



Federal Office of
Consumer Protection
and Food Safety

#20JahreBVL



Identify Risks –
Protect Health



AGES



Classification of other substances – the D-A-CH-lists of substances and other lists on the national level

DI Klaus Riediger

Austrian Agency for Health and Food Safety (AGES), AT

BfR-BVL Joint Meeting: "Super(?)foods and Supplements – Risky or Healthy?"

BfR, Berlin-Marienfelde, 30.06.2022

Disclaimer



„Meine Bemerkungen sind nicht zwangsläufig die offizielle Meinung der AGES bzw. Österreichs“

“My remarks do not necessarily reflect the official view of AGES or Austria”

Novel Food AGES



- Division for Food Safety, Institute for Food Safety Vienna, Department for Foods: Food Supplements and Novel Foods
- Division of Integrative Risk Assessment, Data & Statistics (DSR), Department of Risk Assessment

DACH Lists: Member for AT



Die Mitglieder der AG Stoffliste (Stand 12/2019) von hinten links nach vorne rechts: N. Bakhiya, N. Schramek, T. Böhm, K. Riediger, V. Lander, U. Kürzdörfer, G. Kesseler, B. Schlagintweit, B. Dessloch, C. Struck, R. Maslo, C. Bendadani, S. Urmersbach, U. Deiss, S. Till, I. Krisai-Greilhuber, C. Griehl, M. Meier
Quelle: Breitweg-Lehmann / BVL

Overview



- Specificities of botanicals (+example CHIA)
- Legal background: Botanicals- „OTHER SUBSTANCES“: Not harmonized on EU level
- Legal background: Article 8 and Annex III of Regulation (EC) No. 1925/2006
- Legal background: General aspects to use the D-A-CH lists of substances
- D-A-CH Lists of substances: History, Classification of substances, Decision Tree
- D-A-CH Lists of substances 2nd + 3rd edition: Plants + Mushrooms (Fungi) + Algae
- Overview of lists on botanicals available in the Member States
- Annex

Specificities of botanicals

a) different varieties / cultivars / geographical areas	<ul style="list-style-type: none">• different levels of substances
b) different plant parts	<ul style="list-style-type: none">• different phytochemical composition
c) phytochemical compounds	<ul style="list-style-type: none">• a huge difference in hydrophilic or lipophilic character
d) many different types of extraction	<ul style="list-style-type: none">• plant preparation process ⇒ different extraction time ⇒ different phytochemical content
e) very few clinical studies	<ul style="list-style-type: none">• mostly on purified components
f) substances responsible for adverse / positive effect	<ul style="list-style-type: none">• often not known

Chia (*Salvia hispanica* L.) (NF)

Chia seeds, -oil, -protein authorized, Chia sprouts and leaves are not



Novel Food Unionlist entries

Very exotic- Austrian cultivation- seeds difficult to obtain due to climate difference. Chia sprouts and chia plants (sage-like in taste) would only be permitted after a novel food approval. Not traditionally used in South America. Antinutritives to protect the plant are possible.



Legal background 1



Botanicals- „OTHER SUBSTANCES“: Not harmonized on EU level.

- ☞ The addition of vitamins and minerals to foods, including Food Supplements is regulated, but there is no centralized EU assessment for botanical products (“Other Substances”). Many +/- lists from MS for botanicals. → no real harmonization!
- ☞ Some botanicals are considered as traditional herbal medicinal plants and are used both in medicinal products and in food supplements. The European Medicines Agency (EMA) is responsible for assessing both the safety and efficacy of herbal preparations when used as medicines. It is not the role of EFSA or EMA to determine the classification of a botanical as a medicine or a food supplement- this is in the task of the MS → no harmonization!
- ☞ Health-claims: EFSA is responsible for assessing the level of evidence for efficacy. No safety assessment (→ most are “on hold”)
- ☞ General food law applies in particular to Regulation (EC) No. 178/2002, Novel Food Regulation (EU) 2015/2283.

Legal background 2

Article 8 and Annex III of Regulation (EC) No. 1925/2006 I



L 404/26

EN

Official Journal of the European Union

30.12.2006

REGULATION (EC) No 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

on the addition of vitamins and minerals and of certain other substances to foods

L 404/38

EN

Official Journal of the European Union

30.12.2006

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

No specific legal rules apply to the addition of “certain other substances” including botanical substances apart from a few exceptions in Annex III of Regulation (EC) No. 1925/2006

Legal background 3

Article 8 and Annex III of Regulation (EC) No. 1925/2006 II- EFSA risk assessment → COM

COMMISSION REGULATION (EU) 2015/403

of 11 March 2015

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards *Ephedra* species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

(Text with EEA relevance)

Article 1

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

(1) in Part A, the following entry is added:

'*Ephedra* herb and its preparations originating from *Ephedra* species';

(2) in Part C, the following entry is added:

'Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)'.

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

COMMISSION REGULATION (EU)
2019/650 of 24 April 2019:
Yohimbe bark → Part A!

▼B

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

▼M10

Aloe-emodin and all preparations in which this substance is present

Danthron and all preparations in which this substance is present

Emodin and all preparations in which this substance is present

▼M6

Ephedra herb and its preparations originating from *Ephedra* species

▼M10

Preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives

▼M9

Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

▼M8

PART B

Restricted substances

Restricted substance	Conditions of use	Additional requirements
Trans fat other than trans fat naturally occurring in fat of animal origin	Maximum 2 grams per 100 grams of fat in food intended for the final consumer and food intended for supply to retail	Food business operators supplying other food business operators with food not intended for the final consumer or not intended for supply to retail, shall ensure that supplied food business operators are provided with information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat.

▼B

Part C — Substances under Community scrutiny

▼M10

Preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives

Preparations from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives

Preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives

▼M9

Legal background 4

General aspects to use the D-A-CH lists of substances



- Necessary **case-by-case classification** for each individual substance or for each individual product.
- **Primary legal responsibility** lies with the food business operator, Article 17 of Regulation (EC) No. 178/2002.
- Creation of the **D-A-CH lists of substances** as a **non-legally binding guide** to the classification of substances and their use in food. Deviations from classifications in the lists must be well justified by the food business operator.

