

AAM/ACM Briefing Note

CE positioning on Animal testing/alternatives and the European Citizens' Initiative "Save cruelty-free cosmetics - Commit to a Europe without animal testing"

The issue of animal testing is back on the EU agenda and is likely to stay in the foreseeable future with many initiatives forming part of the external debate landscape. One in particular which is likely to raise the temperature of the debate is the launch, on 31 August 2021, of an NGO campaign at EU and national level on a European Citizens' Initiative (ECI) "Save cruelty-free cosmetics - Commit to a Europe without animal testing".

Contents and objective of this document is to:

- 1. Inform members of the current external environment in relation to the EU Animal testing ban including the ECI pan-European campaign (see pages 1-3)
- 2. Inform members of the CE positioning in relation to this issue as adopted by the Board of Directors on 26 August 2021 (see page 3)
- 3. Inform members of CE external engagement activities (see page 3) and seek action from members at a national level (see page 4)
- 4. Provide members with communication assets to support activities at national level (see communications materials page 4-5)

The annex provides full details of the ECI objectives and process.

1. External environment context

The issue of animal testing has had an increasingly high profile in the EU arena in recent years, starting with the 2018 European Parliament Resolution calling for a global ban on animal testing for cosmetics, more recently with the Chemicals Strategy for Sustainability (CSS) giving rise to concerns of more animal testing being conducted under REACH (as highlighted in the European Parliament Resolution), the Symrise case challenging ECHA's decision to request animal data for two cosmetic ingredients for worker safety under REACH, and in recent days a study in ALTEX also looking at the issue of testing of cosmetics ingredients under REACH and the interface with the Cosmetic Products Regulation (CPR) animal testing ban. The ALTEX report generated limited media attention.

NGOs and civil society have been very active on the issue, generally against an increase in animal testing as a consequence of the CSS and more specifically for our sector against what they see as an undermining of the CPR animal testing ban with the testing of cosmetics ingredients under REACH.

For example, a 2020 joint statement co-signed by more than 400 companies and NGOs condemned several ECHA Board of Appeal's decisions requiring animal tests for occupational safety assessment of cosmetic-only ingredients. The Cosmetics Europe Board of Directors considered and approved Cosmetics Europe's positioning and engagement with ECHA on this issue in March 2021.

On June 30, a **ECI** entitled 'Save cruelty-free cosmetics - Commit to a Europe without animal testing' was registered by the European Commission. The organisers — NGOs People for Ethical Treatment of Animals (PETA), Cruelty Free Europe, Humane Society International (HIS), Eurogroup for Animals and the European Coalition to End Animal Experiments (ECEAE) - will start the process of collecting signatures on August 31. If they reach 1 million statements of support within 1 year from at least 7 different EU Member States, the Commission will have to react and publish a Communication (see further information on the process in the annex).

Officially launched in 2012, the ECI was introduced with the Lisbon Treaty as an agenda-setting tool in the hands of citizens. Since the beginning, the Commission has received 104 requests to launch an ECI, 81 of which were in fields where the Commission has the power to propose legislation and thus qualified to be registered.

The organisers of the 'Save cruelty-free cosmetics - Commit to a Europe without animal testing' initiative would like to strengthen the cosmetics animal testing ban in the EU. They call on the Commission to (see Annex for complete policy process and asks):

- 1. Protect and strengthen the cosmetics animal testing ban: Initiate legislative change to achieve consumer, worker, and environmental protection for all cosmetics ingredients without testing on animals for any purpose at any time and implement marketing of ingredients tested on animals.
- 2. Transform EU chemicals regulation: Ensure human health and the environment are protected by managing chemicals without the addition of new animal testing requirements.
- 3. Modernise science in the EU: Commit to a legislative proposal plotting a roadmap to phase-out all animal testing in the EU before the end of the current legislative term.

