Basic information

2008/0035(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Cosmetic products. Recast. "Cosmetics Regulation" Amended by 2012/0266(COD) **Subject** 3.40.12 Luxury products industry, cosmetics 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	ROTH-BEHRENDT Dagmar (PSE)	26/02/2008

Committee for opinion	Rapporteur for opinion	Appointed
JURI Legal Affairs	The committee decided not to give an opinion.	25/06/2008

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2910	2008-12-01
Agriculture and Fisheries	2976	2009-11-20

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter

Key events

Date	Event	Reference	Summary
05/02/2008	Legislative proposal published	COM(2008)0049	Summary
01/12/2008	Debate in Council		
02/12/2008	Vote in committee, 1st reading		Summary
08/12/2008	Committee report tabled for plenary, 1st reading	A6-0484/2008	
13/01/2009	Committee referral announced in Parliament, 1st reading		

23/03/2009	Debate in Parliament		
24/03/2009	Decision by Parliament, 1st reading	T6-0158/2009	Summary
20/11/2009	Act adopted by Council after Parliament's 1st reading		
30/11/2009	Final act signed		
30/11/2009	End of procedure in Parliament		
22/12/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0035(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
Amendments and repeals	Amended by 2012/0266(COD)
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/59735

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE409.426	22/07/2008	
Amendments tabled in committee		PE412.251	22/09/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0484/2008	08/12/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0158/2009	24/03/2009	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03623/2009/LEX	30/11/2009	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0049	05/02/2008	Summary
Document attached to the procedure	SEC(2008)0117	05/02/2008	
Document attached to the procedure	SEC(2008)0118	05/02/2008	

Commission response to text adopted in plenary	SP(2009)3060	04/06/2009	
Commission document (COM)	COM(2013)0135	11/03/2013	Summary
Commission working document (SWD)	SWD(2013)0066	11/03/2013	
Commission working document (SWD)	SWD(2013)0067	11/03/2013	
Follow-up document	COM(2016)0580	19/09/2016	Summary
Follow-up document	COM(2016)0599	19/09/2016	Summary
Follow-up document	COM(2018)0531	10/07/2018	Summary
Commission document (COM)	COM(2018)0739	07/11/2018	Summary
Follow-up document	COM(2019)0479	15/10/2019	Summary
Follow-up document	COM(2021)0403	22/07/2021	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1193/2008	09/07/2008	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Regulation 2009/1223
OJ L 342 22.12.2009, p. 0059 Summary

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 10/07/2018 - Follow-up document

In accordance with Regulation (EC) nº 1223/2009 of the European Parliament and of the Council, the Commission presents its twelfth report on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics (2015-2017).

The main points in the report may be summarised as follows:

Court of Justice clarification on scope of the marketing ban: in the *European Federation for Cosmetic Ingredients* case (Case C-592/14), main question examined by the Court was whether Article 18(1)(b) of the Regulation may be interpreted as prohibiting the placing on the EU market of cosmetic products containing ingredients that have been tested on animals outside the EU to comply with the cosmetics legislation of a third country. The Court concluded that the provision must be interpreted as meaning that it may **prohibit** the placing on the European Union market of cosmetic products containing some ingredients that have been **tested on animals outside the European Union**, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.

Compliance with the testing and marketing ban: as in the previous reporting period, Member States reported **practically no cases of non-compliance** with the testing and marketing bans. Based on inspections carried out by market surveillance authorities, one Member State reported two cases of infringement of the bans, following which the companies in question were asked to remedy the breach. The main issue raised by several Member States was the fact that the **product information files (PIFs) were incomplete** with regard to data on animal testing – this information is necessary to verify compliance with the bans. The specific issues with PIFs were the following:

- the information on animal testing or alternatives in the PIF (or declaration thereof) was absent or insufficiently detailed (e.g. it did not reference the ingredients and the finished product, or it did not mention testing under other regulatory frameworks and a justification of the need for this);
- the toxicological data was insufficient for some cosmetic ingredients (for instance the ingredients' suppliers did not provide toxicological data on the ingredients but only a declaration).

The report states that competent authorities appear to be properly addressing these shortcomings.

Progress made in alternative methods to animal testing: the report states that **significant progress** has been made in the development, validation and regulatory acceptance of alternative methods, for skin irritation/corrosion, serious eye damage/eye irritation and skin sensitisation. **Integrated approaches to testing and assessment (IATAs)** have been developed and internationally harmonised in the first two areas and are in the process of being approved for skin sensitisation. In particular, priority work in recent years has focused on developing defined and integrated approaches to testing and assessment that look at all existing safety data when assessing a chemical.

