BfR-BVL Joint Meeting:
“Super(?)foods and Supplements – Risky or Healthy?”
Berlin-Marienfelde, 30.06.-01.07.2022

Risk assessment of “superfoods” and supplements (examples)

Prof. Dr. Susanne Alban

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Outline

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- Introduction
- Legislation and its impact on safety risks?
- Risks due to ingredients of superfood and supplements
- Risks due to contamination and adulteration
- Risks due to geographic origin / legislation
- Risks due to consumers
- Conclusions

Growing food supplement market

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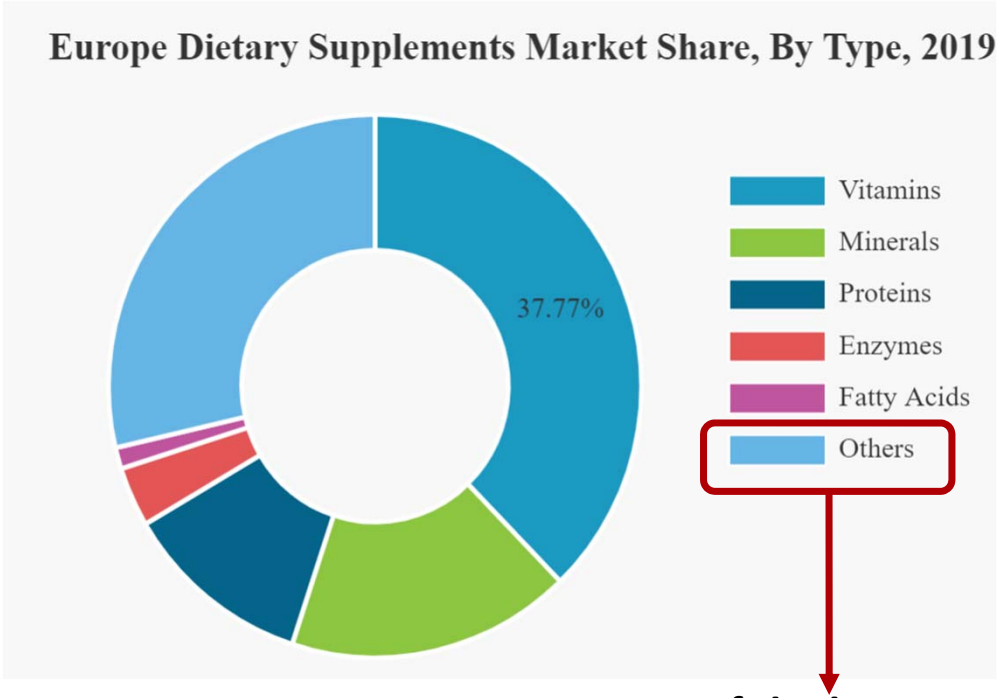
➔ Due to growing health consciousness among consumers



One of the key trends:

BOTANICALS

S. Alban, 01.07.2022

https://www.fortunebusinessinsights.com/industry-reports/infographics/europe-dietary-supplements-market-101918

Growing botanicals* market

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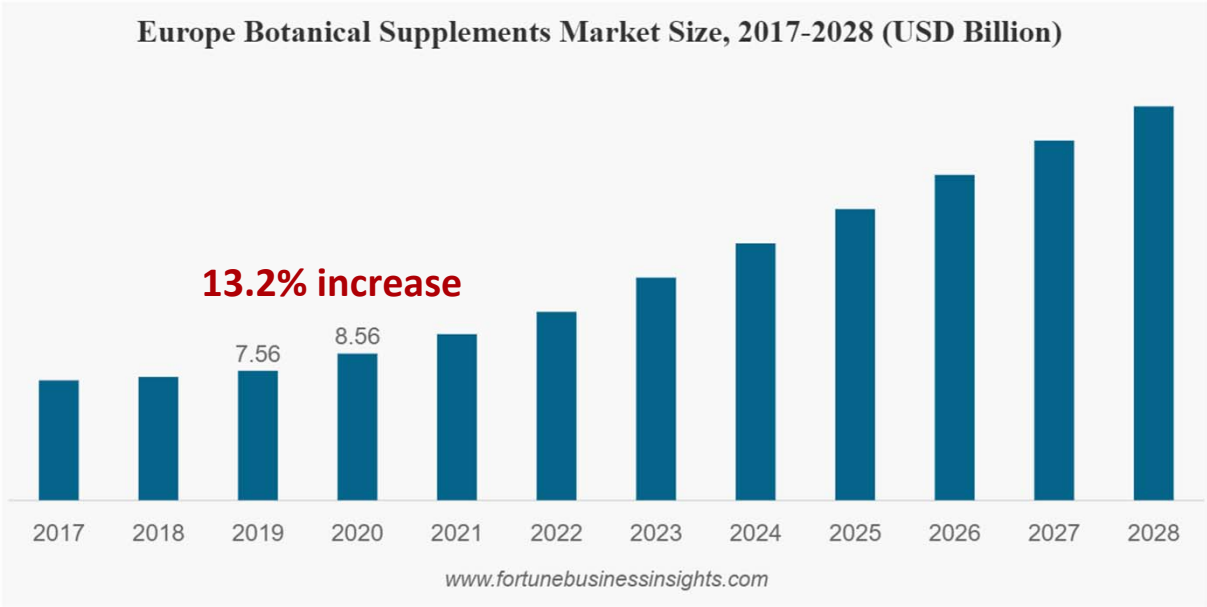
- **Trends:** Demand of clean-label and sustainable ingredients & trust in natural compounds



