

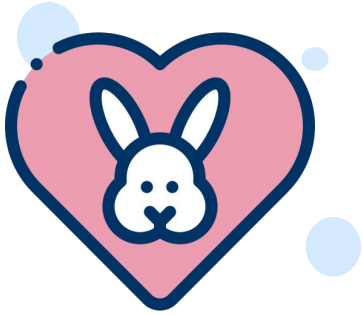
Aligning Animal-Free Testing with Sustainable Practices

*Insights for the cosmetics and
household products industries*

PRESCOUTER

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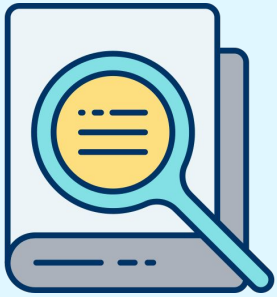


Aside from the humane argument of saving animal lives, animal-free testing can align with a business's sustainability goals and provide other benefits such as decreased costs and higher accuracy during testing.

Increased consumer interest in safe, natural, sustainable and cruelty-free cosmetics and personal care products is causing manufacturers to reassess their supply chains and formulation testing. The chemistries used for animal testing are not a closed system; hazardous chemicals may be present in feed, feces, and urine.

Bolstered by advances in toxicology testing methods and increased computing power, many tests currently exist that can be used to replace current animal-testing procedures. A smarter alternative testing strategy can reduce the use of resources for product development by better prioritization and more efficient screening-level tests, while promoting sustainable and cruelty-free practices. In addition, the growing alternative animal testing market will offer remarkable business opportunities for biotech and IT companies as well as contract research organizations.

In this Intelligence Brief, we highlight opportunities that overlap between the growing alternative testing and cosmetics markets and the business case for adopting alternative test methods where possible to save your organization both time and money.