The launch of the ECI will be accompanied by a significant public affairs advocacy and communications <u>campaign</u> across Europe and we can expect that traditional and social media will also be leveraged at EU and national level as part of the campaign.

The campaign is also likely to get picked up globally, triggering widespread media, stakeholder and indeed consumer attention.

Meanwhile, following the ALTEX report, a policy platform is being launched by CAAT, Johns Hopkins University Center for Alternatives to Animal Testing, which whilst the vision and mission is not yet clear, intends to also look at policy solutions regarding the interface between REACH and the CPR. Cosmetics Europe is following this initiative's evolution.

In parallel, following a <u>parliamentary question</u> for oral answer in July, the European Parliament will be voting on a **Motion for Resolution** on coordinated EU-level action plan to facilitate the transition to innovation without the use of animals in research, regulatory testing and education on September 13. It should also be noted that Cosmetics Europe is organising a virtual Delegation to the European Parliament the week of September 6 – the week prior to the vote on the Resolution. This is likely to heighten the profile of the issue further.

More broadly, this comes at a time when the cosmetics industry is completing its LRSS programme and developing a new science programme to be launched in 2022, and the EU is investing €60m into three research projects to develop New Approach Methodologies (NAMs) through the Horizon 2020 Programme over the next five years. The chemicals sector association CEFIC is also advocating for the development of alternatives to animal testing.

2. CE position on the ATB/AT/ECI

The Cosmetics Europe Board of Directors discussed this issue at an extraordinary Board meeting on 26 August 2021 and agreed that:

- Cosmetics Europe should take a <u>nuanced position</u> on the ECI, <u>not supporting</u> it but welcoming the debate it raises, stating our support for the CPR AT ban, stating our commitment and leadership on AAT and our belief the way forward for the EU is to develop and accept AAT methods.
- Having weighed up the pros and cons, Cosmetics Europe should be <u>proactive</u> in relation to this issue and launch its own series of external engagement activities on 31 August 2021.

The positioning the Cosmetics Europe Board agreed is reflected in the communications wording and materials (see pages 4-5).

3. Cosmetics Europe's actions

On the 31 August 2021 Cosmetics Europe will:

- Publish a statement on the Cosmetics Europe website (see draft statement below).
- Launch social media engagement on Twitter and LinkedIn (see social media posts below).
- Actively outreaching to media, particularly trade press.
- Monitor the issue and track the ECI campaign and media coverage.

We will reflect the positioning in our advocacy including in our upcoming engagement with MEPs within the European Parliament delegation activities taking place in September.

Thereafter as a next step we will engage with the European Commission i.e. DG GROW, DG ENVIRONMENT and ECHA seeking support for our policy asks of a scientific dialogue and an appropriate platform to discuss how the EU can support development and acceptance of non-animal testing methods.

Further external engagement activities will be developed.

4. Request for action at national level

Members are asked to:

- Link to the Cosmetics Europe statement on your website and translate the statement into your own national language.
- Like/ retweet/share Cosmetics Europe social media posts.
- Engage with traditional national media.
- Monitor the debate at national level and track the ECI campaign and take up at national level and send feedback to Cosmetics Europe informing of the traction of the issue/campaign at national level in the media, with policy makers and politicians.

5. Communication materials

Statement

Below you will find Cosmetics Europe draft statement (embargoed until you are informed that it has been published on the CE website), which will be published on the Cosmetics Europe website on 31st August to coincide with the beginning of the European Citizens' Initiative "Save cruelty-free cosmetics - Commit to a Europe without animal testing" campaign. The draft version of the statement might still be subject to amends. Members will be provided with the direct link to the final version as soon as the statement is published.

Draft Statement

Under embargo until publication

Confidential – Do not share externally – Do not use publicly

Alternatives to animal testing – the only way forward for the EU

31 August 2021 – The introduction of the full ban on animal testing for cosmetics in the EU in 2013 was unquestionably a pivotal milestone for animal welfare. Today, when the discussion on animal testing is high on the European agenda again, Cosmetics Europe emphasises its full support for the ban under the EU Cosmetic Products Regulation.