- **Application fields:** Energy & weight management, general health, bone & joint health, cardiac health, immunity, gastrointestinal health, diabetes, anti-cancer, and others

***Food supplements with ingredients from plants, algae, fungi or lichens**

www.fortunebusinessinsights.com/botanical-supplements-market-106514 / www.kbvresearch.com/europe-botanical-supplements-market/

In parallel: Functional food & Superfood consumption

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- **Healthy eating trends**,
  i.e. vegetarian / vegan diets, natural instead of synthetic nutrients, less processed food

Source: Elena Schweitzer - stock.adobe.com

www.mordorintelligence.com/industry-reports/europe-dietary-supplement-market

Legislation and its impact on safety risks? (1)

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Regulation (EC) No 178/2002

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

- Food (under EU law) on the market is safe
- Usually, no information about specific adverse health effects

Directive 2001/83/EC

Article 59

The package leaflet of a medicinal product shall contain …
contra-indications, appropriate precautions for use, … forms of interaction, **special warnings**, ….
undesirable effects

Perception of the consumer

Self-selected food incl. "health products" is safe, whereas medicinal products have adverse health effects

Legislation and its impact on safety risks? (2)

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Crucial differences between the two product categories

Medicinal products

Principle of prohibition with permit reservation

§ § § § § §

✓ Quality
✓ Efficacy
✓ Safety

Market access

Mandatory batch release controls

Pharmacovigilance

➔ Relatively good knowledge of risks

Food & supplements

Principle of banning to that of misuse*

§ § § § § §

Market access

Responsibilities of food business operator

Random official controls

Unmanageable flood of products

➔ Relatively poor knowledge of risks

* Exceptions: novel food, food additives, ..

Risks of superfood and supplements

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Foodstuffs for normal consumption, partly traditionally used in Western diet

Source: Elena Schweitzer - stock.adobe.com

Concentrated sources of nutrients and other substances without natural matrix


https://www.safefood.net/healthy-eating/supplements

- The risk potential of superfood can be supposed to be lower than that of supplements
- However, improper consumption of superfood can lead to health risks
  (e.g. unusually high amounts, special combinations, intake by special populations, non-approved novel food)

Sources of supplement- and superfood-related risks

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Specific ingredients

- Supplements containing very high doses of vitamins and/or minerals
- Substances in complex-composed botanicals causing adverse effects
- Substances in complex-composed botanicals causing drug interactions

Contaminants

Geographic origin / legislation

Consumer

Risks due to ingredients of superfood & supplements

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List A: **Plants with known harmful effects on health and therefore not recommended (!) for use as food**

Examples

- *Aconitum napellus* (blue monkshood)
- *Adonis vernalis* (yellow adonis)
- *Aristolochia* sp.
- *Catha edulis* (kath tree)
- *Datura* sp.
- *Dryopteris filix-mas* (male fern)
- *Ephedra* sp.
- *Rauvolfia serpentina* (squawroot)
- *Piper methysticum* (kava kava)
- *Pausinystalia johimbe* (yohimbe)
- *Salvia divinorum* (diving sage)

www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/07_Stofflisten/lm_stofflisten_node.html?cms_thema=Stofflisten+des+Bundes+und+der+Bundesl%C3%A4nder

Risks due to ingredients of superfood & supplements

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Chinese herbal medicines associated with nephrotoxicity

