PhytoLab

SAFEGUARDING BOTANICAL QUALITY

CONTAMINANTS IN HERBAL RAW MATERIALS AND THEIR ANALYTICS

SCIENTIFIC CONFERENCE OF THE POLISH HERBAL COMMITTEE

14.-15.06.2024, DR. MICHAEL SCHWARZ

MEMBER OF the nature network

WHAT TO EXPECT

1. PhytoLab – safeguarding botanical quality

2. Contaminants in herbal raw materials and their analytics
   - Pesticides
   - Mycotoxins
   - Plant toxins (Pyrrolizidine alkaloids)
   - PAH (Polycyclic aromatic hydrocarbons)

PhytoLab

PhytoLab is an independent, accredited, and officially recognized test lab for herbal medicinal products, foodstuffs, animal nutrition and cosmetics.

Our services include analysis, development, quality control, regulatory approval of herbal products at all processing stages and a comprehensive range of ultrapure herbal reference substances.

We serve the following industries:

- Phytopharmaceutical, homeopathic & anthroposophic products
- Teas & Beverages, Spices
- Baby food
- Dietary supplements
- Animal nutrition

- DIN EN ISO/IEC 17025:2018
- GMP certified laboratory

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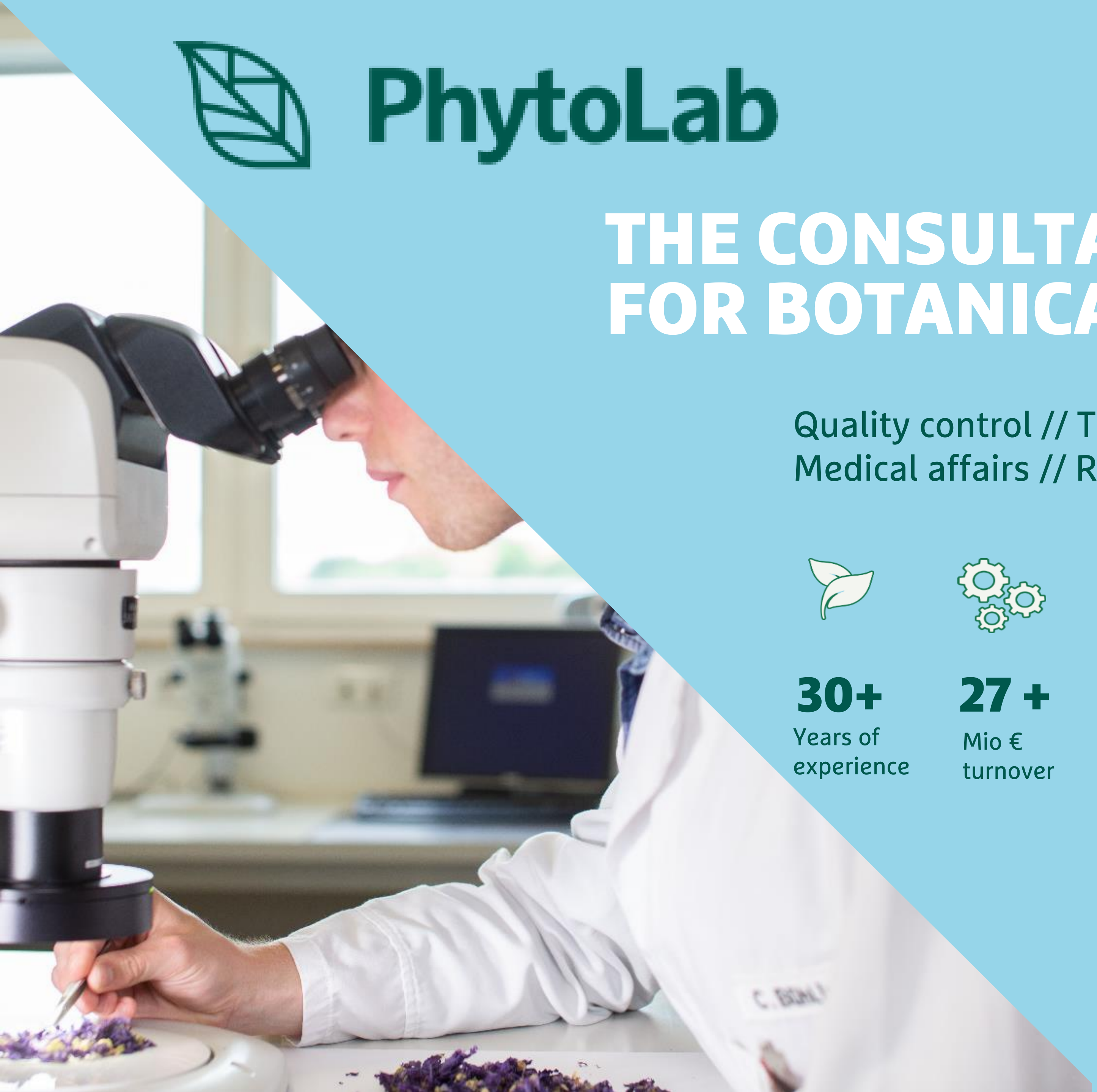

