

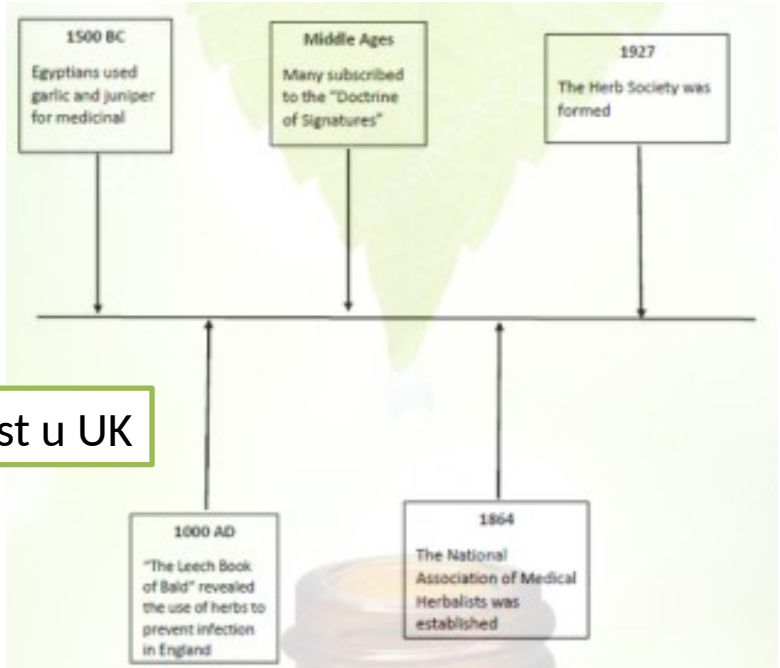
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO

NOOTROPICI I ADAPTOGENI NOVITETI NA TRŽIŠTU I IZAZOVI U ZAKONODAVSTVU

Lea Pollak, Ph.D., MSc Nutr

FITOFARMACIJA…

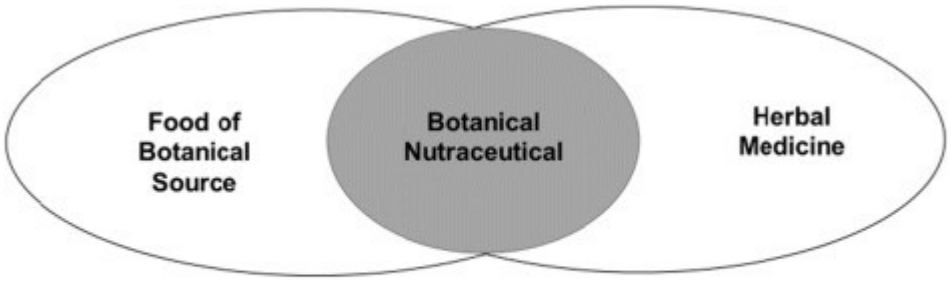




Povijest u UK

- Proučavanje ljekovitog bilja i njegovog djelovanja od prvih civilizacija
- Zapisi koji su i danas priznati i primjenjivani u liječenju potječu iz srednjovjekovnih zapisa – ljekaruša
- Razvoj ljekarništva - prvi ljekarnici skupljali biljke, prikladno ih čuvali, obrađivali i razvijali vještine dobivanja ljekovitih pripravaka, te kasnije i samostalno uzgajali
- Uzgojem i proučavanjem biljaka spoznalo se da svaki dio biljke ima svoju specifičnu strukturu, sastav ljekovitih tvari koje se razlikuju u koncentraciji i variraju ovisno o temperaturi, vlazi, kiselosti tla i izloženosti suncu. Sve to utječe na koncentraciju aktivne tvari u krajnjem ljekovitom pripravku.

BILJKE...



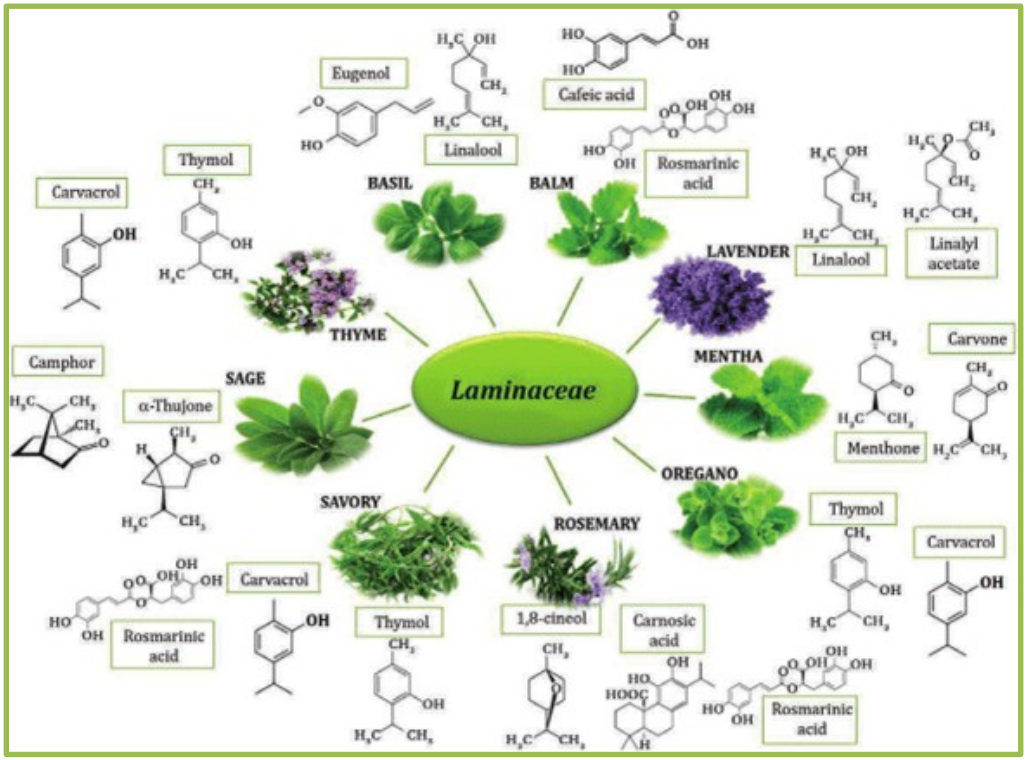
Botanical Nutraceutical occupies position between food and medicine

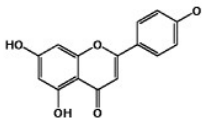
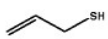
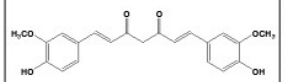
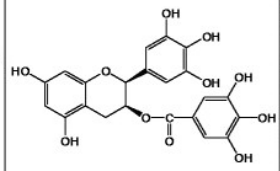
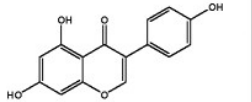
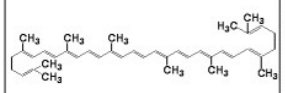
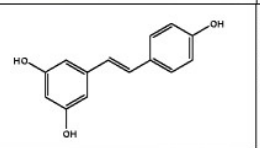
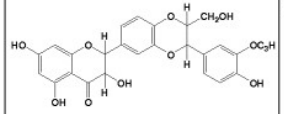
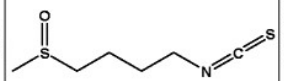
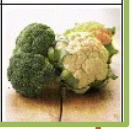


PRODUCTS WITH HERBAL INGREDIENTS "BOTANICALS"

- Pharmaceutical law
  - Conventional drugs and OTC
  - Traditional medicine products
  - Homeopathy and other "alternative" medicine
- Food law
  - Vegetal foods (fruits and vegetables)
  - Functional foods Novel foods Traditional foods from TC
  - **Food supplements**
- Other
  - Medical devices (eye drops, oral solutions, etc.)

AKTIVNE TVARI BILJAKA

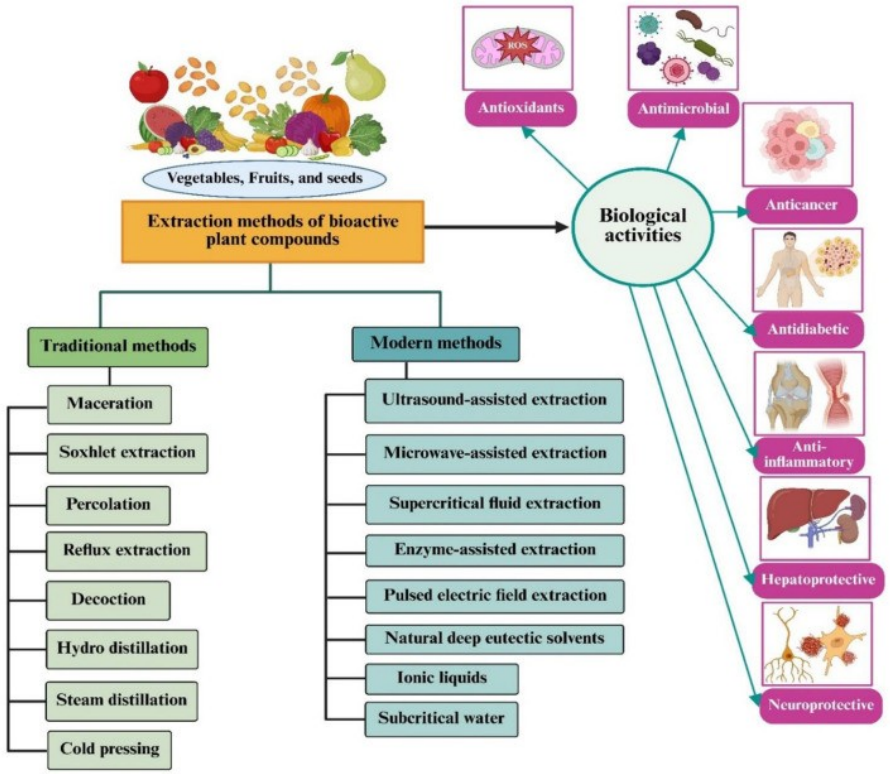


Dietary agents	Structure	Epigenetic effect on Cancer*	Picture of the sources
Apigenin (Parsley)[1] (*Petroselinum*)[2]		DNMT inhibitor *(Fang M et al 2007)*	
Allyl Mercaptan (Garlic)[1] (*Allium sativum*)[2]		HDAC inhibitor *(Lea et al 2001; Druesne et al 2004)*	
Curcumin (Turmeric)[1] (*Curcuma longa*)[2]		DNMT inhibitor *(Liu et al 2009; Fang et al 2007; Fu and Kurzrock 2010)* HDAC and HAT inhibitor *(Chen et al 2007; Liu et al 2005; Kang et al 2006; Cui et al 2007; Balasubramanyam et al 2004)*	
Epigallocatechin-3-gallate (EGCG) (Green tea)[1] (*Camellia sinensis*)[2]		DNMT inhibitor *(Fang et al 2003; Kato et al 2008; Pandey et al 2010; Lee et al 2005)* HAT inhibitor *(Choi et al 2009)*	
Genistein (Soybean)[1] (*Glycine max*)[2]		DNMT inhibitor *(Majid et al 2008; Kikuno et al 2008; Fang et al 2005; Li et al 2009)* HDAC inhibitor and HAT activator *(Fang et al 2005; Li et al 2009; King-Batoon et al 2008; Majid et al 2008)*	
Lycopene (Tomatoes)[1] (*Solanum lycopersicum*)[2]		Demethylates the *GSTP1, RARβ2 and HIN-1* genes in breast cancer cells (MDA-MB-231 and MCF10A) *(King-Batoon et al 2008)*	
Resveratrol (Red grapes)[1] (*Vitis vinifera*)[2]		DNMT inhibitor *(Papoutsis et al 2010; Stefanska et al 2010)* SIRT1 activator *(Kaeberlein et al 2008; Wang et al 2008; Bolly et al 2009)*	
Silymarin (Milk thistle)[1] (*Silybum marianum L.*)[2]		SIRT1 activator *(Li et al 2007)*	
Sulforaphane (Cruciferous vegetables)[1] (*Brassicaceae*)[2]		DNMT inhibitor *(Meeran et al 2010; Traka et al 2005)* HDAC inhibitor *(Myzak et al 2007; Dashwood and Ho 2007; Ho et al 2009; Myzak et al 2004)*	