D-A-CH Lists of substances 1 - History

<https://www.bvl.bund.de/stofflisten>

- **Published 2014**
 - **Classification**
 - of about 590 plants and plant parts
 - according to Regulation (EC) No 1925/2006
 - based on a decision tree
 - Comprehensive national Working group: BfR, BfArM, BVL, Federal State Authorities – Chair: BVL
 - **Not legally binding**
 - **Applicable for FS and fortified foods**
- Free access www.bvl.bund.de/stoffliste_eng



- Update of the relevant monographs
- Inclusion of fungi (2nd list) and algae (draft 3rd list)
- Reconciliation with plant lists of other MS e.g. Belgium, France and Italy ("BELFRIT") ("MUTUAL RECOGNITION" if possible)

Adopted
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Review: Publications of the Substance List working group

2014: Publication of the **1. List „Category Plants and Plantparts“**

591 Entries, (german) Federal and state authorities

01/2020: Drafts of the **2. edition of the foreword** and the **„List of Plants“** and the new **„List of Fungi“** for comment

New: Experts from DE, AT und CH

10/2020: Publication of the **foreword** and the **Lists**

Entries for 870 Plants und 280 Fungi

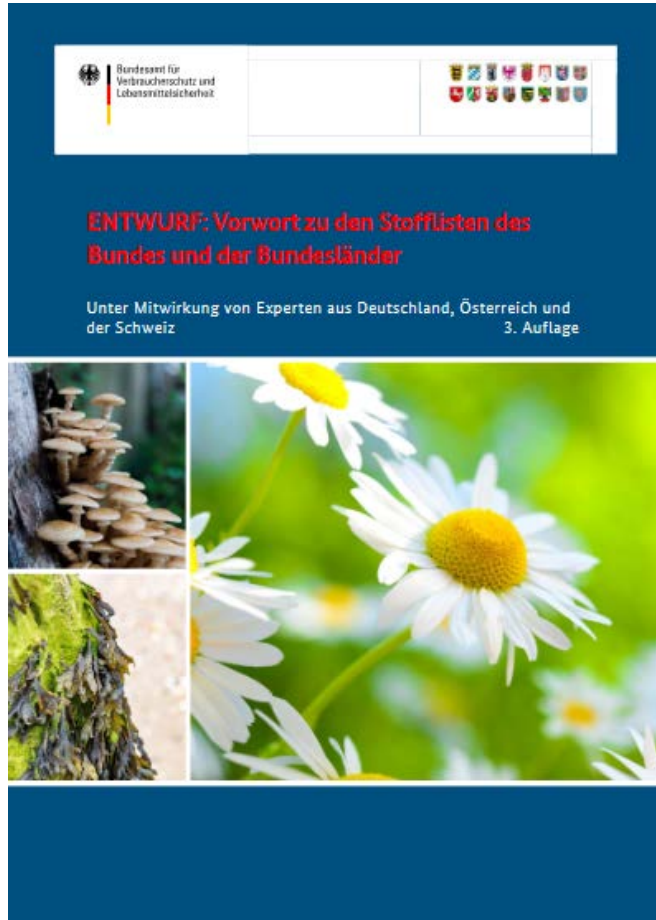


© BVL

D-A-CH Lists of substances 2

3rd edition.: Plants + Mushrooms (Fungi) + **Algae**

<https://www.bvl.bund.de/stofflisten>



The working group (WG) "**D-A-CH Lists of substances**" currently consists of **German** representatives of the responsible federal authorities (BVL, BfR, BfArM) and German representatives of the test centers of the federal states. Two representatives each from **Austria** and **Switzerland** have also joined the WG, so that work is being done on standardizing the assessment of substances in **German-speaking countries**. Of course, small deviations in Austria and Switzerland are possible (e.g. classification of medicines + novel food for CH) **External experts from the respective specialist areas** have also joined the working group as members.

Parallel to the list of **plants and mushrooms (fungi)**, the working group on the list of substances has now also drawn up a positive list in 2022 for **algae (1st edition)** based on the same decision tree.