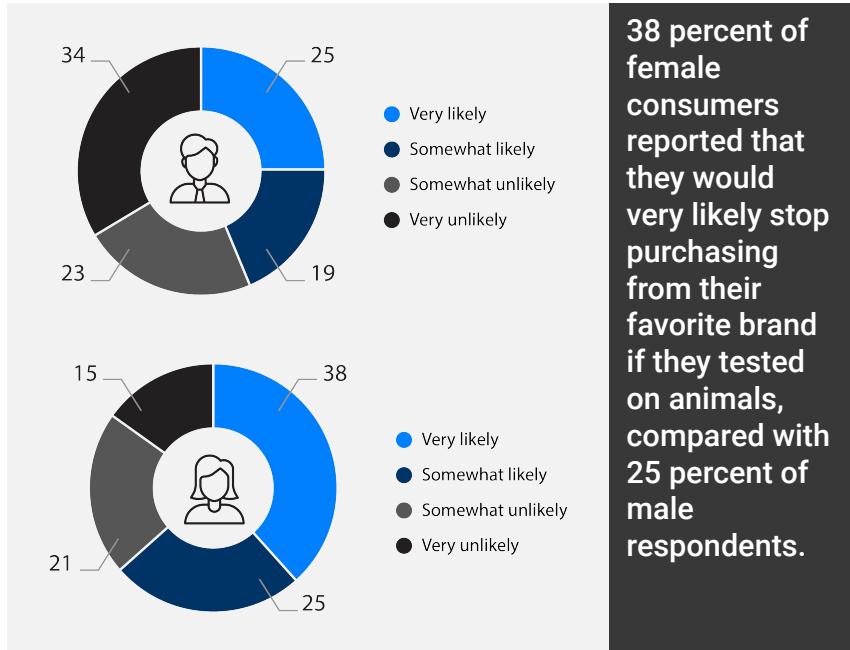


Building the Business Case for Animal-Free testing

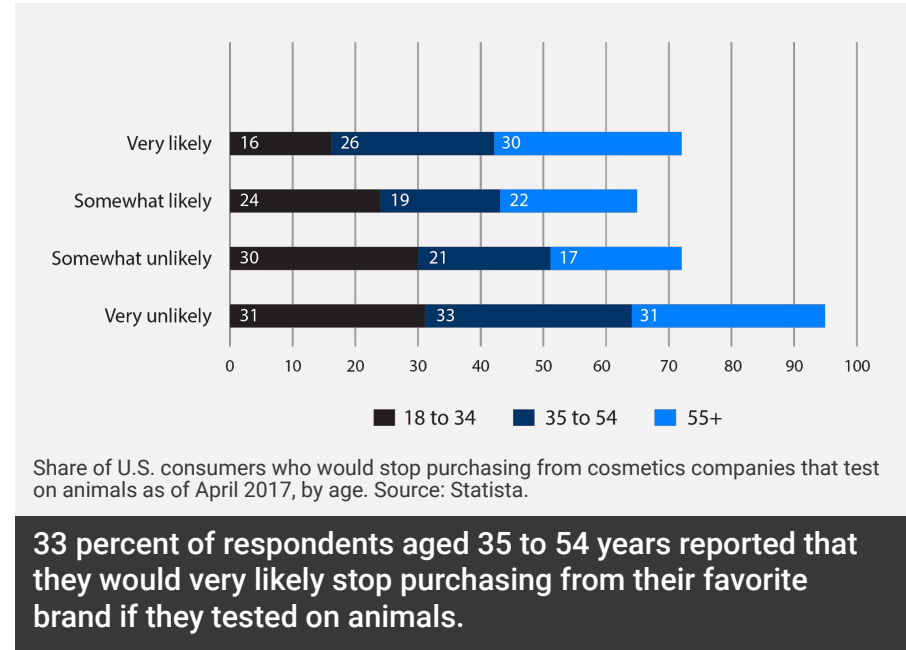
Scientists often study the effects of drugs and chemicals on animals before they deem them safe for humans. Ultimately, the safety of cosmetic and personal care products is paramount for manufacturers, importers, retailers and consumers. However, as product supply chains, testing and manufacturing processes become more transparent, consumer awareness is driving demand for safe, quality products that leave a minimal impact on the environment and do not involve the use of animal products, or that are labelled as cruelty-free.

Consumer awareness is driving demand for safe, quality products that do not involve the use of animal products, or that are labelled as cruelty-free.

Cruelty-free cosmetics are one of the fastest growing segments in the beauty industry. The FDA has not yet defined “cruelty-free,” but most in the industry use the term to describe cosmetics and ingredients that have not been tested on animals.



Share of U.S. consumers who would stop purchasing from cosmetics companies that test on animals as of April 2017, by gender. Source: Statista.



Share of U.S. consumers who would stop purchasing from cosmetics companies that test on animals as of April 2017, by age. Source: Statista.



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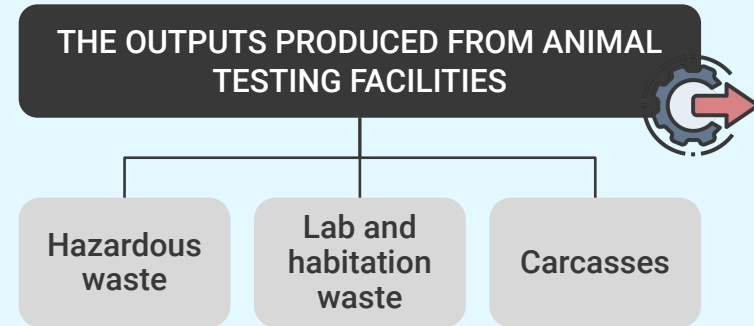
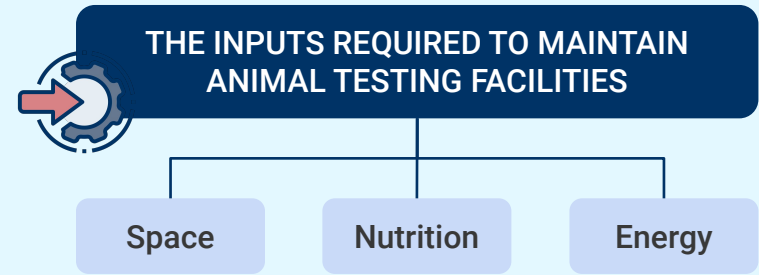
“Consumer preferences for cruelty-free, plant-based and sustainable products are propelling the use of lab-grown ingredients, natural ingredients and biodegradable packaging across the F&B and CPG space.”

- Daniel Morales, PreScouter Technical Director

In addition to winning over consumers, the transition to more animal-free testing methods promotes sustainable practices and a lowered carbon footprint.

Few studies exist that have focused on the environmental consequences of animal use in research; evidence demonstrates that their use and disposal, and the associated use of chemicals and supplies, contributes to pollution as well as to adverse impacts on biodiversity and public health.

