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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics (2015-2017)

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1. INTRODUCTION

This is the 12th Commission report on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics.

Under Article 35 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[1] (the Cosmetics Regulation), each report must include information on:

- progress made in the development, validation and acceptance of methods alternative to animal testing;
- the Commission's progress on obtaining the OECD's acceptance of the alternative methods validated at EU level;
- progress on third-country recognition of the results of safety tests carried out in the EU using alternative methods;
- the specific needs of small and medium-sized enterprises (SMEs).

This report also informs the European Parliament and the Council of compliance with the deadlines for the animal testing bans set out in Article 18(1) and of related technical difficulties, pursuant to Article 18(2) of the Cosmetics Regulation. Article 18(1) prohibits the testing on animals of finished cosmetic products and of cosmetic ingredients (testing ban), as well as the marketing of finished cosmetic products and of cosmetic products containing ingredients tested on animals (marketing ban), to meet the requirements of the Cosmetics Regulation.

Under Article 18(2) of the Cosmetics Regulation, the report should also cover any derogation from Article 18(1) granted in accordance with Article 18(2). However, to date there have been no derogations granted under this provision.

The information in Section 3 on compliance with the testing and marketing bans and the impact of the bans is based on contributions from Member States, mainly covering the years 2015-2016[2]. The information in Section 4 on the progress made in the development, validation and legal acceptance of alternative methods is largely based on the 2016 and 2017 status reports[3] from the European Union Reference Laboratory for Alternatives to Animal

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1 OJ L 342, 22.12.2009, p. 59.

2 Some Member States reported to the Commission later than the requested deadline and also (partly) covered the year 2017.

3 *EURL ECVAM status report on the development, validation and regulatory acceptance of alternative methods and approaches* (2016 and 2017).

Testing (EURL ECVAM) of the Commission's Joint Research Centre[4]. Together, they cover the period from October 2015 to September 2017.

2. CLARIFICATION OF THE SCOPE OF THE MARKETING BAN BY THE COURT OF JUSTICE

In the *European Federation for Cosmetic Ingredients* case, the Court of Justice made an important clarification on the interpretation of the marketing ban as regards animal testing carried out in non-EU countries to comply with the cosmetics legislation of a third country[5]. The main question examined by the Court was whether Article 18(1)(b) 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: *'Article 18(1)(b) of Regulation (EC) No 1223/2009[…] 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'*.

3. COMPLIANCE WITH THE TESTING AND MARKETING BANS AND THEIR IMPACT

In practice, the main way of verifying compliance with the testing and marketing bans is the cosmetic product information file (PIF). The 'responsible person'[6], who has to ensure compliance with the relevant obligations of the Cosmetics Regulation (usually the manufacturer or the importer), must keep a PIF for every cosmetic placed on the EU market. The PIF must include the cosmetic product safety report and data on any animal testing performed relating to the development or safety assessment of the cosmetic product or its ingredients[7]. The Commission Communication of 11 March 2013[8] provides further guidance as to what information should be included in the PIF.

3.1. Inspections and compliance

As in the previous reporting period, monitoring activities and checks related to compliance with the testing and marketing bans were mostly carried out in the course of regular inspections on cosmetic products as part of general control activities. There were no inspection programmes specifically dedicated to monitoring compliance with the testing and marketing bans. Compliance was mainly verified through checks by the competent national authorities on cosmetic products' PIFs.

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4 https://eurl-ecvam.jrc.ec.europa.eu/

5 Judgment of 21 September 2016 in Case C-592/14 *European Federation for Cosmetic Ingredients* (EU:C:2016:703).

6 See Article 4 of the Cosmetics Regulation.

7 Article 11(2)(b) and (e) of the Cosmetics Regulation.

8 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* (COM(2013) 135 final).

Only three Member States reported not monitoring compliance with the bans as part of these inspections. One of these Member States argued that it was not possible to verify the absence of animal tests in the context of general market surveillance, as it is a complex process.

Based on inspections carried out by market surveillance authorities, a Member State reported two cases of infringement of the testing and marketing bans, following which the companies were asked to remedy the breach. Some other Member States reported cases where the breach was actually a lack of (complete) documentation proving compliance with the bans, rather than non-compliance with the ban itself (see Section 3.2.).