The **more complex human health effects (endpoints) still present challenges** and require more research. This is the case, for example, for **acute and chronic systemic toxicity**, areas in which significant knowledge gaps currently limit the development of IATAs. Significant projects, such as EU-ToxRisk, aim to address these challenges. The latter is a major collaborative project funded by Horizon 2020. With a budget of over EUR 30 million, it was launched in January 2016 and will last for six years. The project, aims to make progress towards animal-free safety assessments and tackles complex areas of toxicology, such as repeated dose and reproductive toxicity. The first eight case studies have progressed considerably.

The validation of alternative methods at EU level is progressing steadily, through the activities of the **European Union Reference Laboratory for Alternatives to Animal** (EURL ECVAM), which is currently leading the project to develop a guideline based on defined approaches for skin sensitisation testing.

The Commission also remains engaged in encouraging the regulatory acceptance of alternative methods approved at **OECD level** and maintains international cooperation in this field. These activities aim not only to recognise individual alternative methods, but also to achieve the convergence of safety assessment methods at international level. OECD member countries work together to improve and harmonise assessment methodologies for chemicals and collectively gain experience in the development of IATAs, which has become a priority over recent years as an alternative solution to animal testing.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 15/10/2019 - Follow-up document

In accordance with Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, the Commission presented its thirteenth Commission report on the development, validation and legal acceptance of alternative methods to animal testing in the field of cosmetic products.

The report shall also inform the European Parliament and the Council of the compliance with the deadlines for the bans on animal testing laid down in the Regulation and of the technical difficulties they pose.

The main conclusions of the report are as follows:

Problems encountered

Based on inspections carried out by market surveillance authorities, one Member State reported amongst the hundreds cases of control three cases of non-compliance with the marketing ban, following which the companies were asked to remedy the infringement. The very large majority of the Member States who monitored compliance with the testing and marketing bans did not report any difficulties in carrying out compliance checks.

The main issue encountered by a small number of Member States in their market surveillance activities related to the bans is the presence of a limited number of cases of incomplete animal testing information in PIFs. Immediate corrective measures were imposed on economic operators in all reported cases. Most Member States did not report any cases where a manufacturer, in particular an SME, was not able to place a cosmetic product on the market due to an inconclusive safety assessment of the product or ingredient caused by a lack of alternatives to animal testing. However, two Member States reported that SMEs do not have sufficient knowledge about the testing and marketing bans and sufficient financial resources needed for cost-intensive toxicological tests on new ingredients.

Progress made in the development, validation and legal acceptance of alternative methods to animal testing

For more than 25 years the Commission has been fully engaged at all stages of the process to find replacements to animal testing with alternative test methods. Work is increasingly focused on developing defined approaches and integrated approaches to testing and assessment which look at all existing safety data when assessing a chemical ingredient.

Considerable progress was made on several fronts in the development, validation and regulatory acceptance of alternative approaches to animal testing in 2018:

- EU-ToxRisk is a European collaborative project funded by the EU Framework Programme for Research and Innovation, Horizon 2020 (H2020), to advance mechanism-based toxicity testing and risk assessment. With a budget of over EUR 30 million, it was launched in January 2016 and will last for 6 years;

- the European Union Network of Laboratories for the Validation of Alternative Methods (EUNETVAL) has continued to support the EURL ECVAM validation studies. Two EURL ECVAM validation studies deal with methods for the identification of endocrine disruptors and involve the EU-NETVA;

- the European Partnership for Alternative Approaches to Animal Testing (EPAA) is a public-private partnership between the European Commission, eight European trade associations and 36 individual companies from the relevant business sectors. In 2018, the work of EPAA included seven projects to facilitate the promotion, validation, acceptance and implementation of 3R alternatives in European regulatory testing and decision-making, and to promote international harmonisation of regulatory testing.

Acceptance by the international authorities

Despite considerable progress made in the development, validation and legal acceptance of methods alternative to animal testing, alternative test methods have not yet been accepted by the international regulatory community for the safety assessment of ingredients for some of the most complex endpoints, such as repeated dose toxicity, reproductive toxicity or carcinogenicity.

The report stressed that until all toxicological endpoints can be covered by alternatives, the European cosmetics industry remains limited in its ability to introduce new ingredients, apply for new uses of existing ingredients, or respond to new questions regarding the safety of existing ingredients.

