European Food Safety Authority

EFSA's role in the Risk Assessment of GMOs

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on behalf of EFSA

Dublin Conference on GMO technology
10 October 2013

Outline

1. **EFSA's remit in the GMO area**
2. Who does the risk assessment
3. Risk assessment of GMO applications
4. Other mandates

GMO in Europe

An organism is "genetically modified" if its genetic material has been changed in a way that does not occur under natural conditions through cross-breeding or natural recombination.

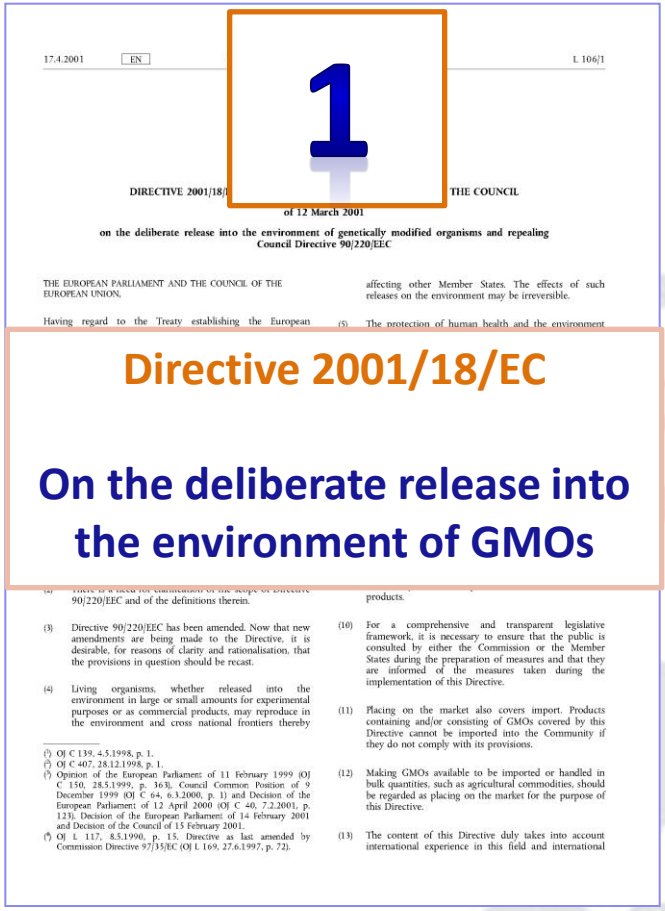
Defined by the European Union Directive 2001/18/EC (Art. 2)

In the EU, products that are, contain, or are produced from Genetically Modified Organisms (GMOs) must have an authorisation prior to entering the market

Legal framework for GMO risk assessment

European Food Safety Authority

EFSA's role is to carry out scientific Risk Assessment on GMOs under two regulatory frameworks:



17.4.2001 EN L 106/1

1

DIRECTIVE 2001/18/[illegible] THE COUNCIL

of 12 March 2001

on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European

affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment

90/220/EEC and of the definitions therein.

(3) Directive 90/220/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby

products.

(10) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

(11) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(12) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(13) The content of this Directive duly takes into account international experience in this field and international

(1) OJ C 139, 4.5.1998, p. 1.
(2) OJ C 407, 28.12.1998, p. 1.
(3) Opinion of the European Parliament of 11 February 1999 (OJ C 150, 28.5.1999, p. 363), Council Common Position of 9 December 1999 (OJ C 64, 6.3.2000, p. 1) and Decision of the European Parliament of 12 April 2000 (OJ C 40, 7.2.2001, p. 123). Decision of the European Parliament of 14 February 2001 and Decision of the Council of 15 February 2001.
(4) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

Directive 2001/18/EC

On the deliberate release into the environment of GMOs

18.10.2003 EN L 268/1

2

REGULATION (EC) No 18[illegible] AND OF THE COUNCIL

of 22 September 2003

on genetically modified food and feed

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Com-

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990 (5) and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms (6): no authorisation procedure exists for feed produced from GMOs: a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

(1) OJ C 304 E, 30.10.2001, p. 221.
(2) OJ C 221, 17.9.2002, p. 114.
(3) OJ C 278, 14.11.2002, p. 31.
(4) Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
(5) OJ L 43, 14.2.1997, p. 1.
(6) OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.
(7) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

Regulation (EC) No 1829/2003

On GM food and feed including derived products

Scope of GMO applications

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Food

- GMO for food use
- Food containing or consisting of GMOs
- Food produced from or containing ingredients produced from GMO

Feed

- GMO for feed use
- Feed containing or consisting of GMOs
- Feed produced from GMOs

Deliberate release into the environment (Cultivation)