Possible Toxic Compound	Latin Name	English Name/Chinese Name	Indications	Kidney Manifestations
Aristolochic acid	*Aristolochia* spp.	Aristolochia, Guan Mu tong, Han Fang Ji	To induce weight loss, liver disease, arthritis, headache, edema	Chronic interstitial nephritis, renal interstitial fibrosis, Fanconi syndrome, urothelial carcinoma
Flavonoid (sciadopitysin)	*Taxus celebica*	Chinese yew	Diabetes, vascular diseases	Acute tubular necrosis, acute interstitial nephritis
Flavonoid	*Cupressus funebris*, End 1	Mourning cypress	Vascular diseases, used instead of "yew"	Acute tubular necrosis, acute interstitial nephritis
Flavonoid oligomeric procyanidins	*Crataegus orientalis*	Hawthorn	Congestive heart failure, hypertension, hyperlipidemia	AKI
Ephedrine, norephedrine, pseudoephedrine	*Ephedra sinica*	Ma huang	Cough, to induce weight loss, to cause sexual arousal	AKI, nephrolithiasis
Glycyrrhetinic acid, glycyrrhizic acid	*Glycyrrhiza glabra*	Licorice, Gan cao	Cough, sore throat, arthritis, to induce weight loss	Acute tubular necrosis, hypokalemic nephropathy, Fanconi syndrome
Anthraquinones, oxalic acid	*Rhizoma rhei*	Rhubarb	Laxative, antiinflammatory	Interstitial fibrosis, tubular atrophy
Active moiety triptolide	*Tripterygium wilfordii*	Lei Gong Teng	Arthritis, antiinflammatory, immunosuppressant	Acute tubular necrosis
Oxidative degradation products	*Aloe capensis*	Cape aloe	Constipation, insect bites	Acute tubular necrosis, parenchymatous nephritis
Colchicine	*Colchicum autumnale*	Autumn crocus	Gout	AKI
Dioscorine, dioscin	*Dioscorea quartiniana*	Yam	Taken as food, to cause poisoning or induce suicide	Acute tubular necrosis
Irritant chemicals in the latex of the plant	*Euphorbia matabelensis*, *Euphorbia paralias*	Spurge	Edema, to induce abortion	Acute tubular necrosis
Andrographolide	*Andrographis paniculata*	Chuan Xin Lian (heart piercing lotus)	Infectious disease, such as upper and lower respiratory tract infection, acute enteritis, bacillary dysentery	AKI, acute tubular necrosis

Abbreviation: AKI, acute kidney injury.
Reprinted with permission of the American Society of Nephrology, from: Yang B, Xie Y, Guo M, Rosner MH, Yang H, Ronco C. Nephrotoxicity and Chinese Herbal Medicine. *Clin J Am Soc Nephrol*. 2018 Oct 8; 13(10):1605-1611; permission conveyed through Copyright Clearance Center, Inc.[7]

Charen & Harbord. Adv Chronic Kidney Dis. 2020;27(1):67-71

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Possible Toxic Compound	Latin Name	English Name/Chinese Name	Indications	Kidney Manifestations
Aristolochic acid	*Aristolochia* spp.	Aristolochia, Guan Mu Tong, Han Fang Ji	To induce weight loss, liver disease, arthritis, headache, edema	Chronic interstitial nephritis, renal interstitial fibrosis, Fanconi syndrome,

Aristolochia ssp and other genera containing aristolochic acids

Ephedrine, norephedrine, pseudoephedrine	*Ephedra sinica*	Ma huang	
Glycyrrhetinic acid, glycyrrhizic acid	*Glycyrrhiza glabra*	Licorice, Gan cao	
Anthraquinones, oxalic acid	*Rhizoma rhei*	Rhubarb	
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Reprinted with permission of the American Society of Nephrology, from: Yang B, Xie Y, Guo M, Rosner MH, *Am Soc Nephrol*. 2018 Oct 8; 13(10):1605-1611; permission conveyed through Copyright Clearance Center,

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 4, Number 1, 1998, pp. 9–13
Mary Ann Liebert, Inc.

Misuse of Herbal Remedies: The Case of an Outbreak of Terminal Renal Failure in Belgium (Chinese Herbs Nephropathy)

JEAN-LOUIS VANHERWEGHEM, M.D., Ph.D.

ABSTRACT

At least 100 cases of extensive interstitial fibrosis of the kidneys were observed in Belgium in women who had followed a weight-loss regimen that included the use of Chinese herbs. The possible relation between the renal disease and these Chinese herbs was investigated. It was shown that the prescribed Chinese herb called *Stephania tetrandra* was, in fact, inadvertently replaced by another Chinese herb, namely *Aristolochia fangchi* in the powdered extracts delivered in Belgium and in France. The development of renal disease in about 100 patients exposed to the so-called *Stephania tetrandra* stresses the need for more stringent control of herbal medicine.