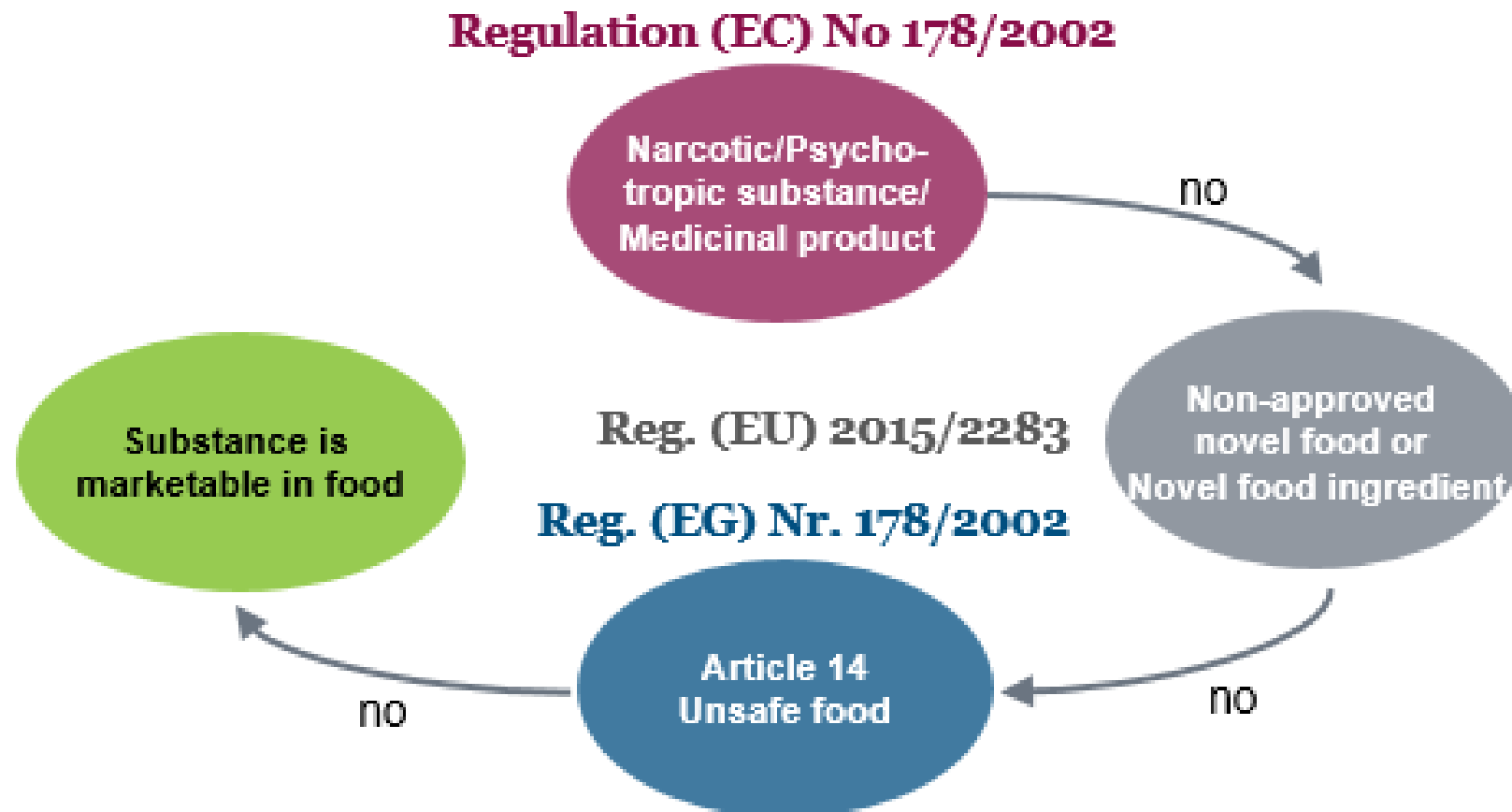
Finden Sie mehr heraus



D-A-CH Lists of substances 3

Classification of substances

According to an exclusion principle

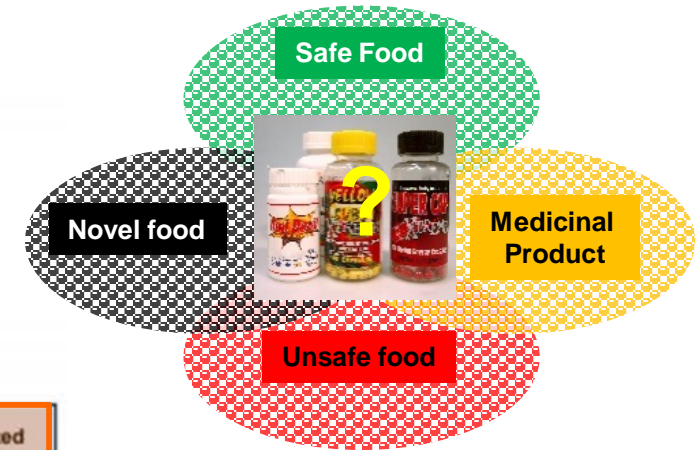
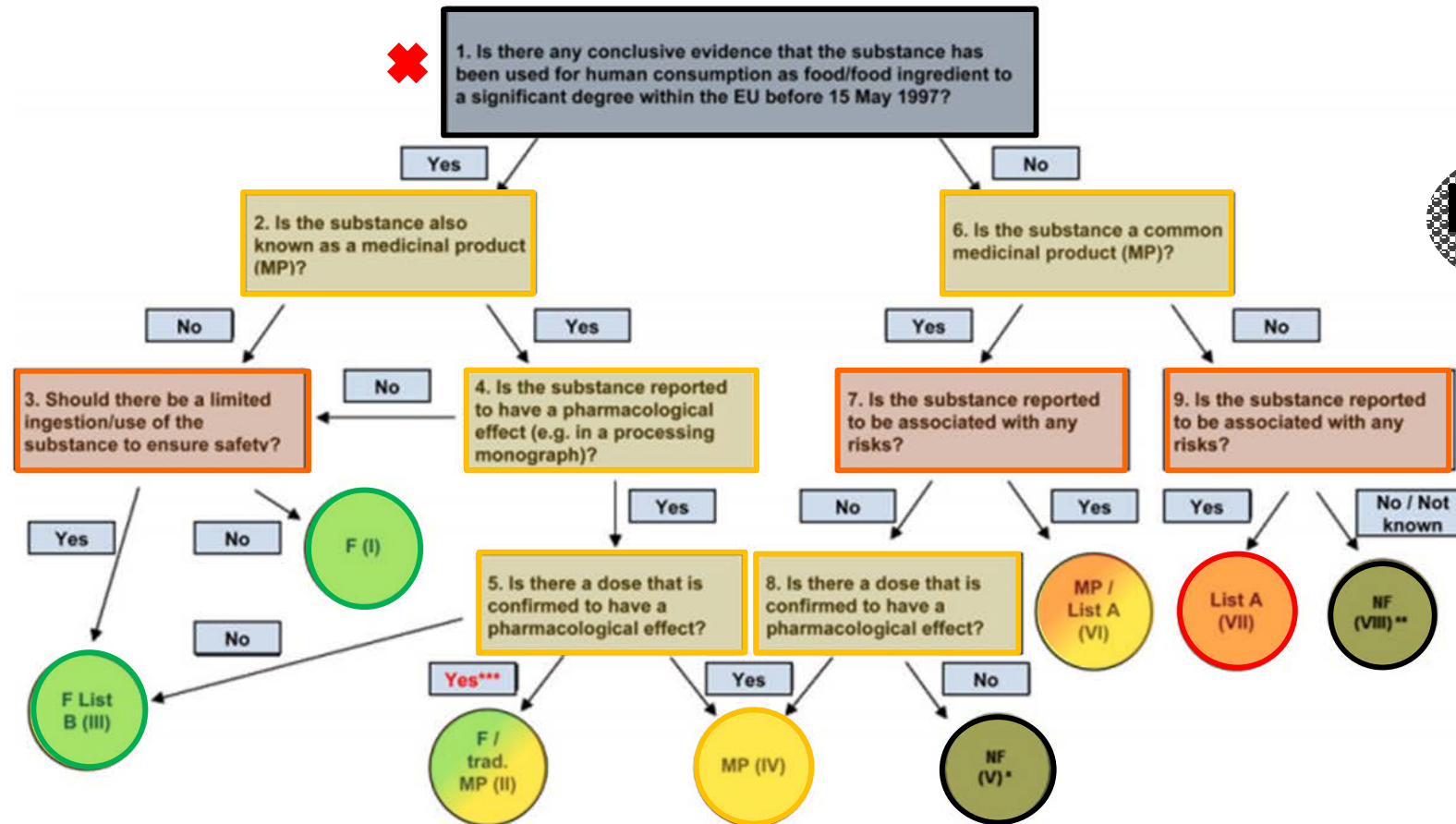


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D-A-CH Lists of substances 4

Decision Tree

✘ According to Art. 2 letter g of the general food law, it must be ruled out that a narcotic or a psychotropic substance is present (supplement 2nd edition)



Adopted,
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Figure 1 Decision tree

* Assessment of potential use as food/food ingredient according to the Novel Food Regulation (If the substance is classified as not novel in food supplements [Not NFS], it may need to be placed on List B.)

** Assessment of potential use as food/food ingredient according to the Novel Food Regulation (If the substance is classified as not novel in food supplements [Not NFS], it may need to be placed on List C.)

