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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

**on the animal testing and marketing ban and on the state of play in relation to
alternative methods in the field of cosmetics**

(Text with EEA relevance)

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1. INTRODUCTION

This Communication has a twofold purpose:

- It informs 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)¹ and in Regulation 1223/2009/EC (Cosmetics Regulation)², the reasons why and the way forward.
- It presents the yearly report in accordance with Article 9 of the Cosmetics Directive and as such the tenth Commission report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics.

2. THE 2013 MARKETING BAN

2.1. The legal framework

The Cosmetics Directive foresees a phasing-out of animal testing for cosmetic products. Animal testing of finished cosmetic products in the Union has been prohibited since 2004 and of cosmetic ingredients since March 2009 ("testing ban"). As from 11 March 2009, it is also prohibited to market in the Union cosmetic products and their ingredients which have been tested on animals in order to meet the requirements of the Directive ("2009 marketing ban"). This marketing ban applies to all but the most complex human health effects ("endpoints") to be tested to demonstrate the safety of cosmetic products (repeated-dose systemic toxicity, skin sensitisation, carcinogenicity, reproductive toxicity and toxicokinetics), for which the European Parliament and the Council extended the deadline to 11 March 2013 ("2013 marketing ban"). The Cosmetics Regulation, which repeals and replaces the Cosmetics Directive as of 11 July 2013, contains the same provisions. Data from animal testing that has been carried out before the respective implementation dates of the marketing ban (11 March 2009/11 March 2013) can continue to be relied on in the safety assessment of cosmetic products.

The testing and marketing bans in the Cosmetics Directive/Regulation apply even in case alternative methods to animal testing are not yet available. This reflects a sector-specific political choice by the European Parliament and the Council. Other Union legislation recognises that animal testing is still needed in the absence of alternative methods to ensure the protection of human health and the environment, but sets very

¹ Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169.

² Regulation 1223/2009/EC of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59.

high animal welfare standards for such testing and requires that whenever possible testing is replaced, reduced and refined.

According to Article 4a (2.3) of the Cosmetics Directive the Commission was called upon to inform the European Parliament and the Council where, for technical reasons, one or more of the tests covered by the 2013 marketing ban would not be developed and validated by 2013 and to put forward a legislative proposal. The Commission has responded to this provision in two steps.

2.2. Availability of alternative methods

The first step was to establish to which extent alternative methods for testing cosmetic products and their ingredients for the relevant endpoints are available by 2013. The Commission has provided a report to the European Parliament and the Council on the availability of alternative methods in September 2011³, based on a comprehensive technical report which was the result of wide scientific input and a public consultation⁴. The basic findings of this technical report are still valid and the full replacement of the 2013 marketing ban endpoints by alternative methods remains not yet possible.

Considerable progress has been made in recent years. Much of this is due to the sustained efforts of the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), run by the Commission's Joint Research Centre (JRC). For the endpoints falling under the 2009 marketing ban, replacement methods have been successfully validated and adopted as OECD test guidelines in the fields of skin irritation and corrosion, phototoxicity and skin penetration. Partial replacement methods suitable for inclusion in testing strategies have been validated in the areas of acute systemic toxicity and eye irritation, and adopted as OECD test guidelines in the field of eye irritation. Refinement of the established *in vitro* genotoxicity tests and testing strategies will contribute to addressing this endpoint. For the 2013 marketing ban endpoints, ECVAM successfully validated test methods in the fields of skin sensitisation and carcinogenicity which are now being discussed at the OECD.

A summary of recent validation activities at ECVAM and advancement concerning regulatory acceptance is provided in Tables 1 and 2 in the Annex. This update covers the period from 2010 to present day. Summaries covering periods prior to 2010 are covered in the ECVAM technical report 2008-2009⁵.

For the outstanding complex endpoints replacement will not be achieved by replacing one animal test with one *in vitro* test. Replacement can only be achieved through integrated testing strategies, combining several *in vitro* and *in silico* approaches. For example, none of the methods under validation for skin sensitisation and referenced in the Annex will replace skin sensitisation testing as a stand-alone method, they constitute mosaic pieces needed for a comprehensive testing strategy.

A more comprehensive description of progress being made in the development, validation and regulatory acceptance of alternative methods in the different

³ Report on the Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics (2009), 13.9.2011, COM(2011) 558 final.