Sukladno Direktivi 46/2002 - Hranjive tvari: vitamini i minerali

Aktivne, druge tvari, u smislu Pravilnika (NN 160/2013), su tvari s određenim hranjivim ili fiziološkim učinkom: aminokiseline, esencijalne masne kiseline, vlakna, biljni organi, biljni ekstrakti, biljni produkti, mikroorganizmi, jestive gljive, alge, pčelinji proizvodi i druge tvari s hranjivim ili fiziološkim učinkom

IZOLACIJA BIOLOŠKI AKTIVNIH TVARI BILJAKA



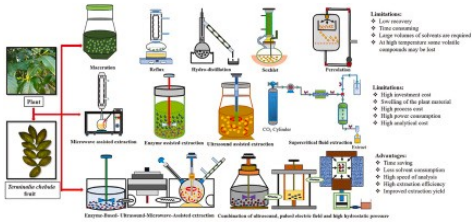
Danas se teži da su svi biljni ekstrakti standardizirani (za medicinske, kozmetičke i prehrambene svrhe)

Standardizacija je postupak kojim se određuje količina ljekovitih/aktivnih tvari u jedinici mjere ljekovitog proizvoda, čime *proizvođač garantira da se u 1 g ili 1 ml proizvoda nalazi određena količina aktivne komponente*

PRIMJERI :
BILJKA – STANDARDIZIRANI EKSTRAKT

- Glog – količina viteksinramnozida
- Ginko – ginkoflavonglikozida
- Odoljen/Valerijana – valerenska kis.
- Divlji kesten – escin
- Maslina – oleuropein
- Crni kim – timokinon

Negativni primjer *loše i krive standardizacije* je npr. kod ginka, gdje se umjesto standardiziranih ginkoflavonglikozida dobivaju omjeri kvercetina, kemferola i izoramnetina koji NE odgovaraju literaturnim podacima za standardizirani ekstrakt lista Ginkgo biloba



PRIHVAĆENOST AKTIVNIH KOMPONENATA U EU = BILJNE VRSTE

Botanicals & botanical extracts	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Aloe (*Aloe vera* (L.))	E	✓	E	E	C	L	✓	C	A	C	✖	C	✓	✓	✓	E	✓	✓	✓	✓	✓	✓	C	L/C	✓	✓	C
Ginkgo (*Ginkgo biloba*)	E	L	E	E	L	✓	✖	C	A	✖	✖	L	✖	C	L	E	✓	✓	✓	✓	✓	✓	L	✖	✖	✖	C
Ginseng (*Panax ginseng*)	E	✓	E	E	L	L	✓	C	A	✖	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C
Garlic (*Allium sativum* (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✖	✖	C
Green tea extract (*Camellia sinensis*)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	C
Garcinia extract (*Garcinia cambogia*)	E	✓	E	E	L	✖	C	✓	A	✖	✖	L	✖	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	C	✖	E	✖
Guarana extract (*Paullinia cupana*)	C	✓	E	E	C	L	✓	✓	A	C/A	✖	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓

Symbols	
✓	Permitted for use in food supplements either under national law or internal guidelines.
L	Permitted for use in food supplements - maximum level established.
C	Permitted for use in food supplements under specific conditions (eg type of extract, ingredients combination in the final product, etc)
E	Permission may be given on a case by case basis following evaluation, considering issues such as ingredient function.
A	Not currently pemitted. May be permitted following a pre-marketing authorisation.
✖	Not permitted for use in food supplements, or regarded as medicinal.

Izvor: EAS, 2012

BILJKE U RH I ZAKONODAVSTVO….

PRAVILNIK O TVARIMA KOJE SE MOGU DODAVATI HRANI I KORISTITI U PROIZVODNJI HRANE TE TVARIMA ČIJE JE KORIŠTENJE U HRANI ZABRANJENO ILI OGRANIČENO (NN 160/13)

Prilog II t.3 = 368 biljnih vrsta na pozitivnoj listi, od toga se 116 može koristiti i u hrani

Prilog II t.4 = 4 vrste gljiva

Prilog III = lista 113 biljnih vrsta koje su zabranjene u hrani i dodacima prehrani

PRIMJENA BILJNIH VRSTA U HRANI(1) I U DODACIMA PREHRANI

Prilog II t.3.

Capsicum annuum longum[1]	Paprika	Nije dopušteno kao monopripravak. Najveći dopušteni udio u smjesi glavnih sastojaka 30% m/m. Upozorenje: može izazvati nadražaj želučano-crijevne sluznice. Osobe koje uzimaju lijekove trebaju se prije uzimanja posavjetovati s liječnikom.
Capsicum frutescens [1]	Kajenska paprika, čili	Nije dopušteno kao monopripravak. Najveći dopušteni udio u smjesi glavnih sastojaka 30% m/m. Upozorenje: može izazvati nadražaj želučano-crijevne sluznice. Osobe koje uzimaju lijekove trebaju se prije uzimanja posavjetovati s liječnikom.
Carduus marianus (Silybum marianum)	Sikavica, obični oslobod	Najveća dnevna doza: 140 mg silimarina. U sastavu je potrebno naznačiti količinu silimarina. Osobe koje uzimaju lijekove trebaju se prije uzimanja posavjetovati s liječnikom. Ne preporučuje se trudnicama, dojiljama i djeci.

POVEZNICA S KATALOGOM NOVE HRANE



Tribulus terrestris

Common Names

Devil´s thorn (EN), caltrop, buzdyganek ziemny (PL), Abrolho (PT), Bettlernuss, Dreispitz, Erdsternchen, Erdwurzeldorn (DE), kotvičník zemní (CZ), királydinnye (HU), malteserkors (DK), navadna zobačica (SL)

Description

Plants belonging to the Zygphyllaceae Family which are most visible towards the end of summer as they reach maximum size after germinating shortly after summer rains.

Novel Food Status

FS What does it mean?

Urtica dioica

Common Names

EN: Nettle, stinging nettle, greater nettle, BG: Kopriva, DK: Stor Nælde, NL: Grote brandnetel, FI: Isonokkonen, FR: Grande ortie, Ortie dioïque, DE: Große Brennessel, GR: Tsucnida, tsucna, scites, IS: Brenninetla, IT: Ortica comune, orticone, ortica maschia, NO: Stornesle, PT: Urtiga, PL: Pokrzywa zwyczajna, ES: Ortiga, chichicaste, SE: Brännässla

Description

The leaves of *Urtica dioica* have been used as food in the EU before 15 May 1997. In addition, according to the "Belgian list of plants that are considered to be not novel for the use in food supplements" the use of all plant parts of stinging nettle or greater nettle is authorized in food supplements.

Nettle is the common name for between 30-45 species of flowering plants of the genus *Urtica* in the family *Urticaceae*, with a cosmopolitan though mainly temperate distribution. They are mostly herbaceous perennial plants, but some are annual and a few are shrubby.

The most prominent member of the genus is the stinging nettle *Urtica dioica*, native to Europe, north Africa, Asia, and North America. The genus also contains a number of other species with similar properties. However, a large number of species names that will be encountered in this genus in the older literature (about 100 species have been described) are now recognized as synonyms of *Urtica dioica*. Some of these taxa are still recognized as subspecies.

Most of the species share the property of having stinging hairs, and might be expected to have similar medicinal uses to the stinging nettle. The stings of *Urtica ferox*, the ongaonga or tree nettle of New Zealand, have been known to kill horses, dogs and at least one human.

Novel Food Status

What does it mean?

Lavandula officinalis

Common Names

Lavende (FR), Lawenda wąkolistna (PL), Lavanda (PT, ES), Laventeli (FI), Lavendel (DE, NL), Tähklavendel (ET), Levandule lékařská (CZ), Orvosi levendula (HU), λεβάντα (EL), ægte lavendel (DK), Dziedniecības lavanda (LV), Navadna sivka (SL), Lavendel-art (SE), Lavandula angustifolia, Common lavender, English lavender (EN)

Description

The edible part of lavender is the flowering top.

Lavandula officinalis is a plant belonging to the Lamiaceae Family and native to the Mediterranean area, cultivated in countries like France, Italy and Spain. Due to its special odor, lavender has found wide application in perfumes and cosmetics throughout history.

Novel Food Status

What does it mean?

This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EU) 2015/2283. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

FS According to information available to Member States competent authorities this product was used only as or in food supplements before 15 May 1997. Any other food uses of this product have to be authorised pursuant to the Novel Food Regulation.

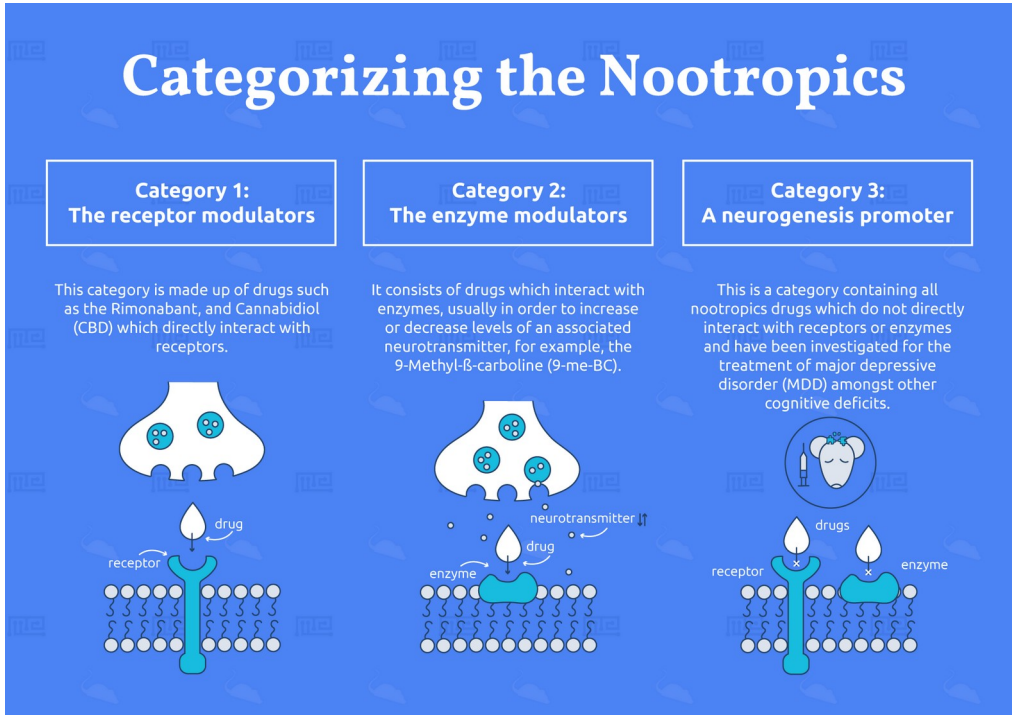
There was a request whether this product requires authorisation under the Novel Food Regulation. According to the information available to Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.