The Commission has been and continues to be fully committed to encouraging the regulatory acceptance of alternative methods approved at OECD level and to promoting the EU animal testing ban in cosmetics at international level, through relevant fora and bilateral and multilateral cooperation. These activities aim not only to recognise individual alternative methods, but also to promote animal welfare and to achieve the convergence of safety assessment methods at international level.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 19/09/2016 - Follow-up document

In accordance with Regulation (EC) No 1223/2009, the Commission presented a report on product claims made based on common criteria in the field of cosmetics.

Product claims and advertising are essential tools for informing consumers about characteristics and qualities and help them choose the products that best suit their needs and expectations. For cosmetic product claims to meet their purposes adequately, it is important to have an efficient framework in place which ensures that they are fair and do not mislead consumers.

The Commission adopted common criteria by Regulation (EU) 655/2013 (the Claims Regulation), for the justification of claims made in relation to cosmetic products.

This report **assesses the legal compliance of cosmetics-related claims with the common criteria adopted** and to specify the corrective measures that the Commission and Member States intend to take in cases of non-compliance.

Applicable European legislation: the report noted that the existing European regulatory framework for claims and advertising of cosmetic products is very comprehensive and ensures a high level of consumer protection. At the same time, it enables the European cosmetics industry to be competitive within the EU and in the world.

Based on Member States' contributions to this report, **90 % of analysed cosmetic claims were found compliant with the common criteria** set out in Regulation (EU) 655/2013.

According to the contributions from 21 Member States, 38 995 cosmetic claims were analysed in total in 2014 and 2015. There were 3730 non-compliant claims out of 38 995 (10 %).

The percentage of compliance and non-compliance **varies significantly according to the type of product distribution**. In some Member States, up to 70 % of non-compliant claims were found online, only 17 % were found on the actual product, and 13 % were found in brochures.

Most samples used for the analysis represented products containing the following categories of claims:

- claims characterising ingredients (e.g. 'anti-ageing');
- claims related to the product's efficacy (e.g. a skin cream with a sun protection factor);
- claims highlighting the absence of substances (e.g. 'free from perfume');
-

- claims addressing skin compatibility of the product (e.g. ‘hypoallergenic’, ‘for sensitive or atopic skin’);
- claims addressing health or additional benefits other than the cosmetic purpose (e.g. sunscreens or intimate hygiene products).

The report noted that the common criteria should **only be applied to products which fall under the definition of a cosmetics product** under the Cosmetics Regulation, and for which any borderlines issues with medical devices or medicinal products have been resolved. It is for Member States to decide on a case-by-case basis whether a product is a cosmetic or not.

Medicinal properties, claims of treatment ability and therapeutic effects: most non-compliant claims were found to be misleading as regards the function and performance of the cosmetic product.

Most Member States identified claims with a medicinal effect as being the most dangerously misleading claims for consumers. Believing that a cosmetic product has therapeutic effects and medicinal properties could lead consumers to delay seeing their doctor and follow their own treatment. Such misleading claims included therapeutic effects on skin, blood circulation, deeper tissue, muscles, joints, veins or adipose tissue, anti-inflammatory function, and healing properties.

Free from authorised ingredients: 20 % of the monitored cosmetic products had a **‘free from’ claim** and many of them were ‘parabens free’. This claim is attractive for marketing purposes because of the media attention. However, Member States considered that it is against the ‘fairness’ criterion because it denigrates legally authorised ingredients.

Hypoallergenic claims: 7 Member States reported cases of ‘hypoallergenic’ claims without supporting documents or evidence. Some national authorities notified claims made about hair dyes, according to which the dyes contained ingredients that guaranteed or offered protection from skin problems (or reduced the risk of allergy) during the colouring process. These products nonetheless contained resorcinol and para-phenylenediamine, which are well known allergens. Claims that attempt to underestimate the risks of allergic reactions associated with the use of hair dyes pose a risk to human health and may prevent consumers from making an informed choice to use the product.

All Member States that contributed to this report concurred that there is a need to **clarify the ‘free from’ and ‘hypoallergenic’ claims**. This could be done through the existing sub-working group on claims and ad hoc technical documents on the two issues.

Corrective action in cases of non-compliance: according to the contributions received from Member States, a wide variety of corrective actions were carried out in reaction to non-compliance of claims with the common criteria. The most frequently reported corrective actions were: (i) written advice to the responsible person, importer or manufacturer, ordering and prohibiting sales until the product complies with the requirements; (ii) request to the responsible person to modify the claim in the advertisement not only on the product but also in the media and on the internet; (iii) instruction to the responsible person to conduct new studies to get enough evidence to retroactively support the claims; (iv) financial sanctions imposed in some Member States.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 19/09/2016 - Follow-up document

In accordance with Regulation (EC) nº 1223/2009 of the European Parliament and of the Council, the Commission presents its eleventh report on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics.

