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List of Substances of the Competent Federal Government and Federal State Authorities Category “Plants and plant parts”

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Explanatory notes on the List of Substances of the Competent Federal Government and Federal State Authorities – Category "Plants and plant parts"

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1.1 Introduction

The Lists of Substances of the Competent Federal Government and Federal State Authorities (lists of substances) are created to facilitate the classification and assessment of substances regarding their use as food or food ingredient. They are designed to serve as a reference guide for authorities and food distributors. The final assessment of products containing these substances or preparations thereof must always be made on a case-by-case basis, giving due regard to all criteria relevant to that assessment.

Lists of Substances of the Competent Federal Government and Federal State Authorities are to be created for various categories. To provide a uniform system for the lists of substances, the entries in the categories are referred to as "substances", although they may not always be chemically defined individual substances. A more detailed definition may be provided in addition to the categories.

The lists of substances do not claim to be complete and do not exempt the food business operator from the responsibility to ensure that the relevant product is safe and legally marketed as a food in Germany. They are subject to updating in order to take account of new scientific findings as well as developments in the food industry.

1.2 Legal framework

Article 2 of the Regulation (EC) No. 178/2002 (General Food Law Regulation)[1] specifies "food" as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Substances used as source materials for flavourings or foods with flavouring properties are governed by the provisions of the Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[2].

Foods or food ingredients which have not been used for human consumption to a significant degree in the EU before 15 May 1997 are governed by the provisions of the Regulation (EC) No. 258/97 on novel foods and novel food ingredients (Novel Food Regulation)[3], if they fall into one of the following categories:

- Foods and food ingredients with a new or intentionally modified primary molecular structure,
- Foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae,
- Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use
- Foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Flavourings for use in foods do not fall within the scope of the Novel Food Regulation. However, if relevant substances are used for purposes other than flavouring, they may need to be classified as novel within the meaning of the Novel Food Regulation.

Article 2 (d) of the General Food Law Regulation stipulates that food does not include medicinal products. The definition of a medicinal product is laid down in Section 2

[1] Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[2] Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC

[3] Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

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Clause 1 of the Law governing the Trade of Medicinal Products (Medicinal Products Act – The Drug Law, AMG)[4], with which the European definition of medicinal products was enacted into national law in accordance with Article 1 of the Directive 2001/83/EC (Medicinal Products Directive)[5].

Article 2 (g) of the General Food Law Regulation stipulates that food also does not include narcotic and psychotropic substances. According to the General Food Law Regulation, this is laid down in the United Nations Single Convention on Narcotic Drugs of 1961[6] as well as in the United Nations Convention on Psychotropic Substances of 1971[7]. Additionally, the Narcotic Drugs Act (BtMG) applies in German law[8].

1.3 Instruction on how to use the List of Substances

"Substances" within the meaning of this category are plants and plant parts. The substances are viewed and categorised as such. Preparations of substances, such as extracts or isolates, may differ from the actual substances regarding their composition, especially in terms of their nutritional and toxicological properties. In each individual case, it therefore needs to be determined whether the classification of a substance can be applied to a preparation thereof. The classification is made on the basis of a decision tree developed for this category (see Chap. 2).

To understand the List of Substances in the category of "plants and plant parts", the following should additionally be noted:

1. The sub lists have the following meanings:
   - List A: Substances not recommended for use in foods
   - List B: Substances for which restricted use in foods is recommended
   - List C: Substances which cannot yet be completely assessed due to lack of sufficient data
2. If substances are usually used in foods only to a very limited extent, for example as spices or as ingredients in the production of spirits, they are designated by the following abbreviations in the "Food (F)" column:
   - F: Known exclusively for use as a food ingredient with flavouring properties or as a source material for flavourings
   - S: Known for use as a spice
   - C: Known for use as a colouring agent
   - T: Known for use as a tea

   Such limitations are generally not documented by placing a substance on List B. In exceptional cases, a substance is also placed on List B if it is associated with effects that necessitate a restriction of its use.