There was a request whether this product requires authorisation under the Novel Food Regulation. Further information is required.

PRIMJERI BILJNIH VRSTA I NUTRIJENATA KAO NOOTROPIKA….?

NOOTROPICI

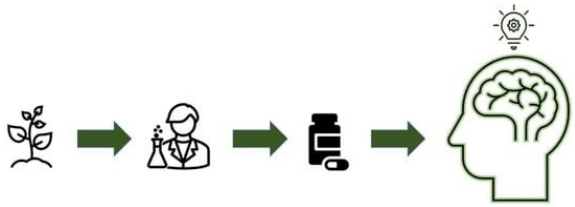
- biološki aktivne tvari biljnih vrsta
- smatraju se moždanim stimulansima
- učinkovito poboljšavaju mentalne i kognitivne funkcije
- „lijekovi za mozak”
- MENTALNE SPOSOBNOSTI!



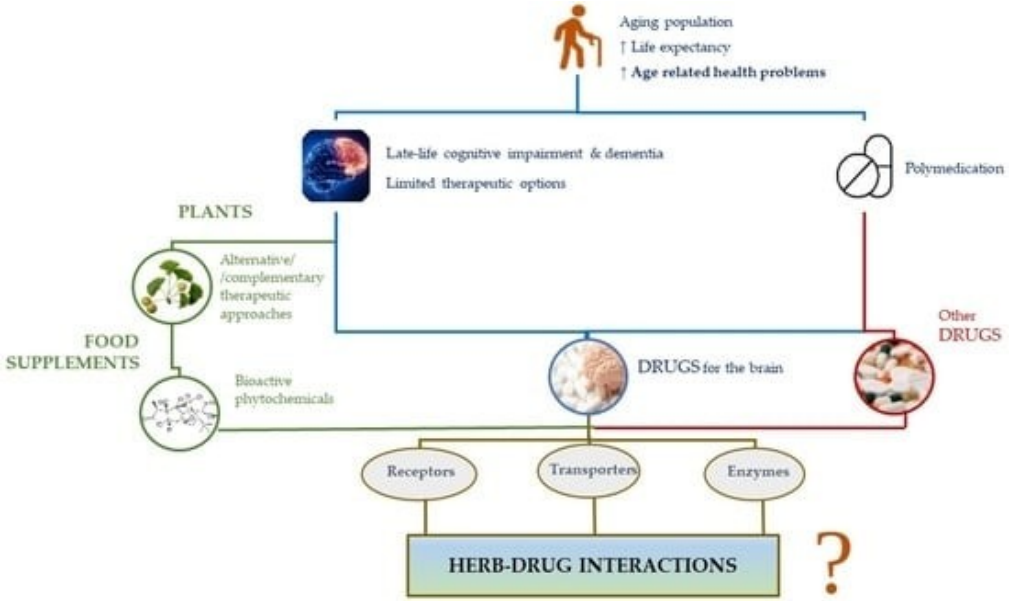
DJELOVANJE NA MOZAK

- poboljšavaju pamćenje
- koncentraciju
- učenje
- svijest
- poboljšavaju mentalne sposobnosti - kao pomoć za učenje, odrađivanje složenih i stresnih poslova
- pomažu u borbi s nekim oblikom zaboravnosti, čak i demencije
- štite mozak od raznih fizičkih ili kemijskih neravnoteža
- povećavaju sposobnost tijela da kontrolira kontrakcije i opuštanja mišića

NOOTROPICI KAO LIJEK



KATEGORIZACIJA
- dodaci prehrani
- **lijekovi koje propisuje liječnik**



- pomoć u liječenju ADHD-a
- kod poremećaja pozornosti s hiperaktivnošću
- raznih oblika demencije - najčešće kod Alzheimerove bolesti

Nootropne lijekove propisuju liječnici specijalisti s iskustvom u liječenju Alzheimerove bolesti i **ADHD-a** s namjerom kontrole bolesti. Oni prate i sigurnost pacijenta.

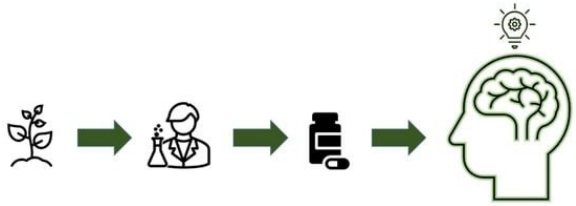
NOOTROPICI KAO DODATAK PREHRANI

KATEGORIZACIJA
- **dodaci prehrani**
- lijekovi koje propisuje liječnik

Potrošnja nootropnih biljnih pripravaka je široko rasprostranjena i u porastu:

- Opskrba se više ne može pokrivati samo sakupljanjem samoniklog bilja

- Žetva relevantnih biljnih dijelova u optimalno vrijeme bitno je jer sadržaj i spektar aktivnih komponenata se mijenja tijekom razvoja biljke



FARMACEUTSKI OBLICI

- ljekoviti pripravci od biljnih dijelova mogu se sušiti kao neka vrsta vodene infuzije ili kroz druge vrste ekstrakcije, u obliku praha, tablete ili kapsule

Nekoliko vrsta biljaka, grmlja i drveća odabrani su za testiranje kao nootropici zbog duge povijest korištenja u tradicionalnoj medicini.

Istraživanja su već identificirala pojedine
obećavajuće prirodne tvari koje bi mogle djelovati kao kognitivni pojačivači

NOOTROPICI

1. GINKO (*GINKGO BILOBA*)

BOTANIČKI STATUS

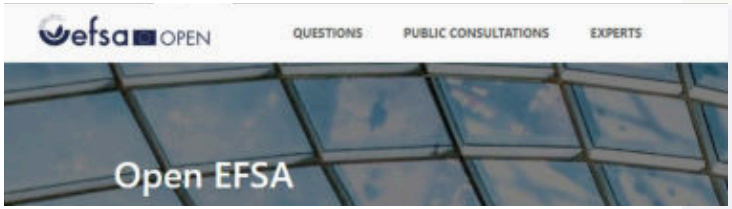
Botanicals & botanical extracts	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Aloe (*Aloe vera* (L.))	E	✓	E	E	C	L	✓	C	A	C	✖	C	✓	✓	✓	E	✓	✓	✓	✓	✓	✓	C	L/C	✓	✓	C
Ginkgo (*Ginkgo biloba*)	E	L	E	E	L	✓	✖	C	A	✖	✖	L	✖	C	L	E	✓	✓	✓	✓	✓	✓	L	✖	✖	✖	C
Ginseng (*Panax ginseng*)	E	✓	E	E	L	L	✓	C	A	✖	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C
Garlic (*Allium sativum* (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✖	✖	C
Green tea extract (*Camellia sinensis*)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	C
Garcinia extract (*Garcinia cambogia*)	E	✓	E	E	L	✖	C	✓	A	✖	✖	L	✖	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	C	✖	E	✖
Guarana extract (*Paullinia cupana*)	C	✓	E	E	C	L	✓	✓	A	C/A	✖	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓

Symbols	
✓	Permitted for use in food supplements either under national law or internal guidelines.
L	Permitted for use in food supplements - maximum level established.
C	Permitted for use in food supplements under specific **conditions** (eg type of extract, ingredients combination in the final product, etc)
E	Permission may be given on a case by case basis following **evaluation**, considering issues such as ingredient function.
A	Not currently pemitted. May be permitted following a pre-marketing **authorisation**.
✖	Not permitted for use in food supplements, or regarded as medicinal.

Ginkgo biloba	Ginko	Dopuštena je upotreba samo standardiziranog ekstrakta lista s najviše 5 ppm ginkolnih kiselina. Najveća dnevna doza: 80 mg ekstrakta. Osobe koje uzimaju lijekove trebaju se prije uzimanja posavjetovati s liječnikom. Ne preporučuje se kod poremećaja zgrušnjavanja krvi, trudnicama, dojiljama i djeci.



OPEN EFSA I *ON-HOLD* TVRDNJE ZA GINKO



Other sites: EFSA | OpenEFSA | EFSA Journal | Connect

efsa OPEN — QUESTIONS | PUBLIC CONSULTATIONS | EXPERTS

Questions

ginkgo

20 results found — Export (20) questions to CSV

Food domain

- Administrative and Technical Support
- Animal Health
- Animal Welfare
- Assessment and Methodological Support
- Biological Hazards

Show All

Substances

Nutrition EFSA-Q-2008-4633
3917 - *Ginkgo* Biloba (Common Name : *Ginkgo*) - brain healt
Last updated on: 19/03/2010
Status: Application Withdrawn

Nutrition EFSA-Q-2008-3540
2807 - *Ginkgo* tree (*Ginkgo* biloba) - Cardiovascular system Eyes Ears
Last updated on: 08/12/2023
Status: Intake

Nutrition EFSA-Q-2008-4487
3768 - *Ginkgo* Biloba (Common Name : *Ginkgo*) - Cognitive function
Last updated on: 08/12/2023
Status: Intake

Nutrition EFSA-Q-2008-4486
3767 - *Ginkgo* biloba (Common Name : *Ginkgo*) - Antioxidant properties
Last updated on: 28/10/2009
Status: Published

Nutrition EFSA-Q-2010-00257
4304 - *Ginkgo* Biloba (Common Name : *Ginkgo*) - blood system microcirculation
Last updated on: 08/12/2023
Status: Intake

Nutrition EFSA-Q-2008-4634
3918 - *Ginkgo* Biloba (Common Name : *Ginkgo*) - neurosensory funtions
Last updated on: 19/03/2010
Status: Application Withdrawn

Feed Additives EFSA-Q-2018-00318 — (-)-BILOBALIDE
***Ginkgo* biloba L. extract for cats and dogs [Article 10]**
Last updated on: 07/12/2023
Status: Published

Nutrition EFSA-Q-2008-3279
2546 - *Ginkgo* biloba - Système nerveux Démence
Last updated on: 08/12/2023
Status: Intake

Nutrition EFSA-Q-2008-4399
3676 - Panax Ginseng (when used in combined formulation with *Ginkgo* biloba) - Cognitive Function
Last updated on: 08/12/2023
Status: Intake

Nutrition EFSA-Q-2008-4095
3364 - *Ginkgo* biloba [dry extract GK501 Pharmaton Dry extract from leaves of *Ginkgo* biloba L., drug/native extract ratio (35 - 45) : 1, solvent of extraction Acetone/Water, 6.0% terpene lactones, 24.5% ginkgoflavonoids] - For cognitive performance/blood circulation



U HZJZ se određuje od 2007. godine.

