



Viten skaps komiteen for mat og miljø

Norwegian Scientific Committee for Food and Environment

**VKM - Norwegian EFSA Focal Point –
Knowledge broker**

Gisle Solstad

Norwegian Scientific Committee for Food and Environment (VKM) – Secretariat

EFSA National Focal Point for Norway

20 May 2022

Setting the scene

Where it started – Several food/feed crises in Europe



Bovine spongiform encephalopathy



Dioxines



Benzene

High speed

THE IRISH TIMES



Fri, Mar 18, 2022

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EU values safety above free trade

Wed, Oct 6, 1999, 01:00

-  Romano Prodi made one of his first policy statements on food safety yesterday in the European Parliament. It may seem surprising that with such issues as
-  East Timor, Kosovo, EU enlargement and the euro in the news, the
-  Commission President chose this issue as one worthy of a major policy statement.

The pre-BSE approach to food law was articulated in the famous Cassis de Dijon court case which enshrined the "mutual recognition" principle whereby, if a food product was marketed in one member-state, it would be given free access to the entire Single Internal Market.

The EU has decided that, in future, enhancing food safety and consumer protection, rather than free movement of goods, is to be the cornerstone of a new EU regulatory regime for foodstuffs.

“The principle of mutual recognition, while preserving local, regional and national traditions, allowed the EU to realise an internal market without having to adopt hundreds of ‘vertical’ directives.¹³ **However, even among European member states, which are relatively similar in terms of regulatory approach, national regulations cannot always ensure equivalent levels of protection.**” (Alemanno, 2010 – see notes in this slide)

«White paper»



(EC) 178/2002

The European response - (EC) 178/2002

- **«EU General Food Law» - Decision on our food safety «model»:**
- **«Risk»** = A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard
- **«Risk analysis»** = A process consisting of three interconnected components: risk assessment, risk management and risk communication
- **«Risk management»** = The process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options
- **«Risk communication»** = The interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings... .

The European response – (EC) 178/2002

- Establishment of the European Food Safety Authority (EFSA):



“The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.”

HEADQUARTERS
in the **heart of Parma**



EFSA



The reference body for risk assessment of food and feed in the European Union. Its work covers the entire food chain – from field to fork

One of the number of bodies that are responsible for food safety in Europe

EFSA

Opprettet
2002



450 ansatte



1500
eksperter



1000 møter/år



5000 publiseringer/
500/år

EFSA – Questions (mandates) and replies (opinions)

- EFSA receives questions (mandates) from the Commission, the Parliament, Member States, and «self mandates»
- EFSA evaluates risks
- EFSA publishes «opinions»
- EFSA (risk) communicates

EFSA - Organisation

- Management Board (EEA-countries are not represented)
- Advisory Forum (Norway is represented by the Director, VKM)
- EFSA national focal points (VKM is the Norwegian Focal Point)
kontaktpunkt)
- Scientific Committee
- Scientific panels: Nutrition, Food Packaging, Food Additives, Chemical Contaminants, Biological Hazards, Animal Health & Welfare, Animal Feed, GMO, Plant Protection, Plant Health = 10 panels (there are Norwegian members of EFSA's panels and working groups.)
- Staff/employees (Norwegians can work in EFSA)

Norwegian Scientific Committee for Food and Environment (VKM)



- From food safety scandals to one food law and one Food Safety Authority
- Holistic approach and distinction between science (risk assessment) and decision making (risk management)
- Safe food and the population's TRUST in safe food: Main drivers

VKM's remit – Food and environment: Cross-disciplinary interaction

- VKM carries out cross-disciplinary risk assessment within the food and environmental areas. Mandates from the Norwegian Food Safety Authority and the Norwegian Environment Agency - Two «clients» – Shared responsibility across different sectoral regulations



- VKM is the Norwegian Focal Point for EFSA and has a seat in the EFSA Advisory Forum
- VKM is the Norwegian CITES Scientific Authority (CITES SA)

VKM - EFSA



VKM as Focal point

Advisory Forum

Focal Point

Communication Expert Network

Deltagelse i faglige nettverk i
EFSA



VKM's role as Focal Point

EFSA Focal Points: a decade of networking for European food safety



For the past 10 years EFSA's Focal Points have been acting as ambassadors in EU Member States and operating as a network of cross-border collaboration on food safety. To mark the occasion, a new interactive timeline highlights the key achievements of the network.