The report is based on the contributions of Member States received between 2014 and the end of 2015.

Background: it is recalled that the animal testing of finished cosmetic products has been prohibited in the EU since 2004, and the testing of cosmetic ingredients since March 2009 (testing ban).

Since 11 March 2009, the marketing in the EU of cosmetic products and their ingredients that have been tested on animals in order to meet the requirements of Directive 76/768/EEC has also been prohibited. This marketing ban applied to all but the most complex human health effects (endpoints) that needed to be tested, in the absence of alternative non-animal tests (repeated-dose toxicity, reproductive toxicity and toxicokinetics). The European Parliament and the Council decided that the ban would take effect on 11 March 2013 (2013 marketing ban).

Main conclusions of the report

Compliance with the testing and marketing bans and the impact of the bans: virtually **no cases** of non-compliance with the testing and marketing bans have been reported by Member States. The main issue encountered in their market surveillance activities related to the bans is the presence of cases of **incomplete animal testing data in product information files.** In practice, the main way of verifying compliance with the testing and marketing bans is the cosmetic product’s product information file. The following gaps in information were remarked:

- the **toxicological data** (including animal testing data) on ingredients was insufficient;
- the product information files did not always contain complete data on compliance with **legislative frameworks** other than the Cosmetics Regulation (e.g. the REACH Regulation);
- the information relating to animal testing was in certain cases limited to a **disclaimer by the person responsible** that no animal testing had been performed on the final product;
- it was found that some **small companies** have an insufficient understanding of the bans or even misinterpret their requirements.

Since the report covers the relatively early stages of the implementation of the 2013 marketing ban, the Commission considers that it will be interesting to **follow future developments in this field**, when economic operators and market surveillance authorities gain more experience regarding the implementation of the full marketing ban. In particular, the competent national authorities should monitor the issue of cases of incomplete animal testing data in the product information file.

Progress made in alternative methods to animal testing: the report notes that significant progress was made in recent years in the development, validation and regulatory acceptance of alternative methods to test for skin irritation/corrosion, serious eye damage/eye irritation and skin sensitisation. However, **considerable scientific challenges remain** for the more complex endpoints for which more research is needed. The current level of alternative methods does not make it possible to fully replace in vivo tests for all toxicological endpoints.

Research and development activities: **major research and development activities** on alternatives to animal testing are ongoing in the EU, particularly through significant research initiatives by public and private actors. **More than EUR 250 million** were dedicated during the Seventh Framework Programme (FP7: 2007-2013), including from the Innovative Medicines Initiative (IMI), to research into alternatives. The five-year SEURAT-1 research initiative, which was completed in 2015, was a unique **EUR 50 million** public-private partnership co-financed by the Commission's FP7 (Health Programme) and the European personal care association.

The Commission is involved in the validation of alternative methods through **EURL ECVAM** (the European Union Reference Laboratory for alternatives to animal testing) and through its support for facilitating the regulatory acceptance of alternative methods by the OECD and international partners.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 07/11/2018 - Follow-up document

The Commission presents a review of Regulation (EC) 1223/2009 of the European Parliament and of the Council on cosmetic products (the Cosmetics Regulation) with regard to **substances with endocrine-disrupting properties** pursuant to Article 15(4) of that Regulation.

The Cosmetics Regulation does not have any specific provisions for endocrine disruptors. However, specific rules under Article 15 of the Cosmetics Regulation apply to the use in cosmetic products of substances which have been classified as **carcinogenic, mutagenic or toxic for reproduction** (CMR) under Regulation (EC) No 1272/200810 on the classification, labelling and packaging of substances and mixtures. Certain categories of CMR substances are, subject to derogations, prohibited from use in cosmetics based on their CMR classification and inserted in the relevant Annex of the Cosmetics Regulation. For cases where the potential endocrine disrupting substance is not classified as a CMR, its use in cosmetics follows the general provisions of Article 31 of the Cosmetics Regulation, which requires a **scientific opinion** of the Scientific Committee on Consumer Safety (SCCS).

Regulatory approaches to endocrine disruptors: different regulatory approaches exist in different pieces of EU law on endocrine disruptors depending on the specificities of each sector. The report cites, *inter alia*, two Regulations that apply in terms of content for biocides and plant protection products, these being Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012, and Commission Regulation (EU) 2018/605 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. Although the criteria for identifying endocrine disruptors do not have direct legal consequences for other areas of EU law than the areas of plant protection products and biocides, they are taken into account, as far as possible, for the purposes of the review of the Cosmetics Regulation.