Određivanje:

- ukupnih ginkoflavonoglikozida i
- pojedinačno: kvercetina, kemferola i izoramnetina.

Određivanje omjera kvercetina i kemferola prema literaturi i specifikaciji

(metoda AOAC – akreditirana ISO 7025 od 2012. godine)

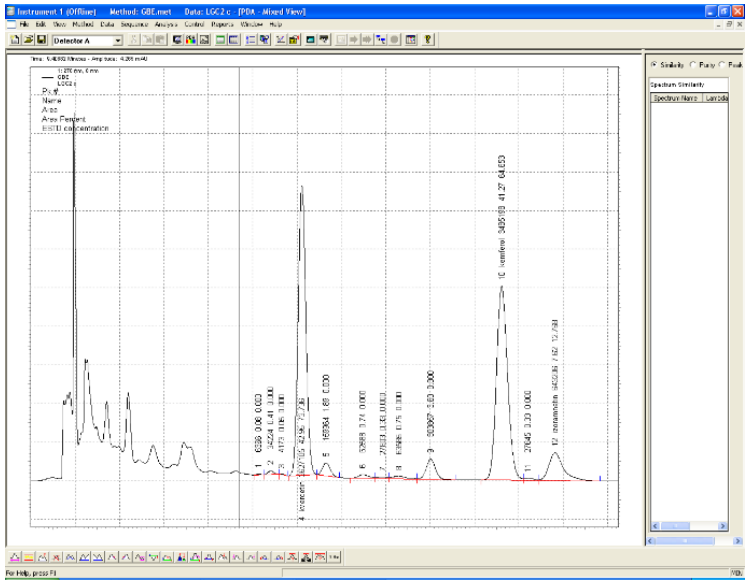
Certificate Of Analysis

PRODUCT	**Ginkgo biloba P.E.**
BATCH NO.	20090120
QUANTITY	1000 kg
APPEARANCE	Light yellow fine powder

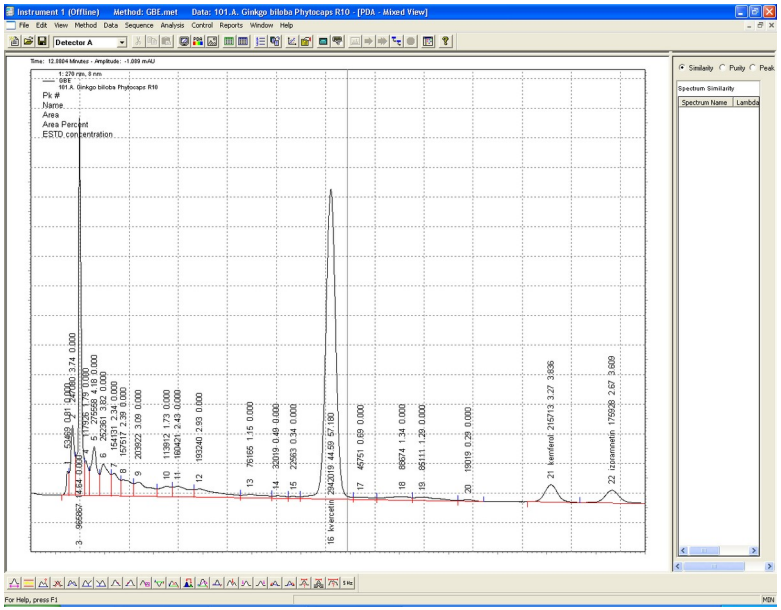
	SPECIFICATION	RESULT
Odor/Taste	Characteri	Conforms
Extract Solvent	Ethanol&Water	Conforms
Excipient	None	Confroms
Particle Size(CP2005)	100% through 80 mesh	Conforms
Bulk Density(CP2005)	0.55g/ml- 0.68g/ml	Conforms
Total Flavone glycosides(by HPLC)	24% min	24.8%
Quercetin(by HPLC)		12.38%
Quercetin / Kampferol ratio		1.07
Total Terpene Lactones	6% min	7.07%
Ginkgolides(A)		2.32%
Ginkgolides(B)		1.12%
Ginkgolides(C)		1.09%
Ginkgolides(J)		0.32%
Bilobalides		2.22%
Total Ginkgolic acid(by HPLC)	5ppm max	3.52 ppm
Loss on Dying(CP2005)	5.00 % max	2.86%
Total heavy metals(Atomic Absorption)	10ppm max	Conforms
Lead	1ppm max	Conforms
Arsenic	1ppm max	Conforms
Cadmium	1.5ppm max	Conforms
Mercury	1ppm max	Conforms
Pesticides Residue	Not Detected	Conforms
Microbiological Test		
Total plate count(CP2005)	1000 cfu/g max	Conforms
Yeast& molds	100 cfu/g max	Conforms
E.Coli.	Negative	Conforms
Salmonella	Negative	Conforms
Staphylococcus	Negative	Conforms
Aflatoxins	20PPB max	Conforms

MANUFACTURING DATE
EXPIRY DATE





LOŠ "KRIVOTVORENI" KROMATOGRAM



DOBAR KROMATOGRAM

KONAČNI PROIZVOD:

- ✓ ANALIZE – ZDRAVSTVENA ISPRAVNOST, SIGURNOST I KVALITETA
- ✓ DEKLARIRANJE SUKLADNO EU i RH ZAKONODAVNOM OKVIRU
- ✓ ON-HOLD TVRDNJE
- ✓ NOTIFIKACIJSKI POSTUPAK

MOŽE SE KAO TAKAV NALAZITI NA TRŽIŠTU DO KONAČNE ODLUKE EFSA-e



NOOTROPICI
2. MACA (*LEPIDIUM MEYENII*)

Već više od 2000 godina maca se koristi kao tradicionalna prehrambena i ljekovita biljka.

- poznata kao peruanski ginseng, iako nije botanički povezan s P. ginsengom.

Godine 1843. Gerhard Walpers je vrstu nazvao *Lepidium meyenii*

-izuzetno je otporna i jaka biljka koja raste na 4.000 m n.v., u području Anda.

-Korijen make sadrži brojne biološki aktivne tvari ključne za farmakološko djelovanje

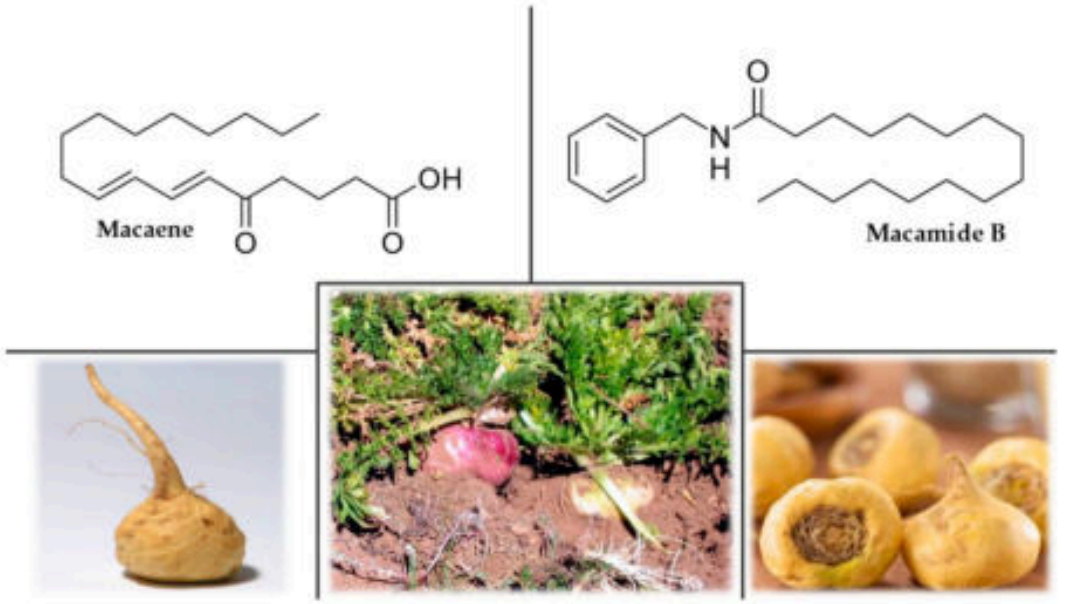
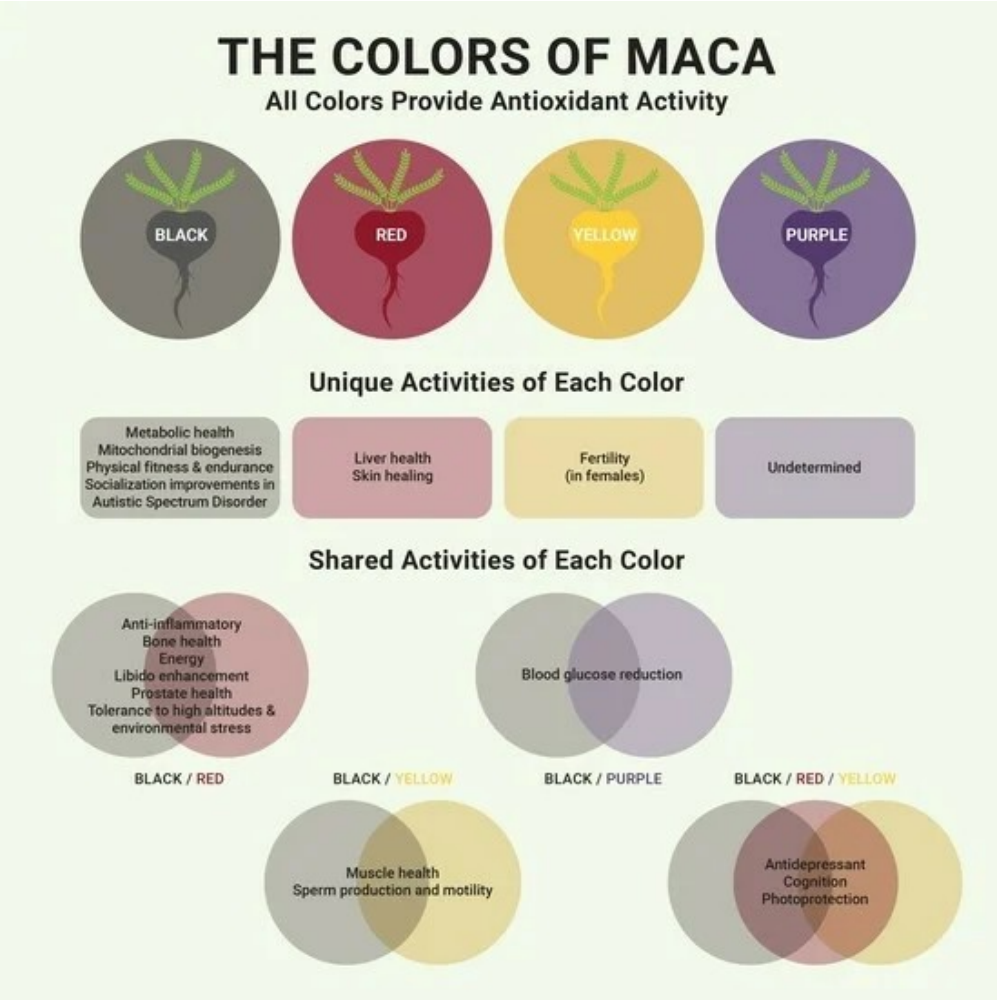