⁴ "Alternative (non-animal) methods for cosmetics testing: current status and future prospects—2010", see: http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/final_report_at_en.pdf

⁵ Zuang et al., 2010, see: http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/at_ecvam_2008-2009_en.pdf

toxicological areas will be provided in the ECVAM technical report 2013, which will become available in parallel with this Communication⁶.

The responsible scientific committee of the Commission, the Scientific Committee on Consumer Safety (SCCS), has recently adopted an updated version of its "Notes of Guidance"⁷, in which it also provides an overview of the use of alternative methods in the safety assessment of cosmetics. Specific guidance was also adopted by the SCCS in relation to the safety assessment of nanomaterials in cosmetics⁸, including availability of alternative methods.

2.3. Assessing the impacts of the 2013 marketing ban

The second step was to carry out an impact assessment and an in-depth reflection on the best way forward in relation to the 2013 marketing ban in light of the unavailability of a full set of alternative methods. The resulting impact assessment is published as a Commission Staff Working document accompanying this Communication⁹.

The options assessed in the impact assessment were to maintain the 2013 marketing ban, to postpone it or to introduce a derogation mechanism. The derogation mechanism would have allowed manufacturers to request the Commission to grant individual derogations from the 2013 marketing ban for innovative ingredients with a significant added value to consumer health, well-being and/or the environment.

The impact assessment shows that the 2013 marketing ban could lead to a reduced access to cosmetic ingredients. However, stakeholder views on the effects diverge. Despite serious efforts to establish a solid body of data, considerable uncertainty remains in relation to the quantification of these impacts; it appears possible to at least mitigate them through appropriate action. Even for the 2009 marketing ban deadline, not all testing endpoints can be fully replaced by alternative methods which did not lead to major negative impacts so far.

The objective to provide a high level of human health, key to the Cosmetics Directive and reinforced in the Cosmetics Regulation, is not impacted by the 2013 marketing ban. If product safety cannot be demonstrated the product simply cannot be placed on the market. New tools are provided in the Cosmetics Regulation to ensure this, such as enhanced market surveillance and new rules on communication of serious undesirable effects.

2.4. Deciding on the way forward

In light of this 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 legal proposal to either postpone the deadline or provide for individual derogations for the following reasons:

First, the Commission considers that further postponements of the 2013 marketing ban would not reflect the political choices of the European Parliament and the Council when adopting the respective provision. Animal welfare considerations were

⁶ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm

⁷ The SCCS'S Notes of Guidance for the testing of cosmetic substances and their safety evaluation, 8th Revision, SCCS/1501/12,

see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

⁸ Guidance on the Safety Assessment of Nanomaterials in Cosmetics, SCCS/1484/12,

see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf

⁹ See http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm

at the origin when the first provisions on a marketing ban of cosmetics tested on animals were introduced 20 years ago¹⁰. The marketing ban, first introduced in 1993 with a deadline for 1998, was introduced with the clear political objective to end animal testing for cosmetics without being based on a scientific estimation when a full set of alternative methods would be available. Similarly, the European Parliament and the Council imposed the testing ban and the 2009 marketing ban in full knowledge that by that time a complete replacement of the relevant animal tests would not be possible. The European Parliament and the Council did not make the 2013 marketing ban dependent on the availability of a full set of replacement methods. In the meantime animal welfare has been enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU) as a European value to be taken into account in Union policies.

Secondly, any change to the 2013 marketing ban could seriously diminish determination to swiftly develop alternative test methods. Past experience demonstrates clearly that animal testing provisions in the cosmetics legislation have been a key accelerator in relation to the development of alternative methods and have sent a strong signal far beyond the cosmetics sector and far beyond Europe. Methods developed in the cosmetics sector, such as reconstructed human skin models, are now used in other sectors as well and the interest in alternative methods for cosmetics has grown in many countries outside the Union. The animal testing provisions motivated the creation of the European Partnership on Alternative Approaches to Animal Testing (EPAA)¹¹, an unprecedented voluntary collaboration between the European Commission, European trade associations, and companies from various industry sectors. The provisions equally contributed to a great increase of the number of validated methods since 2003 when the current deadlines were set¹².

Thirdly, 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. In addition, it would raise controversial decisions by the Commission on what is a significant benefit, a decision for which objective criteria are difficult to establish.