- Import and processing
- Seeds and plant propagation material for cultivation

EFSA carries out **scientific risk assessment** on GMOs to ensure that they are as safe as their conventional equivalent

What EFSA cannot do

- **Give authorisations** (for products such as GMOs, feed additives, food additives, pesticides etc)
- **Be responsible for food safety legislation** (sampling, labelling or other risk management issues such as co-existence measures)
- **Take charge of food safety/quality controls**

Outline

1. EFSA's remit
2. **Who does the risk assessment**
3. Risk assessment of GMO applications
4. Other mandates

Risk assessment performed by

- **The GMO Panel**
  - elaborates guidance documents
  - delivers scientific opinions on applications for market authorisation regarding GMOs
- **Plenary meetings** every 1,5 months for adoption of opinions
- **40 Ad-hoc experts** support the GMO Panel in **Working groups** (4 standing WG and several temporary WGs)
- 13 **GMO Unit scientists** provide support to the GMO Panel and its Working Groups

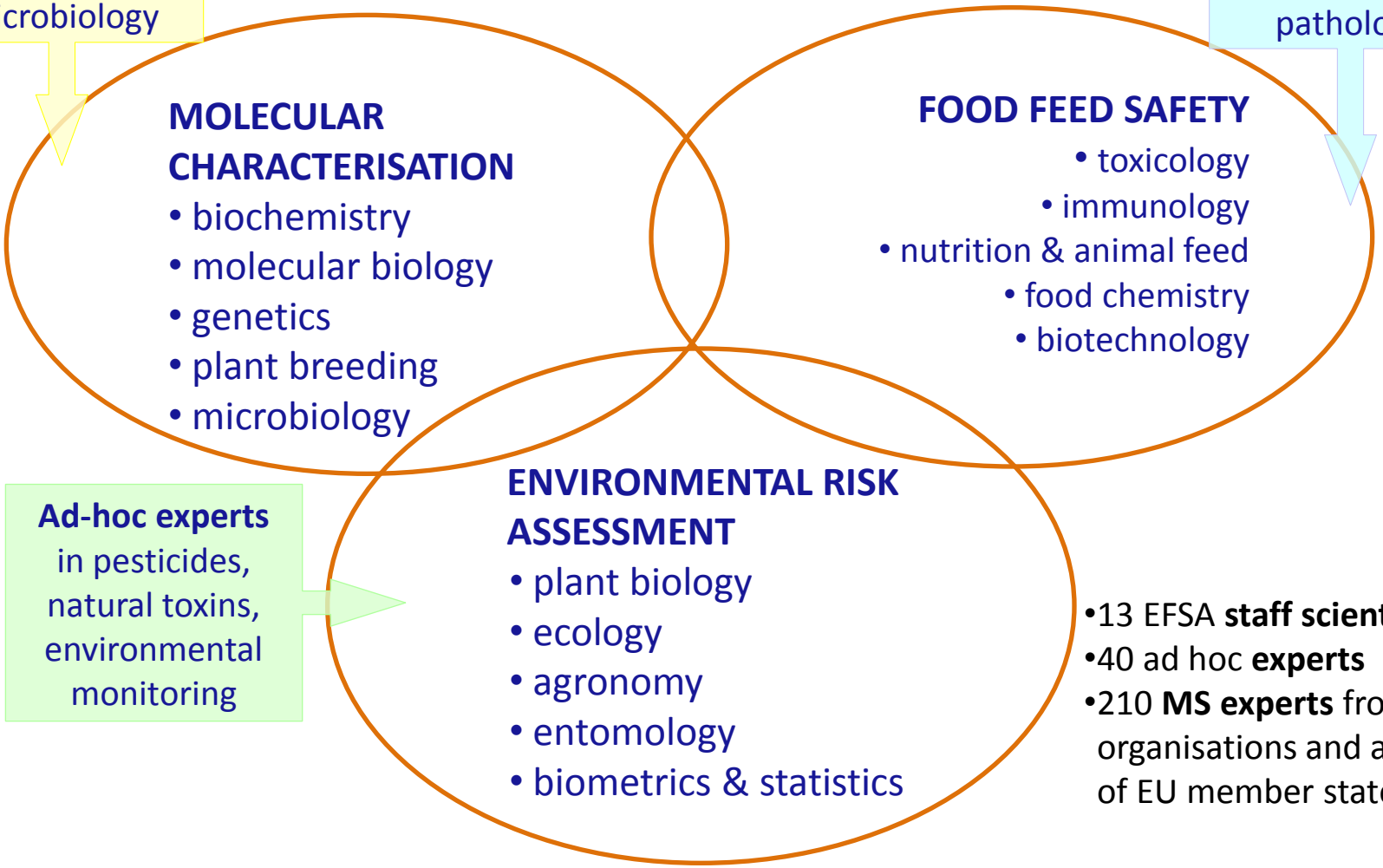
EFSA GMO Panel expertise

European Food Safety Authority

Ad-hoc experts in new techniques, microbiology

EFSA GMO Panel of 21 external experts
Renewed every 3 years (currently one vacancy)