We value all initiatives aimed at promoting animal-free testing and welcome the fact that the European Citizens' Initiative 'Save cruelty-free cosmetics - Commit to a Europe without animal testing' raises important questions. The interface between the EU Cosmetic Products Regulation and the REACH chemicals regulation, which permits the European Chemicals Agency (ECHA), in certain circumstances, to request animal testing data for cosmetic ingredients, has posed challenges

which are ongoing. Cosmetics Europe urges ECHA to ensure an ethical and responsible approach and always consider the use of non-animal testing methods.

The cosmetics and personal care industry has been at the forefront of developing alternatives to animal testing for regulatory safety assessment for more than 30 years. Science, research and innovation have been key drivers for maintaining the industry's leading role in the field. We have shown strong, sustained commitment—and made significant investment—to build on scientific progress, develop new approaches and drive innovative paradigm shifts in safety testing and safety assessment that meet regulatory needs. We are fully committed to continuing our work in this field.

Indeed, Cosmetics Europe, along with the Personal Care Products Council and other global cosmetics associations are working with their members, industry partners and a broad range of stakeholders on the development of a new global cosmetic science programme. This programme will broaden efforts already underway within the industry to promote regulatory acceptance of non-animal test alternatives and will cover safety science in the areas of human health and the environment. We look forward to providing more details in the coming months.

Cosmetics Europe believes the only way forward for the EU is to focus on the development and regulatory acceptance of non-animal testing methods. We believe in an open scientific dialogue to advance this work. We call upon the EU policy makers to facilitate such a dialogue with the cosmetics and personal care industry and all other relevant stakeholders through an appropriate collaborative platform.

Social media posts

Below you will find examples of **draft social media posts** to be published on Cosmetics Europe Twitter and LinkedIn channels. Draft posts **might still be subject to amends**. Members will be provided with direct links to the final versions as soon as the posts are published.

Twitter

"Alternatives to animal testing is the only way forward for the EU". @CosmeticsEur emphasizes its full support for Cosmetic Products Regulation #animaltesting ban & calls for open dialogue to advance work on development & regulatory acceptance of non-animal testing methods.

Hyperlink to the statement

LinkedIn

<u>Cosmetics Europe - The Personal Care Association</u> believes that alternatives to animal testing are the only way forward for the EU. We emphasize our support for the animal testing ban under the EU Cosmetic Products Regulation and call for open scientific dialogue to advance work on development and regulatory acceptance of non-animal testing methods.

Read more in the Cosmetics Europe statement	\downarrow
Hyperlink to the statement	

Additional background information on CE work on AAT

Cosmetics Europe participated in a number of scientific collaboration initiatives such the SEURAT-1 and LRSS Programmes.

- The SEURAT-1 programme running 2010-2015, focused on systemic toxicity. The project was the largest ever private-public initiative in the field of alternatives to animal testing. Partnering with the European Commission, our industry invested €25 million of the total €50 million project budget. SEURAT-1 brought together over 70 universities, research institutes and companies with the aim to develop a consistent research strategy for alternative safety assessment of chemicals. This included establishing innovative animal-free toxicity testing methods for a better understanding of repeated dose toxicity, and identifying gaps in knowledge to be bridged by future research work.
- Cosmetics Europe was also a partner in EUToxRisk an international consortium funded by the European Commission. EUToxRisk comprised 39 partner organisations, including Cosmetics Europe, who together worked on developing new concepts in regulatory chemical safety assessment, aiming to deliver reliable, animal-free hazard and risk assessment of chemicals. The EU-ToxRisk programme was the European flagship initiative for animal-free chemical safety assessment. It built on testing strategies and knowledge developed in previous national and European projects, including the SEURAT-1 programme.
- Long Range Science Strategy (LRSS) is a follow-up programme to SEURAT-1. It has grounds
 in multidisciplinary partnerships between Cosmetics Europe's member companies and other
 groups having a deep interest in non-animal approaches including the international
 regulatory community, validating bodies, academia, research institutes, and industry
 partners.