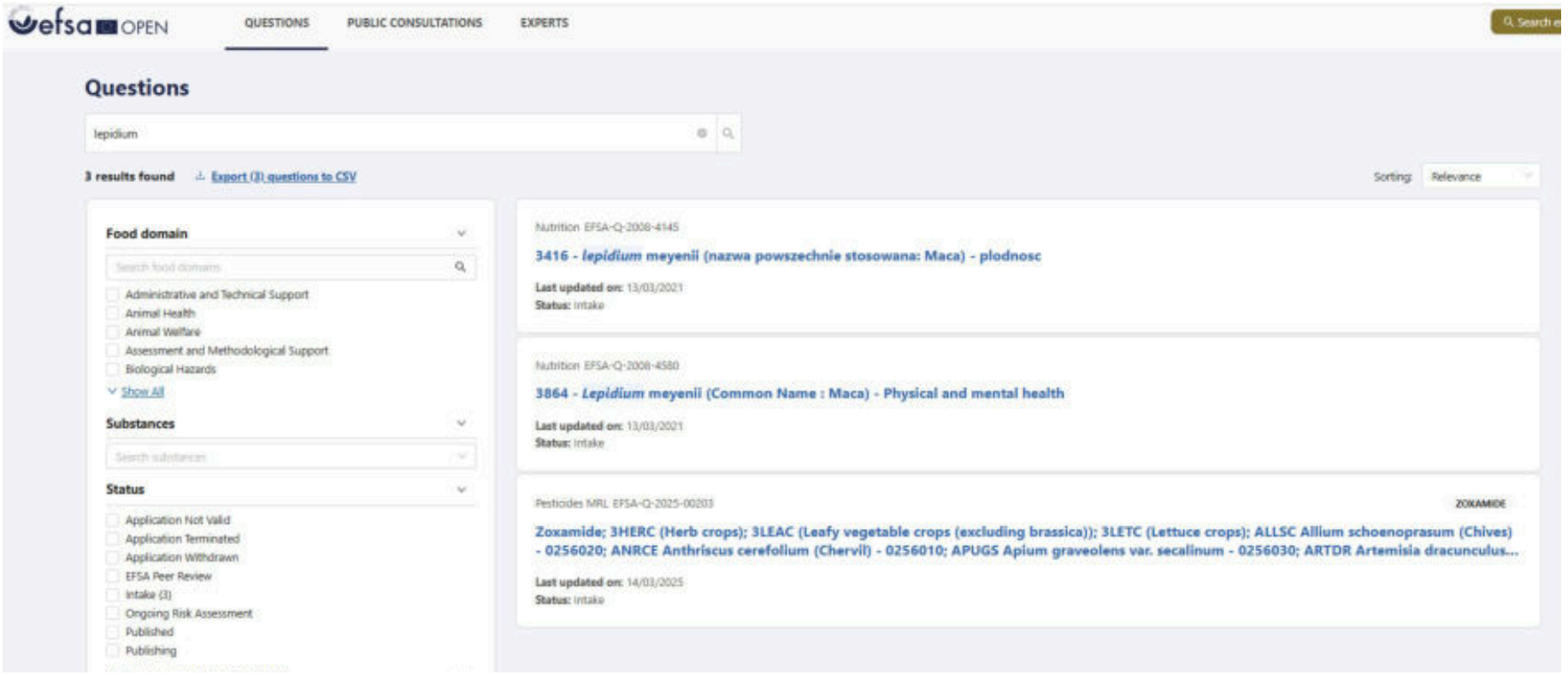
Figure 7. *Lepidium meyenii's* main bioactive compounds, macamides and macaenes, and their chemical structures.

DJELOVANJE



CONDITION	YELLOW MACA	RED MACA	BLACK MACA
Fatigue	✓	✓	✓
PMS	✓	✓	
Menopause	✓	✓	
FemaleFertility		✓	
Female Libido		✓	
Male Fertility			✓
Male Libido			✓
Poor Circulation		✓	
Prostate Function		✓	
Osteoporosis (Bone Density)		✓	
Thyroid Function	✓		
Stamina and Endurance			✓
Strength and Muscle			✓
Poor Concentration			✓
Anxiety and Stress	✓	✓	✓
Depresion		✓	✓
Mental health	✓	✓	✓
Skin Protection	✓	✓	✓
Acne	✓	✓	

ON-HOLD TVRDNJE
MACA (*LEPIDIUM MEYENII*)



NOOTROPICI
3. KOFEIN….

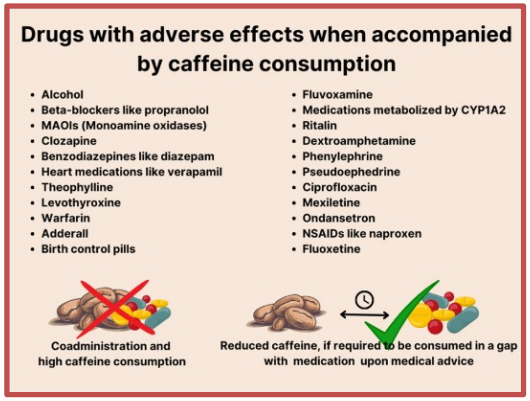






Previsoka konzumacija uzrokuje nervozu, tremor i nesanicu

Efedrin stupa u interakciju s KOFEINOM - Uzimanje kofeina zajedno s efedrinom može uzrokovati prejaku stimulaciju, a ponekad i ozbiljne nuspojave i probleme sa srcem. Ne uzimajte proizvode koji sadrže kofein i efedrin u isto vrijeme.
– EFEDRA JE ZABRANJENA



HR Službeni list Europske unije

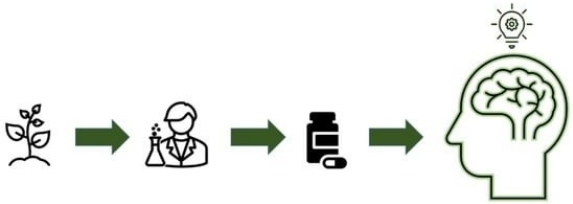
VRSTA ILI KATEGORIJA HRANE	NAVODI
4. **Pića s visokim sadržajem kofeina ili hrana s dodatkom kofeina**	
4.1. Pića, osim pića na bazi kave, čaja ili ekstrakta kave ili čaja čiji naziv sadrži izraz „kava" ili „čaj", koja su: — namijenjena za konzumaciju bez promjene i sadrže kofein iz nekog izvora u količini većoj od 150 mg/l, ili — u koncentriranom ili dehidriranom obliku i koja nakon rekonstitucije sadrže kofein iz nekog izvora u količini većoj od 150 mg/l.	„Visoki sadržaj kofeina. Ne preporučuje se djeci, trudnicama ili dojiljama" treba se nalaziti u istom vidnom polju kao naziv pića, nakon čega se, u skladu s člankom 13. stavkom 1. ove Uredbe, u zagradi navodi sadržaj kofeina izražen u mg na 100 ml.
4.2. Hrana, osim pića, kojoj je kofein dodan u fiziološke svrhe.	Napomena „Sadrži kofein. Ni preporučuje se djeci ili trudnicama" treba se nalaziti u istom vidnom polju kao naziv hrane, nakon čega se, u skladu s člankom 13. stavkom 1. ove Uredbe, u zagradi navodi sadržaj kofeina izražen u mg na 100 g/ml. U slučaju dodataka prehrani sadržaj kofeina iskazuje se po obroku koji je na etiketi preporučen za dnevnu konzumaciju.

Uredba 1169/2011/EC

Depletions: Herbs & Supplements

Vitamins, minerals, and electrolytes: Based on clinical review and human reports, caffeine, particularly in large amounts, may reduce potassium levels (346;257;347;225) and increase sodium loss (591). Based on secondary sources, at high levels (more than 744mg daily), caffeine may increase calcium and magnesium loss in urine. However, a 1994 National Institutes of Health (NIH) advisory panel concluded that caffeine has not been found to affect calcium absorption or excretion significantly and that two tablespoons of milk added to one cup of coffee may counteract any of the calcium lost. Based on secondary information, caffeine consumption may result in a loss of several vitamins and minerals, including thiamine (B1), riboflavin (B2), pyridoxine (B6), vitamin B, vitamin C, potassium, magnesium, zinc, and iron.

NOOTROPICI
ostali....



L-TEANIN
u zelenom čaju; ne djeluje toliko na pojačavanje rada mozga, već na smanjenje stresa i napetosti čime se postiže koncentracija

ACETIL-L-KARNITIN
povećava energiju potrebnu za funkcije mozga, te poboljšava budnost, pamćenje i pažnju

KOLIN
pomaže u metabolizmu acetilkolina u mozgu
najveća dnevna doza do 3 g dnevno

STANDARDIZACIJA NOOTROPIKA

- Većina nootropnih biljnih dodataka prehrani ne djeluje odmah nakon jedne primjene i mora se uzimati u optimalnim dozama dulje vrijeme

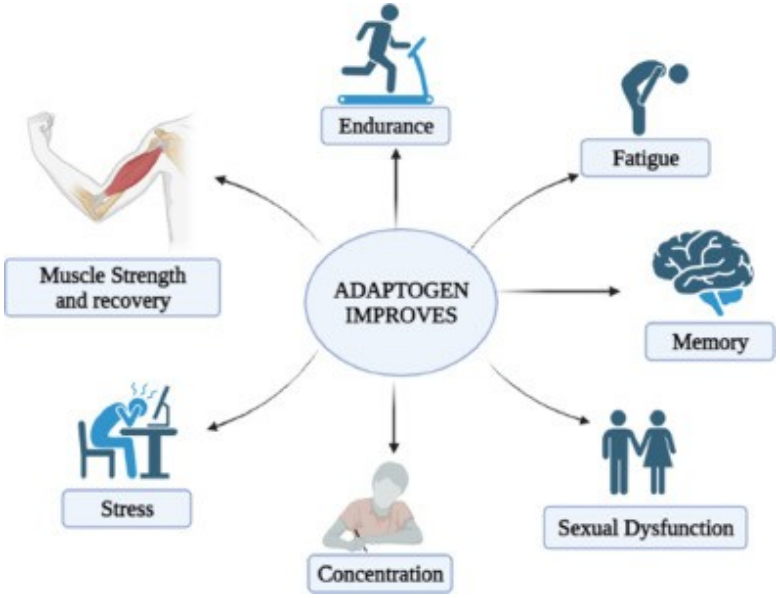
- Mogući problem u istraživanju prirodnih biološki aktivnih tvari i njihovih proizvoda *je standardizacija* oblika i doziranja