Ad-hoc experts in food sciences, animal pathology



Ad-hoc experts in pesticides, natural toxins, environmental monitoring

- 13 EFSA **staff scientists**
- 40 ad hoc **experts**
- 210 **MS experts** from 108 organisations and authorities of EU member states

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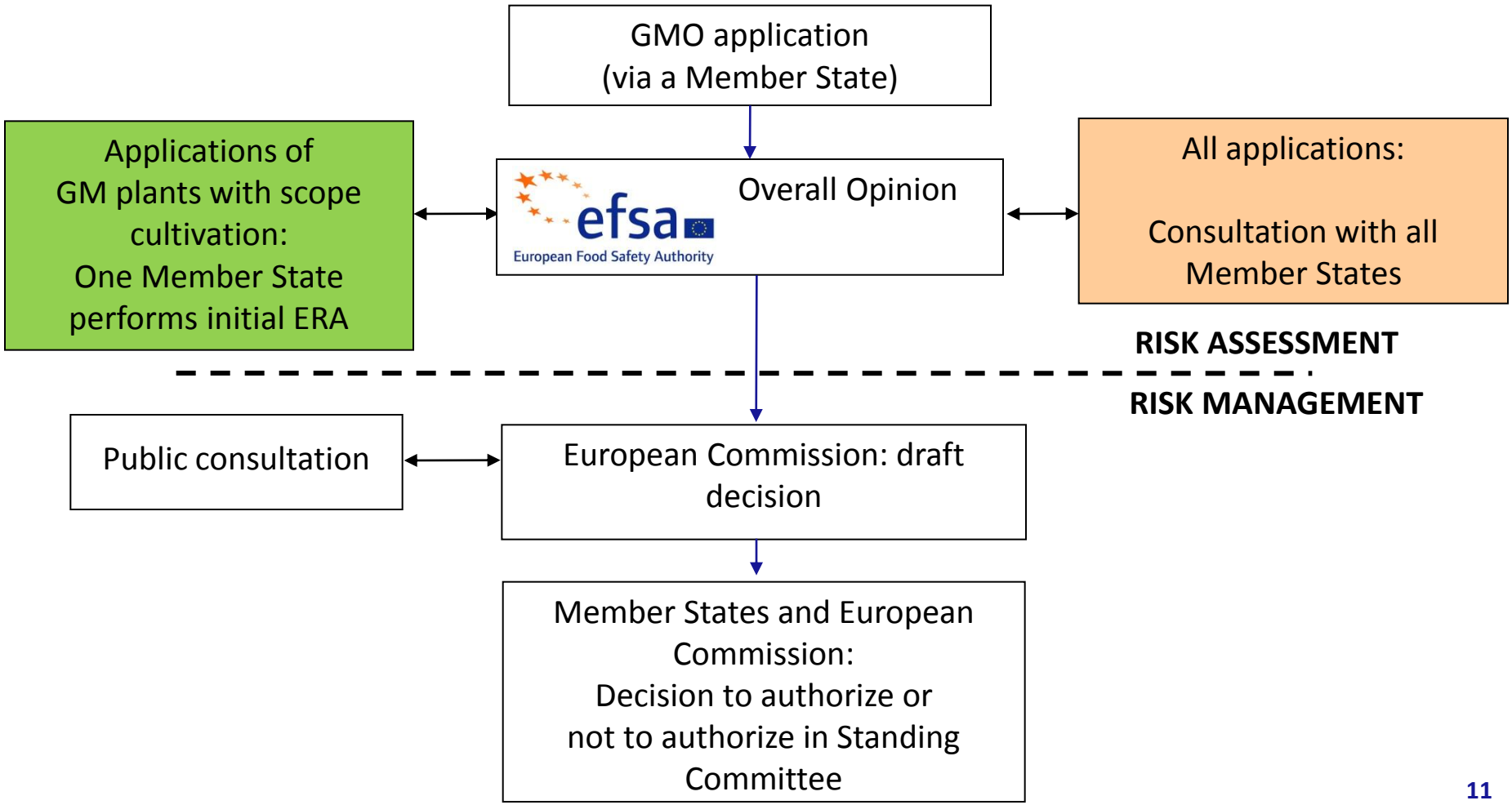
Roles under R. (EC) No 1829/2003: GM food and feed including derived products