Charen & Harbord. Adv Chronic Kidney Dis. 2020;27(1):67-71

Risks due to ingredients of superfood & supplements

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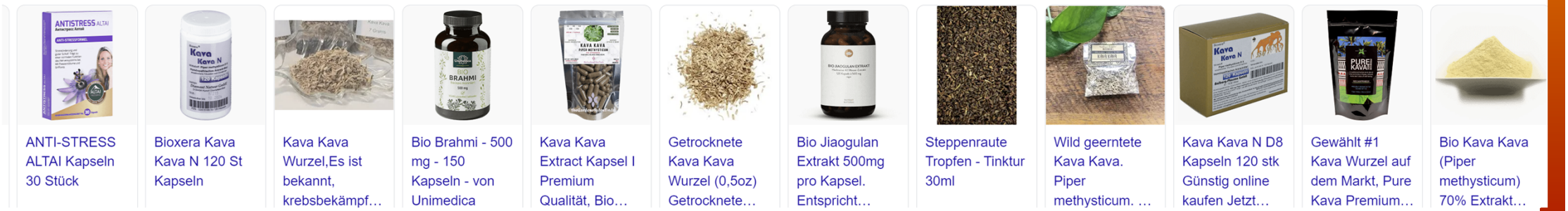
EXAMPLE: **Piper methystici rhizoma (kava-kava)**

- Extracts approved herbal medicinal products for treatment of anxiety for decades
- **BfArM** (23.12.2019): Revocation of marketing authorisations for medicinal products containing kava kava due to liver toxicity

- But still numerous "healthy" products for "careless" intake offered



ANTI-STRESS ALTAI Kapseln 30 Stück | Bioxera Kava Kava N 120 St Kapseln | Kava Kava Wurzel,Es ist bekannt, krebsbekämpf… | Bio Brahmi - 500 mg - 150 Kapseln - von Unimedica | Kava Kava Extract Kapsel I Premium Qualität, Bio… | Getrocknete Kava Kava Wurzel (0,5oz) Getrocknete… | Bio Jiaogulan Extrakt 500mg pro Kapsel. Entspricht… | Steppenraute Tropfen - Tinktur 30ml | Wild geerntete Kava Kava. Piper methysticum. … | Kava Kava N D8 Kapseln 120 stk Günstig online kaufen Jetzt… | Gewählt #1 Kava Wurzel auf dem Markt, Pure Kava Premium… | Bio Kava Kava (Piper methysticum) 70% Extrakt…

https://www.ema.europa.eu/en/documents/public-statement/public-statement-piper-methysticum-g-forst-rhizoma_en.pdf
https://www.ema.europa.eu/en/documents/herbal-report/final-assessment-report-piper-methysticum-g-forst-rhizoma_en.pdf

Risks due to ingredients of superfood & supplements

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EXAMPLE: ***Ginkgo biloba***

- **Refined & quantified Ginkgo dry extracts**
  - → used in medicinal products for cognitive impairment and treatment of dementia
  - → Ph. Eur. 10.0: maximum 5 ppm ginkgolic acids (dried extract)

- **Ginkgo leaves**
  - → Negative monograph of Commission E
  - → No proven efficacy
  - → Risks: content of water-soluble ginkgolic acids being toxic and potent contact allergens

- But wide offer of Ginkgo teas used as food and products containing other Ginkgo extracts*

* 05.052022: Not allowed according to jugdement of OLG Frankfurt am Main 6 U 111/21

Risks due to ingredients of superfood & supplements

EXAMPLE: **Macroalgae as sources of „ natural“ iodine and „healthy“ food**

- Iodine and sodium contents of macroalgae (mg/100g dried algae)[1]

Alga species	Common name	Iodine mg/100g	Portion for AI
Ulva lactuca	Sea salad	0.06 – 2.1	250 – 7.1 g
Porphyra tenera	Nori	0.2 – 7	75 – 2.1 g
Palmaria palmata	Dulse	7 – 26	2.1 g – 0.57 g
Laminaria digitata	Kombu	310 – 625	**0.048 – 0.024 g**
Undaria pinnatifida	Wakame	10-17	1.5 – 0.8 g

Iodine (EFSA):
AI 150 µg/day for adults,
UI 600 µg/day

AI adequate intake
UI tolerable upper intake level

- Human studies: Kombu ingestion associated with suppression of thyroid function[2,3]

EFSA Journal 2014;12(5):3660. doi:10.2903/j.efsa.2014.3660 / [1] Cherry et al. Nutrition Rev. 2019,77: 307–329, doi:10.1093/nutrit/nuy066 /
[2] Miyai et a. Endocr J. 2008;55:1103–1108. / [3] Clark et al. Endocr Pract. 2003;9:363–369.