*** See No. 3 of the explanatory notes

Abbreviations: F = food, MP = medicinal product, trad. MP = traditional medicinal product, NF = novel food/novel food ingredient, FS = food supplement

D-A-CH Lists of substances 5

Classification

Possible categorisations



Food (F)	Novel Food (NF)/ Not NFS	Medicinal product (MP)/ (Trad. MP)
Use without restrictions	Authorisation can be required	MP with restrictions on use Traditional MP (additional information)
<i>Aronia melanocarpa</i> (black chokeberry: fruit) <i>Avena sativa</i> (oat: fruit)	<u>Not NFS:</u> <i>Melaleuca alternifolia</i> (Tea tree: leaf) <u>NF:</u> <i>Rubus fruticosus</i> (blackberry: root), <i>Rubus glaucus</i> (Andean raspberry: fruit)	<u>MP:</u> <i>Urtica dioica</i> (stinging nettle: root) <u>Trad. MP:</u> <i>Matricaria chamomilla</i> (camomile: flower)

Adopted
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D-A-CH Lists of substances 6

Further Classification



Sub-lists (referring to Annex III of Regulation (EU) NO 1925/2006)

List A	List B	List C
Use as food / food ingredient is not recommended	Limited use as food/ food ingredient recommended	Final assessment not possible because of missing data
<i>Aethusa cynapium</i> (fool`s parsley: all plant parts) <i>Kalmia latifolia</i> (laurel rose: leaves)	<u>Adverse effects on health:</u> <i>Borago officinalis</i> L. (borage: semen, herb) <u>Therapeutic effect:</u> <i>Boswellia serrata</i> (Indian frankincense: resin)	<i>Vaccinium myrtillus</i> (blueberry: leave) NOT NFS <i>Sedum roseum</i> (= <i>Rhodiola rosea</i>) (rose root: herb)

Adopted
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D-A-CH Lists of substances 7

Classification as food

Source of information:

- national standard literature on toxicocology
- EFSA compendium of botanicals

Further classification: (English (German))

- **F (A)**: Known as a flavouring
- **S (G)**: Known for use as a spice
- **C (S)**: Known for use as a colouring agent (herbal infusions- “Schmuckdroge”)
- **T (T)**: Known for use as a tea (herbal infusion)
- **FS (NEM)**: use in or as FS according to a notified positive list of an MS

→ Any other use, e.g. in higher doses, can lead to effects that may require a different classification

Stock plant (Latin)	<i>Alcea rosea</i> L.
Stock plant (English)	hollyhock
Plant part	flower
F	x T, FS
NF	
MP	
trad. MP	
List A	
List B	
List C	
Remarks	
Risks	
Therapeutically effective dose	



D-A-CH Lists of substances 8

Members



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- Frau Dr. S. Urmersbach – Vorsitzende
- Frau Dr. C. Bendadani – (frühere) Vorsitzende, derzeit abgeordnet
- Frau M. Meier
- Herr M. Paul

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- Herr Dr. N. Schramek (Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Oberschleißheim)

Mitglieder der amtlichen Lebensmitteluntersuchungseinrichtungen der Länder

- Herr T. Böhm (Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen, Chemnitz)
- Frau Dr. B. Dessloch (Landesamt für Verbraucherschutz, Saarbrücken)
- Frau U. Kürzdörfer, bis Dezember 2021 (Chemisches und Veterinäruntersuchungsamt Rhein-Ruhr-Wupper, Krefeld)
- Frau Dr. V. Lander (Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Oberschleißheim)
- Frau K. Steigerwald (Chemisches und Veterinäruntersuchungsamt Rhein-Ruhr-Wupper, Krefeld)
- Herr C. Struck (Chemisches und Veterinäruntersuchungsamt Münsterland-Emscher-Lippe, Münster)

D-A-CH Lists of substances 9

External experts for Plants + Mushrooms (fungi) + Algae



Behördenexterne Mitglieder

- Frau Prof. Dr. C. Griehl (Leiterin des Kompetenzzentrums Algenbiotechnologie und Direktorin des Life Science Centers, Hochschule Anhalt)
- Herr Dr. C. Hahn (Bayerische Mykologische Gesellschaft, Dießen am Ammersee)
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- Frau Prof. i.R. Mag. Dr. S. Till (Department für Ernährungswissenschaften, Universität Wien)
- Herr Prof. Dr. S. Wölfl (Institut für Pharmazie und Molekulare Biotechnologie - Pharmazeutische Biologie, Pharmazeutische Bioanalytik und Molekulare Zellbiologie, Universität Heidelberg)



D-A-CH Lists of substances 10

Foreword 3rd edition + Algae list 1st edition - 1



Aktuelle Dokumente

- ↓ Sammlung der erforderlichen Änderungen an einzelnen Einträgen, Dezember 2021 (PDF, 6, Deutsch)
- ↓ Vorwort der 2. Auflage der Stofflisten des Bundes und der Bundesländer, Oktober 2020
- ↓ Pflanzenliste - Einträge A-K, 2. Auflage, Oktober 2020
- ↓ Pflanzenliste - Einträge L-Z, 2. Auflage, Oktober 2020
- ↓ Pilzliste, 1. Auflage, Oktober 2020

Ältere Versionen

- ↓ Erste Auflage der Stofflisten des Bundes und der Bundesländer, 2014 (PDF, 8MB, nicht barr)
- ↓ List of Substances of the Competent Federal Government and Federal State Authorities, 1st edition, 2014 (PDF, 9MB, nicht barrierefrei); Englisch)

Bitte richten Sie Ihre Kommentare **ausschließlich elektronisch** und wenn möglich in maschinell lesbarer Form bis zum **13. April 2022** an:

Die AG Stoffliste: stoffliste@bvl.bund.de

Aktuell werden die folgenden Entwürfe zur Kommentierung bereitgestellt:

- ↓ [3. Auflage des Vorworts der Stofflisten](#)
- ↓ [Algenliste](#)



02/2022:
Drafts of the
3rd edition of
the foreword
and the new
"algae list"
for comment

Finden Sie mehr heraus

→ VERÖFFENTLICHUNGEN DER AG STOFFLISTE

→ INFORMATIONEN ZUR VERWENDUNG DER STOFFLISTEN

→ RECHTLICHE GRUNDLAGEN UND HINTERGRUNDINFORMATIONEN

→ MITGLIEDER UND SITZUNGEN DER AG STOFFLISTE

→ AKTUELLE MELDUNGEN DER AG STOFFLISTE

→ KOMMENTIERUNG VON ENTWÜRFEN

→ STOFFLISTEN DES BUNDES UND DER BUNDESLÄNDER



D-A-CH Lists of substances 11 - Algae list 1st edition - 2

https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/07_Stofflisten/Kommentieren/2022-Kommentierung-Algenliste.html?nn=13520846

List of algae with 61 entries!