Estimates of the global annual use of animals for research and testing are variable; the most comprehensive estimates range from 115.3 million to 126.9 million non-human vertebrate animals. The inputs (space, nutrition, energy) required to maintain these animals and their facilities and the outputs (hazardous waste, lab and habitation waste, carcasses) can be inefficient in cases where alternative testing methods can provide the same accuracy and safety for consumers.



The strategies and information provided in this report are an example of the insights clients rely on PreScouter for.

PreScouter is helping companies implement more sustainable practices throughout the entire product lifecycle, while ensuring the safety of products for consumer health, through the following services:



PreScouter's Proven Track Record

500+

Clients Worldwide

4000+

Challenges Conquered

150K+

Hours of Research



"Working with PreScouter is like having a secret information drawer. When you need perspective and insight you can open the drawer and, presto, you have what you need."

Rowena Pullan, Strategic Innovation Leader, VP Wellness R&D at Pfizer

PreScouter's research consultancy has helped drive strategic planning and specific solution development decisions for some of the most sustainable and prominent companies in the world, for years.

- 1 Identifying novel biobased and/or natural sources with similar or better efficacy compared to currently sourced ingredients
- 2 Assessing actionable technologies that enable consumers to tailor the use of active ingredients to their specific needs
- 3 Reviewing and ranking competitor activity to determine areas of opportunity and differentiation

Resources Used and Generated During Animal Testing



Energy and Carbon Emissions

- ❑ Increased energy utilization is observed as airflow exchange in a standard laboratory is up to 12 air exchanges per hour (ach) compared to an animal research facility that can be up to 20 ach. [1]
- ❑ The transport and disposal methods of the general waste, hazardous waste and animal carcasses: rendering, landfill disposal and incineration.
- ❑ Environmental and space needs of the animals, barrier protection from outside pathogens, indoor air quality, lighting and the requirement for power-intensive equipment in research. [2]



Hazardous Waste

- ❑ Many animals do not survive the animal testing process and are subsequently disposed of in large numbers. This results in environmental exposure to toxic chemicals, diseases and other risks. In other words, the disposal process poses potentially dangerous exposure to biohazards, including radioactive materials.
- ❑ The OLAW Institutional Animal Care and Use Committee (IACUC) Guidebook notes that due to the chemical used, hazardous chemicals may be present in feed, feces and urine. [3]



General Waste Production

- ❑ Animal excrement, bedding, excess feed, caging, needles, syringes and gavages



Chemicals

- ❑ Various chemistries are utilized for every step of animal research and testing, including chemicals for sanitation, disinfection, sterilization, animal care and research and testing procedures.

Hence, animal testing can be an unnecessarily wasteful process.

Keeping animals for research and testing has an environmental impact – for example, in 18 months from 2011 to 2013, waste collection reports from the NIH Division of Intramural Research Laboratories indicate that just these labs produced over 1.5 million pounds of animal bedding, excrement and excess food waste. [10]

In 2011, just 13 of hundreds of facilities engaged in animal research and testing generated approximately 700 tons of hazardous wastes at research-related facilities that the Environmental Protection Agency considers large generators. [11]

Carcasses, as well as other laboratory waste, may not be hazardous or infectious due only to exposure of the animals to diseases and chemicals, but may contain a combination of chemical, radioactive and/or biological hazards. Wastes that are chemically and biologically hazardous are difficult to dispose of, and few waste facilities can handle them. Disposal methods for these biological wastes raise additional environmental concerns. Carcass disposal methods include rendering, landfill disposal and incineration. [1]

Sources of Pollution from Animal Testing



Air Pollution

Air pollution is produced by the emission of gases and particulates resulting from incineration of animal carcasses and laboratory supplies such as animal bedding that may contain experimental chemicals, drugs and other toxins.