- Biljke sadrže mnoge biološki aktivne tvari koje mogu izazvati različite biološke učinke, ali ovise ne samo o svom genotipu, već i mjestu rasta, sastavu tla, klimi, što automatski utječe na kemijski sastav biljnih tkiva

- Nemaju dovoljno kliničkih istraživanja vezano na primjenu kod trudnica, dojilja i djece stoga je potreban oprez

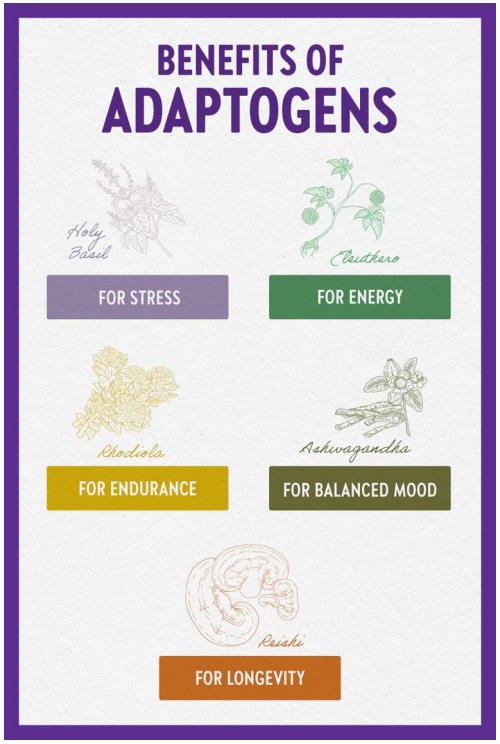
PRIMJERI BILJNIH VRSTA I NUTRIJENATA KAO ADAPTOGENA….?

ADAPTOGENI



KORISTE SE ZA:

- poboljšanje pažnje,
- povećanje izdržljivosti u situacijama u kojima je prisutan umor,
- smanjenje broja bolesti i oštećenja povezanih sa stresom u tijelu,
- poboljšanje fizičke izdržljivosti, snage i razine energije,
- poboljšanje seksualne disfunkcije,
- vraćanje kognitivnih performansi na koje je utjecao stres te
- održavanje kortizola (hormona stresa) i drugih razina hormona pod kontrolom



✓ učinkovito pomažu tijelu u „borbi“ sa stresom i toleranciji simptoma i posljedica stresa = PRILAGODBA STRESU

ADAPTOGENE BILJNE VRSTE

Znanstveno najopsežnije proučavani adaptogeni su:
Withania somnifera
Rhodiola rosea
Schisandra chinensis
Eleutherococcus senticosus

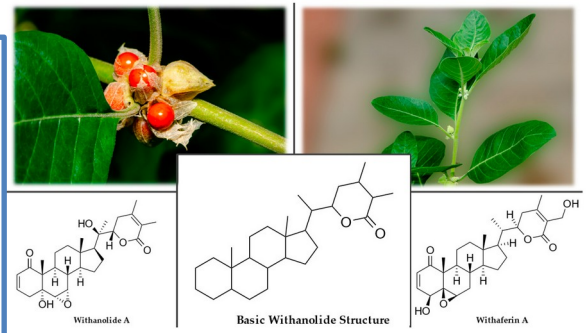
Table 1
Actions and side effects of adaptogens in athletes.

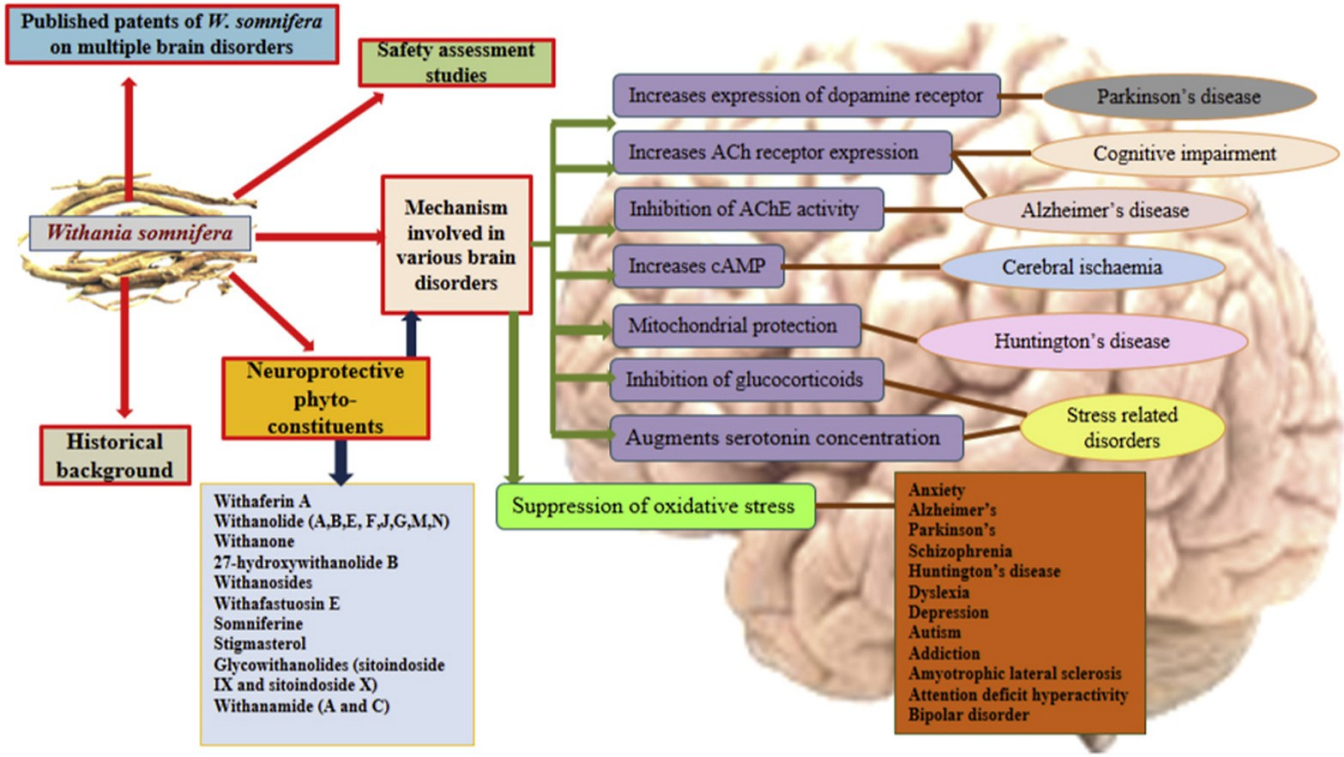
S. No.	Adaptogen	Biological Name	Action	Caution/side effect
1	Ashwagandha	*Withania somnifera*	Improves muscle strength, endurance, and quality of life	Rhinitis, constipation, decreased appetite
2	Astragalus	*Astragalus membranaceus*	Improves endurance and muscle recovery	It is immunomodulatory, so persons with autoimmune diseases cannot use it
3	Cordyceps	*Ophiocordyceps sinensis*	Improves endurance and energy	Dry mouth, nausea, and diarrhea
4	Ginseng	*Panax ginseng*	Enhances muscle strength, endurance, and muscle recovery	Mild insomnia, hot flushes, and dyspepsia
5	Holy Basil	*Ocimum sanctum/ Ocimum tenuiflorum*	Muscle recovery	Mild nausea
6	Rhodiola Rosea	*Rhodiola rosea*	Enhances physical strength, endurance and	Dizziness, dry mouth, or unrestrained saliva production
7	Schisandsra	*Schisandra chinensis*	Improve muscle strength, endurance, and overall physical performance	May interfere with CYP-450 isoenzyme
8	Turmeric	*Curcuma longa*	Protects against inflammation and enhances muscle recovery	In some cases, diarrhea, headache, and rash

ADAPTOGENI
1. ASHWAGANDHA (*WITHANIA SOMNIFERA*)

- indijska biljka - korijen ima „miris po konju”
- aktivne tvari su steroidni laktoni vitanolid A, vitaferin A i vitanozid IV
- isključivo se koristi korijen, a ne nadzemni dio biljke

Ashwagandha djeluje neuroprotektivno te smanjuje pretjerano povišeni kortizol. Preporučuje se najviše 600 mg ekstrakta dnevno.





NUSPOJAVE, ON-HOLD TVRDNJE

Questions

ashwagandha

4 results found Export (4) questions to CSV

Food domain
- Administrative and Technical Support
- Animal Health
- Animal Welfare
- Assessment and Methodological Support
- Biological Hazards

Show All

Substances

Status
- Application Not Valid
- Application Terminated
- Application Withdrawn
- EFSA Peer Review
- Intake (3)
- Ongoing Risk Assessment
- Published (1)
- Publishing

Transparency Regulation (TR)
- Pre-TR (4)
- Post-TR

Nutrition EFSA-Q-2008-3983
3251 - *Ashwagandha* root (Withania somnifera) - Adaptogenic properties
Last updated on: 12/03/2021
Status: Intake

Nutrition EFSA-Q-2008-2916
2183 - Withania somnifera (common name: *Ashwagandha*) - Mental Health and relaxation
Last updated on: 12/03/2021
Status: Intake

Nutrition EFSA-Q-2010-00460
4507 - Withania somnifera-roots-*Ashwagandha*, Winter cherry - Antioxidant Activity
Last updated on: 05/08/2010
Status: Published

Nutrition EFSA-Q-2008-3236
2503 - Withania somnifera (Withania, horse smell, ginseng Indian, *ashwagandha*) - Cardiovascular health
Last updated on: 12/03/2021
Status: Intake

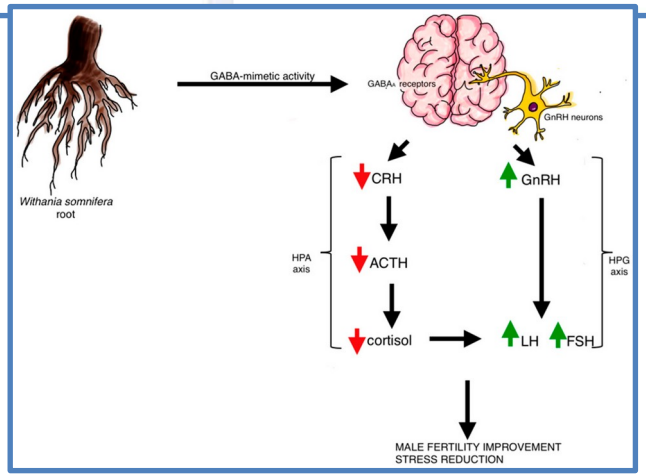
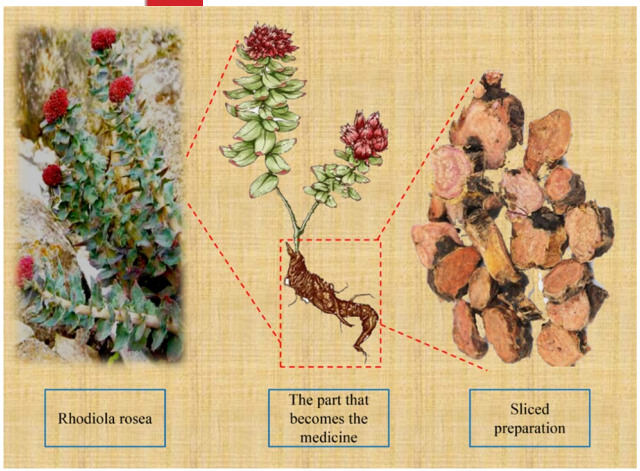
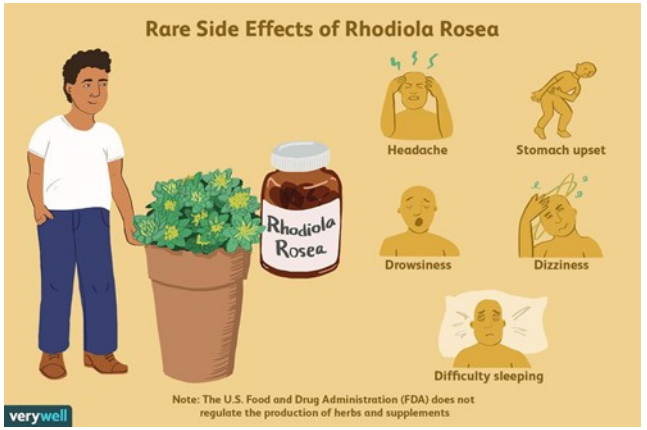