PhytoLab

THE CONSULTANCY LABORATORY FOR BOTANICAL PRODUCTS

Quality control // Trace analysis // Regulatory affairs // Medical affairs // Reference substances

30+	27 +	300 +	3,600 M²	200 +	400 +
Years of experience	Mio € turnover	Experienced and motivated employees	Laboratory space	Analytical instruments	Samples daily

MEMBER OF the nature network

PhytoLab
SAFEGUARDING BOTANICAL QUALITY

CONTAMINANTS IN HERBAL RAW MATERIALS AND THEIR ANALYTICS

PESTICIDES

PESTICIDES – GENERAL INFORMATION

Pesticides are applied in agricultural production of food plants as a single or mixture of several active ingredients to protect crops from pest infestation or disease.

Insecticides, acaricides, herbicides, and fungicides are the best-known representatives of plant protection products, as well as **molluscicides, plant growth regulators, and repellents**.

In the further production process of the plant products or during the supply chain, **stock protection agents** may also be applied.

While only a few pesticides are authorised for application in the cultivation of herbs, they may be contaminated by wind drift from pesticides used in the nearby cultivation of other agricultural commodities such as cereals, corn, wine grapes, fruits, and vegetables.

Therefore, **maximum residue levels** for the products have been **stipulated in pharmacopoeias, food, and feed laws.**

PESTICIDES
REQUIREMENTS IN EUROPEAN PHARMACOPOEIA

2.8.13 Pesticides residues

Unless otherwise indicated in the monograph, the herbal drug to be examined at least complies with the limits given in Table 2.8.13. – 1

The limits applying pesticides that are not listed in Table 2.8.13. – 1 **and whose presence is suspected** for any reason comply with the limits (levels) cross-referred to the Regulation (EC) No. 396/2005 including annexes and successive updates.

Limits for pesticides that are not listed in Table 2.8.13. - 1 or in European Union texts are calculated using a formula (see Ph. Eur. 2.8.13.) considering the ADI value (acceptable daily intake published by FAO-WHO), the body mass (60 kg) and the daily dose of the herbal drug

The limits for pesticides in herbal drug preparations are calculated by including the drug/extract ratio and the daily dose in addition to the MRL (maximum residue limit)

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PESTICIDES – DIFFERENCES IN REGULATIONS

Ph. Eur. 2.8.13.-1:

- 69 pesticides are listed
- each pesticide has one MRL for all kind of herbal drugs
- MRL for pesticides that are neither specified in the table nor in the EC Regulation, are calculated with the following formula

$MRL = (ADI \times M) \ / \ (MDD_{HD} \times 100)$

ADI: acceptable daily intake in mg/kg body weight; published by FAO/WHO

M: body mass in kg (60 kg)