Soil and Water Pollution

Soil contamination and runoff of animal waste and other debris related to drug and chemical testing may result in ground water contamination. Similar to what occurs on a larger scale with pollutants in the animal agriculture industry, these potential toxins may then be carried into surface water, groundwater tables and public drinking water supplies. [4]



"As many as 500,000 animals are being tested on for cosmetics alone across the world each year with the largest proportion of these animals – more than 375,000 in 2015 – being used to meet test requirements in China alone." [8]



Animal-free testing alternatives and market opportunities for the cosmetics industry



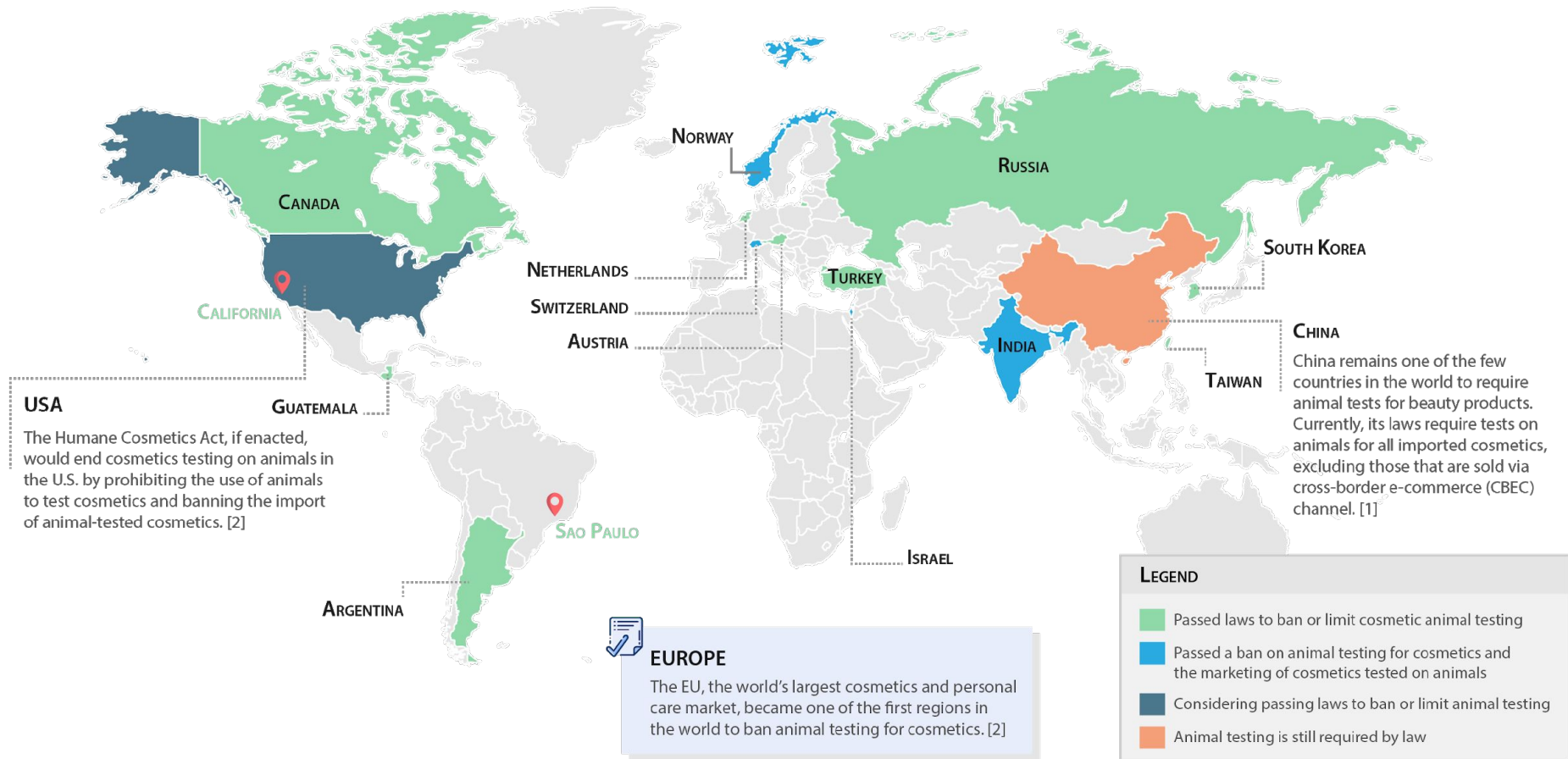
Opposition to animal testing of cosmetic products and ingredients, as well as an outright ban across Europe, has been a significant driver to the *in vitro* testing sector for cosmetics in recent years.

The amendment of the European Union's Cosmetics Directive banned the sale of any cosmetics or cosmetic ingredients that have been tested on animals. This has led to the replacement of animal testing in Europe with *in vitro* methods and also reduced the number of animals and tests required in other regions.