Risks due to ingredients of superfood & supplements

EXAMPLE: **Red (yeast) rice products**

- Rice fermented with red yeast *Monascus purpureus* contains
  0.3 - 4.0 (!) mg/g monakolin K ≡ lovastatin
- Health claim for daily consumption of 10mg monacolin K:
  "… contributes to the maintenance of normal blood cholesterol concentrations"
- Adverse effects like lovastatin (i.e. HMG-CoA reductase inhibitors)
  common (1-10%): creatine phosphokinase elevation, dizziness, headache, blurred vision, muscle aches or pains, muscle cramps, rash, flatulence, abdominal pain, constipation, diarrhoea, nausea, indigestion, weakness …
  Rare (0.01-0.1%): myopathy, rhabdomyolysis, hepatotoxicity, dermatomyositis, …
- Numerous drug interactions, esp. increased side effects by combin. with CYP3A4 inhibitors
- Variable contents of nephrotoxic citrinin (0.3 µg/g – 2400 µg/g)
  → Reg. (EC) No 212/2014: maximum level 2.0 µg/g food supplement

Stellungnahme der Gemeinsamen Expertenkommission BVL/BfArM. Einstufung von Rotschimmelreisprodukten (02/2016)

Risks due to interactions of SF and FS with drugs

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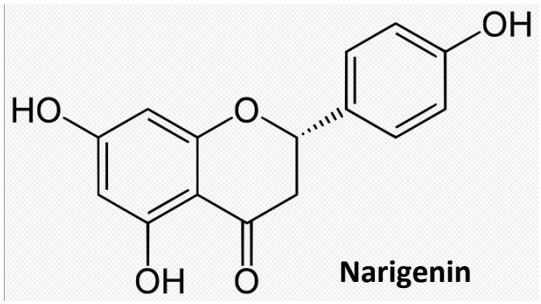
EXAMPLE: ***Citrus paradisi* (grapefruit)**

- Used in form of fruits, juice, extracts, seed extracts

Wikipedia.org



Narigenin

- Potent irreversible inhibition of the cytochrome-P450 isoenzyme CYP3A4
  → inreased bioavailability and side effects of numerous drugs,
  e.g. immunosuppressants, statins, PDE-5 ihibitors
  → reduced bioactivation & efficacy of cyclophosphamide and ifosfamide

*a cytochrome-P450 isoenzyme

Risks due to interactions of SF and FS with drugs

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Further examples of **reported** interactions of herbal preparations with prescribed medicines

St John's wort (*Hypericum perforatum*)	• Interferes with the action of cyclosporine, causing acute transplant rejection • Causes intermenstrual bleeding in women using oral contraceptives • Reduces the anticoagulant effect of warfarin • Reduces the bioavailability of theophylline, amitriptyline, indinavir (HIV-1 protease inhibitor), methadone, and digoxin • Potentiates the side effects of tricyclic and selective serotonin re-uptake inhibitor (SSRI) antidepressants; can lead to serotonin syndrome
Asian ginseng (*Panax ginseng*)	• Reduces the effects of immunosuppressant drugs • Increases the effects of oral hypoglycaemic agents • Potentiates the side effects of monoamine oxidase inhibitors • Has an additive effect with benzodiazepines
Garlic (*Allium sativum*)	• Increases the liver toxicity of paracetamol • Enhances the effects of oral hypoglycaemic agents • Increases the incidence of bleeding in patients using anticoagulants
Evening primrose (*Oenothera* species) and borage (*Borago officinalis*) oils (contain gamolenic acid)	• Lower the seizure threshold in people with epilepsy • Interfere with the actions of certain anti-epileptic medications, including phenytoin
Dong quai (*Angelica sinensis*) Devil's claw (*Harpagophytum*) Ginseng (*Panax* species) Dan shen (root of *Salvia miltiorrhiza*)	• Potentiate the action of warfarin

- Reduced absorption of drug substances by herbal drugs containing swelling polysaccharides, e.g. Ispaghula husk, linseed

Byard et al. Med J Austral. 2017

Outline

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- Introduction
- Legislation and consumer perception
- Food vs. medicinal products legislation → impact on safety risks
- Risks due to ingredients of superfood and supplements
- Risks due to contamination and adulteration
- Risks due to geographic origin / legislation
- Risks due to consumers
- Conclusions

Risks due to contaminations of herbal drugs / prepar.

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Pharmaceutical quality control tests according to Ph. Eur. 10.0 include

- Pesticides (ppm limits for 69 pesticides)
- Heavy metals (limits: Cd 1.0 ppm; Pb 5.0 ppm, Hg max. 0.1 ppm, where necessary others)
- Aflatoxin B_1
- Ochratoxin A
- Radioactive contamination
- Microbial contamination
- NEW: pyrrolizidine alkaloids
  (limit 1 µg/day via herbal medicinal products)

Regulations for food

- Commission Reg. (EC) No 1881/2006:
  maximum levels for certain **contaminants** in foodstuffs
  (nitrate, mycotoxins, metals, 3-MCPD, dioxins and PCB, polycyclic aromatic hydrocarbons)
- Reg. (EC) No 396/2005:
  maximum residue levels of **pesticides** in or on food and feed of plant and animal origin
- Commission Recommendation (EU) 2018/464:
  monitoring of **metals** and **iodine** in seaweed, halophytes and products based on seaweed

Risks due to contaminations of herbal drugs / prepar.