Safety assessments of cosmetic ingredients by the SCCS: the SCCS and its predecessors have **already evaluated cosmetic ingredients suspected of having endocrine-disrupting properties**. The report gives examples of ingredients on which the SCCS and its predecessors delivered scientific opinions including several parabens (which are cosmetic preservatives), triclosan (used as a preservative and deodorant), and homosalate (used in sunscreens as UV-filter but also for its skin conditioning properties). In the risk assessment procedure for substances used as cosmetic ingredients, the SCCS also considers the exposure assessment for **specific vulnerable groups**, such as children and pregnant women.

These opinions show that the scientific concerns with regard to the endocrine-disrupting properties of substances can be addressed in the safety assessment of the SCCS. The report notes as an example that the SCCS carried out a case-by-case safety assessment of the different **parabens**. Based on the SCCS safety assessment, the Commission took the appropriate **measures to restrict or ban the use of certain parabens** where there was a potential risk for human health, including the use of some parabens in products designed for application on the nappy area of children under the age of three. The use of other parabens was confirmed as safe.

Consequently, substances identified as endocrine disruptors are currently subject to the general safety assessment of the SCCS. They are treated like substances of concern for human health and are subject to **case-by-case regulatory action** based on the general requirements of the legislation that are aimed at ensuring product safety. The Commission states that, bearing in mind the different approaches taken in relevant pieces of EU legislation to address endocrine disruptors in different sectors, the experience collected since the entry into application of the Cosmetics Regulation has **not revealed elements which would justify deviating from the regime designed by the legislator** to address the safety concerns related to the use of endocrine disruptors in cosmetics.

Next steps: the Commission will establish by spring of 2019 a **priority list of potential endocrine disruptors** that are not already covered by the bans laid down in the Cosmetics Regulation. It will require data from Member States, stakeholders and academia. Upon receipt of such data, the Commission will **mandate the SCCS to evaluate the substances** in the shortest time-frame. On that basis, the Commission will take the appropriate action to ban or restrict the use of the different substances in cosmetics.

Lastly, as stated in the Commission Communication 'Towards a comprehensive European Union framework on endocrine disruptors', the Commission will analyse the efficiency, effectiveness and coherence of the different risk-management approaches to endocrine disruptors laid down in EU law, including the Cosmetics Regulation.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 11/03/2013 - Follow-up document

The Commission presents a Communication on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. It has a **twofold purpose:**

- to inform the European Parliament and the Council of the Commission's decision **not to propose any changes in the animal testing related provisions** in Directive 76/768/EEC (Cosmetics Directive) and in Regulation (EC) No 1223/2009 (Cosmetics Regulation), the reasons why and the way forward.

- to present the **annual report** in accordance with the Cosmetics Directive which is the tenth Commission report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics.

The 2013 marketing ban: the deadline for the 2013 marketing ban in the Cosmetics Directive/Regulation enters into force on 11 March 2013. This completes a 20-year long process on phasing out animal testing for the purpose of cosmetic safety assessment. **Promising progress has been made in advancing alternative methods** to animal testing over the last few years, but **full replacement of this kind of testing will not be possible for some time.**

In light of an impact assessment, the Commission has come to the conclusion that it is most appropriate to **let the 2013 marketing ban enter into force** and not to present a legislative proposal either to postpone the deadline or to provide for individual derogations. The reasons are as follows:

- the Commission considers that a further postponement of the 2013 marketing ban would not reflect the political choices of the European Parliament and the Council when adopting this provision ;

- any change to the 2013 marketing ban could seriously diminish the determination swiftly to develop alternative test methods ;

- a case-by-case derogation allowing the Commission to deviate from the 2013 marketing ban for individual ingredients offering significant benefits for the consumer or the environment would benefit mainly larger manufacturers capable of gathering the necessary evidence.

The way forward: the Commission considers that the most appropriate way forward is to let the marketing ban enter into force and to turn the challenges that the 2013 marketing ban is posing into an opportunity.

1°) Ensure a coherent implementation of the 2013 marketing ban and monitoring its impacts.

Currently, there is no jurisprudence of the Court of Justice of the European Union on the interpretation of the scope of the 2013 marketing ban. The Commission recalls that only the Court can provide a legally binding interpretation. **Under the supervision of the Court, the Commission will oversee the application of the 2013 marketing ban.** It will do so in accordance with its current understanding of the scope of the 2013 marketing ban, which is based on the Cosmetics Regulation/Directive.