3.2. Difficulties encountered with monitoring the ban and suggestions for improvement

Of the Member States who monitored compliance with the testing and marketing bans, the very large majority did not report any difficulties in carrying out compliance checks.

In the previous reporting period, the main issue raised by several Member States was the fact that PIFs were incomplete with regard to data on animal testing – this information is necessary to verify compliance with the bans. The Commission therefore asked the Member States specific questions on this aspect, in particular regarding what type of data was missing and what measures had been taken.

The issue of PIFs being incomplete as regards data on animal testing was confirmed by seven Member States. Most of these Member States did not mention or note any changes to the situation compared to the previous period. They did not specifically monitor the issue of incomplete PIFs or monitored it through continued reviews of PIFs as part of market surveillance activities.

The 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).

Three Member States noted a correlation between the size of the operator (SMEs) and the issue of incomplete information on animal testing in the PIF. Four Member States raised the issue with respect to cosmetics imported into the EU, where information from the non-EU suppliers was missing. Two Member States noted that importers and/or SMEs lack knowledge regarding the application of the animal testing ban requirements. One of those Member States highlighted the difficulty for SMEs of finding an appropriate safety assessor[9] for their product and noted that the safety assessment was sometimes incomplete. (However, this point is not specifically linked to the animal testing ban.)

Nevertheless, the competent authorities appear to be properly addressing the few above-mentioned shortcomings. Operators with PIFs that did not provide complete animal testing

[9] A person who carries out the safety assessment of a cosmetic product.

information were required to take corrective action. They had to provide the missing information, for instance by asking their suppliers for that information or by producing toxicological data based on alternatives. If the information was not provided, the ultimate consequence was the withdrawal of the product(s) from the market. However, one Member State stressed the limits of this approach with regard to missing toxicological data: for new ingredients, alternative methods would not always be available or affordable for SMEs.

Four Member States suggested that guidelines/ information should be developed on the PIF and on the application of the animal testing ban. One of these Member States also reported that their authorities engage with operators, in particular SMEs, through for instance information events to explain the regulatory requirements.

Other types of difficulty were reported in a few instances. One Member State mentioned the difficulty of verifying the accuracy of an operator's declaration that no animal testing had been performed. This is due to the fact that supply chains for cosmetic ingredients are very long. Another Member State reported the issue of the reliability of information provided with respect to cosmetics imported from non-EU countries.

Two Member States argued that checking compliance with the bans is a lengthy and complex process, as it requires in-depth verification of documents, specific training for inspectors and appropriate technical equipment (implying increased financial costs). In particular, according to one of these Member States, the PIF checks are hampered by the fact that the PIF is only accessible onsite, with no possibility of making copies and carrying out checks at the competent authority's offices.

One Member State raised the issue of market surveillance of cosmetic products for which the 'responsible person' is based in another Member State, in which case the authority has no direct access to the PIF[10], or where the Member State in which the 'responsible person' is based takes time to reply to an information request. This difficulty is not specific to the animal testing ban, but is linked to PIF checks in general.

3.3. Ban-related issues encountered by manufacturers, in particular SMEs, and the bans' impact on the innovativeness of the cosmetics sector

Most Member States did not report[11] 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. On the question of how the testing and marketing bans have affected the innovativeness of the cosmetics sector, most Member States either did not provide any information or reported that this information was not available to them or had not been received from the industry.

However, five Member States reported the issues below.

[10] Article 30 of the Cosmetics Regulation allows a competent authority of a Member State to ask the competent authority of the Member State where the PIF is accessible to verify whether the PIF is complete.

[11] Some of these Member States explicitly stated that they were unaware of such cases or they had not encountered any; the others did not specifically address this question.

One Member State mentioned feedback received from some operators regarding difficulties in placing cosmetic products on the market due to insufficient data to prove product safety without animal testing. Another Member State reported the concern raised by its cosmetics industry that it was not possible to perform a full safety assessment of a cosmetic ingredient in the absence of animal testing and that it was not possible to develop new ingredients for cosmetic applications.

Another Member State mentioned feedback from an operator, which stated that, although it is not impossible to develop innovative products, it takes more time and involves more costs, as alternative (*in vitro* and *in silico*) methods require new knowledge and more time to be analysed.