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EXAMPLES: **Warnings of the public about sufficiently suspected health risks by (super)food**
(§ 40 (1)/(2) LFGB) in the period from March to June 20222 (https://lebensmittelwarnung.de/)

- Apricot seeds → exceeding of cyanide limits
- 5x Sesame → salmonella
- Mate → pesticide anthrachinone
- Poppy → excessive morphine content
- Whet grits → pesticide chlorpyriphos
- Kombu → excessive iodine content
- Vegetable fine granules → salmonella
- Soft dried mango → allergen sulfite
- Dried apricots → allergen sulfur dioxide
- Dried figs → ochratoxin A
- Cinnamon → ethylen oxide (2-chloroethanol)
- Calcium carbonate tablets → ethylen oxide
- CBD gum → high delta-9-THC levels
- Roasted peanuts → aflatoxins
- Coconut meat → salmonella
- Bio Chanca Piedra FS → 2-chlor<oethanol
- Roasted green wheat → polyaromatic hydrocarbons

What is the real number of contaminated products on the market?

Risks due to adulteration of food suppl. with APIs*

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100% PURE NATURE
contained sibutramine

Review

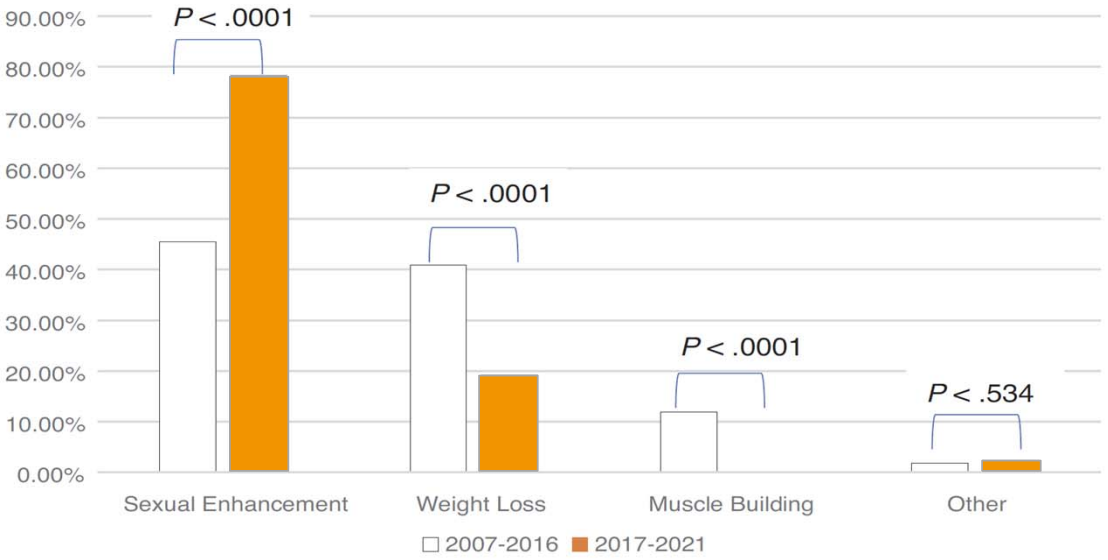
ACCP
American College of Clinical Pharmacology

Continued Risk of Dietary Supplements Adulterated With Approved and Unapproved Drugs: Assessment of the US Food and Drug Administration's Tainted Supplements Database 2007 Through 2021

The Journal of Clinical Pharmacology
2022, 0(0) 1–7

DOI: 10.1002/jcph.2046

Result: 1068 unique products adulterated with APIs*



Percentage of adulterated food suppl. per category over time

*** API = active pharmaceutical ingredient**

White M. J Clin Pharmacol 2022, 0(0): 1-7. DOI: 10.1002/jcph.2046

Risks due to adulteration of food suppl. with APIs*

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Undeclared APIs found in food supplements

Drug class	API
FS for sexual enhancement	
PDE-5 inhibitors	sildenafil, tadalafil, sardenafil, …
	fibanserin
SSRI	dapoxetine
FS for weight loss	
Stimulant	sibutramine*, analogues
Laxatives	phenolphthalein*
SSRI	fluoxetine
Stimulants	1,3-dimethylamylamine*
Diuretics	e.g. furosemide
Antitussive	benproperine