In the Chinese cosmetics market (~\$50 billion in domestic sales), end-product testing on animals carried out by Chinese authorities is still required. However, there are signs of change:

- “In September 2016, China’s Zhejiang Institute for Food and Drug Control (ZJIFDC) opened a lab in collaboration with the Institute for *In Vitro* Sciences (IIVS), a U.S. non-profit research and testing laboratory based in Gaithersburg, MD, that has been training Chinese scientists in tests using reconstructed skin.” [7]
- In April 2019, China’s National Medical Products Administration (NMPA) began to accept certain non-animal test methods for the regulation of cosmetics. [12]

Geographic Overview of Animal Testing Legislation



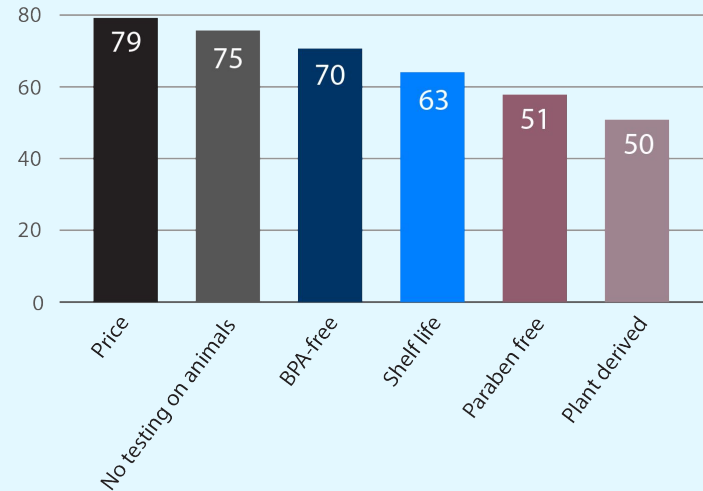
Today's consumers want products that work well, are safe to use, are sustainable and do not involve the use of animal products.

The global cosmetics industry is growing at a significant rate with the growing consumer demand for skin care products, anti-aging products and organic cosmetics.

“On average, large industry companies have a product portfolio of around 10,000 different cosmetic products and they reformulate around 25% to 30% of their products every year. Out of these reformulations, about 10% depend on ingredients that are new to the market or to the cosmetics industry.” [6]

Increased demand for complex functionality such as hair dyes, preservatives and UV filters require novel reactive chemistries, which can be linked to skin sensitization and mutagenicity/cancer.

As of 2018, price was the main factor consumers took into consideration when deciding to purchase natural or organic beauty and personal care products. It was also important to consumers that products were BPA-free and were not tested on animals.



Main factors consumers consider when purchasing organic or natural beauty and personal care products in the United States as of 2018.

Advances in alternative testing methods can accommodate the demand for new products while addressing consumer needs.

Scientists study the effects of novel drugs and chemicals on animals to confirm the lack of certain toxic properties in cosmetic and personal care products, as well as their ingredients, before they deem them safe for humans. Examples included tests undertaken for skin and eye irritation, skin corrosion, absorption through the skin, phototoxicity, cytotoxicity and mutagenicity.

Advances in alternative methods development (AI, lab on chip, organoid development, etc.) enable scientists to move away from animal testing by **replacing** animals with non-animal models, **reducing** the number of animals required or **refining** the existing method to reducing animal suffering.



A **replacing alternative** is a method that substitutes animal models with non-animal systems or replaces one animal species with a less developed one.



A **reduction alternative** is a method that reduces the number of animals used.



A **refinement alternative** is a method that reduces animal suffering.

Animal-Free Test Types



In Vitro

Primary cultures, cell lines, 3-D cell cultures



Ex Vivo

Isolated animal tissues and organs



In Silico

Mathematical models and computer simulations

The growth of the *in vitro* market can be aligned with the growing cosmetics market.



Drivers

- Increased opposition to animal testing
- Increased awareness and interest in ethically and sustainably sourced ingredients [1]
- Advancements in computational models
- Advancements in material innovations as animal model substitutes [3]
- Legislation banning or limiting animal testing for cosmetics



Opportunities

- Win-win marketing of sustainability, cruelty-free and increased accuracy
- Increasing focus on molecule discovery and personalized cosmetics/medicines using *in vitro* methods [2]
- Increasing number of toxicology databases

The cosmetics and household products industry is poised to see the largest growth from 2020-2025 (CAGR 12.2%), followed by the pharmaceutical and food industries.