The Commission will also monitor the **socio-economic impacts** of the 2013 marketing ban.

2°) Continue the support for research, development and validation of new alternative methods for human safety testing.

The Commission has made about **EUR 238 million** available between the years 2007 and 2011 for research into alternative methods to animal testing alone. It is also important to mention the **SEURAT-1 initiative** ('Safety Evaluation Ultimately Replacing Animal

Testing') which is a jointly funded initiative by the European Commission and the cosmetics industry, each of which contributes EUR 25 million between 2011 and 2015.

The research into alternative methods is by no means near an end. Horizon 2020 is the financial instrument that will ensure the framework for the research activities between 2014 and 2020. **At the same time, strong commitment is required from the sectors that would benefit from the development of new alternative methods, including the cosmetics sector**. The Commission will engage with stakeholders from such sectors to define the research priorities, which, for example, could take the form of a new public-private partnership.

3°) Make alternative methods an integral part of the Union's trade agenda and international cooperation.

A key instrument in agreeing on tools for safety assessment is the development of **OECD Test Guidelines** in the framework of the Existing Chemicals Programme and the Mutual Acceptance of Data. Alternative methods have been included in OECD Test Guidelines and this has been key in leading to their international acceptance. Commission services are actively involved in the OECD work. If significant progress is to be made, the Commission feels it necessary to consider how to reflect Integrated Testing Strategies in OECD Guidelines.

It will endeavour to put these issues on the agenda of all relevant multi and bilateral meetings in the cosmetics field in 2013, notably with the United States and China, but also in contacts with Brazil and India.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 05/02/2008 - Legislative proposal

PURPOSE: to recast EU legislation on cosmetic products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

CONTENT: the simplification of EU cosmetic legislation was included in the Commission's annual Policy Strategy for 2007. The purpose of this proposal, therefore, is threefold:

1. To remove legal uncertainties and inconsistencies in cosmetic legislation.
2. To avoid divergences in national transpositions.
3. To ensure that cosmetic products placed on the EU market are safe.

The Cosmetics Directive has been amended 55 times. One of the key objectives of this proposal is to bring all 55 amendments together under one legal text. The Commission has chosen to present this codification in the form of a Regulation in order to facilitate and harmonise transposition of the provisions.

In addition to merging the 55 amendments into one legal text, the Commission is proposing a number of substantive changes.

Introducing a set of definitions: A set of new definitions is being proposed. The present Directive contains virtually no legal definitions resulting in legal uncertainty and inconsistent compliance. The proposal offers coherence with existing definitions particularly in the field of the free movement of good.

Glossary of ingredient names: The proposal includes a system to update the glossary of ingredient names. The glossary will contain the names of all relevant cosmetic ingredients (approximately 10 000). The names used are independent of any national language and usually much shorter than the chemical name. Thus, these names will help avoid the need for translation of the labelled list of ingredients. Further, the glossary refers to names that have global acceptance. This will help EU producers to export their goods.

Cosmetic safety assessment: Annex I of the proposal sets out the requirements for cosmetic product safety assessment in terms of content. One crucial element of the recast is clarification as to what information has to be contained in the cosmetic product safety assessment to provide evidence of the products safety.

Strengthening in-market control: The proposal strengthens the role of in-market controls, with a view to increasing imports from third countries. The proposed provisions include: defining the person responsible for products supplied to consumers from outside of the EU; a simplified, centralised and electronic notification requirement; communicating information on certain undesirable effects to a competent authority; and strengthening rules that apply to non-compliant products,

CMR Substances: A new CMR (carcinogenic, mutagenic or reprotoxic) regime is introduced. CMR substances will be classified based on their intrinsic properties ("Hazard") without taking exposure into account – i.e. future use. CMR substances are categorised into 3 categories based on the degree of evidence of the properties. Until now, CMR 1 and 2 substances were automatically banned in cosmetic products, whilst CMR 3 substances were banned unless the Scientific Committee had found the substances to be safe for use in cosmetics. The proposal, however, intends to include a risk management regime for CMR 1 and 2 substances which allows, subject to rigid conditions, the use of these substances if they have been found to be safe by the Scientific Committee for Consumer Products.