Established in 2008, the [Focal Point network](#) comprises members from all 28 EU Member States, Iceland and Norway, as well as observers from Switzerland and pre-accession countries. It promotes information exchange, networking and engagement,

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Hjem / Om EFSA

EFSA's kontaktpunkt i Norge

EFSA, den europeiske myndighet for næringsmiddeltrygghet, skal bidra til å bedre mattryggheten, beskytte forbrukerne og bevare tilitten til EU-landenes matvareproduksjon.

Som kontaktpunkt skal VKM fremme utveksling av informasjon og kunnskap mellom EFSA og medlemslandene og bidra i fellesprosjekter. I tillegg skal VKM arbeide for å synliggjøre EFSA's arbeid i Norge.

EFSA gjør risikovurderinger og gir råd til EU-kommisjonen, EU-parlamentet og medlemslandene.

[Mer om EFSA](#)

Kontakt

**Gisle Solstad**
Administrasjonssjef og
ansvarlig for EFSA-kontakten
M: 98 36 72 86
[Send e-post](#)

**Ingrid Margretha**
Kommunikasjonssjef
M: 97 02 16 58
[Send e-post](#)

Siste fra EFSA

20.01.2023

► Saker kandidater til stipendprogrammet EU-FORA

12.12.2019

► Salmonella forårsaker flest matbårne sykdommer i EU-land

[Alle meldinger fra EFSA](#)

Søk etter innspill til EFSA

EFSA ber med jevne mellomrom om innspill til arbeidet med retningslinjer for risikovurderingsarbeidet, konkrete risikovurderinger av stor politisk eller faglig betydning eller en annen type uttalelse.



EFSA's nettverk

EFSA har opprettet nettverk som arbeider og bidrar til faglig sam

Gisle Solstad, who represents the Focal Point at the Norwegian Scientific Committee for Food and Environment (VKM), added: "Working as a Focal Point representative provides a rewarding and positive opportunity for a multidimensional and multicultural approach to strategic work and capacity building, with the aim of enhancing food safety for consumers across Europe."

Key achievements

To mark the 10-year anniversary, a new [interactive timeline](#) highlights the milestones

VKM's role as Focal Point

- Exchange of information
- Sharing of expertise
- Data sharing
- Promote harmonisation
- Participation in the Focal Point Network (together with all MS, potential MS, and observer countries)
- Assist EFSA in the development of networks
- Identify and assist art.36 institutions.

New role as of 2019

- Advise Norwegian stakeholders on application procedures for regulated products:
- EFSA is registering about 500 mandates
- Governed by about 34 different directives and regulations
- Following 39 workflows

Regulated products – Novel food and traditional food

.. ..



Biological hazard applications: overview and procedure

Animal by-product treatments, decontamination substances.



Feed additive applications: overview and procedure

Additives and products or substances used in animal feed.



Food contact material applications: overview and procedure

Materials, plastic recycling processes, active and intelligent substances.



Food improvement agents applications: overview and procedure

Food additives, food enzymes and flavourings, smoke flavourings.



GMO applications: overview and procedure

GMOs for use as food or feed and/or for cultivation.



Novel food and traditional food applications: overview and procedure

Novel foods and food ingredients, traditional food.



Nutrition applications: overview and procedure

Health claims, novel foods, infant formulae, food allergies, nutrient sources.



Pesticide evaluations: overview and procedure

Active substances, maximum residue levels.

Where to start?