Industry	2020	2021	2025	CAGR (2020-2025)
Pharmaceutical	4681.8	5176.9	7607.7	10.2
Cosmetics and Household Products	2571.2	2895.6	4579	12.2
Food Industry	1149.7	1247.7	1701.6	8.2
Chemical Industry	781	839.6	1102.5	7.1
Total	9183.7	10159.8	14990.8	10.3

In Vitro Toxicology Market, by Industry 2020 - 2025 (USD Million)



Validated alternative testing methods currently exist and proponents argue testing methods such as the use of organoids will ultimately be more accurate than animal models.



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“There are so many ways that in-vitro testing can facilitate doing more rather than less. Consumers are always going to be on the look-out for that next big breakthrough, but they’re also increasingly concerned with exactly how that breakthrough came to be. In-vitro testing can deliver for both companies and consumers looking to do more with limited resources – without unnecessary waste and energy expenditure.”

- Daniel Morales, PreScouter Technical Director

However, before making the full transition to animal-free testing, a number of challenges need to be addressed.

Alternative testing methods still have a ways to go before recreating the myriad complexities of the human body to prevent toxic chemicals from entering the environment and consumer products.

Challenges that still need to be addressed include:

- Animal testing for cosmetics is still required for products sold within the Chinese market
- Lack of skilled professionals in the space

Three main restraints are hindering the full transition to animal-free testing



Restraints

- Reluctance of regulatory authorities to consider alternative methods for proving efficacy and safety
- Challenges in replicating the complexities of *in vivo* conditions
- Lack of *in vitro* models to study complex endpoints [2]

There were approximately **82,000** chemicals in commerce in 2005 with **700** new chemicals introduced each year.



At this time, it took 30 years and \$2 billion to screen 300 chemicals using traditional animal toxicity tests.

In contrast, as part of the Environmental Protection Agency's new ToxCast program, it took about **five years to test 300 chemicals using 600 different rapid, automated *in vitro* tests** with equal or greater predictive value. [1]



Key Players & Competitive Analysis

Who are some key players in animal-free testing?



ALTERNATIVES RESEARCH & DEVELOPMENT FOUNDATION

Established in 1993, the Alternatives Research & Development Foundation (ARDF) has been a mainstay of support for developing alternatives to animal-based methods in science. Through grant programs, achievement awards and sponsorship of scientific conferences, ARDF advances high-quality scientific research that aims to replace and reduce the use of animals.



Non-animal Methods for Toxicity Testing

AltTox.org is a website dedicated to advancing non-animal methods of toxicity testing, both to better protect the health of humans, animals and the environment and to reduce the numbers and suffering of animals used in current toxicology assessments. The website is designed to encourage the exchange of technical and policy information on *in vitro* and *in silico* methods for all types of toxicity tests. The target audience includes stakeholders in industry, government, academia and non-governmental organizations.



Altweb, the Alternatives to Animal Testing Web Site, was created to serve as a gateway to alternatives news, information and resources on the Internet and beyond. Altweb now is the U.S. home of the journal ALTEX: Alternatives to Animal Experimentation, which is the official publication of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT).



The American Society for Cellular and Computational Toxicology (ASCCT) is a scientific society dedicated to the promotion of toxicology testing and research that reduces and replaces the use of animals.

Who are some key players in animal-free testing?



The vision of EU-ToxRisk is to drive the required paradigm shift in toxicological testing away from “black box” animal testing toward a toxicological assessment based on human cell responses and a comprehensive mechanistic understanding of cause-consequence relationships of chemical adverse effects.

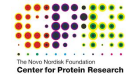
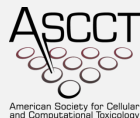


ToxCast is a multi-year effort launched in 2007 that uses automated chemical screening technologies called high-throughput screening assays to expose living cells, isolated proteins or other biological molecules to chemicals. The cells or proteins are then screened for changes in biological activity that may suggest potential toxic effects.



The Human Toxicology Project Consortium (HTPC) is a group of stakeholders currently drawn from the corporate and public interest communities that share the objective of accelerating implementation of a biological pathway-based approach to toxicology

What companies and organizations are associated with these key players*?