MDD_{HD}: daily dose of the herbal drug in kg

- For preparations of herbal drugs (e.g. extracts), the processing factor may be taken into account

Regulation (EC) No. 396/2005:

- more than 1.400 pesticides are listed
- each product has its own MRL for each pesticide (or default MRL of 0,01 mg/kg)
- some products used as medicinal drugs are regulated as "fresh“, others as "dried“:

  e.g.: Mint: fresh, Chamomile: dried

- for "fresh" regulated products, a drying factor can be taken into account under certain circumstances

WHAT CHARACTERISES THE QUALITY OF A MEASUREMENT?

1. **High measurement accuracy**
   → i.e. a measurement result that reflects the real content as accurately as possible
2. **High reproducibility**
   → i.e. the lowest possible scattering of measurement results with repeated measurements
3. As little **room for interpretation** as possible
   → i.e. there is no overlapping of peaks of different analytes
4. Measurement result is within the **permissible (linear) measuring range**
5. **Interfering matrix effects are excluded** or taken into account in the interpretation of the measurement result
6. Ideally, the analytical method is **validated (or verified) for the analyzed matrix**
7. In **case of doubt, measurement results are confirmed** by dilution and/or multiple standard additions
8. Employees have **sound experience** in dealing with the measurement method and matrix
9. **LOQ** determined **according to regulatory requirements**

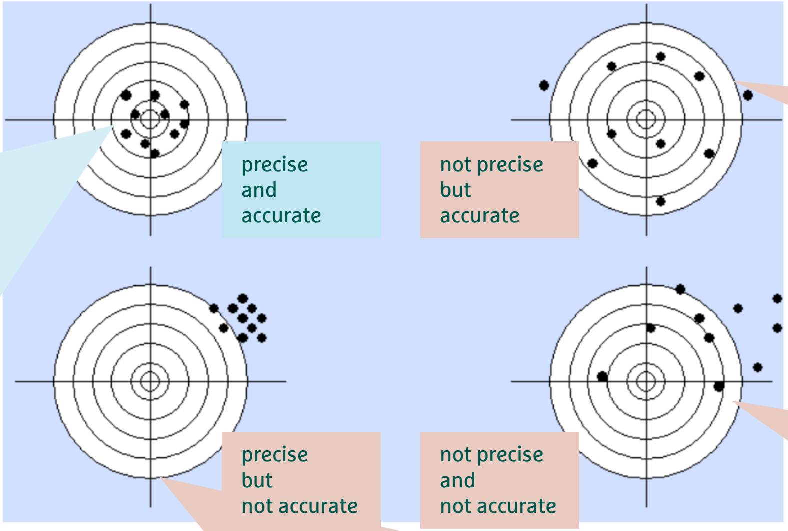
WHAT CAN HAPPEN IF THE CRITERIA ARE NOT GUARANTEED?

1. **High accuracy missing** → Result can significantly differ from the real value
2. **High reproducibility missing** → repeated measurements lead to largely differing results
3. **Possibility of interpretation** → Overlapping peaks of analytes lead to deviating results
4. Results **outside of linear range** → Too high or too low a concentration is shown with linear extrapolation
5. **Interfering matrix effects unknown** → measured values for individual analytes may be too high or too low
6. A **lack of method validation** for the matrices investigated can lead to partial to complete uselessness of the measurement result
7. **Missing confirmation** of results (especially at the LOQ) can lead to false positive or false negative findings
8. **Missing experience of employees** in handling the measurement method and matrix can lead to false positive or false negative findings
9. **LOQ,** which are **not determined according to the regulatory requirements** can lead to false negative results

Even ONE unfulfilled criterion destroys the quality of results

INTERACTION OF THE INDIVIDUAL QUALITY DRIVERS:

1. High measuring accuracy
2. High reproducibility
3. Little room for interpretation
4. Measurement result in the linear range
5. Matrix effects excluded
6. Method validated / verified for matrix
7. Confirming measurements if required
8. Employees experienced with method/matrix
9. Limits of quantification according to legal requirements



Measurement accuracy / reproducibility too low

- Matrix effects not taken into account
- Measurement result not in the linear range

- Method not validated/ verified e.g. extraction insufficient
- Employees insufficiently trained (integration of interfering peaks)

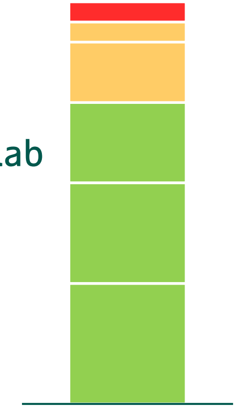
5. + 6. METHOD DEVELOPMENT - DETERMINATION OF THE MATRICES TO BE VALIDATED

SANTE requirements: at least 1 Matrix for each group

High water content	High fat content	High sugar content
High water content and acidic	Low water content	Difficult matrix

Simple Matrix
Medium difficulty Matrix
Difficult Matrix

Commodity lab



Composition of analyzed matrices

Specialized lab for herbal products

Realization other laboratories – conform with accreditation:

Cucumber	Olive	Honey
Orange	Dried Lentils	Black Tea

Validation according to ISO 17025-requirements:

Hibiscus	Dried Apple	Chamo-mile	Orange peel	Fruit tea
Valerian root	Rose hip	Herbal extract	Pepper-mint	Licorice
Stinging nettle	Linden blossoms	Herbal tea	Pomeranian leaves	Thyme
Fennel	Ginger	Melisse	Black Tea	Lemon grass

PESTICIDES – RISK ASSESSMENT

The following questions, among others, should be asked as part of a risk assessment:

- Which country does the raw material come from?
- What environmental conditions prevail in the cultivation, what is grown in the immediate neighborhood?
- Do I know if pesticides are used in the neighborhood? And if so – which ones?
- Do I know the crop rotation?
- Do I know about the use of pesticides in the crop?
- Can contamination occur via irrigation?
- Are there large-scale pesticide applications via aircraft in the cultivation area?
- Am I aware of any protection measures using insecticides or fungicides in storage and during transport?
- .....

PESTICIDES IN HERBAL DRUGS – 20 YEARS – TOP 20 POSITIVE (IN RAW MATERIAL)

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Top 20 of positive samples

Top List	Substance	number of samples analysed	number of positive samples	% positive	Ph.Eur. Table 2.8.13.-1
1	Chlorpyrifos (-ethyl)	58814	6841	12%	X
2	Bromide	6080	5034	83%	
3	DDT, total	59302	4936	8%	X
4	Nicotin	5917	3653	62%	
5	Glyphosate	13948	2892	21%	
6	Anthraquinone	17714	2624	15%	
7	O-Phenylphenol, total	25132	2235	9%	
8	Carbendazim, total	23253	2030	9%	
9	Pendimethalin	50510	1970	4%	X
10	Dithiocarbamate	17130	1950	11%	X
11	Cypermethrin, gesamt	50853	1894	4%	X
12	Biphenyl (Diphenyl)	25585	1568	6%	
13	Trifluralin	49593	1486	3%	
14	Azoxystrobin	26510	1339	5%	
15	Endosulfan, total	59272	1325	2%	X
16	Malathion & Malaoxon	59481	1206	2%	X
17	Profenofos	58177	1139	2%	X
18	Cyhalothrin, lambda	48650	964	2%	X
19	Lindane	58508	950	2%	X
20	Bentazone, total	9477	787	8%	

Top 20 of % positive samples (ref. to samples analysed)

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16	Biphenyl (Diphenyl)	25585	1568	6%	
17	Flonicamid, total	365	22	6%	
18	Tribromphenol-2,4,7	225	13	6%	
19	Chlormequat	89	5	6%	
20	Azoxystrobin	26510	1339	5%	

