Deutsche Juristische Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108 • 10179 Berlin

Deutsche Juristische Gesellschaft
für Tierschutzrecht e.V.

Berlin, March 21, 2025

Position paper

of the German Legal Society

for Animal Protection Law (DJGT)

Demand for changes of European food and feed law:

Obligation to share animal testing data

Animal testing as a requirement for the authorisation and marketing of consumer goods in the European Union represents an ethical and moral challenge that urgently needs to be further restricted in order to avoid animal suffering and strengthen animal protection. Social acceptance of animal testing is increasingly being rejected, as the majority of the public disapprove of it. Furthermore, with the '3R principle' ('*Replace, Reduce and Refine*'), the European Union has committed itself to replacing animal testing with alternative methods, reducing the number of laboratory animals and refining experimental methods.

While the REACH Regulation (EC No. 1907/2006) already provides for rules to avoid and reduce animal testing and to share animal testing data in the area of chemical registration, there is no comparable legal basis in food and feed law. We demand an adaptation of the European legal framework to introduce a mandatory sharing of animal testing data in the field of food and feed as well.

Deutsche Juristische Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

Deutsche Juristische Gesellschaft
für Tierschutzrecht e.V.

1. Legal requirement to conduct animal testing for the permissible placing on the market of feed additives, novel foods, genetically modified food/feed, so-called food improvement agents (food additives, enzymes, flavourings) and so-called food contact materials (materials and articles intended to come into contact with food)

In order to obtain authorisation and to ensure that **feed additives, novel foods, genetically modified food/feed, food improvement agents (food additives, enzymes, flavourings) and food contact materials (materials and articles intended to come into contact with food)** are lawfully placed on the market, animal testing is prescribed in accordance with the following legal provisions:

a) Regulation (EC) No. 1831/2003 (**Regulation on Feed Additives**) governs the authorisation of feed additives. According to Article 5, paragraphs 1 and 2 of the Regulation on Feed Additives, a feed additive may only be authorised if the applicant has demonstrated that the substance has no adverse effect on animal health, human health or the environment. To this end, the European Food Safety Authority (EFSA) publishes guidelines to support applicants in accordance with Article 7 paragraph 6 of the Regulation on Feed Additives.

EFSA Guidance on the assessment of the safety of feed additives for the target species (26 September 2017, doi [digital object identifier]**: 10.2903/j.efsa.2017.5021):**

- Toxicity data: Safety for target animals can be derived from toxicological studies with oral administration in laboratory animals (p. 6).

- Safety tests for target animals: If safety for the target species cannot be established by other methods at the proposed maximum concentration, in vivo studies in the relevant target species are required (p. 7).

EFSA Guidance on the assessment of the safety of feed additives for the consumer (27 September 2017, doi: 10.2903/j.efsa.2017.5022):

- Toxicity data: The safety of the additive is assessed on the basis of toxicological studies performed in vitro and in vivo in laboratory animals (p. 8).

EFSA Guidance on the assessment of the efficacy of feed additives (6 June 2024, doi: 10.2903/j.efsa.2024.8856):

- Efficacy studies: in vivo animal testing is foreseen for all additives exerting the intended effect in the target species (p. 15).

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

b) Regulation (EU) 2015/2283 (**Regulation on Novel Foods**) regulates the authorisation of novel foods (e.g. foods with new ingredients or new production processes). According to Article 10 of the Regulation on Novel Foods, an application for the authorisation of the placing on the market of novel foods must include scientific evidence demonstrating that the novel food does not pose a safety risk to human health. The Commission Implementing Regulation (EU) 2017/2469 lays down the administrative and scientific requirements pursuant to Article 10 of the Regulation on Novel Foods. The EFSA publishes scientific guidance for the preparation of applications for authorisation of novel foods.

EFSA Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (27 June 2024, doi: 10.2903/j.efsa.2024.8961):

- Both the ADME (absorption, distribution, metabolism, excretion) and the toxicological assessment of novel foods follow a tiered approach: (Tier) I-III.

- ADME assessment: In level II (Tier II), ADME information from in vivo studies is needed (p. 24).

- Genotoxicological assessment: In Tier II, information from in vivo studies is needed (p. 28).