   Classification is made under the assumption that the relevant substance is used as documented in the list. Any other use, e.g. in higher doses, can lead to effects that may require a different classification.
3. Substances that should be treated before consumption (e.g. heated) are designated by the letter "b" in the "Food (F)" column.
4. When classifying a substance as a novel food/novel food ingredient (NF) within the meaning of the Novel Food Regulation or as not novel in food supplements (Not NFS), the Novel Food Catalogue of the European Commission[9] was taken into account. However, it should be noted that this catalogue does not have any entries for a large number of substances from the List of Substances in the category "plants and plant parts". Any other available information regarding use for human consumption to a significant degree before 15 May 1997 was also taken into account.
5. If any restrictions of use as a food or food ingredient are recommended for a substance (List B) due to evidence of a pharmacological effect (No. 4 in the explanatory notes on the decision tree), such a restriction always refers to the substance described in that evidence (e.g. dried plant or dried plant part). Evidence of a pharmacological effect that leads to a classification as a medicinal product in accordance with Section 2 Clause 1 No. 2a AMG included court-approved sources such as monographs, marketing authorisations or classifications of competent authorities. Other evidence (e.g. results of clinical studies) may additionally be relevant to the classification of a substance as a medicinal product.
6. Substances for which a pharmacological effect or efficacy as a medicinal product is plausible based on use and experience over many years ("traditional evidence") in accordance with Sections 39a ff. of the Medicinal Products Act will not be placed on List B based on that traditional evidence alone. For a substance to be placed on List B, pharmacological effects,

[4] Law governing the Trade of Medicinal Products (Medicinal Products Act – AMG)
[5] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
[6] Single Convention on Narcotic Drugs of 30 March 1961
[7] Law approving the Convention on Psychotropic Substances of 21 February 1971
[8] Law governing the Trade of Narcotic Drugs (Narcotic Drugs Act – BtMG)
[9] http://ec.europa.eu/food/food/biotechnology/novelfood/novel_food_catalogue_en.htm

as specified above in item 5, or risks must be reported due to which restricted use in foods is recommended.

7. The classification of substances into this list is made only on the basis of their effect after oral ingestion. Substances which, according to monographs, are intended for external use only are not designated as medicinal products in the List of Substances.

2 Decision tree: Explanatory notes on the classification of substances in the List of Substances of the Competent Federal Government and Federal State Authorities – Category "Plants and plant parts"

The decision tree serves as the basis for the classification of substances in the category of "plants and plant parts" as "food (F)", "medicinal product (MP)" and/or "novel food/novel food ingredient (NF)" as well as possible combinations thereof (ambivalent substances). It also provides instructions for the classification of the substances in the Lists A, B and C.

Classification as a medicinal product – except for ambivalent substances (see No. 3 below) – is made based on the definition of medicinal products by function set out in Section 2 Clause 1 No. 2a of the Medicinal Products Act (AMG). These are characterised by their pharmacological, metabolic or immunological effect. For the sake of clarity, the term "pharmacological effect" is used in the decision tree for this definition. Classification as a medicinal product by presentation as defined in Section 2 Clause 2 No. 1 AMG is not taken into account.

Based on the answers to the questions in the decision tree, plants and plant parts are classified as follows:

No. 1: Food
(Decision tree I – via question 3)
Common foods without any known use as medicinal products. Based on their previous use, any restrictions of use are not required.

No. 2: Food + List B
(Decision tree III – via question 3)
Common foods without any known use as medicinal products.

Dose restrictions and restrictions of use are required due to risks posed by the constituents of the plant or plant part. Such restrictions are expressed by placing the substance on List B.

No. 3: Food + traditional medicinal product
(Decision tree II – via question 5)
For traditional herbal medicinal products, a pharmacological effect is plausible based on use and experience over many years in accordance with Sections 39a ff. of the Medicinal Products Act (AMG). At present, processing monographs for plants/plant parts that can be contained in traditional medicinal products are being created or revised by the European Medicines Agency (EMA). Where these monographs have been adopted and published, they are taken into account accordingly. Some of the plants/plant parts used therein have also long since been used in food. A restriction (List B) was not recommended in individual cases where it would have been done exclusively on the basis of traditional evidence of pharmacological effect. Despite such evidence of pharmacological effect, classification as ambivalent substance (F/MP) without any restrictions is therefore made **in this case only**.