EUROPEAN RAPID ALERT SYSTEM (RASFF) TOP 20 PESTICIDE REPORTS

Top 20 of reported pesticides in RASFF

Top List	Substance	Ph.Eur. Table 2.8.13.-1
1	Chlorpyrifos	X
2	Tricyclazol	
3	Ethylenoxid	
4	Thiametoxam	
5	Acetamiprid	
6	Imidacloprid	
7	Chlorfenapyr	
8	Cyhalothrin	X
9	Formetanat	
10	Anthrachinon	
11	Carbendazim	
12	Chlorpyrifos-methyl	X
13	Cypermethrin	X
14	Dimethoat	X
15	Methamidophos	X
16	Buprofezin	
17	Omethoat	X
18	Acephat	X
19	Carbofuran	
20	Fipronil	

European Commission

The **RASFF (Rapid Alert System for Food and Feed)** was set up to allow food safety authorities to quickly exchange information on health risks from food and feed so that they can take immediate action to avert the risks.
RASFF provides a round-the-clock service to ensure that urgent notifications are sent, received and responded to collectively and efficiently.
The exchange of important information via RASFF can lead to products being recalled from the market.

PESTICIDES

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- The data situation in herbal pharmaceutical products shows that there are some substances with positive findings, some of which also exceed the maximum residue limits according to the European Regulation, **which are not mentioned in Ph.Eur. Chapter 2.8.13** and should therefore be taken into account in the manufacturer's risk assessment. This is in line with the reference to Regulation (EC) No. 396/2005 which is made in Ph.Eur. Chapter 2.8.13.“
- The basis of comprehensive pesticide analysis is formed by a **combination of GC and LC-MS/MS methods** (multi-methods, group methods, screening or individual methods for certain analytes, not included in the multi-methods)

The publication “*Pesticide residues in herbal drugs: Evaluation of a database*” published in the “*Journal of Applied Research on Medicinal and Aromatic Plants 15 (2019) 100223*”, provides a good overview of the pesticide residue situation in medicinal drugs.

Journal of Applied Research on Medicinal and Aromatic Plants 15 (2019) 100223

Contents lists available at ScienceDirect

Journal of Applied Research on Medicinal and Aromatic Plants

journal homepage: www.elsevier.com/locate/jarmap

ELSEVIER

JARMAP

Pesticide residues in herbal drugs: Evaluation of a database

Bernhard Klier[a], Elmar Häfner[a], Hagen Albert[b], Gerald Binder[c], Matthias Knödler[d], Martin Kühn[e], Alexander Schenk[f], Barbara Steinhoff[g,*]

https://doi.org/10.1016/j.jarmap.2019.100223

SOME OF THE TOP-LIST NOT LISTED IN „2.8.13“

Glyphosate is the **most widely used herbicide** worldwide, **positive test results** can therefore be found in products in all regions of the world!

- Data in Phytopharmaceuticals: **21 %** positive, **2 %** >MRL
- MRL exceedances e.g. with elderberry, marjoram, lemon balm, sage, tea, thyme, hawthorn
- Glyphosate has a **very bad reputation**:
  - "probably carcinogenic“
  - detection in human urine
  - overcomes the placenta barrier
  - responsible for bee mortality
  - the majority of the European population is allegedly in support of a complete “Glyphosate-exit”
  - NGOs have long been calling for a ban on glyphosate

SOME OF THE TOP-LIST NOT LISTED IN „2.8.13“

Alternative to glyphosate: **acidic herbicides (e.g. Bentazone)**

In conventional agriculture, numerous alternatives are already being used instead of the total herbicide glyphosate: The so-called ‘acid herbicides’

These substances are used not only as ‘free acids’ but also as ‘esters’. Together with the conjugates bound in the crop plant, they are equally toxicologically relevant and are therefore regulated in Regulation (EC) 396/2005, each calculated as a free acid.