Finally, the Commission considers that the possible risks from the 2013 marketing ban can be turned into an opportunity for the Union to set an example of responsible innovation in cosmetics with positive impact beyond Europe. The need for a new risk assessment paradigm from a scientific perspective is by now widely recognized¹³. Impacts go beyond the cosmetics sector – the objective is to develop strategies that will lead to better and more predictive, faster and cheaper tools to assess consumer safety of chemical substances.

Fully reaping the potential of alternative methods is a challenging endeavour that will require a shift in thinking of all involved. The cosmetics sector can - once again - act as an accelerator and a pioneer in the development of these novel approaches. Considering however that a full safety assessment for cosmetics only relying on alternative methods and approaches is not yet achieved and in some respects is not even close, it is necessary to set the appropriate framework by:

¹⁰ Directive 93/35/EEC, OJ L 151, 23.06.1993, p. 0032.

¹¹ See: <http://ec.europa.eu/enterprise/epaa/>

¹² Between 2003 and 2009 there were 13 new methods, compared to only 6 between 1998 and 2002.

¹³ See recent Discussion Paper of the Scientific Committees "Addressing the New Challenges for Risk Assessment" (http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_037.pdf)

- Implementing the 2013 marketing ban while carefully monitoring its effects;
- Continuing to support research, development and validation of alternative methods to assess human safety; and
- Making alternative methods part of the Union's trade and international agenda.

3. THE WAY FORWARD

3.1. Implementing the 2013 marketing ban and monitoring its effects

Effective and coherent implementation and enforcement of the 2013 marketing ban are of key importance – not only to ensure that it actually achieves its objectives, but also to ensure a level playing field for economic operators. This Communication focuses on the 2013 marketing ban. However, the described implementation mechanisms and principles apply equally to the testing ban and the 2009 marketing ban.

Going forward the Cosmetics Regulation provides the adequate legal framework to ensure the implementation of the 2013 marketing ban and its provisions are directly applicable in all Member States as of 11 July 2013. It is accordingly the task and responsibility of the Member State authorities to monitor compliance with the Cosmetics Regulation via in-market controls of the cosmetic products made available on the market¹⁴. The Cosmetics Regulation lays down the obligation of the responsible person¹⁵ to ensure compliance with the animal testing provisions¹⁶. It requires Competent Authorities to take all appropriate measures to ensure compliance with the animal testing provisions¹⁷ and requires Member States to have effective, proportionate and dissuasive penalties in place in case of infringements¹⁸. Until 11 July 2013 the existing implementation mechanisms under the Cosmetics Directive will continue to apply¹⁹.

The main source enabling Member State authorities to verify compliance with the 2013 marketing ban is the product information file in accordance with Article 7a (1) h of the Cosmetics Directive/Article 11 of the Cosmetics Regulation. This file must contain data on "*any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries*". In addition to this requirement, the product information file must also contain the cosmetic product safety report as specified in Annex I of the Cosmetics Regulation, which must include information on the toxicological profile of the substance for all relevant toxicological endpoints and a clear identification of the source of the information. From this information it will become evident to Competent Authorities if animal testing data has been relied on in the safety assessment.

Currently, there is no jurisprudence of the Court of Justice of the European Union ('the Court') on the interpretation of the scope of the 2013 marketing ban. The Commission recalls that only the Court can provide a legally binding interpretation

¹⁴ Article 22 of Regulation 1223/2009/EC.

¹⁵ As defined in Article 4 of Regulation 1223/2009/EC.

¹⁶ Article 5 (1) of Regulation 1223/2009/EC.

¹⁷ Article 25 (1) (g) and Article 25 (5) of Regulation 1223/2009/EC.

¹⁸ Article 37 of Regulation 1223/2009/EC.

¹⁹ Article 3 of Directive 76/768/EEC.

of Union law. The Commission will, under the control of the Court oversee the application of the 2013 marketing ban. The Commission 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 and which does not create any new rights and obligations. The practical application of the 2013 marketing ban will remain a case-by-case decision of the respective Member State authority. Under the Cosmetics Directive and its national transpositions Member States already oversee compliance with the testing ban and the 2009 marketing ban. The Commission has reported in its last two Annual Reports on the measures taken by Member States to ensure compliance with these bans.²⁰

The majority of ingredients used in cosmetic products are ingredients that are equally in use in many other consumer and industrial products, such as in pharmaceuticals, detergents and food, and animal testing may be necessary to ensure compliance with the legal frameworks applicable to these products. Ingredients used in cosmetics will generally also be subject to the horizontal REACH²¹ requirements and animal testing may be necessary as a last resort to complete the respective data packages. It therefore is for Member States to assess and decide whether such testing for compliance with other frameworks is considered to be falling in the scope of the 2013 marketing ban. Critical to this is the wording '*in order to meet the requirements of this Directive/Regulation*' used in the Cosmetics Directive and the Cosmetics Regulation²² in order to qualify the scope of the 2013 marketing ban.