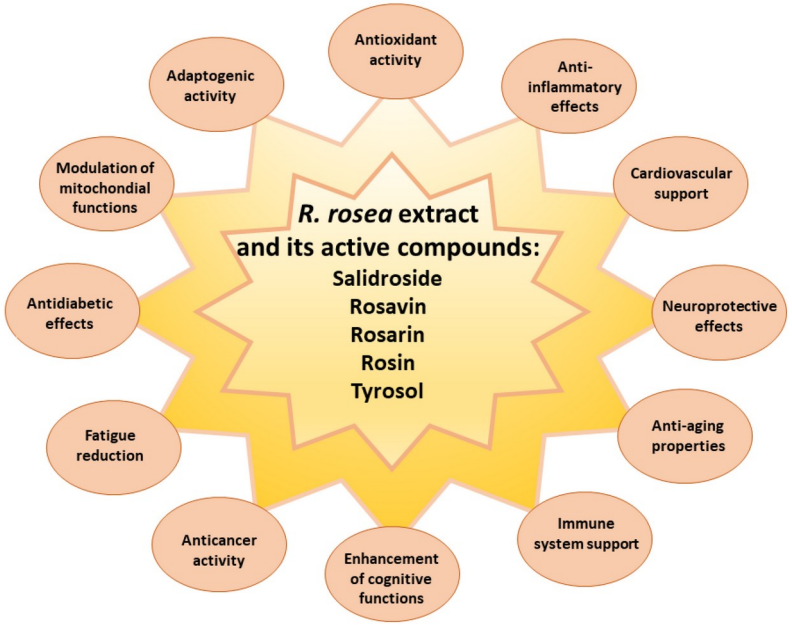
TABLE 2
SIDE EFFECTS OF ASHWAGANDHA

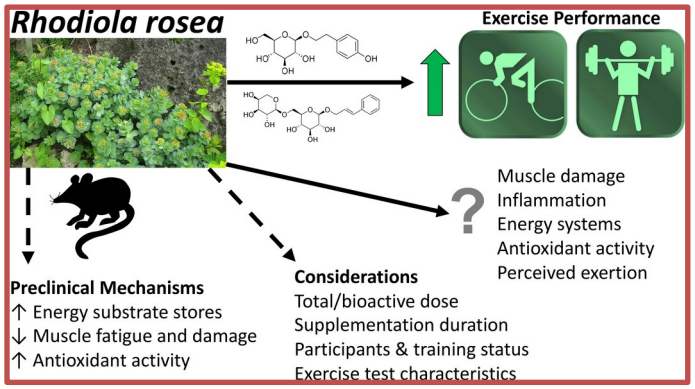
Side Effect
Mild to moderate transient drowsiness
Somnolence
Giddiness
Vertigo
Loose stool
Gastrointestinal discomfort
Nausea
Vomiting
Constipation
Changes in appetite
Drug-induced liver injury
Nasal congestion (rhinitis)
Cough and cold
Increased libido
Thyroid effects
Hypotension
Dermatitis
Increase sperm count and motility in males
Lower blood glucose levels

ADAPTOGENI
RODIOLA (*RHODIOLA ROSEA*)



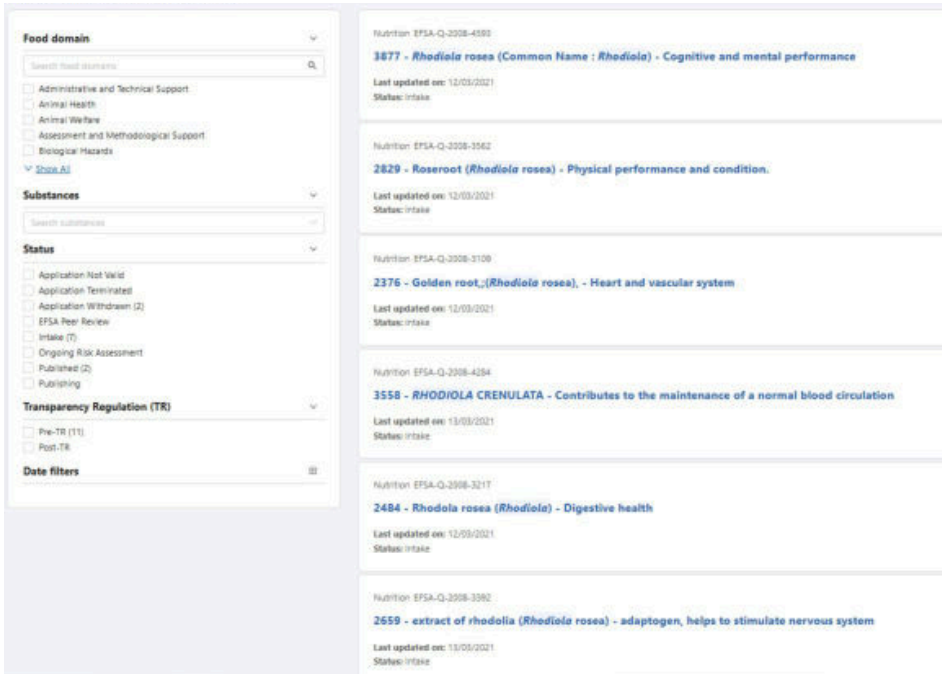






Primjena kod sportaša

ADAPTOGENI
RODIOLA (*RHODIOLA ROSEA*)



KOLIČINE:

- Znanstvena istraživanja potvrđuju upotrebu rhodiole kao dnevne preventive protiv umora učinkovita već u dozama od samo 50 mg
- za akutnu upotrebu protiv osjećaja umora i za antistres efekte 288-680 mg
- Preporuča se ne prekoračiti spomenutu dozu od 680 mg, budući da veće doze u pravilu mogu biti neučinkovite

Rhodiola rosea	Rodiola crvena	Nije dopušteno kao monopripravak. Najveća dnevna doza: 50 mg ekstrakta podanka i korijena. Ne preporučuje se uzimanje duže od 2 tjedna u kontinuitetu. Osobe koje uzimaju lijekove trebaju se prije uzimanja posavjetovati s liječnikom. Ne preporučuje se trudnicama i dojiljama.

Pravilnik o tvarima NN 160/2013

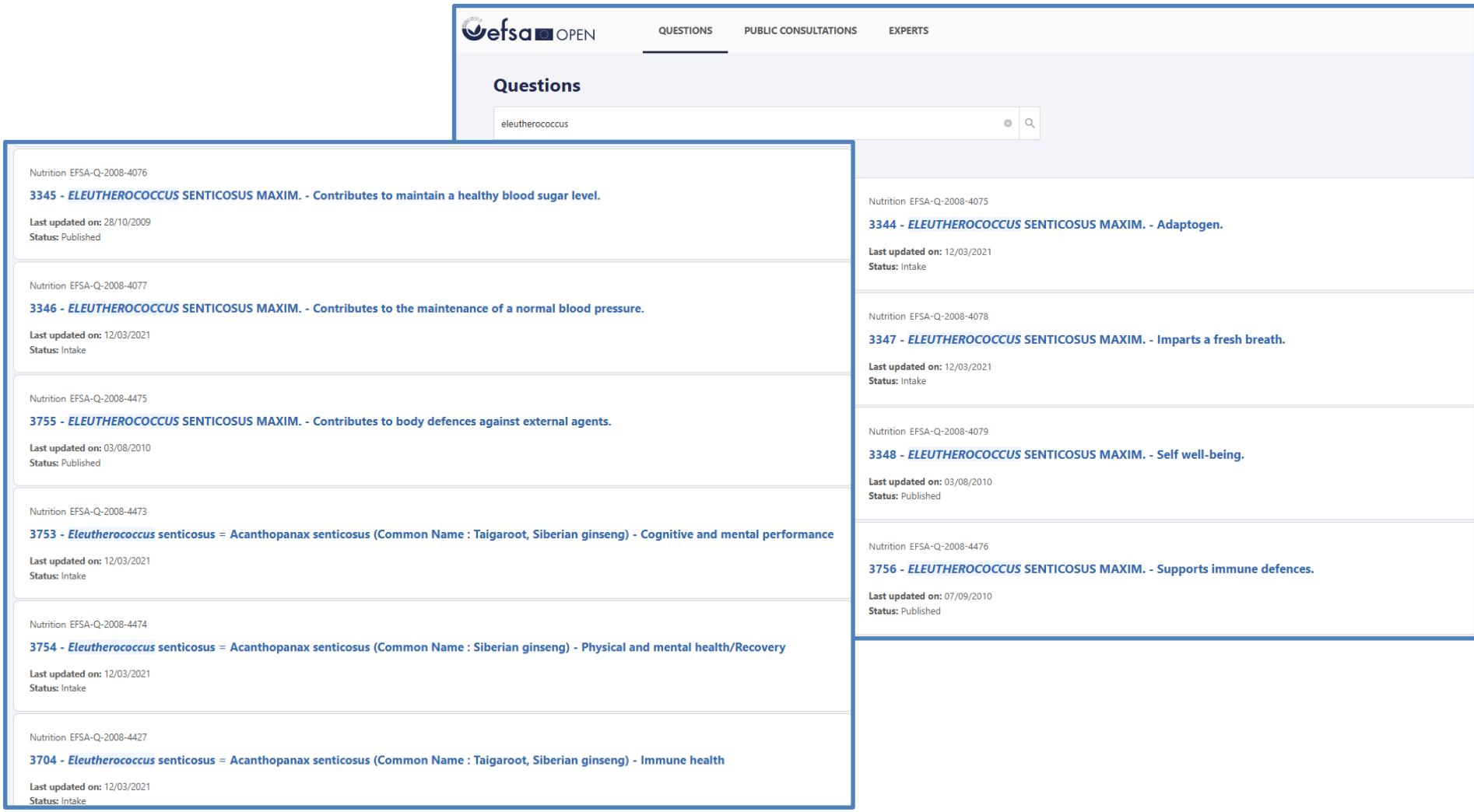
ADAPTOGENI
3. SIBIRSKI GINSENG (*ELEUTHEROCOCCUS SENTICOSUS*)

Tradicionalno se koristi u azijskim zemljama no njegova konzumacija, popularnost i rasprostranjenost manji su od azijskog ginsenga (Panax ginseng).