- Repeated dose toxicity studies: Often a 90-day subchronic toxicity study is already required in Tier I, which is carried out in accordance with the OECD Guideline Test. No. 408 (p. 28); thereafter, the substance of interest is administered orally to several groups of test animals daily in graduated doses over a period of 90 days.

c) Regulation (EC) No. 1829/2003 (**Regulation on genetically modified food and feed**) governs the authorisation of genetically modified food and feed. According to Article 5 paragraph 3 (e) and Article 17 paragraph 3 (e), copies of studies, including, where available, independent, peer-reviewed studies and other documents must be submitted for the authorisation, which prove what is required in Article 4 paragraph 1 or Article 16 paragraph 1:

All food and feed falling within the scope of the Regulation

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

• must not have adverse effects on human health, animal health or the environment,

• must not mislead the consumer (user),

• must not harm or mislead the consumer by impairing the distinctive features of animal products,

• must not differ from the food feed which it is intended to replace to such an extent that normal consumption would cause nutritional deficiencies for the consumer (human or animal).

Explanations of the required evidence can be found in Commission Implementing Regulation (EU) 503/2013. In the scientific data in Annex 1, Part 2, a toxicological test is required under 1.4, which specifically requires the following tests for the examination of the whole genetically modified food or feed:

• 90-day feeding study in rodents,

• Animal studies with respect to reproductive, developmental and chronic toxicity,

• Other animal studies to examine the safety and characteristics of the genetically modified food and feed.

d) Regulation (EC) No. 1331/2008 **(Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings**) governs the authorisation of so-called 'food improvement agents'. In detail, food enzymes are regulated by Regulation (EC) No. 1332/2008, food additives by Regulation (EC) No. 1333/2008 and food flavourings by Regulation (EC) No. 1334/2008. Article 5 paragraph 1 of Commission Implementing Regulation (EU) No 234/2011 stipulates that 'the dossier submitted in support of an application for the safety evaluation of a substance shall enable a comprehensive risk assessment of the substance and shall permit verification that the substance does not pose a risk to consumers within the meaning of Article 6 (a) of Regulation (EC) No. 1332/2008, Article 6 paragraph 1 (a) of Regulation (EC) No. 1333/2008 and Article 4 (a) of Regulation (EC) No. 1334/2008'.

Depending on the substance to be examined, the EFSA requires the following specific data for risk assessment: toxicokinetics, subchronic toxicity, genotoxicity, chronic toxicity/carcinogenicity, reproductive and developmental toxicity (Article 6 paragraph 2, for

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

food additives), subchronic toxicity, genotoxicity (Article 8 paragraph 2, for food enzymes) and genotoxicity; subchronic toxicity where applicable; developmental toxicity where applicable; chronic toxicity and carcinogenicity data, where applicable (Article 10 paragraph 2 (b) - e), for flavourings).

The European Food Safety Authority (EFSA) has published the following explanatory note on the authorisation of food enzymes:

EFSA Technical Report: Explanatory Note for the Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (14 November 2024, EN-68):

- Genotoxicity data: in vitro tests are required to demonstrate that the use of the product does not cause chromosomal changes and gene mutations in consumers.

- Systemic toxicity data: data from a 'subchronic oral toxicity study' (in vivo) should be used to identify possible systematic toxicological effects.

e) Regulation (EC) No. 1935/2004 (**Regulation on materials and articles intended to come into contact with food**) governs the authorisation of so-called 'food contact materials'. According to Article 3 paragraph 1, materials and articles manufactured in compliance with good manufacturing practice (GMP) must not pose any danger to human health, bring about any unacceptable change in the composition of the food or bring about any deterioration in the organoleptic characteristics thereof. The Authority shall provide published guidelines for the application for authorisation according to Article 9 paragraph 1 (a) (ii) of Regulation (EC) No. 1935/2004.

EC Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact material prior to its authorisation (SCF/CS/PLEN/GEN/100 Final, 19 December 2001):

The so-called core set for the toxicological assessment of food contact materials consists of:

- Three invitro mutagenicity studies,

- Normally in two animal species in vivo oral toxicity studies,

- ADME studies,

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

- Normally in two animal species developmental toxicity studies and in one animal species reproduction toxicity studies,

- Normally in two animal species studies on long-term toxicological/carcinogenic effects.

EFSA Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials (9. September 2020, doi: 10.2903/j.efsa.2008.21r):

For the safety assessment of the plastic substances, the EFSA differentiates according to the degree of migration of the contact material. The full data set for materials with a high migration potential requires the following studies according to EFSA:

- two in vitro mutagenicity studies,

- one 90-day oral toxicity study (in vivo),

- ADME studies,

- Developmental toxicity studies and reproduction toxicological studies,

- Studies on long-term toxicological/carcinogenic effects.