The Commission considers that animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out '*in order to meet the requirements of this Directive/Regulation*'. The resulting animal testing data should not trigger the marketing ban and could subsequently be relied on in the cosmetics safety assessment. Reliance on such data is subject to its relevance for the cosmetics safety assessment and its compliance with data quality requirements²³.

Testing carried out for cosmetics relevant endpoints on ingredients that have been specifically developed for cosmetic purposes and are exclusively used in cosmetic products would in the Commission's view always be assumed to be carried out '*in order to meet the requirements of this Directive/Regulation*'.

The Commission considers that the marketing ban is triggered by the reliance on the animal data for the safety assessment under the Cosmetics Directive/Regulation, not by the testing as such. In case animal testing was carried out for compliance with cosmetics requirements in third countries, this data cannot be relied on in the Union for the safety assessment of cosmetics.

²⁰ See: http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/annual_report2009.pdf and http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/at_report_2008.pdf

²¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Official Journal L 336, 29.5.2007, p. 3.

²² See Article 4a (1(b)) of the Cosmetics Directive and Article 18 paragraph 1 (b) of the Cosmetics Regulation.

²³ Article 7a (2) Directive 76/768/EEC and Article 10 (3) of Regulation 1223/2009/EC

In the context of the obligation to ensure compliance with the Cosmetics Directive/Regulation, Member States should ensure that the appropriate and effective mechanisms are put into place in order to counter the potential risks of abuse in the application of the testing and the marketing ban. Where needed, the Commission will work with Member States on guidance for the application of the 2013 marketing ban based on practical experiences and concrete case studies. The Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) provides a dedicated structure for cooperation on market surveillance.

In order to allow effective market surveillance, responsible persons should ensure that for any animal testing data relied on in the product information file the date and place of the test is clearly documented. If testing took place after the 2013 marketing ban deadline, the product information file should allow verification on whether the testing was carried out in order to meet the requirements of the Directive/Regulation or for other purposes. To this end the file should contain documentation on any use of the substance in products other than cosmetic products (product examples, market data etc.), as well as documentation on compliance with other regulatory frameworks (e.g. REACH or other legal frameworks) and a justification of the need for the animal testing under that other framework (e.g. testing proposal under REACH).

The 2013 marketing ban applies to all cosmetic products placed on the Union's market, thus to those produced in the Union and to imported cosmetic products alike. Competent authorities should ensure a level playing field between the different products on the market.

Considering that the non-availability of alternative test methods could have an impact on the innovation in cosmetic ingredients and products and the competitiveness of the sector, the Commission will closely monitor the situation in the coming years. A key tool for the monitoring will be the yearly Commission reports required under Article 35 of the Cosmetics Regulation. These reports give a regular review of the state of play of the development, validation and regulatory acceptance of alternative methods in the field of cosmetics. They will, as has been the case in the past, be based on technical reports prepared by the Commission's JRC (EURL ECVAM). Given that the testing bans are fully applicable, the reports will no longer contain statistical data on the number and type of animal experiments carried out relating to cosmetic products in the Union. The reports will cover any derogations granted in accordance with Article 4a (2.4) of the Cosmetics Directive and Article 18 (2) of the Cosmetics Regulation. These provisions allow Member States to request a derogation in case a human health problem is substantiated for an ingredient that is in wide use and cannot be replaced by another ingredient capable of performing a similar function. So far only one such request has been received and the analysis is still on-going.

In addition, the Commission will monitor instances in which a conclusive safety assessment is not feasible as a result of the 2013 marketing ban. The Commission will equally monitor the socio-economic impacts of the 2013 marketing ban, notably in comparison to the data cited in the Impact Assessment and the estimates and predictions made in that context.