+ other organizations



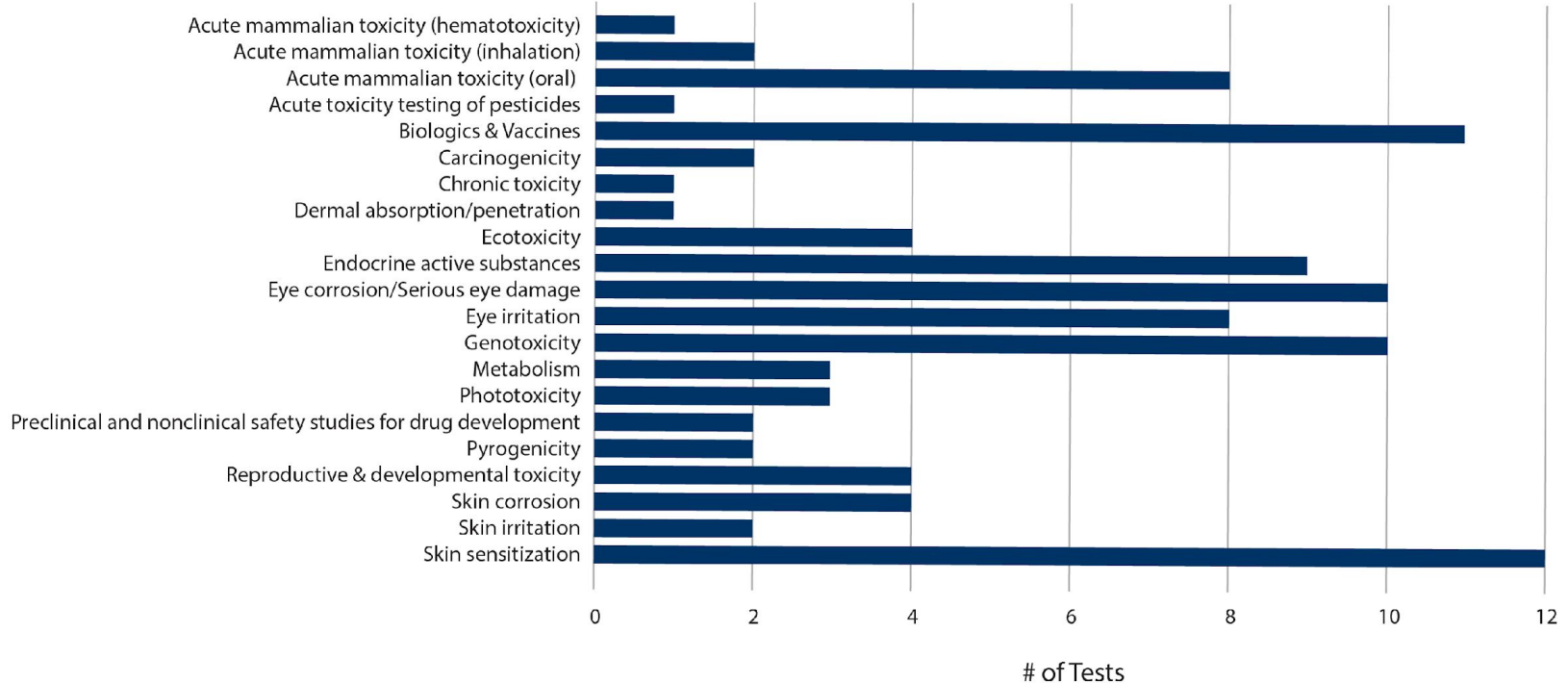
+23 other organizations



* Association confirmed by sponsorship, board of directors or membership.

According to AltTox.org, the following is a list of validated and accepted alternative methods:

of Tests vs. Type



A number of companies are leading the way in the animal-free testing market through developing and using alternative testing methods. Three examples are presented below.



Unilever

A CPG leader championing alternative testing



InVitro International

A leader in the development of non-animal testing alternatives



Cyprotex

A leader in the development of *in vitro* and *in silico* ADME-Tox services



Unilever – A CPG leader championing alternative testing

Experts at Unilever’s Safety & Environmental Assurance Centre (SEAC) work with teams to assess the safety and environmental sustainability of products, packaging and manufacturing processes. Unilever’s commitment to ending animal testing is underpinned by its work since the 1980s in developing and using alternatives to animal tests for assessing safety, for example, computer-based modeling and cell-based *in vitro* methods. Their framework for safety assessment is exposure-based, which enables them to use a wide range of non-animal approaches to assess product safety.