	A	D
1	Alge (lateinisch)	<i>Aphanizomenon flos-aquae</i> Ralfs ex Bornet & Flahault
2	Ihr Kommentar	
3	Synonyme	<i>Byssus flos-aquae</i> Linnaeus, <i>Conferva flosaquae</i> (Linnaeus) Roth, <i>Oscillatoria flosaquae</i> (Linnaeus) C.Agardh, <i>Nostoc flosaquae</i> (Linnaeus) Lyngbye, <i>Nostoc papyraceum</i> S.F.Gray, <i>Sphaerozyga flosaquae</i> (Linnaeus) Corda, <i>Limnochlide flosaquae</i> (Linnaeus) Kützing, <i>Trichormus flosaquae</i> (Linnaeus) Ralfs, <i>Micraloa flosaquae</i> (Linnaeus) Trevisan, <i>Aphanizomenon cyaneum</i> Ralfs ex Bornet & Flahault, <i>Aphanizomenon holtsaticum</i> Richter, <i>Aphanizomenon americanum</i> E.G.Reinhard
4	Alge (deutsch)	Grüne Spanalge
5	Größenordnung	Mikroalge
6	Großgruppe	Blaualge
7	LM	x
8	NF	
9	AS	

10	trad. AM	
11	Liste A	
12	Liste B	x
13	Liste C	
14	Anmerkungen	Die Alge <i>Aphanizomenon flos-aquae</i> darf höchstens 2 Mikrogramm Microcystine pro Tagesration für Erwachsene enthalten, berechnet als Microcystin-LR (µg/l) in der Trockenmasse.
16	Risiken	
16	kritische Inhaltsstoffe	Microcystine, Toxine
17	Therapeutisch wirksame Dosierung	

Identification of relevant algae:

- Lists from BE, FR, CH
- CEN/TC 454 Norm: Algae and algae products
- Draft of JRC List (with IT)
- NF- Unionlist
- NF-Catalogue

D-A-CH Lists of substances 12 - Algae list 1st edition - 3

https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/07_Stofflisten/Kommentieren/2022-Kommentierung-Algenliste.html?nn=13520846



	A	O	P	AC
1	Alge (lateinisch)	<i>Ecklonia cava</i> Kjellman	<i>Eisenia bicyclis</i> Setchell	<i>Haematococcus lacustris</i> (Girod-Chantrons) Rostafinski
2	Ihr Kommentar			
3	Synonyme	<i>Ecklonia latifolia</i> Kjellman	<i>Eisenia bicyclis</i> (Kjellman) Setchell, <i>Ecklonia wrightii</i> Harvey, <i>Ecklonia bicyclis</i> Kjellman	<i>Volvox lacustris</i> Girod-Chantrons, <i>Haematococcus pluvialis</i> Flotow, <i>Sphaerella lacustris</i> (Girod-Chantrons) Wittrock ex Hansgirg
4	Alge (deutsch)		Arame, Kajimi, Sagarame	Blutregenalge
5	Größenordnung	Makroalge	Makroalge	Mikroalge
6	Großgruppe	Braunalge	Braunalge	Grünalge
7	LM		x	
8	NF	x (siehe Anmerkungen), Not NFS		Not NFS, x (siehe Anmerkungen)
9	AS			

D-A-CH Lists of substances 13 - Algae list 1st edition - 4

https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/07_Stofflisten/Kommentieren/2022-Kommentierung-Algenliste.html?nn=13520846



	A	O	P	AC
1	Alge (lateinisch)	<i>Ecklonia cava</i> Kjellman	<i>Eisenia bicyclis</i> Setchell	<i>Haematococcus lacustris</i> (Girod-Chantrons) Rostafinski
7	LM		x	
8	NF	x (siehe Anmerkungen), Not NFS		Not NFS, x (siehe Anmerkungen)
9	AS			
10	trad. AM			
11	Liste A			
12	Liste B			
13	Liste C			
14	Anmerkungen	Zugelassenes neuartiges Lebensmittel: Phlorotannine aus <i>Ecklonia cava</i> , siehe Ausführungen im Vorwort zur „Unionsliste“ und https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en	Das Etikett muss den folgenden Warnhinweis enthalten: Nicht mit Antikoagulanzen einnehmen. the label must include the following warning: do not take with anticoagulants	Zugelassenes neuartiges Lebensmittel: Astaxanthinreiches Oleoresin aus der Alge <i>Haematococcus pluvialis</i> , siehe Ausführungen im Vorwort zur „Unionsliste“ und https://ec.europa.eu/food/safety/novel_food/authorisations/union-list-novel-foods_en
	Risiken			

15-17 are empty lines for all 3 algae.

D-A-CH Lists of substances 14- Plant list 2nd edition - 1

<https://www.bvl.bund.de/stofflisten>



› Arbeitsbereiche › Lebensmittel › Aufgaben im Bereich Lebensmittel › Stofflisten des Bundes und der Bundesländer
› Pflanzenliste Einträge A-K, 2. Auflage › Zustimmung zum Download

Pflanzenliste - Einträge A-K, 2. Auflage

⬇ Herunterladen (xlsx, 263KB, nicht barrierefrei; Deutsch)

Hinweis: Im Rahmen der Erarbeitung der 2. Auflage der Stofflisten Kategorie „Pflanzen und Pflanzenteile“ wurden die Daten aus Gründen der übersichtlichen Darstellung transponiert. D.h. die Stoffe sind nun nicht mehr in den Spalten aufgeführt, sondern in der Kopfzeile alphabetisch sortiert.

Das Vorwort enthält wichtige Informationen, die zur korrekten Benutzung der Stofflisten bekannt sein müssen.

⬇ [Link zum Vorwort der Stofflisten](#)

Hiermit bestätige ich, dass ich das Vorwort zu den Stofflisten heruntergeladen und gelesen habe.

→ Ich stimme zu

→ Zurück

D-A-CH Lists of substances 15- Plant list 2nd edition - 2

<https://www.bvl.bund.de/stofflisten>



	A	EB	EC	ED
1	Stammpflanze (lateinisch)	<i>Borago officinalis</i> L.	<i>Borago officinalis</i> L.	<i>Boswellia serrata</i> Roxb. ex Colebr.
2	Synonyme			<i>Boswellia glabra</i> Roxb., <i>Boswellia thurifera</i> Roxb. ex Flem., <i>Libanus thuriferus</i> Colebr.
3	Trivialnamen	Garten-Borretsch, Einjähriger Borretsch, Gurkenkraut Borage	Garten-Borretsch, Einjähriger Borretsch, Gurkenkraut Borage	(Indischer) Weihrauch, salai tree, incense tree, Indian olibanum tree, salai (Indien)
4	Pflanzenteil	Kraut Herb	Samen Seeds	Harz Resin
5	LM	x G x Spice	x (cold pressed borage seed oil)	
6	NF			Not NF's
7	AS			x
8	trad. AM			
9	Liste A			
10	Liste B	x	x	x
11	Liste C			