2. Rules for the sharing of animal testing data for chemical registration under REACH

In accordance with Regulation (EC) No. 1907/2006 (REACH Regulation), tests on vertebrate animals in connection with chemical substances, mixtures and products must be carried out with restraint. According to Article 25 paragraph 1 sentence 1 of the REACH Regulation, they shall be undertaken only as a last resort. According to Article 13 paragraph 1 sentence 1, 2 of the REACH Regulation, information on intrinsic properties of substances may be generated by means other than tests and, in particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests. Alternative methods such as in vitro methods, qualitative or quantitative structure-activity relationship models or information from structurally related substances may be used for this purpose (Article 13 paragraph 1 sentence 3 REACH Regulation). According to Article 13 paragraph 2

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

sentence 1, these methods shall be regularly reviewed and improved to reduce the testing on animals and the number of vertebrate animals involved.

If a substance has already been registered, a new registrant is entitled to refer to the study summaries or robust study summaries submitted earlier for the same substance, according to Article 13 paragraph 5 sentence 1 REACH Regulation. To do this, the new registrant must prove that the substance to be registered is the same as the substance registered previously and that the previous registrant has given permission to refer to the full study reports for the purpose of registration. Registrants are obliged under Article 10 (a) (vi) and (vii) of the REACH Regulation to submit both a study summary and a robust study summary. According to Article 25 (3) of the REACH Regulation, any study summaries or robust study summaries of studies submitted in the framework of a registration under the REACH Regulation at least 12 years previously can be used for the purposes of registration by another manufacturer or importer. To this end, each potential registrant shall inquire from the European Chemicals Agency (ECHA) whether a registration has already been submitted for the same substance (Article 26 paragraph 1 sentence 1 REACH Regulation). If the same substance has previously been registered less than twelve years earlier, the ECHA shall inform the potential registrant without delay of the name and address of the previous registrant and of the relevant summaries or robust study summaries, already submitted by the previous registrant (Article 26 paragraph 3 REACH Regulation). Studies involving vertebrate animals shall not be repeated. In addition, the ECHA informs the previous registrant of the name and address of the potential registrant. Pursuant to Art. 26 paragraph 3 subparagraph 3 of the REACH Regulation, the available studies shall be shared with the potential registrant. In addition, Article 27 paragraph 1 (a) of the REACH Regulation stipulates that, for substances registered less than twelve years previously, the potential registrant is obliged to request from the previous registrant the information required for his registration in accordance with Article 10 (a) (vi) and (vii) if the information includes vertebrate animals. The previous and potential registrant shall make every effort to reach an agreement on sharing the requested information; in the absence of an agreement, submission of the matter to an arbitration panel may serve as a substitute for an agreement.

In addition, the ECHA contributes to the development of alternative methods and approaches and promotes their use – for example:

- The read-across approach is the most commonly used alternative method under REACH Regulation. It allows the use of relevant information from analogous substances to predict properties of the target substances. To this end, ECHA developed a Read-across Assessment Framework (RAAF) and published it together with an illustrative application example.

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

- Companies are requested to share any available data on their substance if a registrant of an analogue substance asks for it.

- The QSAR Toolbox is a software application that helps companies identify data that may be relevant for assessing the hazards of chemicals. ECHA develops and maintains the tool in collaboration with the OECD (Organisation for Economic Co-operation and Development).

- ECHA organises training sessions, webinars and workshops on alternative methods. The agency also publishes tips on how to use them, including guidelines, fact sheets and practical guides such as the practical guide to avoiding animal testing. The report 'The use of alternatives to testing on animals for the REACH Regulation' is published every three years.

- Much of the data submitted to ECHA on registrations is published on the agency's website. This helps existing and future registrants to identify additional data that they would like to use in their registrations.

- ECHA provides expert advice and technical support for the development of alternative test methods.

3. Lack of regulations for the sharing of animal testing data in food and feed law

In the area of food and feed law, there is no legal basis for sharing animal testing data comparable to that provided by the REACH Regulation. According to its website, the European Food Safety Authority (EFSA) supports risk assessment approaches that minimise the use of animals in testing (in vivo testing) or improve animal welfare and promote the use of data obtained from alternative approaches whenever possible. However, there is a lack of legally binding principles that oblige companies or registrants to share animal testing data or prohibit the repetition of animal testing.