No. 4: Food + medicinal product + List B
(Decision tree III/IV – via question 5)
Common foods that are also used as medicinal products. Pharmacological effects are reported above a certain dose. If no significant pharmacological effects are identified, the substance can be classified as food. When reaching the pharmacologically effective dose, it is defined as a medicinal product by function. This is expressed by placing the substance on List B.

No. 5: Novel food
(Decision tree VIII – via question 9)
The substance is not known to be used as either food or a medicinal product. The substance is also not known to be associated with any risks that would restrict its use in food. The further assessment takes place in accordance with the Novel Food Regulation.

No. 6: Novel food + medicinal product
(Decision tree IV/V – via question 8)
The substance has so far been known as a medicinal product only. However, it is not associated with any risks that would restrict its use in food. Its use in food would there-

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fore be conceivable after assessment in accordance with the Novel Food Regulation.

Medicinal products and novel foods are distinguished on the basis of the pharmacologically effective dose (by analogy with No. 4). The substance cannot be placed on List B as it is no common food.

No. 7: Novel food (Not NFS) + List C
(Decision tree VIII – via question 9)
A number of substances are classified as not novel exclusively when used in food supplements. When used in foods other than food supplements, these substances are usually placed on List C, since no sufficient information is available for their conclusive assessment.

No. 8: Novel food (Not NFS) + List B + medicinal product
(Decision tree IV/V – via question 8)
The substance is known as a medicinal product. It is additionally used in food supplements and is classified as not novel in this case only. The necessary restriction of use in FS due to the pharmacological effect is expressed by placing the substance on List B.

No. 9: Medicinal product + List A
(Decision tree VI – via question 7)
The substance has so far been known as a medicinal product only. Due to the associated risks, its use in food is not recommended, irrespective of the dose.

No. 10: List A substance
(Decision tree VII – via question 9)
The substance, which is not a medicinal product, is associated with risks. Its use in food is therefore not recommended, irrespective of the dose.

2.1 Classification in the lists A, B and C

List A
Substances that are not recommended for use as food or food ingredient due to known risks (No. 10) are placed on List A. These substances may be or may have been used as medicinal products (No. 9).

List B
Substances that are only used in food and for which a dose restriction is required due to certain constituents (No. 2) are placed on List B.

Furthermore, substances that are known as both foods and medicinal products with a pharmacological effect demonstrated on the basis of clinical data are placed on this list. This is also done by strict application of the decision tree in respect of basic foods in usual amounts of intake (No. 4).

Finally, substances that are used as food exclusively in food supplements (but are otherwise novel foods) and are known as medicinal products with a demonstrable pharmacological effect are placed on list B (No. 8).

Substances that are known as both foods and medicinal products with exclusively traditional evidence of pharmacological effect (No. 3) are not placed on List B.

List C
Substances that have so far been used exclusively in food supplements but are otherwise novel foods are placed on list C (No. 7).