- The Competent Authority in Norway is the Norwegian Food Safety Authority (NFSA)

A screenshot of the Mattilsynet website. The header includes the Mattilsynet logo, the text "Statens tilsyn for planter, fisk, dyr og næringsmidler", a "VARSLE OSS" button, and a search bar. A navigation bar below the header lists categories: MAT OG VANN, DYR OG DYREHOLD, FISK OG AKVAKULTUR, PLANTER OG DYRKING, KOSMETIKK, and OM MATTILSYNET. The main content area is titled "Ny mat" and includes a publication date (02.12.2019), a last updated date (03.05.2021), and a "Skriv ut" button. The text explains that "Ny mat" refers to food products not previously used in Norway or other EFTA countries, including EU products from May 15, 1997. It provides examples of new food products like isolated phospholipids and UV-irradiated food products. It also mentions that new food products must be approved by the EU Commission and included in the union list. The page includes a "Innhold på siden" (Table of contents) section with links to "Regelverk og veiledning", "Regelverk under utvikling", "Kontakt oss", and "Relaterte kunngjøringer". A "Denne siden hører til under" (This page belongs to) section lists "Produksjon av mat" and "Mat og vann". The footer includes a "Mer om ny mat" link.

EFSA – Detailed guidelines



English **EN**

TECHNICAL REPORT

APPROVED: 15 February 2021

IMPLEMENTATION DATE: **27 March 2021**

doi:10.2903/sp.efsa.2021.EN-6471

TECHNICAL REPORT

APPROVED: 15 February 2021

IMPLEMENTATION DATE: **27 March 2021**

doi:10.2903/sp.efsa.2021.EN-6472

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Administrative guidance for applications for

EF

EFSA's Catalogue of applications for

Novel food applications: regulations and guidance

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check they are using the latest version before applying.

Abstract

EFSA is continuously striving to enhancing a customer-oriented approach to products life-cycle. EFSA is registered on a yearly basis governed by more workflows. In this context, EFSA processes applications for regulated products to ensure that a coherent, sound and consistent approach is taken in each sectoral legislation.

This administrative guidance for the general workflow of applications, of suspension/extension of the assessment process, the publication by the General Food Law in the submission advice by EFSA, specific intended studies, including their submission advice by EFSA, not non-confidentiality decision-making requirements, as implemented by 27 March 2021.

This administrative guidance applies to the re-evaluation of food additives for submitting additional/supplementary

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Key words: Applicants, applications, assessment, scientific outputs, workflows

Abstract

As part of EFSA's ongoing work of its scientific risk assessment in the area of application: responsive evaluation process support initiatives targeted cycle of applications for regulated products (phase) to the adoption and includes the nature and the format, the unit in charge, type of outcome expected describing the details of evaluation and especially encourage applications by March 2021.

The Catalogue includes the introduction by the Transparency acts, as new possibilities enterprises are also introduced

© European Food Safety Authority

Key words: Applicants, scientific

Novel foods

Regulatory framework

- [Regulation 2017/2469 on administrative and scientific requirements for novel foods applications](#)
- [Regulation 2017/2468 on administrative and scientific requirements concerning traditional foods from third countries](#)
- [Regulation 2017/2470 on establishing the Union list of novel foods](#)
- [Regulation 258/1997 concerning novel foods and novel food ingredients](#)
- [Regulation 2015/2283 on novel foods](#)
- [Regulation 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information](#)

Administrative guidance and support initiatives

Applicable to applications submitted as of 27 March 2021

- [Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation \(EU\) 2015/2283](#)
- [Administrative guidance for the processing of applications for regulated products](#) (update 2021)
- [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#) (update 2021)

Applicable to applications submitted until 26 March 2021

- [Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation EU 2015/2283](#)
- [Administrative guidance for the processing of applications for regulated products](#)
- [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)

