Draft of regulation of XXXX 2006 concerning products for external use for care and marking using chemical means of animals

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 and third subsection, § 8, § 11 second subsection, § 12 first and third subsection, § 13 third subsection, § 14 third subsection, § 15, § 16 sixth subsection, § 19 and § 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 external use for care and marking of animals with chemical means are safe for those animals which are being treated and those humans who are using the products 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. *Virkeområde*

Scope

This regulation encompasses all situations associated with developing, producing, importing, processing, distributing, exporting and selling of products for external use for care and marking using chemical means of animals and animal health care personnel's duty to report any side effects when using such products. Products meant for use in the eyes or which are consumed orally are not included. Products which are fixed items are not included.

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 products for cutaneous injection for cosmetic purposes or regulation xxxx concerning external healthcare products.

This regulation does not encompass products which are reckoned 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 reckoned to be a product for external use for care and marking using chemical means of animals or other product as mentioned in the third subsection, this question will be decided in cooperation with the competent authority in these product areas.

§ 3. *Definitions*

In this regulation, the following definitions apply:

1. *Product*: Product for external use for care and marking using chemical means of animals.

2. *Product for external use for care and marking using chemical means of animals:* Substance or combination of substances which is used for external care of animals for hygienic purposes or for reasons of welfare, appearance or protection, and substances which are injected in animals subcutaneously to mark them. External care also encompasses care of bodily orifices (mouth, teeth, etc).
3. *Inspection authority:* The Norwegian Food Safety Authority is the inspection authority pursuant to this regulation
4. *Use:* Use of product which can reasonably be predicted. Purposeful misuse is not included.
5. *Side effect:* A reaction when using the product - stated in appendix I.
6. *Business:* Private or public concern or individuals who perform an activity mentioned in § 2 first subsection, apart from private or non-commercial activities.
7. *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 pet shops, etc and for the purposes of advertising.
8. *Ingredients:* Chemical substance or mixture of such of synthetic or natural origin which is used in products encompassed by this regulation.
9. *INCI-name:* A pan-European name of an ingredient as drawn up by the EU Commission (INCI: International Nomenclature Cosmetic Ingredient).
10. *Animal health personnel:* People who are endorsed or licensed pursuant to §§ 4 and 5 in the Act of 15 June 2001 no. 75 concerning veterinary and other animal health personnel.

Part II. Ban on products which are not safe from the point of view of health and certain ingredients

§ 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. *Restrictions on ingredients*

Apart from those exceptions and customization mentioned in subsections 2 and 3, the ingredients regulations pursuant to the regulation of 26 October 1995 no. 871 concerning production, import and sale etc of cosmetics and bodycare products (the Cosmetics Regulation) apply to the products encompassed by this regulation.

The decisions in the cosmetics regulation which concern children especially do not apply in this regulation.

It is forbidden to use an ingredient which is:

1. classified as hazardous to the environment pursuant to directive 67/548/EEC, or
2. classified as a medicine pursuant to the Medicines Act, with regards 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).

Part III. Labelling

§ 6. § 7. *Location and language*

When selling a product, both the container and the packaging shall have the information mentioned in §§ 7-12 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 §§ 8-10 and 12 shall be stated in Norwegian or a language which in meaning and spelling resembles Norwegian. The information in § 13 as well as in any directions for use shall be stated in a language which is easy for the person who is going to use the product to understand.

§ 7. *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.

§ 8. *Contents*

The nominal amount on the day of packaging shall be stated in weight or volume, except for items which are less than 5g or 5ml, 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 weight and volume is of little significance, provided that the number of packages is clear from the packaging. If the number of items can be readily ascertained without breaking open the packaging, or the product is usually sold individually, it is not necessary to state this.

§ 9. *Expiry date*

A product's expiry date shall be the latest date 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.

§ 10. *Special precautions which shall be taken when using product*

Special precautions which shall be taken to ensure safe use shall be stated by using the directions for use or on warning labeling which in each individual case are necessary to ensure safe use. Such precautionary rules concern in particular those stated in the appendices to the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc. of cosmetics and bodycare products) in the field “statutory directions for use and warning labeling”.

Information pursuant to the first subsection may, because of the product's size or shape, be stated on the label, in an attached brochure, ribbon or card which is affixed to the product. Attention shall be drawn to this, either by using an abbreviated reference to the information attached or by having the symbol below on the container and packaging.

§ 11. *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.

§ 12. *The product's function*

The product's function shall be stated, if this is not obvious from the way in which the product is presented otherwise.

§ 13. *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. It is enough for the information to 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 the 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 and container to the ingredients list.

If the product is of a shape that reference is not possible pursuant to the second subsection, the ingredients list shall be on a sign in immediate proximity to the container where the product is being offered for sale.

The following are not regarded to be ingredients:

1. Impurities in the raw ingredients used.
2. Technical media which are used during production, but which the finished product does not contain.

Perfumes or aromas and combinations thereof and their basic ingredients shall be stated using the word ”perfume” or other definition endorsed by the inspection authority. Perfumes as listed in appendix II must be stated in the ingredients list, if the concentration in the finished product is greater than 0.001 % (10 ppm) if the product is not meant to be rinsed off quickly after use and 0.01% (100ppm) for products which are meant to be rinsed off quickly after use.