Working procedure

When scope includes CULTIVATION

Completeness Check by EFSA staff

Member State

Panel WG on food and feed safety

Panel WG on environmental risk assessment

Panel WG on molecular characterisation

GMO Panel Opinion

CC- check

Risk Assessment by a MS

by the GMO Panel

adopted

efsa
European Food Safety Authority

Risk assessment methodology and principles

- Science-based
- Step-by-step principle (tiered approach)
- Comparative approach
- Case-by-case principle

The Principle Logic

COMPARATIVE APPROACH

Compare the GMO and derived products to their non-GM counterparts

Assessment of the identified differences regarding:

Environmental impact

Food/Feed safety

Nutritional impact

- **Intended effects**: those occurring because of the genetic modification
- **Unintended effects**: additional effects which were NOT the objective of the genetic modification

Food/Feed Risk Assessment of GM Plants

Molecular Characterisation

- Genetic modification
- Characteristics of the GM plant

Food and Feed safety

- Compositional and agronomic assessment
- Toxicological assessment
- Allergenicity assessment
- Nutritional assessment

Environmental Risk Assessment (ERA) of GM plants

European Food Safety Authority

Strategies for ERA of GM plants

Issues to be addressed

1. Persistence and invasiveness
2. Horizontal gene transfer
3. Target organisms (TO)
4. Non-target organisms (NTO)
5. Farming practices
6. Biogeochemical processes
7. Human and animal health
8. PMEM

Outputs: Scientific opinions

	GM Plants Including food/feed use (1829/2003/EC)		GM Plants release into environment (2001/18/EC)	
Year	**Received**	**Finalised**	**Received**	**Finalised**
2003 - 2006	**36**	**9**	**13**	**11**
2007	**38**	**5**	**1**	**-**
2008	**13**	**5**	**-**	**1**
2009	**13**	**18**	**1**	**-**
2010	**13**	**10**	**-**	**1**
2011	**14**	**7**	**-**	**-**
2012	**8**	**7**	**-**	**-**
Jan-Aug 2013	**5**	**6**	**2**	**-**
Total 2003-Aug 2013	**140**	**67 (17 withdrawn)**	**17**	**13 (2 withdrawn)**

Currently finalised: 80 (19 withdrawn) Currently ongoing: 58

EFSA's Guidance Documents

EFSA Guidance documents

- Provide guidance for applicants how to prepare and present the applications
- Detailed guidance needed as only full dossiers are considered
- Based on internationally agreed principles and protocols (Codex Alimentarius, OECD)
- Regularly updated
- Undergo public consultation

Current EFSA's Guidance documents on GMOs

- **Guidance for risk assessment of food and feed from GM plants** (2011)
- **Environmental Risk Assessment (ERA) of GM Plants** (2010)
- **Post Market Environmental Monitoring** – PMEM (2011)
- **Risk assessment of genetically modified microorganisms and their products intended for food and feed use** (2011)
- **Food and feed RA from GM animals and GM animal health and welfare** (2012)
- **Environmental Risk Assessment (ERA) of GM animals** (2013)

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Post Market Environmental Monitoring (PMEM)

European Food Safety Authority

PMEM is compulsory for GMOs approved for cultivation

- To identify the occurrence of adverse effects of GM plants that were **not anticipated** in the ERA (general surveillance)
- To confirm the assumptions of the ERA = to assess whether **anticipated** effects related to cultivation of a GM crop occur (Case-Specific Monitoring)

PMEM reports are submitted by the applicant on a yearly basis

EFSA evaluates these reports since 2010

➢2009 and 2010 PMEM reports on MON810 maize

Cultivated in Czech Republic, Poland, Portugal, Romania, Slovakia and Spain

➢2010 and 2011 PMEM reports on Amflora potato

Cultivated in Czech Republic, Germany and Sweden

EFSA's role in the ERA – PMEM cycle of cultivated GMOs

dossier

EFSA Pre-market risk assessment

Scientific opinion

Member State and EC consent (including PMEM)

10 years of commercial cultivation

Scientific opinion

EFSA reviews annual PMEM report

After 10 years: Renewal dossier (includes annual PMEM reports)

EFSA risk assessment of renewal application

Scientific opinion

Member State and EC consent (including PMEM)

Prolonged cultivation

Safeguard clauses

- National measure (invoked by a MS) aiming at the restriction/prohibition of the use/sale of the GMO on its territory
- After the placing the GMO in question on the market
- On the basis of new scientific data supporting the fact that the GMO constitutes a risk for human health and the environment

Mandates to EFSA:

« … to assess whether the documents provided by the MS comprises new information, such that detailed grounds exist to consider that the GMO in question constitutes a risk to the human and animal health and the environment ».

Scientific opinion

17 Opinions on safeguard clauses raised by 5 Member States on 10 approved GM crops

Task of risk managers to decide

THANK YOU!

QUESTIONS?

GMO Unit

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