EFSA – Detailed guidelines

Applications helpdesk –

Novel foods application procedure as of 1 January 2018

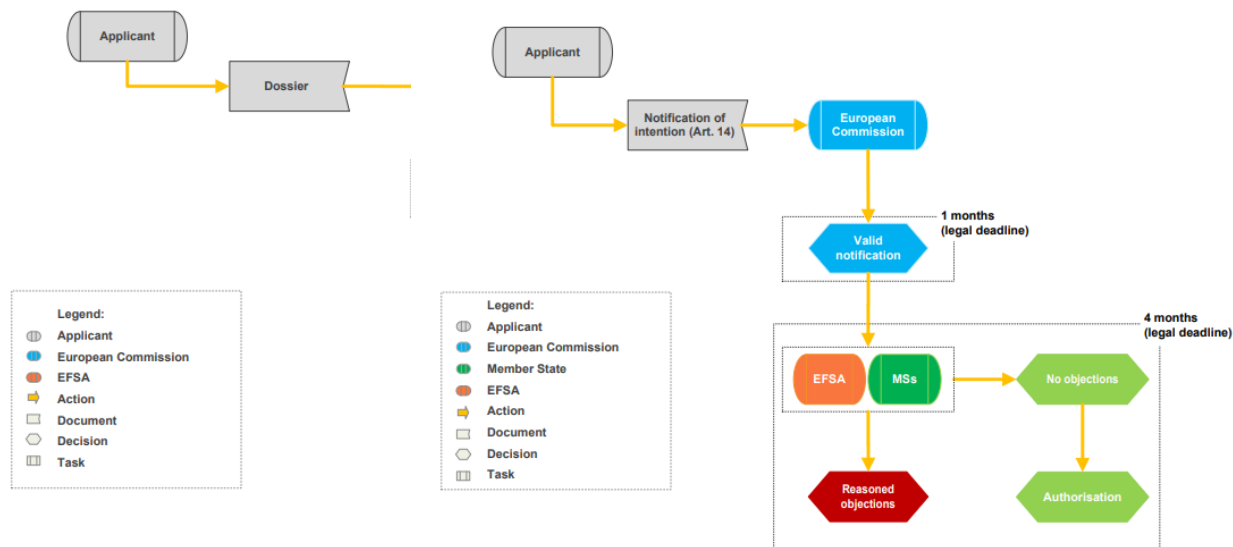
Authorisation and use of novel foods and food ingredients has been regulated since 1997 when Regulation EC 258/1997 on novel foods and novel ingredients was adopted. In 2015, the Commission presented a proposal for a new regulation on the matter. They have reached an agreement with the new Regulation EU 2015/2283. A novel food should submit an application to the European Commission available to the Member States and mandate EFSA for a scientific opinion within nine months from the date of receipt of a valid application on 1 January 2018.

Applications helpdesk –

Traditional food notification/application procedure as of 1 January 2018

An applicant who intends to place on the EU market a traditional food from a third country, may opt to submit a notification of that intention to the European Commission (Article 14). In this event and after having verified its validity, the Commission shall forward the notification to the Member States and to EFSA. Within four months from this date the Member State or the Authority may submit to the EC duly reasoned safety objections to the placing on the market of the traditional food concerned. If duly reasoned safety objections have been submitted to the Commission the traditional food concerned shall not be authorised for its placing on the market (Article 15). In that case, the applicant may submit an application to the Commission including the documented data relating to the safety objections raised (Article 16). EFSA will issue an opinion within 6 months from receipt of a valid application. Such procedure shall apply as of 1 January 2018.

Regulation EU 2015/2283



EFSA channel on YouTube

The screenshot shows the YouTube interface for the EFSA channel. At the top, the YouTube logo and a search bar are visible. The video player displays a webinar titled "Webinar on application procedure for novel food" dated "23 September 2021" and "APDESK webinars". The video thumbnail features a collage of food items (tomatoes, green beans, a cow) and a molecular structure. The EFSA logo and the tagline "Trusted science for safe food" are also present. A "Play (k)" button is visible in the bottom left of the video player. Below the video player, the video title "Webinar: novel food applications" is shown, along with the view count "1,060 views Sep 30, 2021" and a description snippet. The channel name "EFSASchannel" and subscriber count "18.1K subscribers" are displayed, along with a "SUBSCRIBE" button. The comments section shows "6" likes, "Dislike", "Share", "Download", "Clip", "Save", and a "Comments" tab with an "Add a comment..." input field.