3.2. Commitment to support research, development and validation of alternative methods to assess human safety

The Union wishes to set an example of responsible innovation in cosmetics without new dedicated animal tests. It is therefore crucial to continuously support the

research and development of methods to better assess human safety and capitalize on past efforts by ensuring that the latest scientific advances are translated into animal-free solutions.

The Commission has made about EUR 238 million available between the years 2007 and 2011 for research into alternative methods to animal testing alone. The major part of this budget, around EUR 198 million, was spent on projects funded through the 6th and 7th Framework Programmes and the LIFE+ Programme. The second most important tranche, about EUR 38 million, was committed through the institutional budget of the JRC, in particular to support the activities of its Institute for Health and Consumer Protection in the alternatives area including the operation of the European Reference Laboratory for Alternative Methods to Animal Testing (EURL ECVAM).

The SEURAT-1²⁴ initiative ('Safety Evaluation Ultimately Replacing Animal Testing') is unique in that it is a jointly funded initiative by the European Commission and the cosmetics industry, each of which are contributing EUR 25 million between 2011 and 2015. It is proof of the active role assumed by the cosmetics industry in the development of alternative testing methods. SEURAT-1 brings together more than 70 European research teams working together within a cluster of six complementary projects and facilitated by a coordination action. The goal of the 5-year SEURAT-1 programme is to use knowledge of toxicological processes to develop and rationally assemble novel technology building blocks required for predicting repeated dose systemic toxicity in humans potentially caused by exposure to chemicals. Ultimately SEURAT-1 aims to prove key concepts underpinning the credible use of combinations of computational and *in vitro* methods for supporting safety assessment decisions.

The research into alternative methods is by no means near an end: in many areas the research currently underway is only a first step. Horizon 2020²⁵ is the financial instrument which implements the Innovation Union²⁶ and will ensure the framework for the research activities between 2014 and 2020. Horizon 2020 offers the opportunity to continue and expand the Union's commitment to research in alternative, better methods of human safety assessment and capitalize on possible innovation in this field.

The Commission recognizes the importance of research in this field. 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 going ahead and the best implementation instruments which, for example, could take the form of a new public-private partnership. A recent Discussion Paper of the Scientific Committees on "Addressing the New Challenges for Risk Assessment" points to research needs for comprehensive open access databases, *in silico* methods, (toxicological) mode-of-action studies and exposure assessment tools. The EPAA can also play a role in defining research needs and

²⁴ See <http://www.seurat-1.eu>

²⁵ Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020), COM(2011) 809 final.

²⁶ Communication from the Commission, Europe 2020 Flagship Initiative, Innovation Union, COM (2010) 546 final.

priorities across industry sectors with special attention being paid to how to involve small and medium sized enterprises in these efforts.

A crucial factor for success is to make sure that alternative methods, once developed, are rapidly made available for end-users to generate toxicological information acceptable to regulators. The Commission therefore commits to work with the relevant European and international bodies to further improve the validation process for new test methods.

Validation is an intrinsic part of the scientific process and of fundamental importance in gaining acceptance of alternative methods and trust in the information they generate. In recent years JRC's EURL ECVAM has further refined and streamlined its validation processes and has increased the resources it commits to the alternatives area including dedicating the efforts of more than 50 scientific and technical staff. ECVAM is now expressively referenced in Directive 2010/63/EU²⁷ and its responsibilities are clearly spelled out. In addition to undertaking validation studies, ECVAM will also play a stronger role in guiding the development of alternatives and in early and frequent engagement with regulators and stakeholders to ensure that priority is given to the most relevant methods that will have the greatest impact. To this end, ECVAM has also established its regulatory advisory body²⁸ and its stakeholder forum²⁹.

The ECVAM Scientific Advisory Committee will continue to offer impartial expert advice, particularly during its peer review of validation studies, while ECVAM Recommendations will be the key instrument for communicating the outcome of validation studies and additional advice on how an alternative method should be utilised to most effect. ECVAM will also carry on its active dissemination of comprehensive information on available methods to end-users through ECVAM's publicly accessible Data Base service on Alternative Methods³⁰ and the ECVAM Search Guide.

Commission Regulation (EC) 440/2008³¹ brings together all regulatory accepted test methods on Union level. An overview of how methods are progressing through the acceptance process is available through the Tracking System for Alternative test methods Review, Validation and Approval in the Context of Union Regulations on Chemicals³². It is important to note that although suitable for the safety assessment of cosmetics, the alternative methods validated and accepted so far are not solely applicable to cosmetic ingredients but can successfully be used for other purposes. Thus Annex IX of the Cosmetics Directive³³ has not been amended and does not list any specific alternative methods.