Ingredients at a concentration lower than 1 % can be stated in any order, after those whose concentration is greater than 1%.

§ 14. *Exemption from inclusion in ingredients list*

The producer, its representative or anyone responsible for importing a product may, because of business secrets, apply to the inspection authority for an exemption from including one or more ingredients in the ingredients list pursuant to § 13.

The application must give reasons for this, re. appendix VIII in the regulation of 26 October 1995 no. 871 (general regulation concerning production, import and sale etc. of cosmetics and bodycare products).

The inspection authority shall treat the application in accordance with the applicable rules for administrative case handling and the public's right to access such.

§ 15. *Labeling concerning testing on animals*

If labeling is used concerning testing on animals, information must be provided on whether this applies to the finished product and/or the ingredients. This also applies when stating that such testing has not taken place.

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

§ 16. *Ban on 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.

§ 17. *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.

§ 18. *Statutory reporting of side effects*

Animal health personnel who while performing their duties 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. *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 address of Norwegian producer or importer.
2. Producer and country of production.
3. Name of the relevant product series.

This report shall already have been provided before the product is marketed.

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

§ 20. *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 § 7.

1. The qualitative and quantitative composition of the product.

   As far as any perfumes are concerned, identification can be limited to the trade name and the supplier's code number for the perfume mixture which has been added to the product. In addition, the company name and address of the supplier of the perfume mixture shall be stated.
2. The physical/chemical and microbiological specifications of the raw ingredients and the finished product as well as the criteria for purity and microbiological control of the product.
3. The production method in accordance with national or international GPP for the relevant product. The person responsible for production, or for the first import, must have relevant qualifications.
4. Documentation of the safety of using the finished product from the point of view of health. The safety assessment shall take into consideration the ingredients' toxicological properties.
5. Name and address of those competent persons who are responsible for the documentation which is mentioned in point 4. These persons must have documentary evidence that they are qualified within relevant areas of expertise, e.g. veterinary medicine or similar.
6. Existing data on undesirable health effects due to the use of the product.
7. Documentation of the effect the product is claimed to have if the nature of the effect or the product justifies this.
8. Data on any animal testing carried out by the manufacturer, its representatives or suppliers in connection with the development or safety evaluation of the product or its constituent parts, including any animal testing performed to meet requirements of third countries' laws or regulations.

If the information mentioned in points no. 1 - 8 is not kept at the addressee in Norway, these must be available either in Norwegian, English or a language which in its spelling or meaning is similar to Norwegian.

The dossier information shall be easily accessible to the inspection authority with the importer's assistance if the dossier is at a foreign address.

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.

§ 21. *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

§ 20. *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.

§ 21. *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.

§ 22. *Penalties*

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

II

§ 23. *Coming into force*

This regulation comes into force 1.1. 2007.

APPENDIX ONE I

REACTIONS RECKONED TO BE SIDE EFFECTS, RE. § 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. Loss of fur
11. Misc.

APPENDIX II:
PERFUMES WHICH MUST BE STATED IN THE LIST OF INGREDIENTS IF THE CONCENTRATION IN THE FINISHED PRODUCT EXCEEDS 0.001 % (10 ppm) IF THE PRODUCT IS NOT RINSED OFF QUICKLY AFTER USE AND 0.01% (100ppm) IF THE PRODUCT IS RINSED OFF QUICKLY AFTER USE

Substance	**CAS -number**
alpha-hexylcinnamaldehyde INCI: Hexyl cinnamal	101-86-0
Amylcinnamaldehyde INCI: 2- Benzylideneheptanal	122-40-7
Amylcinnamyl alcohol INCI: Amylcinnamyl alcohol	101-85-9
Anise alcohol INCI: Anise Alcohol	105-13-5
Benzyl alcohol INCI: Benzyl Alcohol	100-51-6
Benzyl benzoate INCI: Benzyl benzoate	120-51-4
Benzyl cinnamate INCI: Benzyl cinnamate	103-41-3
Benzyl salicylate INCI: Benzyl salicylate	118-58-1
2-(4-tert-Butylbenzyl)-propionaldehyde INCI: Butylphenyl methylpropional	80-54-6
Citral INCI: Citral	5392-40-5
Citronnellol INCI: Citronnellol	106-22-9
d-Limonene INCI: Limonene	5989-27-5
Evernia Prunastri INCI: Evernia Prunastri	90028-68-5
Eugenol INCI: Eugenol	97-53-0
Farnesol INCI: Farnesol	4602-84-0
Geraniol INCI: Geraniol	106-24-1
Hydroxycitronellal	107-75-5

INCI: Hydroxycitronellal	
Hydroxymethylpentyl Cyclohexen Carboxaldehyde INCI: Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4
Isoeugenol INCI: Isoeugenol	97-54-1
Cinnamal INCI: Cinnamal	104-55-2
Cinnamyl alcohol INCI: Cinnamyl alcohol	104-54-1
Coumarin INCI: Coumarin	91-64-5
Linalool INCI: Linalool	78-70-6
Methyl heptine carbonate INCI: Methyl 2-octynoate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on INCI: Alpha-isomethyl ionone	127-51-5
Evernia Furfuracea INCI: Evernia Furfuracea	90028-67-4