4. Scientific evidence of comparability of animal testing for the registration of chemicals and animal testing for the authorisation of feed additives, novel food, genetically modified food/feed and so-called food improvement agents (food additives, enzymes, flavourings).

In the course of an approval procedure for certain food and feed, the Authority requires, among other things, a toxicological risk assessment of the respective substances. Toxicological data are comparable if:

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

1. the same substances of the same purity are being investigated,

2. the same standardised and validated tests are being carried out,

3. the test laboratories are subject to the same standards when conducting the tests and documenting/evaluating the test results (e.g. GLP – Good Laboratory Practice).

Many toxicological test guidelines are harmonised via OECD guidelines (Organisation for Economic Co-operation and Development), such as the sub-chronic oral toxicity study in rats (OECD Test Guideline No. 407). If such a test is required for the approval of various regulated products by different regulatory authorities, this means that the respective registrants are required to conduct this study precisely according to the presented OECD test protocol using the pure substance X.

Compared to the ECHA, the EFSA does not provide registrants with the opportunity to identify potential applicants for the same or similar substances before submitting their dossiers. Therefore, direct planning and joint execution of tests is not possible.

However, it is conceivable that future applicants for a particular substance might purchase test data from those applicants who have already obtained approval for the same substance. This scenario is currently rare. Sharing test data is, however, not always in the interest of market participants and is not explicitly requested by the EFSA.

Furthermore, it frequently occurs at the EFSA that registrants of similar substances are asked to conduct certain investigations at approximately the same time. In this context, it could be envisioned that mixtures of the substances of the registrants would be jointly tested in one study. If the study shows, for example, that there is no genotoxicity (i.e., no safe exposure threshold or dose) of the mixture, this conclusion can scientifically be extended to all individual components of the mixture.

5. Demand: Implementation of a legal requirement for the sharing of animal testing data

In order to avoid animal testing and to harmonise legislation, we call on the European Commission to introduce a comparable regulation for the sharing of animal testing data for food and feed, in particular for **feed additives, novel foods, genetically modified food/feed, so-called food improvement agents (food additives, enzymes, flavourings) and so-called food contact materials (materials and articles intended to come into contact with food)**.

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

To this end, we request that

- **Article 5 of Regulation (EC) No. 1831/2003 (Regulation on Feed Additives),**
- **Article 10 of Regulation (EU) No. 2015/2283 (Regulation on Novel Foods),**
- **Article 5 and Article 17 of Regulation (EC) No. 1829/2003 (Regulation on genetically modified food and feed),**
- **Article 5 of Implementing Regulation (EU) No. 234/2011 (Commission Implementing Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings),**
- **Article 3 of Regulation (EC) No. 1935/2004 (Regulation on materials and articles intended to come into contact with food)**

be aligned with the provisions of the REACH Regulation, so that applicants are obliged to share their animal testing data with other (future) applicants.

We also call for each

- **Regulation (EC) No. 1831/2003 (Regulation on Feed Additives)**,
- **Regulation (EU) No. 2015/2283 (Regulation on Novel Foods).**
- **Regulation (EC) No. 1829/2003 (Regulation on genetically modified food and feed),**
- **Regulation (EC) No. 1331/2008 (Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings**),
- **Regulation (EC) No. 1935/2004 (Regulation on materials and articles intended to come into contact with food)**

to clarify that tests involving vertebrates should be carried out sparingly and only as a last resort.

6. Benefits of a legal regulation

- **Significant Reduction of animal testing:** Mandatory data sharing avoids animal testing.

- **Increase in scientific quality:** Joint use of data leads to a broader and more profound scientific basis.

Deutsche Juristische
Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin

Deutsche Juristische Gesellschaft
für Tierschutzrecht e.V.

- Cost and resource savings: Companies do not have to carry out costly animal testing independently.

- Ethics and social acceptance: Greater protection of laboratory animals meets social expectations and political goals of the European Union.

Berlin, March 21, 2025

Deutsche Juristische Gesellschaft für Tierschutzrecht e.V.
Littenstraße 108
10179 Berlin
Fax: +49 (0)30-400 54 68 69
poststelle@djgt.de
www.djgt.de

GLS Bank
Konto: 1106048000
IBAN: DE74430609671106048000
BIC: GENODEM1GLS

Registergericht
Amtsgericht Charlottenburg, VR 29716 B

1. Vorsitzender
Dr. Christoph Maisack

Sitz des Vereins
Berlin