3.3. Alternative methods as part of the Union's trade and international agenda

There are compelling reasons for a strong international cooperation on the development of alternative test methods for cosmetics. Cosmetic products and their

²⁷ Directive 2010/63/EU on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p.33.

²⁸ PARERE (Preliminary Assessment of Regulatory Relevance)

²⁹ ESTAF (ECVAM Stakeholder Forum)

³⁰ <http://ecvam-dbalm.jrc.ec.europa.eu/>

³¹ See Article 10 (3) of Regulation (EC) 1223/2009 of the European Parliament and the Council on cosmetics products, 22.12.2009, OJ L 342, p. 59 – 209.

³² See <http://tsar.jrc.ec.europa.eu/>

³³ Equivalent to Annex VIII in the Cosmetics Regulation, both list validated alternative methods which are not listed in Commission Regulation (EC) 440/2008.

ingredients are traded worldwide and the Union is home to some of the world-leading brands in the cosmetics field. A common understanding of the safety assessment for cosmetics and acceptance of alternative methods will improve human safety, help animal welfare and trade, but cooperation is also a must because the underlying scientific challenges are far too big to be shouldered by one region alone. Cooperation at the research level is therefore a first important step.

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. The Commission services are actively involved in the OECD work. One particular challenge to be addressed if significant progress is to be made is how to reflect Integrated Testing Strategies in OECD Guidelines, since the information required to address the more complex health-effect endpoints will require the optimum combination of both testing and non-test alternative methods.

In the field of cosmetics, the International Collaboration on Cosmetics Regulation (ICCR) provides an important forum for cooperation between the United States of America, Canada, Japan and Europe. Alternatives to animal testing have been a key focus since the inception of ICCR. ICCR has recently started work on *in silico* (computational) prediction models, something that in addition to *in vitro* methods is of central importance in advancing alternative safety assessment approaches. ICCR has also started reaching out beyond its membership, to countries such as Australia, Brazil and the People's Republic of China.

One of ICCR's key achievements in relation to alternative methods is clearly the setting up of the International Cooperation on Alternative Test Methods in 2009. It brings together validation bodies of Europe, the United States, Japan and Canada. The South Korean validation body joined in 2010. The objective is to promote and harmonise the validation of alternative methods worldwide, to avoid duplication of effort and to ensure that recommendations on validated methods are mutually acceptable and can be directly used in different jurisdictions. Importantly too it works towards establishing common positions on validated methods between member countries and organisations of the OECD to accelerate their international acceptance.

EPAA concentrated its activities in 2012 on international cooperation and will continue to do so in 2013, offering another opportunity to promote alternatives internationally. The cosmetics industry (Cosmetics Europe³⁴ and several companies) is one of the driving forces and has in 2012 been joined by the Fragrances and Flavours industry (IFRA).

The Commission is convinced that the overall long-term objective to replace animal testing wherever possible and to move to new ways of improved safety assessment will eventually be shared by many of the Union's trading partners, even though different regions may be at different steps of the process and the approaches to achieve the objective may differ. In the last weeks, there have been encouraging signals that other countries such as Israel or India are considering to follow the Union's example on animal tests for cosmetics.

³⁴

Cosmetics Europe is the Trade Association representing the European cosmetics industry.

The Commission is therefore convinced that the issue of alternative test methods for cosmetics merits a prominent place on the EU's trade and international cooperation agenda. 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. The Commission will in this effort look for synergies with the international initiatives of industry and animal welfare organisations.

4. CONCLUSIONS

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 years, but full replacement is not yet possible and will not be possible for some time. The Commission nevertheless believes 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, in particular by

- ensuring a coherent implementation of the 2013 marketing ban and monitoring its impacts;
- continuing the support for research, development and validation of new alternative methods for human safety testing; and
- making alternative methods an integral part of the Union's trade agenda and international cooperation.

The marketing ban gives an important signal, not only in relation to the value attached to animal welfare in the European Union, but also in relation to the overall paradigm shift in relation to human safety assessment.