D-A-CH Lists of substances 16- Plant list 2nd edition - 3

<https://www.bvl.bund.de/stofflisten>



Stammpflanze (lateinisch)	<i>Borago officinalis</i> L.	<i>Borago officinalis</i> L.	<i>Eoswellia serrata</i> Roxb. ex Colebr.
Anmerkungen	<p>Kommission E: Negativmonographie aufgrund von Risiken</p> <p>giftig II (Wink/ Wyk), nicht - kaum giftig (+) (Roth/ Daunderer)</p> <p>als pyrrolizidin-haltige Droge ist Borretsch bedenklicher Stoff (AMK), sollte wegen des Gehaltes an Pyrrolizidinalkaloiden nur sparsam verwendet werden (Teuscher), Stufenplan des BfArM vom 05. Juni 1992 für pyrrolizidinalkaloid-haltige Arzneimittel</p>	<p>giftig II (Wink/ Wyk), zugelassene Anthroposophika, Indikation: Hämorrhoiden, variköser Symptomkomplex als pyrrolizidin-haltige Droge ist Borretsch bedenklicher Stoff (AMK)</p> <p>Stufenplan des BfArM vom 05. Juni 1992 für pyrrolizidinalkaloid-haltige Arzneimittel, als Lebensmittel wird üblicherweise das kaltgepresste Öl der Borretschsamen verwendet.</p>	<p>WHO-Monograph: <u>Uses supported by clinical data:</u> Orally for the management of arthritis, bronchial asthma, Crohn's disease and ulcerative colitis. <u>Uses described in pharmacopoeias and well established documents:</u> Orally for the treatment of rheumatism and arthritis. <u>Uses described in traditional medicines:</u> Treatment of abdominal pain, asthma, coughs, dysentery, fever, jaundice, kidney stones, pimples, sores and stomach disorders. Also used as an antivenin and an emmenagogue.</p> <p>ESCOP-monograph: Relief of painful osteoarthritis; symptomatic treatment of inflammatory bowel disease.</p>

D-A-CH Lists of substances 17- Plant list 2nd edition - 4

<https://www.bvl.bund.de/stofflisten>



	A	EB	EC	ED
1	Stammpflanze (lateinisch)	<i>Borago officinalis</i> L.	<i>Borago officinalis</i> L.	<i>Boswellia serrata</i> Roxb. ex Colebr.
	Risiken	<p>Borretsch enthält wechselnde Mengen toxischer Pyrrolizidinalkaloide (PA), von denen organotoxische, insbesondere hepatotoxische Wirkungen bekannt sind. Tierexperimentell wurden für PA kanzerogene Wirkungen mit einem genotoxischen Wirkungsmechanismus nachgewiesen (Hager). Pyrrolizidinalkaloide in wechselnden Mengen in allen Pflanzenteilen enthalten.</p>	<p>Borretsch enthält wechselnde Mengen toxischer Pyrrolizidinalkaloide (PA), von denen organotoxische, insbesondere hepatotoxische Wirkungen bekannt sind. Tierexperimentell wurden für PA kanzerogene Wirkungen mit einem genotoxischen Wirkungsmechanismus nachgewiesen (Hager). Pyrrolizidinalkaloide in wechselnden Mengen in allen Pflanzenteilen enthalten. Kaltgepresstes Borretschsamenöl enthält keine oder nur Spuren von Pyrrolizidinalkaloiden (Frohne/Pfänder)</p>	<p>ESCOP-monograph: Two cases of neutropenia have been reported after long-term, uncontrolled consumption of up to 10 g of dry extract per day.</p>

D-A-CH Lists of substances 18- Plant list 2nd edition - 5

<https://www.bvl.bund.de/stofflisten>



	A	EB	EC	ED
1	Stammpflanze (lateinisch)	<i>Borago officinalis</i> L.	<i>Borago officinalis</i> L.	<i>Boswellia serrata</i> Roxb. ex Colebr.
14	Kritische Inhaltsstoffe	Pyrolizidinalkaloide	Pyrolizidinalkaloide	
	therapeutisch wirksame Dosierung			<p>ESCOP-monograph: <u>Adult daily dose:</u> <u>for osteoarthritis:</u> 250-1200 mg of an Indian frankincense alcoholic dry extract, divided into 3 doses. <u>For inflammatory bowel disease:</u> 900-3600 mg of an Indian frankincense alcoholic dry extract, divided into 3 doses. <u>Children above 12 years:</u> Proportion of adult daily dose according to body weight and/or age. The use of Indian frankincense in children has been documented.</p> <p>WHO-monograph: (Unless otherwise indicated) <u>Crude drug:</u> 1-3 g daily (frequency not specified). <u>Extracts:</u> 300-350 mg three times daily.</p>

- The list of substances includes only information about the therapeutic efficacy:
- The pharmacologically active dose might be lower.
 - The distinction between food and medicinal products is a case-by-case decision and is not the subject of the list of substances

D-A-CH Lists of substances 19- Fungi list 1st edition

<https://www.bvl.bund.de/stofflisten>



- Identification of relevant mushrooms (fungi)
→ Consideration of lists from
BE, IT, AT, SE, UK
- Classification based on the same decision tree
- Additional line "Category": Distinction
between fungus and lichen
- In the case of mushrooms (fungi) that are
listed in the Red Lists of D, A, CH, the degree
of danger is pointed out
- Conditions of use are indicated

Pilz/Flechte (lateinisch)	<i>Lobaria pulmonaria</i> (L.) Hoffm.*	<i>Lycoperdon perlatum</i> Pers.*
Kategorie	Flechte	Pilz
Anmerkungen	*Die empfohlene Tagesdosis darf nicht zu einer Einnahme von Usninsäure von mehr als 30 mg führen. Die Usninsäurekonzentration darf 3 % nicht übersteigen.	*nur jung essbar, solange innen weiß

Pilz/Flechte (lateinisch)	<i>Leccinum duriusculum</i> (Schulzer ex Kalchbr.) Singer
Pilz/Flechte (deutsch)	Pappel-Raufuß, Pappel-Raufuß, Brauner Pappel-Raustielröhrling, Harter Pappel-Raufuß, Brauner Pappelraufuß, Härtlicher Birkenröhrling, Pappelröhrling
Kategorie	Pilz
LM	x
NF	
AS	
trad. AM	
Liste A	
Liste B	
Liste C	
Anmerkungen	<p>Rote Liste gefährdeter Pilze Deutschlands: Gefährdungskategorie: 3 gefährdet</p> <p>Rote Liste Makromyzeten Österreich: IUCN Gefährdungskategorie: NT Near Threatened</p> <p>Rote Liste gefährdeter Pilze der Schweiz: Gefährdungskategorie: VU verletzlich</p>
Risiken	roh giftig