2.2 Decision tree

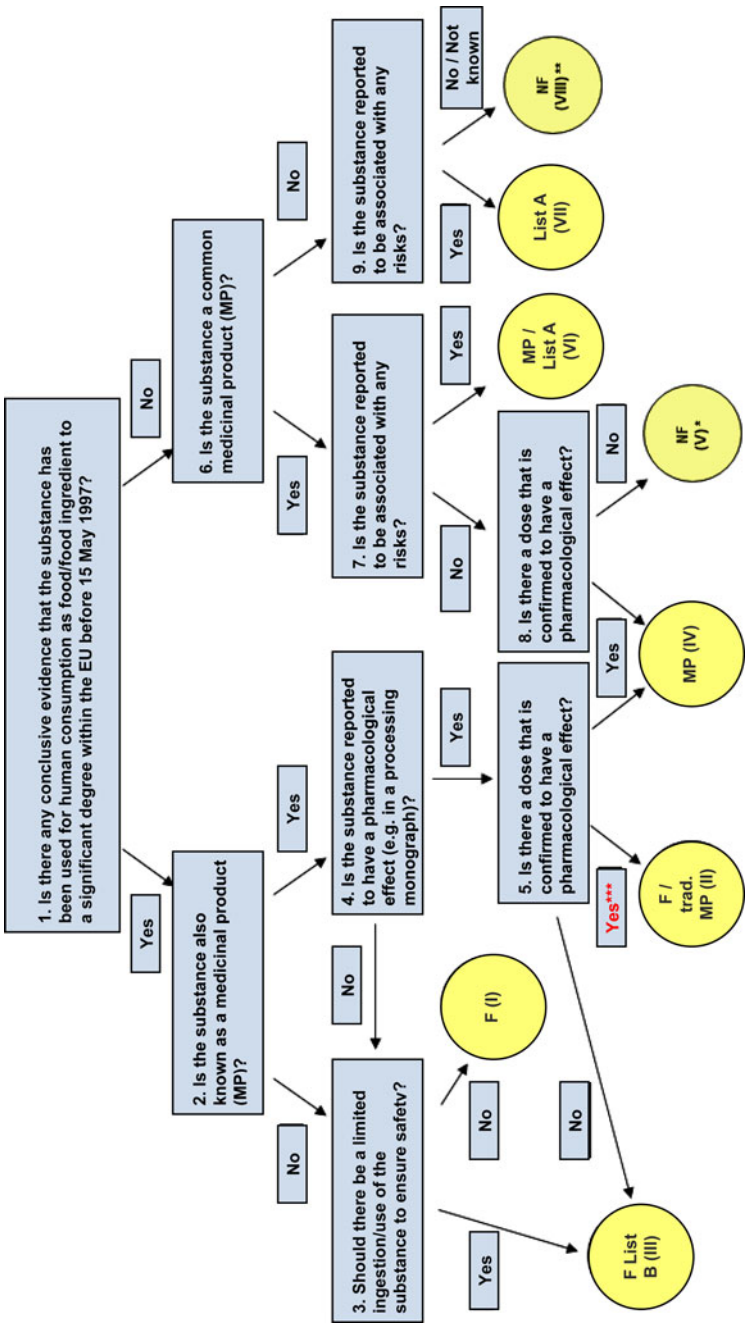

Figure 1 Decision tree
* Assessment of potential use as food/food ingredient according to the Novel Food Regulation (If the substance is classified as not novel in food supplements [Not NFS], it may need to be placed on List B.)
** Assessment of potential use as food/food ingredient according to the 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

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Table 1 List of Substances – Category "Plants and plant parts"

Stock plant (Latin)	Plant part	F	NF	MP	trad. MP	List A	List B	List C
Abies spp.	Shoot (tip)	× T						
Achillea millefolium L.	Herb, flower	× S, T		×	×		×	
Aconitum napellus L.	all plant parts			×		×		
Acorus calamus L., syn. Acorus aromaticus GARZ., Oronthium cochinchinensis LOUR.	Rhizome	× F			×		×	
Actinidia deliciosa (CHEV.) A.R. FERG.	Fruit	×						
Adonis vernalis L., syn. Adonanthe vernalis SPACH	Herb			×		×		
Aegopodium podagraria L., syn. Aegopodium angelicaefolium ST. LAGER, Aegopodium latifolium TURCZ.	Leaf	×						
Aesculus hippocastanum L., syn. Aesculus castanea GILIB., Aesculus procera SALISB., Hippocastanum vulgare GAERTNER	Leaf, flower		Not NFS					×
Aesculus hippocastanum L., syn. Aesculus castanea GILIB., Aesculus procera SALISB., Hippocastanum vulgare GAERTNER	Bark		Not NFS		×			×