Annex

| Nr. | Toxicity area | Test method description | Validation status ³⁵ |
|-----|----------------------|---|---|
| 1 | Carcinogenicity | Cell Transformation Assay (CTA) SHE | EURL ECVAM recommendation published in 2011 |
| 2 | | Cell Transformation Assay (CTA) Balb/C | EURL ECVAM recommendation published in 2011 |
| 3 | | Cell Transformation Assay (CTA) BHAS | ESAC peer review finalised |
| 4 | Skin sensitisation | Keratinosens test method | ESAC peer review finalised |
| 5 | | Direct Peptide Reactivity Assay (DPRA) | ESAC peer review finalised |
| 6 | | human Cell line Activation Test (h-CLAT) | ESAC peer review foreseen to start in 2013 |
| 7 | Acute oral toxicity | 3T3 Neutral Red Uptake (NRU) test method | EURL ECVAM draft recommendation underwent public commenting in 2012 |
| 8 | Toxicokinetics | Cytochrome P450 (CYP) induction assay using the human cryopreserved HepaRG [®] cell line and cryopreserved human hepatocytes | ESAC peer review foreseen to start in 2013 |
| 9 | Eye irritation | Reconstructed human tissue model (EpiOcular [™] EIT) | ESAC peer review foreseen to start in 2013 |
| 10 | | Reconstructed human tissue model (SkinEthic [™] HCE) | ESAC peer review foreseen to start in 2013 |
| 11 | Endocrine disruption | MELN [®] estrogen receptor transactivation assay (agonist and antagonist protocols) | ESAC peer review foreseen to start in 2013 |
| 12 | | Androgen receptor transactivation assay (agonist and antagonist protocols) | EURL ECVAM validation foreseen to start in 2013 |
| 13 | | Androgen receptor transactivation assay (agonist and antagonist protocols) | EURL ECVAM validation foreseen to start in 2013 |

| Nr. | Toxicity area | Test method description | Acceptance status |
|-----|-----------------|--|---|
| 1 | Skin corrosion | Reconstructed human Epidermis test methods (RhE) as included in OECD TG ³⁶ 431/EU TM ³⁷ B.40 bis | Accepted in 2004, updated version (sub-categorisation, performance standards, inclusion of SkinEthic [™] RHE and epiCS [®]) will be discussed at WNT ³⁸ in 2013 |
| 2 | | Transcutaneous electrical resistance (TER) test as included in OECD TG 430/EU TM B.40 | Accepted in 2004, updated version (performance standards) will be discussed at WNT in 2013 |
| 3 | Skin irritation | Reconstructed human Epidermis test methods (RhE) as included in OECD TG 439/EU B.46 | Accepted in 2010, updated version (performance standards, inclusion of |

³⁵ 'Validation Status' refers to the different steps of the validation process.

³⁶ 'OECD TG' refers to OECD Test Guidelines.

³⁷ 'UNION TM' refers to methods included in Commission Regulation (EC) 440/2008.

³⁸ Working Group of National Coordinators of the OECD Test Guideline Programme.

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|----|----------------------|--|---|
| | | | LabCyte EPI-model) will be discussed at WNT in 2013 |
| 4 | Eye irritation | Fluorescein Leakage (FL) test method as included in OECD TG 460 | Accepted in 2012 |
| 5 | | Bovine Corneal Opacity and Permeability (BCOP) test method as included in OECD TG 437/EU TM B.47 | Accepted in 2009, updated version (positive control, use in a bottom-up approach to identify non-classified chemicals) will be discussed at WNT in 2013 |
| 6 | | Isolated Chicken Eye (ICE) test method as included in OECD TG 438/EU TM B.48 | Accepted in 2009, updated version (use in a bottom-up approach to identify non-classified chemicals) will be discussed at WNT in 2013 |
| 7 | | Cytosensor Microphysiometer (CM) test method | New draft TG will be discussed at WNT in 2013 |
| 8 | Carcinogenicity | Cell Transformation Assay (CTA) SHE | New draft TG will be discussed at WNT in 2013 |
| 9 | Genotoxicity | Existing OECD TGs under revision | Draft OECD TG 473 (<i>in vitro</i> chromosome aberration assay) and OECD TG 487 (<i>in vitro</i> micronucleus test) will be discussed at WNT in 2013 |
| 10 | Endocrine disruption | Estrogen receptor transactivation assay (BG1Luc ER TA; agonist and antagonist protocols) as included in OECD TG 457 | Accepted in 2012 |
| 11 | | Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists (OECD TG 455) | Accepted in 2012 |