Benefiti ginsenga prema tradicionalnoj kineskoj medicini su "oživljavanje qi-ja i jačanje slezene, toniziranje bubrega za ublažavanje mentalnog naprezanja", dok se upotreba u Sibiru (odakle biljka originalno potječe) i Rusiji obično povezuje s promicanjem fizičke izdržljivosti, poboljšanog nespecifičnog imuniteta te dugovječnosti.



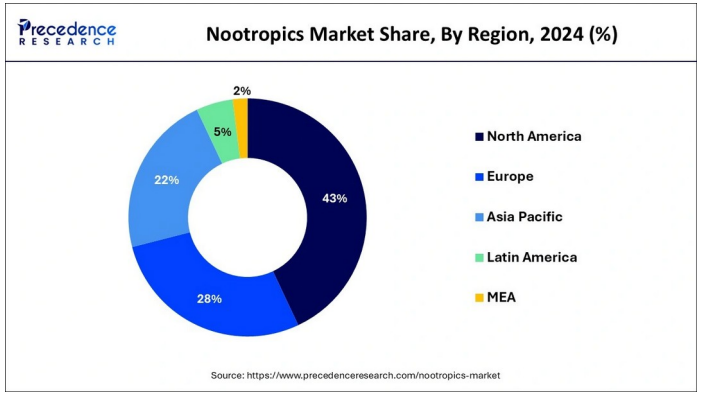
ADAPTOGENI
SIBIRSKI GINSENG (*ELEUTHEROCOCCUS SENTICOSUS*)

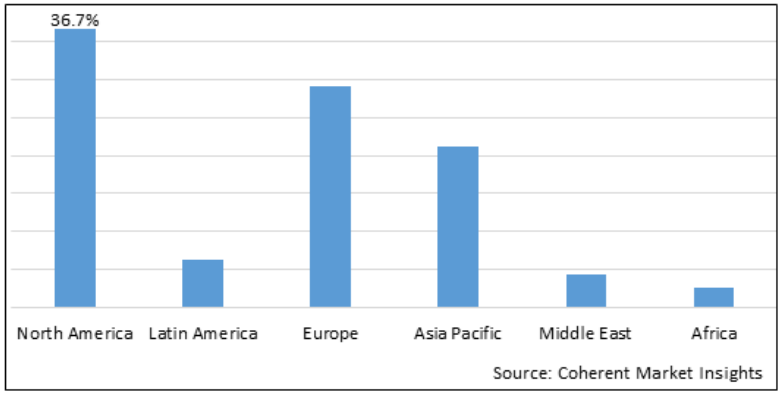


GLOBALNI TRENDOVI

BUDUĆNOST NOOTROPIKA

Globalno gledano – dodaju se u sve više proizvoda - i dodataka prehrani i hrani te se očekuje rast novih proizvoda i konzumacija









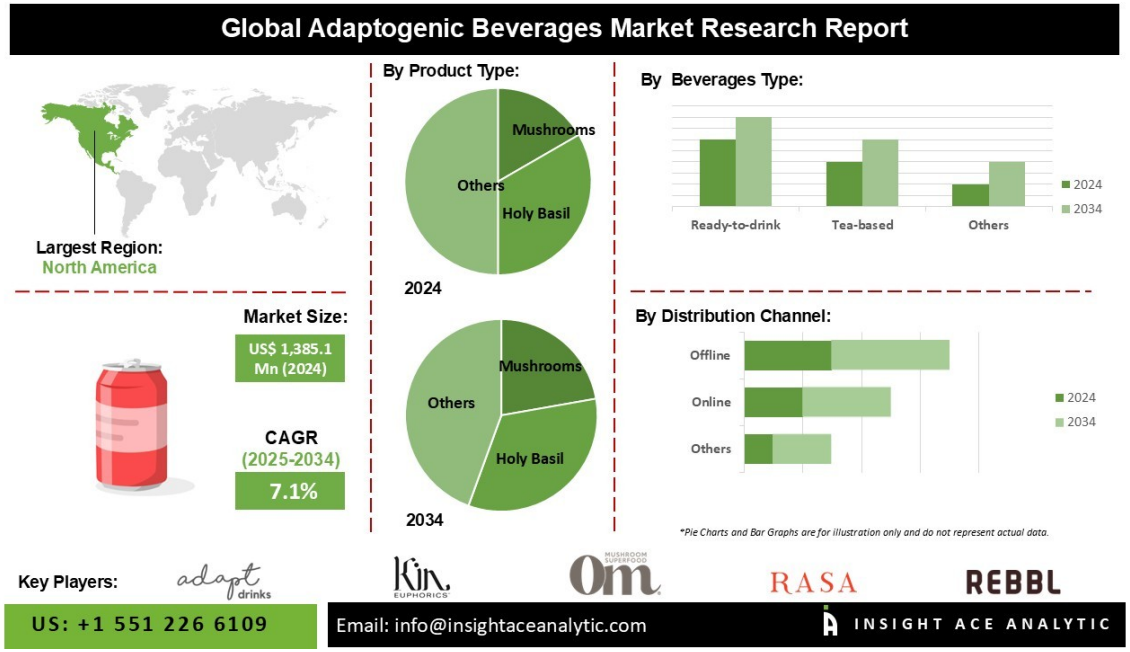


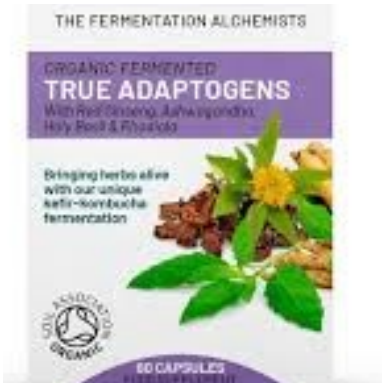




BUDUĆNOST ADAPTOGENA

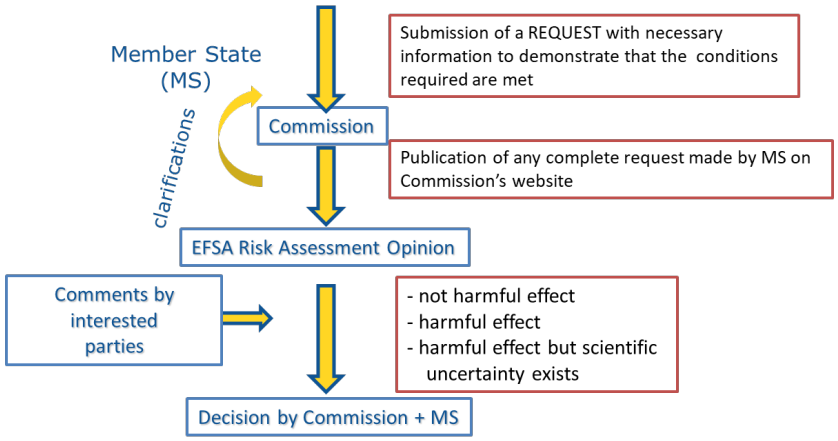
Globalno gledano i oni se dodaju u sve više proizvoda - i dodataka prehrani i hrani te se očekuje i njihov rast i konzumacija



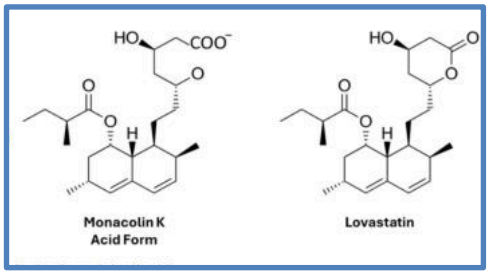




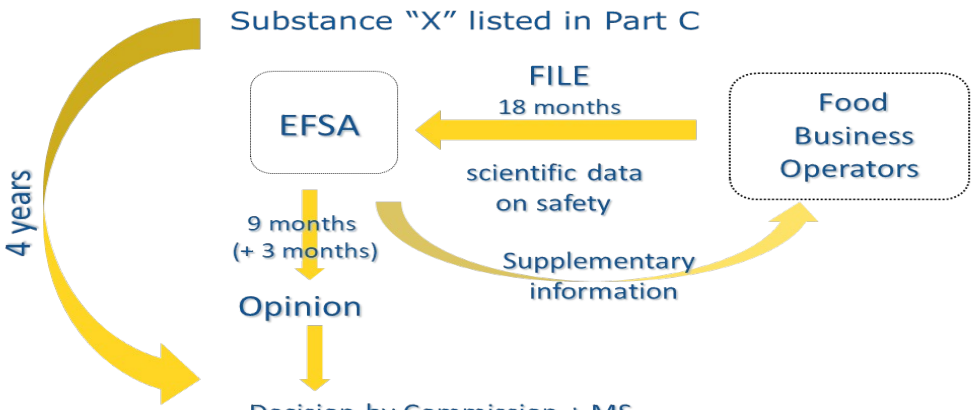
BITNO - NOVE EVALUACIJE SIGURNOSTI, članak 8



UREDBA (EZ) br. 1925/2006 EUROPSKOG PARLAMENTA I VIJEĆA
od 20. prosinca 2006.
o dodavanju vitamina, minerala i određenih drugih tvari hrani



SUBSTANCES UNDER COMMUNITY SCRUTINY



PRILOG III.

TVARI ČIJA JE UPORABA U HRANI ZABRANJENA, OGRANIČENA ILI POD NADZOROM ZAJEDNICE

Dio A — Zabranjene tvari
Dio B — Ograničene tvari
Dio C — Tvari pod nadzorom Zajednice

ZA KRAJ…

- Istraživanja pokazuju da pravovremena konzumacija **adaptogena** može pomoći u borbi sa stresom, ali i u starosnim poremećajima, kao što su neurodegenerativne i krvožilne bolesti. S njima možemo dulje održati svoj zdravstveni status na normalnoj razini, poboljšati kvalitetu života, zdravlje i dugovječnost

- Istraživanja **nootropika** pokazuju da izravno sudjeluju u neurotransmisiji, metabolizmu energije te djeluju na promjene razine hormona koji utječu na zdravlje i funkciju mozga, zaštitu mozga od oštećenja i disfunkcije te ublažavanje poremećaja koji mogu utjecati na mentalna stanja/bolesti poput depresije, anksioznosti i nesanice

- Razvoj sve većeg broja prehrambenih proizvoda prati trendove i dodaju se biljne vrste, njihove biološki aktivne tvari i nutrijenti u razne proizvode

- No, bez obzira na obećavajuće rezultate istraživanja potrebno ih je konzumirati umjereno i prema preporukama nutricionista i liječnika, bez obzira na navedene prednosti biološki aktivnih tvari

HVALA VAM NA PAŽNJI!

lea.pollak@hzjz.hr