Other changes: The proposal also: obliges the responsible person for cosmetic product safety to keep up to date report; deletes reference to the appropriate level of qualification for the manufacturers and the importers; provides for harmonised standards in the field of good manufacturing practices and sampling/analysis of cosmetic products; introduces the comitology procedure with scrutiny for granting a derogation from the animal testing regime; introduces the possibility of highlighting, on the label, the relevant address for the competent authorities; allows for the printing, on the label, a date of minimum durability by way of a pictogram; introduces the option of making use of harmonised standards to address issues of claims; introduces a clear procedure for the application of the safeguard clause; clarifies rules applying to amending the Annexes of the text; introduces the comitology procedure with scrutiny; allows for the formal objection against harmonised standards; introduces an obligation on the Member States to adopt provisions on penalties; establishes rules for the repeal of the cosmetics Directive; and deletes Annex V of the Cosmetics Directive.

From a budgetary point of view, the proposal envisages the establishment of a central electronic interface for the product notification to the competent authorities of the Member States.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 30/11/2009 - Final act

PURPOSE: to recast EU legislation on cosmetic products.

LEGISLATIVE ACT: Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (recast).

CONTENT: This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health. To recall, Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it has been recast as one single text in the interests of clarity.

European companies are market leaders in cosmetics. This regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health. It simplifies the rules and procedures for the marketing and safety of cosmetics.

Consumers will benefit through the uniform application of rules, the enhanced coordination of market surveillance activities as well as the increased responsibilities placed on economic operators with a view to ensuring a higher level of consumer protection, notably with the introduction of a product information file.

Another advantage for consumers and businesses alike will be the free movement of cosmetic products resulting from the harmonisation of procedures and technical requirements.

Cosmetic products include make-up products, soaps, bath and shower preparations (salts, foams, oils and gels), perfumes, depilatories, deodorants, hair products (lotions, powders, shampoos, creams and lacquers), creams and emulsions for the skin, face masks, tinted bases, shaving products, lip-sticks and tooth-paste.

The main elements of the regulation are the following:

Safety: a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

Responsible person: only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market. The text contains new provisions concerning the obligations of responsible persons, obligations of distributors and the identification within the supply chain. The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in sucha way that compliance with the applicable requirements may be affected.

Safety assessment: the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up. The responsible person shall ensure that: (a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment; (b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources; (c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

Product information file: when a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of 10 years following the date on which the last batch of the cosmetic product was placed on the market. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.

Sampling and analysis: sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

Notification: prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission: (a) the category of cosmetic product and its name or names, enabling its specific identification; (b) the name and address of the responsible person where the product information file is made readily accessible; (c) the country of origin in the case of import; (d) the Member State in which the cosmetic product is to be placed on the market; (e) the contact details of a physical person to contact in the case of necessity; (f) the presence of substances in the form of nanomaterials; (g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenicor toxic for reproduction (CMR), of category 1A or 1B, (h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

Restrictions for substances listed in the Annexes: cosmetic products shall not contain any of the following: (a) prohibited substances listed in Annex II; (b) restricted substances which are not used in accordance with the restrictions laid down in Annex III; (c) colorants; (d) preservatives; (e) UV-filters.

Substances classified as CMR substances: the use in cosmetic products of substances classified as CMR substances, of category 2 and category 1A and 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products.

By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the Scientific Committee for Consumer Safety (SCCS), the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, drawing, as appropriate, on relevant best practice.

When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

Nanomaterials: for every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured. Moreover, the text lays down the minimum information to be notified to the Commission. In the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress. The first review shall be undertaken by 11 July 2018.

Animal testing:the regulation sets out provisions as regards the prohibition of animal testing. The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration.

Every year the Commission shall present a report to the European Parliament and the Council on: (i) progress made in the development, validation and legal acceptance of alternative methods; (ii) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by third countries of the results of the safety tests carried out in the Community using alternative

methods, in particular within the framework of cooperation agreements between the Community and these countries; (iii) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Labelling: cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering.

Date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer.

The text states that the country of origin shall be specified for imported cosmetic products. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.

Product claims: in the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have. The Commission shall, in cooperation with Member States, establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim. By 11 July 2016, the Commission shall submit to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria adopted under the second subparagraph. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

In-market control: Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples. They shall also: (i) monitor compliance with the principles of good manufacturing practices; (ii) entrust to market surveillance authorities the necessary powers, resources and knowledge in order for those authorities to properly perform their tasks; (iii) periodically review and assess the functioning of their surveillance activities.

Communication of serious undesirable effects: in the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred: (i) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him; (ii) the name of the cosmetic product concerned, enabling its specific identification; (iii) the corrective measures taken by him, if any.

Where the responsible person, distributors and end users report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information to the competent authorities of the other Member States.

Safeguard clause: in the case of products meeting the requirements listed in the regulation, where a competent authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted.