Remarks	Risks	Critical plant substances	Pharmacologically effective dose
Positive monograph, indications: loss of appetite, digestive problems such as mild gastrointestinal cramps, **standard marketing authorisation:** 1249.99.99, **ESCOP monograph:** loss of appetite, dyspeptic disorders such as mild spasmodic complaints in the abdominal region, **WHO monograph:** loss of appetite, common cold, dyspeptic ailments such as mild spastic discomfort of the gastrointestinal tract, as a choleretic and for the treatment of fevers, **HMPC monograph:** traditional use	Contraindications: hypersensitivity to yarrow or other Asteraceae species (Commission E monograph)	Proazulenes, azulenes, monoterpenes (e.g. camphor, eucalyptol [=1,8-cineol])	**Commission E:** 4 g drug/day, equivalent preparations **ESCOP:** 2–4 g drug/3–4 times a day, equivalent preparations, administration to children aged between 3 and 12 only under medical supervision **WHO:** 4.5 g drug/day or 3 g flower tea/day
Negative monograph: due to risks, use in MP only in homeopathic doses, monkshood (Aconitum napellus), extremely toxic Ia (Wink/Wyk), extremely toxic +++ (Roth/Daunderer)	Aconitine is a strong nerve and muscle poison, numbness, paraesthesia, paralysis (Wink/Wyk), cardiac arrhythmia, sensitivity to cold, nausea, cramps, paralysis of tongue, facial and extremity muscles, circulatory failure (Roth/Daunderer)	Alkaloids (e.g. aconitine)	
Risks reported (in dependence on the variant used), use of tetraploid subspecies as source material for flavourings and foods with flavouring properties prohibited by Reg. (EC) No. 1334/2008, maximum amount of beta-asarone in alcoholic beverages: 1 mg/kg, licensed anthroposophic medicinal product acc. to Section 21 AMG, toxic + (Roth/Daunderer), mildly toxic II to toxic III (Wink/Wyk)	Risks reported for tetraploid variants e.g. A. calamus var. angustatus BESS. because of their high beta-asarone content. Beta-asarone demonstrated a mutagenic and carcinogenic effect in animal experiments (Hager, Frohne/Pfänder); diploid subspecies e.g. A. calamus L. var. americanus (RAF.) WULFF. are free from beta-asarone	Beta-asarone	
Positive monograph, indications: slightly reduced cardiac output, especially when accompanied by nervous symptoms, very toxic Ib (Wink/Wyk), highly toxic ++ (Roth/Daunderer)	Nausea, vomiting, cardiac arrhythmia, contraindications and interactions reported (Commission E monograph), cardiac arrest, symptoms of cardiac glycoside poisoning, diuresis, digestive tract irritation (Wink/Wyk)	cardioactive glycosides (some prescription-only)	**Commission E:** 0.6–3 g standardised Adonis powder (DAB 9)/day, equivalent preparations
Neutral monograph			
Neutral monograph, HMPC monograph: traditional use			

Stock plant (Latin)	Plant part	F	NF	MP	trad. MP	List A	List B	List C
Aesculus hippocastanum L., syn. Aesculus castanea GILIB., Aesculus procera SALISB., Hippocastanum vulgare GAERTNER	Seed		Not NFS	×	×		×	
Agrimonia eupatoria L., syn. Agrimonia adherens GILIB., Agrimonia officinalis LAM., Agrimonia parviflora SPRENG., Amonia agrimonoides STEUD., Aremonia agrimonoides D.C.	Herb	× T		×			×	
Agrimonia procera WALLR., syn. Agrimonia odorata auct. non MILLER, Agrimonia odorata WALLR.	Herb	× T		×			×	
Agropyron repens (L.) P. BEAUV., syn. Elymus repens (L.) GOULD, Elytrigia repens DESV. ex NEVSKI, Triticum repens L.	Root	× T		×	×		×	
Alchemilla alpina L. em. BUSER	Herb		×		×			
Alchemilla vulgaris auct., Alchemilla vulgaris L.	Herb	× T		×			×	
Alkanna tuberculata (FORSSK.) MEIKLE, syn. Alkanna tinctoria (L.) TAUSCH, Alkanna tuberculata GREUTER, Lithospermum tinctorium L.	Root					×		
Allium cepa L., syn. Allium esculentum SALISB., Cepa esculenta S.F. GRAY, Cepa vulgaris RENAULT, Kepa esculenta RAFIN., Porrum cepa RCHB.	Bulb	×		×			×	