YouTube NO

Search

23 September 2021
APDESK webinars

Webinar on application
procedure for novel food

Trusted science for safe food

efsa
European Food Safety Authority

Play (k)

0:01 / 1:25:55

#webinar #Transparency #EFSA

Webinar: novel food applications

1,060 views Sep 30, 2021 The third #webinar in this series provided participants with a comprehensive explanation of the new requirements for novel food applications th...more

efsa EFSASchannel
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Add a comment...

VKM – Also a starting point for information

Reviderte rutiner som følge av «Åpenhetsforordningen»

EUs nye forordning om åpenhet (åpenhetsforordningen), innebærer blant annet at de som søker om godkjenning av regulerte produkter må følge reviderte rutiner. Forordningen gjelder fra 27. mars 2021.

Forordningen skal styrke påliteligheten, objektiviteten og uavhengigheten til vitenskapelige studier som EFSA legger til grunn i sine vurderinger, og styrke styringen av EFSA. Du kan lese mer om bakgrunnen for åpenhetsforordningen på EU-kommisjonens [nettsider](#).

Verktøy og nettportal

EFSA har utviklet nye verktøy og en nettportal for å hjelpe berørte parter til å sette seg inn i og lære om hvordan de nye reglene som følger av «åpenhetsforordningen» vil fungere i praksis.

Verktøyene omhandler åpenhet, konfidensialitet, varsling av vitenskapelige studier, rådgivning før innsendelse av søknader, og høringer. De er utarbeidet i samråd med EFSA's berørte parter, EU-kommisjonen og medlemslandene. De er først og fremst rettet mot EFSA's berørte parter, for eksempel søkere som vil ha matvarer på det europeiske markedet.

- Du finner oversikt over verktøyene på EFSA's nettsider [her](#).
- Du finner verktøy for tilgang til dokumenter på EFSA's nettsider [her](#).
- Du finner EFSA's nettportal for åpenhetsforordningen på EFSA's nettsider [her](#).

Reviderte rutiner for søknader vedr. regulerte produkter

EFSA har også utarbeidet reviderte rutiner for søknadsprosesser for regulerte produkter.

- Du finner oversikt over disse, og prosesser for søknader innenfor grupper av regulerte produkter på EFSA's nettsider ([EFSA Application Helpdesk](#)).

Opplæringsprogram for berørte parter

EFSA og EU-kommisjonen har utviklet en serie webinarer og opplæringsprogrammer (video) for å sikre en god overgang.

- Du finner oversikt over webinarer og opplæringsprogrammer på EFSA's nettsider [her](#).

Hva kan VKM hjelpe deg med?

Som nasjonalt kontaktpunkt for EFSA kan VKM bistå med informasjon om åpenhetsforordningen og de praktiske endringene denne medfører for berørte parter, også for søkere av regulerte produkter. VKM er ikke kompetent nasjonal myndighet når det gjelder regulerte produkter, men kan gi råd om søknadsprosessene, og om hvem som er riktige kontaktpersoner i EFSA og Mattilsynet.

Kontakt



Gisle Solstad

Administrasjonssjef og ansvarlig for driften av EFSA's kontaktpunkt i Norge

M: [98 36 72 86](tel:98367286)

[Send e-post](#)

Relaterte lenker:

- ▶ [Transparency and sustainability of the EU risk assessment in the food chain](#)
- ▶ [Transparency Regulation and stakeholder engagement](#)
- ▶ [Transparency Regulation: Practical Arrangements](#)
- ▶ [Processing of applications for access to documents](#)
- ▶ [Applications helpdesk](#)
- ▶ [Transparency Regulation Implementation Training Programme](#)

More about EFSA and/or VKM?

- Get in touch!