In October 2018, Unilever announced that they will be supporting a global initiative by Humane Society International that aims to reform regulatory legislation with the aim of **achieving a global ban on animal testing for cosmetic safety assessment by 2023.**

“Our leading-edge approach has one clear purpose: to continue to develop, apply and let others know about the research we do to guarantee that our products are safe, without the need for animal testing.” - Julia Fentem, Head of SEAC

Program: Safety and Environmental Assurance Centre (SEAC)

Relevant partners:



Testing methods: Skin Allergy, Immune Modulation, Exposure Science, etc.

Example products:



InVitro International – A leader in the development of non-animal testing alternatives

InVitro International develops and markets *in vitro* assay kits and systems to detect, rank and predict the potential level of irritancy, toxicity or corrosivity of substances to human eye and/or skin tissue.

In addition, InVitro performs outsourced standard testing services for their Irritation Assay System and Corrositex System, and they provide customized technology services using their *in vitro* test results database of several decades.



“The Irritation Assay System is a standardized, quantitative *in vitro* test method which utilizes changes of relevant macromolecules to predict the ocular and dermal irritancy of chemicals, mixtures and product formulations.”



“Corrositex is an *in vitro* test that determines chemical corrosivity and permits assignment of GHS Category and U.N. Packing Group classification for Class 8 corrosives. This test fully replaces the rabbit test for dermal corrosivity by providing a reliable means of mimicking that test.”

Location: Placentia, CA

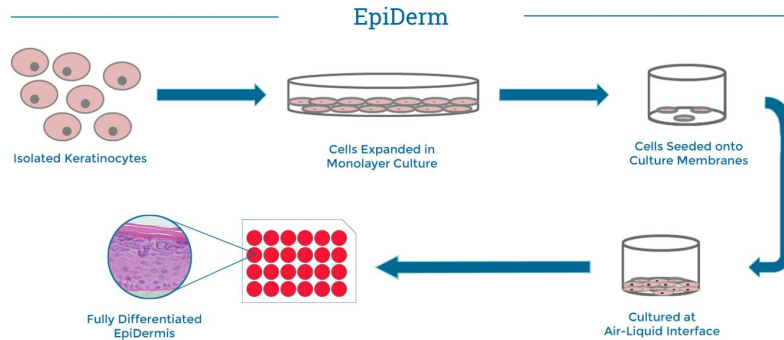
Function: Develops and markets *in vitro* assay kits and systems

Relevant partners:



Cyprotex offers *in vitro* assays for assessing skin irritation and corrosion, ocular irritation and serious eye damage.

Their novel *in vitro* approaches to cosmetic and ingredient safety assessment include High Content Imaging (HCI) in 2D and 3D cellular models and next-generation risk assessment cell stress panels. This panel, in combination with other cellular assays and in silico approaches, could provide a powerful decision-making tool with regard to non-animal safety assessments.



MatTek's EpiDerm is accepted by most regulatory authorities for non-animal *in vitro* testing of skin irritation and skin corrosion under the OECD test guidelines. Cyprotex uses this synthetic tissue for *in vitro* skin testing that replaces the Draize Rabbit Skin Irritation and Corrosion Tests.

Location: Macclesfield, UK, and Boston, USA

Function: Specializes in *in vitro* and in silico ADME-Tox services

Relevant partners:



About the Author



Daniel Morales, PhD

PreScouter Technical Director | CPG

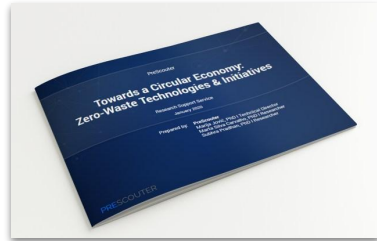
Daniel is an alumnus of PreScouter's advanced degree researcher network and has worked with PreScouter for more than three years and on over 70 projects, spanning across areas such as innovation strategy and roadmapping, product and process improvement and development, sustainability and technology trends throughout the CPG industry. Daniel earned his PhD in Chemical Engineering from the NC State University, where his research focused on developing stimuli-responsive polymer networks for microrobotics applications.

After his graduate studies, he completed postdoctoral work at INSA Toulouse, France, where his work focused on the intersection of nanoparticle assembly, nanofabrication and microfluidics to develop novel sensors. Before joining PreScouter, Daniel gained industrial experience in pharma manufacturing, polymer processing and science manuscript editing, and he is based in Raleigh, North Carolina.

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