Three Member States mentioned the need for alternatives to animal testing to be developed, in particular for repeated-dose toxicity, reproductive toxicity and toxicokinetics. These are areas in which it is not yet possible to completely replace animal testing with alternative methods. These shortcomings can potentially make it difficult to fully assess the safety of new cosmetic ingredients.

The absence of full replacement alternative methods for the most complex toxicological areas is widely recognised. Therefore, research is ongoing to develop these methods. For the other toxicological areas, progress has been made towards the validation and regulatory acceptance of alternative methods. In particular, work is being done to develop 'integrated approaches to testing and assessment'[12] (IATAs). This is explained further in Section 4 below.

4. PROGRESS MADE IN THE DEVELOPMENT, VALIDATION AND LEGAL ACCEPTANCE OF ALTERNATIVE METHODS

As mentioned in the last Commission report, 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.

Current research into and development of methods alternative to animal testing mainly focus on integrating a variety of testing and non-testing methods. These include *in vitro* technologies, bioinformatics and computational toxicology, and they are grouped into the IATAs mentioned above. IATAs have been developed and internationally harmonised in the areas of skin irritation/corrosion and serious eye damage/eye irritation, and are in the process of being approved for skin sensitisation[13].

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.

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[12] An IATA is a framework used for hazard identification, hazard characterisation and/or safety assessment of a chemical or group of chemicals, which strategically integrates and weights all relevant existing data and guides the targeted generation of new data where required to inform regulatory decision-making regarding potential hazard and/or risk.

[13] See Section 4.1.2.1.

4.1. Progress in the EU

4.1.1. Research and development activities

Major research and development activities on methods alternative to animal testing are ongoing in the EU.

The EUR 50 million SEURAT-1 research initiative, co-funded by the Commission and Cosmetics Europe (the European personal care association) and completed in 2015, developed a workflow to assess safety without relying on animal testing, designed for cosmetic ingredients but also applicable to other types of chemicals. The outcome was published in 2017 and is freely accessible online[14].

EU-ToxRisk[15], the integrated European 'flagship' programme driving mechanism-based toxicity testing and risk assessment for the 21st century, is a major collaborative project funded by the EU framework programme for research and innovation, Horizon 2020. With a budget of over EUR 30 million, it was launched in January 2016 and will last for six years. The project, which builds on the results of SEURAT-1, 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, establishing collaborations with the US Tox21[16] and the Commission, through EURL ECVAM.

Several other large Horizon 2020 research projects to assess chemical mixtures have begun in recent years, including EuroMix[17] and EDC-MixRisk[18]. EuroMix aims to develop a strategy for the risk assessment of mixtures of chemicals from multiple sources, while EDC-MixRisk focuses on improving the risk assessment of exposure to mixtures of endocrine-disrupting compounds. Both explore mixture assessments including *in vitro* and *in silico* methods. The Commission collaborates on these projects through EURL ECVAM. The human biomonitoring project HBM4EU[19], in which the Commission and several EU agencies are involved, includes one work package dedicated to mixtures.

4.1.2. Validation and regulatory acceptance of alternative methods

EURL ECVAM is mandated under Article 48 of and Annex VII to Directive 2010/63/EU[20] to validate alternative test methods at EU level and promote their regulatory acceptance.

The progress of a test method from submission towards acceptance as a recognised test method for use in various sectors and its final adoption into a regulatory framework can be

14 http://www.seurat-1.eu/
15 http://www.eu-toxrisk.eu/
16 Toxicology in the 21st century.
17 https://www.euromixproject.eu/
18 http://edcmixrisk.ki.se/
19 https://www.hbm4eu.eu/
20 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

followed through a new version of the tracking system for alternative test methods towards regulatory acceptance (TSAR)[21].

4.1.2.1. Evaluation and validation of test methods

In the period covered by its 2016 and 2017 status reports, EURL ECVAM evaluated 11 test submissions. It carried out or assessed (in the context of submissions) several validation studies in the areas of endocrine disruption, developmental neurotoxicity, skin sensitisation and genotoxicity. In addition, the EURL ECVAM Scientific Advisory Committee peer-reviewed validation studies carried out by the industry in the areas of (serious) eye damage / eye irritation, skin sensitisation and skin irritation.