The Long Range Science Strategy (LRSS) Programme is supported and funded by a consortium of Cosmetics Europe members. The programme started in 2016 and is scheduled to run until 2021. Numerous partners bring their expertise together across the five most relevant areas for evaluating the safety of cosmetic ingredients: (i) ocular toxicity, (ii) genotoxicity/mutagenicity, (iii) skin sensitisation, (iv) toxicokinetics, and (v) toxicodynamics. The data and outcomes generated in each of the five research areas have already allowed us to develop several robust safety assessment approaches based on alternative methods.

Cosmetics Europe is currently involved in three new publicly funded projects on alternatives to animal testing, representing a total value of over 40 million Euros.

 The Virtual Human Platform for Safety Assessment (VHP4Safety) is an ambitious project to develop the world's first virtual human platform to determine the safety of chemicals and pharmaceuticals for human health based solely on human biology. By integrating innovations in data science, human tissue culture models and transition management, its aim is to accelerate the transition to animal-free safety assessment.

- RISK-HUNT3R, the successor of EU-ToxRisk, aims to develop a reliable, efficient, and costeffective chemical safety assessment approach. It will be based entirely on non-animal
 methods and provide improved protection of the human population against the systemic
 health effects caused by (chronic) chemical exposure.
- ONTOX builds on the joint Cosmetics Europe/CEFIC (European Chemical Industry Council)
 ontology project on systemic toxicity. The vision of the ONTOX consortium is to provide a
 functional and sustainable solution for advancing human risk assessment of chemicals
 without use of animals, in line with the principles of 21st century toxicity testing and
 NGRA.RISK-HUNT3R and ONTOX are funded under the Horizon Europe Programme.

Links to additional supporting documents

This content is available publicly and can be used proactively and support communication around the publication of the statement.

- o LRSS website:
 - About LRSS
 - Projects and Research
 - Collaboration & Partnership
- LRSS Long Range Science Strategy Programme 2016-2021 Brochure -https://www.lrsscosmeticseurope.eu/wp-content/uploads/2021/08/LRSS-brochure-2016-2021.pdf

Below are the links to materials confidential to CE members and which should be used <u>only</u> reactively:

- Standby Statement on ALTEX report on animal testing cosmetic ingredients under REACH and media articles
 - https://members.cosmeticseurope.eu/component/attachments/?task=download&id=37e4ff186f8aafd70e86944d5501cb3e
- Newsflash on CE LRSS participation in the 11th World Congress on Alternatives and Animal Use in the Life Sciences:
 - https://members.cosmeticseurope.eu/newsflash.html?layout=article&id=184:don-t-miss-cosmetics-europe-lrss-at-wc11

ANNEX: ECI 'SAVE CRUELTY FREE COSMETICS - COMMIT TO A EUROPE WITHOUT ANIMAL TESTING'

1. Objectives of the ECI.

To achieve the objective of protecting and strengthening the cosmetics animal testing ban, we urge the European Commission to ensure that the following mandates are met:

- Immediately implement the existing EU bans on animal testing for cosmetics and the marketing of ingredients tested on animals as intended by legislators to ensure that only non-animal methods are used for the safety assessment of cosmetics ingredients.
- Clarify that the requirement to rely on non-animal data for the safety assessment of cosmetics ingredients must be applied and animal data rejected, regardless of the location and purpose of animal tests conducted after the cut-off periods described in Article 18(2) of the EU Cosmetics Regulation.
- Initiate legislation to strengthen and broaden the cosmetics testing bans to ensure that consumers, workers, and the environment are protected without new tests on animals.
- Devise a robust testing strategy for cosmetics ingredients using only available non-animal assessment strategies so that the implementation of the Chemicals Strategy for Sustainability reflects the overwhelming support for strengthening rather than weakening the protection of animals in Europe.