Adopted
Copyright BVL

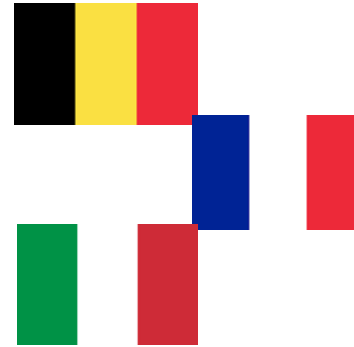
Overview of lists on botanicals available in the Member States 1



- ☞ There is currently no single exhaustive list on botanicals available in the literature
- ☞ National lists vary greatly - MS use different approaches:
 - Applicable to all foods versus applicable to food supplements only
 - Negative list versus positive list or both
 - Some MS have no lists or only list of plants classified as medicinal
 - Some MS have specific lists on mushrooms (fungi) or tea (herbal infusions)
- ☞ Available information is often ambiguous or outdated
- ☞ Where national lists do exist, often it is difficult to access them (difficult to find, foreign language)

Overview of lists on botanicals available in the Member States 2

- **BelFrlt**-List (Cooperation between Belgium, France and Italy):
 - **Belgium:** Negative List with 380 Substances
+ Positive List with 650 Substances
 - **France:** Positive List with 540 Substances
 - **Italy:** Positive List with about 1200 Substances
- > **800 of these substances are not listed in the D-A-CH list of substances**



Challenge:

- Different classification of individual substances in Belgium, Italy and France
- Not all substances of the individual notified lists are in the BelFrlt list

Goal: Successive inclusion of individual substances

Overview of lists on botanicals available in the Member States 3



Lists of Botanicals (n=14)	Regulatory (n=9)	Non-Regulatory (n=5)
Positive Lists	IT (FS), FR (FS)	BelFrIT (FS)
Negative Lists	BG (FS), CH (Food), LT (FS), NL (FS)	LV (Food- in the consultation process)
Positive- and Negative Lists	BE (FS), CZ (FS), RO (FS), CR (FS)	D-A-CH (Food)

2021-03-04

Adopted
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Other Lists (n=13)	
Medicinal plants	IE, FI, SE, SI, EE
"other substances"	DK
Tea (herbal infusions)	AT, SK, ES
Spices	ES
Mushrooms (fungi)	HR, AT, CH, BE

Outlook



What is the working group currently working on?

- Regular updating of the published documents
- Final publication of the "Algae List" and the 3rd edition of the foreword to the lists of substances
- Translation of the foreword and lists into English
- Transfer of the lists to a database
- Addition of further substances to the lists
- Creation of further lists

ANNEX

Interesting HP (Botanicals: Plants, Fungi, Algae, ...)



- ☞ <http://www.worldfloraonline.org/> <http://powo.science.kew.org/>
- ☞ Dr. Duke`s Phytochemical and Ethnobotanical Databases: <https://phytochem.nal.usda.gov/phytochem/search>
- ☞ PFAF Plant Search (Plants For A Future) <http://www.pfaf.org/user/Default.aspx>
- ☞ FDA Poisonous Plant Database <https://www.fda.gov/food/science-research-food/fda-poisonous-plant-database>
- ☞ <https://www.iucnredlist.org/>
- ☞ <http://www.algaebase.org/> <https://algaecrop.web.app/index.html>
- ☞ <http://www.indexfungorum.org/> <http://www.speciesfungorum.org/Names/Names.asp>
- ☞ <http://gernot-katzers-spice-pages.com/engl/index.html>
- ☞ FATS AND OILS (USEFUL LINKS FOR THE STUDY OF LIPIDS) <https://www.gerli.com/en/useful-links/>
- ☞ FEDIOL, the EU vegetable oil and proteinmeal industry association <http://www.fediol.eu/web/fediol/1011306087/list1023110705/f1.html>
- ☞ Prospector: The Trusted Materials & Ingredients Global Search Engine <https://www.ulprospector.com/en>
- ☞ <https://examine.com/supplements/>
- ☞ https://www.bfarm.de/EN/Home/_node.html;jsessionid=37C22858A07BE20E0268C206D1230A68.intranet232
- ☞ https://www.bfarm.de/EN/Medicinal-products/Information-on-medicinal-products/Research-medicinal-products/_node.html;jsessionid=53AA0F2320A13612A3D2D9DEC8C756FA.intranet232

Other MS Lists, Algae: Norms, COM, EABA, JRC (COM) 1



BELFRIT, FIN:

- https://www.economie.gouv.fr/files/files/directions_services/dgccrf/imgs/breve/2014/documents/harmonized_list_Section_A.pdf
- <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000029254516/>
- <https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=67517&parte=2&serie=>
- <https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/novel-foods/establishing-novel-food-status-of-a-food/>

Algae: Standardization (CEN/TC 454 - Algae and algae products), COM, EABA, JRC (COM) 1:

- https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0:::FSP_PROJECT,FSP_ORG_ID:69023,2278882&cs=13170F39E28F894E9E017EB9396340A21
- https://knowledge4policy.ec.europa.eu/glossary-item/algae_en
- <https://www.eaba-association.org/en> European Algae Biomass Organisation
- <https://publications.jrc.ec.europa.eu/repository/handle/JRC118214>

Algae: JRC (COM) 2

<https://publications.jrc.ec.europa.eu/repository/handle/JRC125913>



2021

Technical reports

Agriculture and food security

Algae as food and food supplements in Europe

Abstract: The use of algae biomass in food applications is still a growing market in Europe. One key consideration is the regulatory status of algae items potentially used as food and food supplements. In the European Union, foods classified as novel are subject to the pre-market authorisation requirements of the novel food regulation (EU) 2015/2283 before they can be freely placed in the European market without the need for pre-market novel food authorisation. In addition, novel and non-novel foods placed on the European market are subject to the requirements of all applicable food safety related EU Legislation. This technical report presents a comparative list of algae items (*sensu lato*) referred on the novel food catalogue, the Union list of authorized novel foods and official Member States' lists of food and food supplements. Additionally, other algae food and food supplement items referred in available non-official lists are included. A final table merging all the information included in the official lists is presented following the most updated species taxonomic designation.

Authors: DOS SANTOS FERNANDES DE ARAUJO Rita; PETEIRO Cesar

Citation: Dos Santos Fernandes De Araujo, R. and Peteiro, C., Algae as food and food supplements in Europe, EUR 30779 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-40548-1, doi:10.2760/049515, JRC125913.