In 2017, EURL ECVAM published a recommendation on the use of non-animal approaches for skin sensitisation (allergy) testing. The performance of a number of 'defined approaches'[22] based on different types of non-animal data is considered to be comparable with that of the standard animal test for identifying potential skin allergens. It was therefore recommended that these approaches be used where applicable and appropriate, instead of the standard animal test. As a consequence, a project is currently running within the OECD test guidelines programme, under the leadership of EURL ECVAM, the US Environmental Protection Agency and Health Canada, to develop a guideline based on defined approaches for skin sensitisation testing.

The European Union Network of Laboratories for the Validation of Alternative Methods (EU-NETVAL[23]) has supported the EURL ECVAM validation studies. It has also helped develop guidance documents and training materials for good *in vitro* method development and provided input into drafting OECD technical guidance on that topic.

It is worth noting that, in future, validation work may have to focus on standards for classes of methods rather than on validating individual methods.

More details on these activities can be found in the 2016 and 2017 EURL ECVAM status reports.

4.1.2.2. Regulatory uptake

Since the last Commission report, Commission Regulation (EC) No 440/2008[24], which brings together all regulatory accepted testing methods at EU level, has been updated once[25].

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21 https://tsar.jrc.ec.europa.eu/

22 A defined approach consists of a fixed data interpretation procedure applied to data generated with a defined set of information sources to derive a result that, depending on the regulatory requirements, can be used instead of standard animal testing to support an assessment.

23 https://eurl-ecvam.jrc.ec.europa.eu/eu-netval

24 Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

25 Commission Regulation (EU) 2017/735 of 14 February 2017 amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to

Under the REACH Regulation[26], the *in vivo* tests previously required for skin irritation/corrosion, serious eye damage / eye irritation and skin sensitisation have been fully replaced by *in vitro* testing. The last amendment to the annex on skin sensitisation was adopted in April 2017.

4.1.2.3. European Partnership for Alternative Approaches to Animal Testing

The Commission and industry representatives continue to facilitate the regulatory acceptance of alternative methods and approaches under the European Partnership for Alternative Approaches to Animal Testing (EPAA)[27]. According to its updated action programme for 2016-2020, the EPAA plans to:

- address science and technology gaps and optimise translation from research to regulatory practice;
- improve intra- and inter-sectoral collaboration and coordination;
- facilitate regulatory acceptance of additional sources of evidence in the current regulatory framework;
- communicate scientific reality; and
- 'educate the educated' (improve access to information, training opportunities and tools).

In 2017 the EPAA launched the Partners Forum, which provides an opportunity for all EPAA members to share information about their existing research initiatives, learn from each other's experience and build synergies across business sectors to potentially speed up the development and acceptance of alternative methods for regulatory purposes. The 2017 forum was dedicated to toxicokinetics and 'read-across', and similar events will be organised annually focusing on an area that is of current common interest to several sectors.

EPAA has been very active, for example in the area of skin sensitisation in recent years, in making progress on and facilitating the uptake of alternatives. The project on optimised strategies for assessing skin sensitisation evaluated the reliability and predicting capacity of the three most advanced skin models. Other recent or ongoing EPAA projects have focused on alternative approaches for toxicokinetics (exposure), acute toxicity and genotoxicity testing, and for vaccine potency and safety assessment.

4.1.2.4. Dissemination of information on alternatives

Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 112, 28.4.2017, p. 1).

[26] 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 (OJ L 396, 30.12.2006, p. 1).

[27] *EPAA annual report 2017*; http://ec.europa.eu/docsroom/documents/26811

The availability of information on alternatives is crucial. Therefore, information has been compiled in several databases at EURL ECVAM, including TSAR, the DB-ALM database on *in vitro* methods and the QSAR model database on *in silico* methods.

EURL ECVAM has also carried out a number of awareness-raising activities regarding alternatives to animal testing, such as knowledge-sharing and training.

In December 2016, the Commission held a scientific conference in Brussels to engage the scientific community and relevant stakeholders in a debate on how to exploit cutting-edge advances in biomedical and other research in the development of scientifically valid alternatives to animal testing. The event was one of the four actions announced in the Commission Communication responding to the European citizens' initiative 'Stop vivisection'[28].

4.2. Progress at international level

4.2.1. Activities at OECD level

The Commission, through EURL ECVAM, plays an active role at OECD level in the regulatory acceptance of alternative methods and their international adoption.