Transforming Chemicals Regulation

We call on the European Commission to transform EU chemicals regulation.

The European Green Deal introduces a worthy commitment to a toxic-free environment whilst also presenting a golden opportunity for modern and sustainable regulation of chemicals. With the right investment and careful design, the EU could use non-animal approaches to provide the best protection of human health and the environment without wasting resources on an over-burdened and unreliable system dependent on the suffering and death of animals.

To achieve the objective of ensuring sustainable chemicals regulation with recourse to additional animal test requirements, we urge the Commission to ensure that, at a minimum, the following mandates are met:

- Put in place concrete steps with dedicated funding, ambitious timelines and cross-sectoral support to develop, validate, and implement human-relevant, non-animal approaches to identifying toxic chemicals.
- Ensure that the rapid uptake of non-animal New Approach Methodologies is aligned between the European agencies with administrative responsibility for chemicals, biocides, plant protection products, pharmaceuticals, and other products.

• Ensure that test requirement deadlines are not applied at the expense of scientific rigour or human and environmental safety by allowing a default fallback to reliance on unreliable tests on animals.

Modernising Science in the EU

We call on the European Commission to modernise science in the EU.

The EU is at a crossroads. Decision-makers can choose either to continue relying on archaic animal tests or to lead the world by fostering a new era of animal-free science. Seventy-two per cent of adults in EU member states agree that the time is right for the EU to plot a roadmap — containing concrete, measurable targets with associated timelines — towards its final goal of ending animal tests.

To achieve the objective of working towards a roadmap for the phase-out of all animal testing in the EU, we urge the Commission to ensure that, at a minimum, the following mandates are met:

- Openly endorse the desirability of phasing out the use of animals in science and state the belief that this is achievable. To illustrate this commitment, prioritise a transition to non-animal approaches as an integral part of all EU research, innovation, and education initiatives, while also acknowledging that Directive 2010/63/EU does not in and of itself represent a roadmap towards full replacement.
- Prioritise the development and validation of non-animal methods in the EU budget and new overarching policies such as the European Green Deal, the Chemicals Strategy for Sustainability, and post-COVID recovery plans and redirect funding away from animal studies to alternatives.
- Coordinate actions across the directorates-general and agencies responsible for aspects of research, regulatory testing, education, and funding with the involvement of all member states to achieve a strategic focus on the final goal of fully replacing the use of animals in scientific procedures.
- Include in the legislative proposal ambitious and achievable science-based targets with regard to a reduction in numbers of animals used, investments in advanced non-animal models and infrastructures, education and training synergy, and regulatory acceptance of non-animal methods.
 - 2. ECI policy process once the initiative is registered

Step 1: Get statements of support

- 12 months for the organisers to collect the support of at least 1 million people with minimum numbers in at least seven EU Member States (very likely according to our assessment).
- EU Citizens must fill in a specific statement of support form.

Step 2: Get statements of support verified

- 3 months for the organisers to send the statements of support for verification to the competent authorities in each EU Member State.
- 3 months for the authorities to verify that statements of support are valid.

Step 3: Submit the initiative

3 months for the organisers to submit the initiative to the Commission, once the last certificate from the national authorities is received.

Step 4: Examination of the initiative

- Within 1 month: meeting with the Commission and the organisers to explain the issues in detail.
- Within 3 months: opportunity for the organisers to present the initiative at a European Parliament public hearing. Parliament may also hold a debate in a plenary session, which could lead to it adopting a resolution related to the issue.
- Within 6 months: The Commission will spell out what action it will propose, and its reasons for taking (or not taking) action. This response will be in the form of a communication formally adopted by the Commissioners. The Commission is not obliged to propose legislation. Even where it responds positively, the most appropriate follow-up to an initiative may be nonlegislative in nature. The Parliament may also assess the measures taken by the Commission.

ENDS