-8 INCI: Dichlorobenzyl Alcohol	0.15 %	
2-Phenoxyethanol CAS-no. 122-99-6 INCI: Phenoxyethanol	1.0%	

Substance or substance group	Highest permitted concentration in finished product	Statutory directions for use and warning labeling
1,1-Hexamethylenebis-(5-(p-chlorphenyl)biguanide) and its digluconate, diacetate and dihydrochloride (Chlorhexidine) CAS-no. 55-56-1	0.3% calculated as chlorhexidine	
Hexamethylenetetramine CAS-no. 100-97-0 INCI: Methenamine	0.15%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Hydroxybenzoic acid and its salts and esters CAS-no. 99-96-7 INCI: 4-Hydroxybenzoic Acid	0,4% (acid) for a ester. 0.8% (acid) for ester mixtures.	
Imidazolidinyl urea CAS-no. 39236-46-9 INCI: Imidazolidinyl Urea	0.6%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Isopropyl-m-cresol CAS-no. 3228-02-2 INCI: Isopropyl Cresols	0.1%	
1-(3-Chlorallyl)-3,5,7-triaza-1-azonia-adamantane chloride (Methenamine-3-chlorallylchloride) CAS-no. 4080-31-3	0.2%	"CONTAINS FORMALDEHYDE" if the concentration of formaldehyde in the finished product is higher than 0.05
4-Chloro-m-xylenol CAS-no. 88-04-0 INCI: Chloro Xylenol	0.5%	
3-(4-Chlorophenoxy)-1,2-propanediol (Chlorphenesin) CAS-no. 104-29-0 INCI: Chlorphenesin	0.3%	
Formic acid and its natrium salt CAS-no. 64-18-6 INCI: Formic Acid	0.5% expressed as acid	
N-hydroxymethyl aminoacetate CAS-no. 70161-44-3 INCI: Sodium Hydroxymethylglycinate	0.5%	
Poly(1-hexamethylendi-guanide)hydrochloride CAS-no. 70170-61-5 INCI: Polyaminopropyl Biguanide	0.3%	
Propionic acid and its salts CAS-no. 79-09-4 INCI: Propionic Acid	2% (acid)	
Sorbic acid and its salts (2,4-Hexadienic acid) CAS-no. 110-44-1 INCI: Sorbic Acid	0.6% (acid)	
Undecylenic acid and its salts CAS-no. 112-38-9 INCI: Undecylenic Acid	0.2% (acid)	