The OECD test guideline programme is the main instrument for promoting a globally harmonised safety assessment of chemicals[29]. From 2016 to 2017, a total of 24 new and updated test guidelines were approved, of which four were based on *in vitro* methods (on skin sensitisation, skin corrosion and endocrine disruption). A summary of the adoption status of test guidelines in the OECD from 2011 to 2017 based on alternative methods can be found in Annex 1 to the 2017 EURL ECVAM status report. In addition, 16 guidance documents or supporting documents were approved during that period, in particular the guidance document on the IATA to testing and assessment for serious eye damage / eye irritation, which is a basic requirement for the safety assessment of chemicals in many regulations.

Activities within the OECD working party on hazard assessment also play an important role in improving technical convergence on alternative 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.

4.2.2. Other international cooperation

The Commission, through EURL ECVAM, has continued its cooperation with other members of the International Cooperation on Alternative Test Methods (ICATM)[30]. An overview of the

[28] http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2012/000007

[29] The methods for which OECD test guidelines are adopted are legally implemented at EU level through Commission Regulation (EC) No 440/2008.

[30] ICATM is an international cooperation that includes governmental organisations from the EU, the United States, Japan, Canada, South Korea, Brazil and China. ICATM partners work together to promote enhanced international cooperation and coordination on the scientific development, validation and regulatory use of alternative approaches.

validation status of alternative test methods validated/peer-reviewed by ICATM partners and their regulatory acceptance status can be found in Annex 2 to the 2016 and 2017 EURL ECVAM status reports. In October 2016, in collaboration with ICATM, EURL ECVAM held a two-day workshop on the international regulatory applicability and acceptance of alternative non-animal approaches to the skin sensitisation assessment of chemicals used in a variety of sectors.

Since its creation, the International Cooperation on Cosmetics Regulation (ICCR)[31] has focused on advancing work related to alternatives to animal testing worldwide. At the ICCR's 11th annual meeting held in Brasilia, Brazil from 12 to 14 July 2017, the joint regulators-industry working group on integrated strategies for safety assessments of cosmetic ingredients gave a presentation on the major overarching principles for an integrated strategy for the risk assessment of cosmetics ingredients incorporating 'new approach methodologies'. Its document was endorsed by the ICCR Steering Committee and is publicly available on the ICCR website. Further work now continues with the objective of illustrating how these methodologies may be used in the cosmetic safety evaluation process, related to the principles, with examples of methods and their current strengths and limitations.

The Commission is involved in other international projects, for instance in the context of the UN subcommittee on globally harmonised system of classification and labelling to further explore the use of non-animal methods for classification.

The European Parliament has recently voted in favour of a resolution calling for a global animal testing ban in cosmetics[32]. The Commission will continue to promote the EU animal testing ban in cosmetics at international level, in various fora and through bilateral cooperation, including with the OECD. It will also remain fully engaged in the development, validation and promotion of methods alternative to animal testing to support the promotion of a global ban.

5. CONCLUSION

As in the previous reporting period, the Member States reported practically no cases of non-compliance with the testing and marketing bans. The main issue encountered by a small number of Member States in their market surveillance activities related to the bans is the presence of incomplete animal testing information in PIFs. However, corrective measures should be imposed on operators in such cases.

Considerable progress continues to be made in the development, validation and legal acceptance of methods alternative to animal testing and the Commission is fully engaged at all stages of the process. In particular, work has focused on developing defined and integrated approaches to testing and assessment which look at all existing safety data when assessing a chemical; these have become a priority in recent years.

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[31] ICCR is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the EU, Japan and the United States founded in 2007. It discusses common issues on cosmetics safety and regulation and is in dialogue with relevant cosmetics industry trade associations; http://www.iccr-cosmetics.org/

[32] European Parliament resolution of 3 May 2018 on a global ban to end animal testing for cosmetics (2017/2922(RSP)).

Nevertheless, the current level of alternative methods does not yet make it possible to fully replace *in vivo* (animal) tests for all toxicological endpoints in the safety assessment of cosmetics. Challenges still remain for the most complex endpoints, where more research is needed. Significant projects, such as EU-ToxRisk, aim to address these challenges.

The validation of alternative methods at EU level is progressing steadily, through the activities of the EURL ECVAM. 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.

The Commission has always been highly committed to animal welfare. The EU legal framework in this regard provides for very strict requirements and represents a model to be promoted at international level.