Kontakt



Gisle Solstad

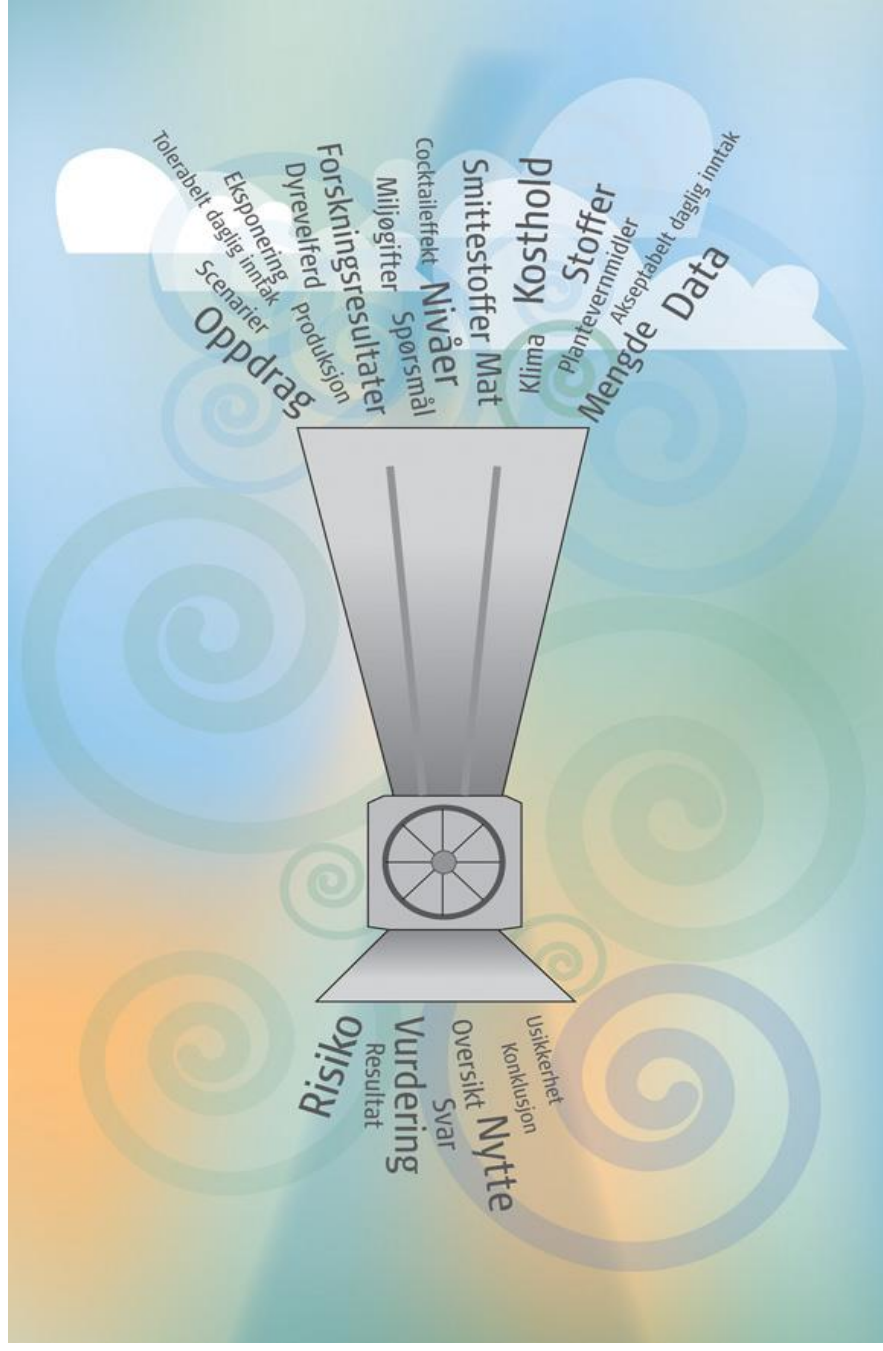
*Administrasjonssjef og ansvarlig for driften av
EFSA's kontaktpunkt i Norge*

M: 98 36 72 86

[Send e-post](#)

- Or get in touch with your own [national EFSA Focal Point](#)

Questions?



Thank you for your attention!