Publisher: Publications Office of the European Union

JRC number: JRC125913

ISBN: 978-92-76-40548-1



Novel Food: Austria, Germany, Switzerland and Food Supplements Europe



- <https://www.ages.at/en/human/nutrition-food/food-information/novel-foods>
- https://www.verbrauchergesundheit.gv.at/Lebensmittel/neuartige_Im/neuartigelm.html
- <http://www.lebensmittelbuch.at/>
- https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/05_NovelFood/Im_novelFood_node.html
- https://www.bfr.bund.de/de/neuartige_lebensmittel_novel_food_-215.html
- https://www.ua-bw.de/pub/beitrag.asp?subid=0&ID=825&Thema_ID=2&lang=DE
- <https://www.blv.admin.ch/blv/de/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung.html>
- <http://www.foodsupplementseurope.org/publications-guidelines>

GUIDANCE FOR FOOD BUSINESS OPERATORS ON THE VERIFICATION OF THE STATUS OF A NEW FOOD UNDER THE NEW NOVEL FOODS REGULATION 2015/2283 (NFR)



The Novel Foods Regulation 2015/2283 and its Implementing Regulations 2017/2468 (novel foods from a third country), 2017/2469 (novel foods requirements) and 2017/2470 (Union list of novel foods) take full effect from 19 January 2018.

With this legislation, it becomes a legal obligation for food business operators to verify whether a new food falls under the scope of the novel food definition and in case of uncertainty to consult a Member State authority.

The aim of these guidelines is to help food business operators understand the scope of the new NFR and the principles to apply when verifying the status of their products. It focuses on all foods, including food supplements and ingredients thereof. Other European food associations have contributed to this work to ensure it covers all foods on the EU market.

The second edition of the guidance document was published in January 2019 and takes into account experience gathered during the first year of the application of the new Regulation.

Austria Codex (ÖLMB)- Wild Plants and Flowers 1



<https://www.lebensmittelbuch.at/leitlinien/leitlinien-richtlinien-empfehlungen-usw-der-codexkommission/essbare-wildpflanzen-und-blueten/empfehlung-oesterreichische-liste-essbarer-wildpflanzen-und-blueten.html>

Trifolium pratense 1

Rotklee



Pixabay license



Anhang I Positivliste

Legende		Fassung 09.04.2019
Kurzzeichen		Erläuterung
☛		Wurzel, Rhizom, Zwiebel, Knolle
✱		Blüte
●		Blatt
A		Einlegen in Alkohol (Ethanol); (Details dazu siehe Bemerkungen)
BL		Blütensaft = Phloemsaft
BS		wie Blattspinat (gekocht)
G		Gewürz; würzende oder dekorative Zwecke
WG		„Wurzel“gemüse
WV		weitere Verwendung (z.B. Marmelade, Saft, Sirup etc.)
M		in Mischungen (gekocht, geringere Menge pro Pflanze als für Blattspinat)
FG		Frischgewicht
FR		Frucht
S		Salat (roh)
SA		Samen
KD		Kontaktdermatitis
Allgemein gilt:	Verwendung normalerweise frisch (wenn getrocknet, dann Zusatzangabe) Auswahlkriterien/ Pflanzen: nicht gefährdet in der Natur, häufig, Verwendung (siehe Präambel)	



Austria's positive and negative list for wild plants and flowers used in food, because of new trends using botanicals from the wild more and more especially for home uses.

This list is not harmonized with the Novel Food Status, but gives an impression on safety issues and possible uses in small amounts.

Wissenschaftliche Bezeichnung	☛	✱	●	BL	BS	G	WG	WV	M	FR	S	SA	A	Pflanzl. Familie	Trivialname	Bemerkungen
Thymus serpyllum s.str.		x	x			x								Lamiaceae	Sand-Quendel	
Thymus vulgaris		x	x			x								Lamiaceae	Gewürz-Thymian, Garten-Thymian	
Thymus zygis		x	x			x								Lamiaceae	Spanischer Thymian	
Tilia cordata und andere Arten		x	x			x								Tiliaceae	Winter-Linde, und andere Linden	
Tragopogon dubius	x	x	x					x		x				Asteraceae	Groß-Socksbart	
Tragopogon orientalis	x	x	x					x		x				Asteraceae	Großer Wiesen-Socksbart	
Tragopogon pratensis	x	x	x					x		x				Asteraceae	Mittlerer Wiesen-Socksbart	
Trifolium repens		x	x			x				x				Fabaceae	Kriech-Klee, Weiß-Klee	
Trifolium pratense		x	x			x				x				Fabaceae	Wiesen-Klee, Rot-Klee	



Austria Codex (ÖLMB)- Wild Plants and Flowers 2



<https://www.lebensmittelbuch.at/leitlinien/leitlinien-richtlinien-empfehlungen-usw-der-codexkommission/essbare-wildpflanzen-und-blueten/empfehlung-oesterreichische-liste-essbarer-wildpflanzen-und-blueten.html>

Rhododendron spp. 1 (Alpenrosen Arten)

(Product = Novel Food; in negative list + list A in D-A-CH)

Anhang II Negativliste



Wissenschaftliche Bezeichnung	Trivialname	Pflanzenfamilie	Bemerkungen/Inhaltsstoffe
Myosotis spp.	Vergissmeinnicht-Arten	Boraginaceae	Pyrrrolizidinalkaloide
Oenanthe aquatica	Groß-Wasserfenchel	Apiaceae	Polyine
Paris quadrifolia	Vierblatt-Einbeere	Trilliaceae	Saponine
Petasites spp.	Pestwurz-Arten	Asteraceae	Pyrrrolizidinalkaloide
Polygonatum spp.	Weißwurz, Salomonssiegel	Ruscaceae	Saponine
Physalis alkekengi	Echt-Blasenkirche, Judenkirsche	Solanaceae	Steroide (Withanolide)
Pulmonaria officinalis	Echt-Lungenkraut	Boraginaceae	Pyrrrolizidinalkaloide
Pulsatilla spp.	Küchenschellen-, Kuhschellen-Arten	Ranunculaceae	Alkaloide
Ranunculus spp.	Hahnenfuß-Arten	Ranunculaceae	Protoanemonin
Rhamnus spp.	Kreuzdorn-Arten	Rhamnaceae	Anthraderivate
Rhododendron spp.	<u>Alpenrosen-Arten</u>	Ericaceae	Diterpene



In the negative list there are some plants which are even recommended in some books for collecting wild plants in the nature- especially pyrrrolizidinalkaloide containing plants like borage.



„grayanotoxins“

Table with 4 columns: Name, Strukturformel, Molgewicht, and other data. It lists various grayanotoxin derivatives.



AGES



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