Drug class	API
FS for muscle building, performance increase	
Anabolic steroids	e.g. testosterone, nandrolone, dehydroepiandrosteone (DHEA)
SARMs	e.g. ostarine, ibutamoren
Other anabolics	e.g. clenbuterol
Aromatase inhibitors	various
FS for sleep	
Sedatives	zoplicone, eszopiclone
Antihistamines	chlorpheniramine
FS for pain	
NSAIDs	e.g. diclofenac, ibuprofen
Corticosteroids	e.g. dexamethasone
FS for lipid lowering	
Statins	e.g. lovastatin

*** No marketing authorization or withdrawn**

White M. J Clin Pharmacol 2022; 1DOI: 10.1002/jcph.2046

Risks due to adulteration of food supplem. with APIs*

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Review of 50 studies investigating the presence of undeclared APIs in FS commonly used by athletes:

28% of the analysed FS (875/ 3132) contained APIs, most frequently sibutramine and anabolic-androgenic steroids

Problems of undeclared APIs

- Fraud
- Each API does have both therapeutic and adverse effects
- Unknown dosage and thus effects
- Unknown interactions with other ingredients
- Impossible to consider individual intolerance and drug interactions
- Challenge to causally treat adverse reactions
- Risk of unintentional doping

Kozhuharov et al. Biomed Res Internat 2022; DOI:10.1155/2022/8387271

Risks due to geographic origin / legislation

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Risks of herbal drugs used in Traditional Chinese Medicine and Ayurvedic Medicine

MEDIZIN

Nierenkiller aus Fernost

Eine wachsende Zahl von Ärzten und Heilpraktikern verschreibt Medikamente der traditionellen chinesischen Medizin. Doch bei der Einnahme mancher Heilkräuter-Mixturen kommt es zu gefährlichen Nebenwirkungen: Angeblich sanfte Arzneimittel enthalten hochgiftige Substanzen.

Lebensgefährliche Therapie im Urlaub

Bleivergiftung durch ayurvedisches Diabetesmittel

Quelle: springermedizin.de

Ein junger Mann mit krampfartigen Bauchschmerzen

Dr. med. Thomas Kron Medizinische Nachrichten 04.04.2022

Cannabis-Abusus hätten keine Vorerkrankungen bestanden. Auf Nachfrage habe der Patient berichtet, von einem Freund einem indisches Präparat erhalten zu haben, und zwar ein ayurvedisches Heilmittel; davon habe er seit etwa einem Monat täglich zwei Kapseln eingenommen.

- **Contaminants**
  - → heavy metals
  - → pesticides
  - → mycotoxins
  - → microorganims
- **Further quality issues**
  - → unknown composition
  - → misidentification, confusion, accidental adulteration
  - → fraudulent adulteration with APIs or cheaper herbals
- **Missing knowledge on efficacy & safety**
- **Not covered by EU regulation**

Stellungnahme der Gemeinsamen Expertenkommission BVL/BfArM. Einstufung von Produkten der ayurvedischen Tradition (Juli 2020)

Risks due to geographic origin / legislation

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Risks of herbal drugs used in Traditional Chinese Medicine and Ayurvedic Medicine

Risks due to geographic origin / legislation

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Do you like Russian roulette, then order on the internet !

Basisdaten

Produkt-Name	Kräutersex-Pillen für Männer, männliche Wachstums-Pillen ohne Nebenwirkungen
Marke	Sexfire
Produkt-Platz	China
Lagerung	Keep versiegelte und Speicher in einem kühlen, schattigen und trockenen Platz
Produkt-Form	Kapsel
Spezifikation	12Kapseln/Kasten
Bestandteile	Maulbeere, Rhizom polygomati, cinnamomun Kassie, Fenchel
Gebrauchs-Anmerkung	Nehmen Sie 1 Kapsel 30-60 Minuten vor sexueller Aktivität
Anwendbar für	1. Männliche Funktionsstörung, Niere, schwacher Mangel an Energie, Geschlechtsverkehr, Ermüdung
	2. sexuelle Lebensqualität waren zu niedrig
	3. die Härte ist nicht genug durch genitale Ansammlung

https://german.menherbalenhancementpills.com/sale-11457807-herbal-sex-pills-for-men-male-growth-pills-without-side-effects.html

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Warnings of purchase orders on the internet

Bundeskriminalamt

Arzneimittelkauf über das Internet
Vorsicht vor dubiosen Anbietern

Die Nutzung des Internet ist für viele Menschen alltäglich geworden. Verlockend wirken die Preisvorteile, die auch beim Arzneimittelkauf per Mausklick angeboten werden. Zahlreiche Anbieter werben mit der vermeintlichen Diskretion und Anonymität des Internet.
Illegal vertriebene Arznei- und Nahrungsergänzungsmittel bergen eine große Gefahr für Ihre Gesundheit. Daher gilt es, die Risiken zu kennen und besondere Vorsicht beim Arzneimittelkauf im Internet walten zu lassen.