ENTRY INTO FORCE: 11/01/2010.

APPLICATION: from 11/07/2013, with the exception of provisions concerning the CMR substances which shall apply from 01/01/2010 and provisions concerning nanomaterials which shall apply from 11/01/2013.

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 24/03/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 633 votes to 29, with 11 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast).

The amendments were the result of a compromise negotiated with the Council. The main amendments were as follows:

Definitions: Parliament defined 'nanomaterial' as an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. It also stated that, in view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adapt this definition to technical and scientific progress and with definitions subsequently agreed at international level, in accordance with the regulatory procedure with scrutiny. Members also inserted definitions for "substance", "mixture", "end user", distributor and "frame formulation".

Responsible person: Parliament stipulated in the text that only cosmetic products for which a legal or natural person is designated within the Community as responsible person shall be placed on the market.

New provisions in the text set out the **obligations of the responsible person**, the obligations of the **distributors** and **identification within the supply chain**. A new recital notes that Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators..

Safety assessment: Members expanded and clarified the duties of the responsible person. This person must ensure that the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation is taken into account in the safety assessment.

This also shall also apply to cosmetic products that have been notified under Directive 76/768/EEC. He must also ensure that an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources. The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable enterprises, in particular small and medium-sized enterprises, to comply with the requirements laid down in the text.

Product information file: this must be kept during a period of 10 years following the date when the last batch of the cosmetic product was placed on the market. Should the development and/or manufacturing activities be subcontracted, responsibilities relating to preservation of the product information file may be shared, by written contract, between the person responsible for placing the product on the market and the subcontractors.

Notification: Parliament made substantial amendments to the provisions regarding information to be submitted to the Commission.

Restrictions for certain substances: these substances are listed as follows: prohibited Substances; restricted substances; colorants; preservatives; and UV-filters. Use of these substances, other than those listed in the text, is prohibited.

Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR): Members tightened up the derogation for CMR substances. The use of such products under category 1A and 1B under part 3 of Regulation (EC) 1272/2008 is prohibited unless certain conditions are met. These include the conditions that the application is made for a particular use of the product category with a known exposure; and they have been evaluated and found safe for use by the SCCS in cosmetic products in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, as well as under particular consideration of vulnerable population groups. The Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing as appropriate on relevant best practice.

A new clause states that when Community or internationally agreed criteria for identifying substances with **endocrine-disrupting properties** are available, or at the latest five years after this Regulation has entered into force, the Commission shall review the Regulation with regard to substances with endocrine-disrupting properties..

Nanomaterials: a new Article is inserted stating that for every product that contains nanomaterials, a high level of protection of human health shall be ensured. The Article details the information that must be notified to the Commission in addition to the notification requirements already existing under the text, and sets out the procedure that the Commission must follow if it has safety concerns. The Commission will request the **SCCS** to give its opinion on the safety of these nanomaterials for the relevant categories of cosmetic products and the reasonably foreseeable exposure conditions, and it will make this information public. 48 months after the date of entry into force of this Regulation. It will make available a catalogue of all nanomaterials used in cosmetic products, including those used as colorants, UV-filters and preservatives in a separate section, placed on the market, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available. The Commission shall submit an **annual status report**, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section.

Traces of prohibited substances: The non intended presence of small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be allowed provided that such presence is in conformity with the provisions on safety.

Labelling: Parliament stipulates that the country of origin shall be specified for imported cosmetic products. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.

Product claims: Parliament tightened up the provisions on labelling, stating that labelling and advertising of cosmetic products must not be used to imply that these products have characteristics or **functions** which they do not have. The Commission must establish an **action plan regarding claims** used and fix priorities for determining common criteria justifying the use of a claim. After consultation of the SCCS or other relevant authorities, the Commission shall adopt a **list of common criteria for claims** which may be used in respect of cosmetic products, in accordance with the regulatory procedure with scrutiny, taking into account provisions of Directive 2005/29/EC. After 3 years, it will submit a report regarding the use of claims on the basis of the common criteria. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

In-market control: Member States' obligations are increased. They are required to perform appropriate checks of products and on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples. Market surveillance authorities should be entrusted with the necessary powers, resources and knowledge in order to properly perform their tasks.

Communication of serious undesirable effects: the competent authority is required to transmit information as stated whether information in undesirable effects are reported by the responsible person, the distributor, the end user or health professionals.

Lastly, Parliament made a series of amendments to provisions on **non compliance by the responsible person and the distributor.** The regulation will apply 42 month after entry into force except for certain parts on CMR substances and nanomaterials, which will apply from an earlier stage.