Remarks	Risks	Critical plant substances	Pharmacologically effective dose
Positive monograph, indications: symptomatic treatment of diseases of crural veins (chronic venous insufficiency), e.g. pain and feeling of heaviness in legs, night leg cramps, itching and swollen legs, **WHO monograph:** treatment of symptoms of chronic venous insufficiency, including pain, feeling of heaviness in the legs, nocturnal calf-muscle spasms, itching and oedema, **ESCOP monograph:** chronic venous insufficiency, varicosis, **HMPC monograph:** treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves, traditional use, slightly toxic + (Roth/Daunderer), mildly toxic III (Wink/Wyk)	Nausea, gastrointestinal complaints, hot flushes, oedemas, vomiting, diarrhoea, hypertension, loss of consciousness, circulatory collapse (Wink/Wyk, Roth/Daunderer)	Saponins	**Commission E:** 100 mg aescin/day, equivalent to 250–312.5 mg extract in delayed release form 2 times a day **ESCOP:** equivalent to 50–150 mg triterpene glycosides (calculated as aescin), no administration to children **WHO:** 250–312.5 mg standardised comminuted extract, equivalent to 100 mg aescin
Positive monograph, indications: mild, non-specific, acute forms of diarrhoea, inflammations of oral and pharyngeal mucosa, **ESCOP monograph:** Agrimony has widely documented uses as a remedy to treat mild diarrhoea, **HMPC monograph:** in progress, **standard marketing authorisation:** 2379.99.99			**Commission E:** 3–6 g drug/day, equivalent preparations **ESCOP:** 3–12 g drug, 3 times a day, children!
Positive monograph, indications: mild, non-specific, acute forms of diarrhoea, inflammations of the oral and pharyngeal mucosa, **HMPC monograph:** in progress			**Commission E:** 3–6 g drug/day, equivalent preparations
Positive monograph, indications: increase of urinary output for catarrhs of the lower urinary tract, adjuvant treatment of catarrhs of the upper respiratory tract, **standard marketing authorisation:** 1169.99.99, contraindications reported, **ESCOP monograph:** irritable bladder and other urinary tract disorders, **HMPC monograph:** traditional use	Contraindications: irrigation therapy of oedemas associated with cardiac or renal insufficiency (Commission E monograph)		**Commission E:** 6–9 g drug/day, equivalent preparations **ESCOP:** 5–10 g drug/day, no administration to children under the age of 12
Neutral monograph			
Positive monograph, indications: mild, non-specific forms of diarrhoea			**Commission E:** 5–10 g drug/day, equivalent preparations
Substance of concern (AMK – Drug Commission of German Pharmacists), BfArM [Federal Institute for Drugs and Medical Devices] graduated plan of 5 June 1992 concerning medicinal products containing pyrrolizidine alkaloids, toxic II (Wink/Wyk), toxic + (Roth/Daunderer)	Pyrrolizidine alkaloids contained in the drug are mutagenic, carcinogenic, ingestion of high doses causes digestive problems and CNS disorders (Wink/Wyk)	Pyrrolizidine alkaloids	
Positive monograph, indications: loss of appetite, prevention of age-dependent vascular changes, **WHO monograph:** the principal use of Bulbus Allii Cepae today is to prevent age-dependent changes in the blood vessels, and loss of appetite, non-toxic but irritating to skin (Roth/Daunderer), mildly toxic III (Wink/Wyk), **HMPC assessment report**	Ingestion of higher doses, especially in children, causes digestive tract irritation accompanied by vomiting, nausea, colic and diarrhoea (Wink/Wyk)	Allicin, allyl sulphide	**Commission E:** 50 g fresh onions or 20 g dried drug, equivalent preparations **WHO:** 20 g drug/day, equivalent preparations