Illegale Arzneimittel bergen Risiken!

Insbesondere durch
- falschen, zu hohen oder zu niedrig dosierten Wirkstoff
- fehlenden Wirkstoff
- nicht deklarierten Wirkstoff, z.B. in als „rein pflanzlich" bezeichneten Arzneimitteln

Die Einnahme dieser Arzneimittel kann eine Gefahr für Leib und Leben bedeuten!

Vorsicht bei:

- der Möglichkeit einer **online-Rezepterstellung**. Diese ist nicht zulässig. Um ein rezeptpflichtiges Arzneimittel bestellen zu können, müssen Sie das von Ihrem Arzt ausgestellte Rezept im Original der Versandapotheke zusenden.
- **Beratungen und Arzneimittelempfehlungen über Internetforen.** Eine Diagnose mittels Internetrecherchen kann niemals die persönliche medizinische Beratung durch einen fachkundigen Apotheker ersetzen.
- **mangelnder Beratungsleistung im Internet.** Auch Versandapotheken sind zur Beratung des Kunden zur Anwendung von Arzneimitteln gesetzlich verpflichtet. Die Beratungshotline muss mit deutschsprachigem pharmazeutischem Personal besetzt sein.

- **überzogenen Werbeversprechen.** Es gibt weder Allheilmittel, noch Arzneimittel, die für alle Verbraucher nebenwirkungsfrei sind.

Kaufen Sie daher Arzneimittel im Internet nur über Apotheken, die über eine Erlaubnis für den Versandhandel in Deutschland verfügen.

Meist führt die Suche nach einem Arzneimittel zu einer Vielzahl von Anbietern. Daher müssen Sie einen legalen Anbieter von einem illegalen Anbieter unterscheiden können.

Wie erkenne ich einen in Deutschland berechtigten Versandhändler?

Prüfen Sie selbst auf der Seite des Versandhändlers!

https://

Risks due to consumers

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- Uncritical reliance on „natural“ herbal supplements
- Overdosed comsumption or
  combined intake of several FS containing the same or similarly acting ingredients

Harmless herbs? A case report of acquired long QT syndrome and torsades de pointes in a patient taking herbal supplements

Marion Déléaval, MD, Haran Burri, MD, Elise Bakelants, MD

From the Department of Cardiology, University Hospital of Geneva, Geneva, Switzerland.

Self-medication:

- For 4 months, hemp oil containing cannabidiol (CBD; 61 mg/mL) and cannabigerol (CBG; 1 mg/mL), 3–4 times daily (up to 6 times the recommended dose)
- For the last 6 weeks, herbal supplement containing 250 mg of berberine

→ Pharmakodynamic & -kinetic interactions
→ Significant QTc prolongation

Déléaval et al. Heart Rhythm Case Reports 2022;8:309–312

Risks due to consumers

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- Uncritical reliance on „natural“ herbal supplements
- Overdosed comsumption or
  combined intake of several FS containing the same or similarly acting ingredients

  (e.g. vitamins A, B12, D, beta carotene, selenium, green tea extract, algae (iodine))
  (including unconscious overdosage of vitamins and/or minerals due to their content in botanicals to utilize the corresponding health claims)
- Pharmacokinetic or pharmacodynamic interactions with prescribed medicinal products
  → increase of MP-related side effects (e.g. red rice products & statins)
  → reduction of the efficacy of prescribed MP (e.g. antioxidants in cancer, curcumin)
- Replacement of prescribed medicinal products by food supplements
  (e.g. cinnamon for type II diabetes)

Déléaval et al. Heart Rhythm Case Reports 2022;8:309–312

Conclusions

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- Food supplements and superfoods can pose health risks, but compared to medicinal products the evidence of their frequency and severity is often limited. In such cases of uncertainty, precautionary risk managing measures may be considered.
- A significant part of the health risks by food supplements and superfoods may, in principle, be avoidable. This includes quality-related risks that could be reduced by stricter quality requirements and control systems.
- For another part of the health risks, the consumers themselves are responsible by consuming (individually) inappropriate (amounts of) food supplements and superfoods, respectively, due to missing knowledge or misleading advertising. This underlines the importance of proper information and education of the public about risks, risk prevention measures and limited, questionable or absent, respectively, benefits.

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Thank yor for your attention!