Examples of regulations Regulation (EC) 396/2005:

- Fluazifop-P (sum of all isomer components of fluazifop, its esters and its conjugates, expressed as fluazifop)
- 2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D)
- Quizalofop (sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates), expressed as quizalofop (any ratio of the isomer components)
- Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone)
- etc.

SOME OF THE TOP-LIST NOT LISTED IN „2.8.13“

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Alternative to glyphosate: acidic herbicides

The analytical challenge is that only a few esters and the free acids can be detected with the conventionally used multi-methods.

In order to detect all esters and conjugates, the analytes must be converted into the respective free acid by means of hydrolysis so that the residue definitions stipulated in the regulation can be fulfilled.

Based on our risk analysis, we recommend analysing the following products for acidic herbicides using hydrolysis:

St John's wort, chamomile, coriander, lemon balm, peppermint, thyme and others

SOME OF THE TOP-LIST NOT LISTED IN „2.8.13“

Ethylene oxide, a fumigant used to protect herbs and spices in storage. The substance is also frequently used in shipping ports in transport containers (sometimes unnoticed by the distributor)

Ethylene oxide itself is not stable and is degraded to 2-chloroethanol

The toxicity of the degradation product has not yet been conclusively assessed, which is why the residue definition for the maximum residue level remains '*ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide)*'

- Data in Phytopharmaceuticals: up to **18 %** positive, **2 %** >MRL
- **MRL exceedances** e.g. with blond psyllium, pepper, ginger and turmeric, marigold flowers, …
- RASFF notifications with product recalls on sesame, spice mixtures, bay leaves, chili, curcuma, cumin, cinnamon, locust bean gum and guar gum, food supplements, …
  - mainly from India, but also from China, Turkey, Madagascar, Thailand or the United States.

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CHLORMEQUAT – EXAMPLE ABOUT A RAPID INCREASE IN AWARENESS IN THE US

PhytoLab

Brief Communication | Open access | Published: 15 February 2024

A pilot study of chlormequat in food and urine from adults in the United States from 2017 to 2023

Alexis M. Temkin, Sydney Evans, Demetri D. Spyropoulos & Olga V. Naidenko https://doi.org/10.1038/s41370-024-00643-4

Journal of Exposure Science & Environmental Epidemiology **34**, 317–321 (2024) | Cite this article

- Here we report, the presence of chlormequat in urine samples collected from people in the U.S., with **detection frequencies of 69%, 74%, and 90% for** samples collected in 2017, 2018–2022, and 2023, respectively. Chlormequat was detected at low concentrations in samples from 2017 through 2022, with a **significant increase in concentrations for samples from 2023**.
- Chlormequat is a growth regulator, used mainly on wheat, oats and barley; in the US only permitted on imported foods. Use authorized in EU, UK, Canada
- Food samples purchased in the U.S. from 2022 and 2023 show detectable levels of chlormequat in all but two of 25 conventional oat-based products, with concentrations ranging from non-detectable to **291 µg/kg, indicating a high prevalence of chlormequat in oats**. Median levels were similar between samples collected in 2022 and 2023, at 90 and 114 µg/kg respectively.

HEALTHWATCH

What is chlormequat, and can the chemical found in foods like Quaker Oats and Cheerios impact fertility?

NEWS • HEALTH NEWS

Cheerios and Oats Might Contain a Toxic Pesticide. Here's What You Should Know

By Stephanie Brown | Published on February 27, 2024

Fact checked by Nick Blackmer

Photo composite by Amelia Manley for Verywell Health; Getty Images

This article is more than **3 months old**

A chemical linked to fertility problems in animals has been found in oats in the US. Should we be worried?

A study shows that chlormequat is in your oatmeal in levels exceeding 100 parts per billion – here's what to know

PRODUCT RECALLS **Published** February 26, 2024 2:49pm EST

Chlormequat: What is the chemical found in Cheerios, Quaker Oats?

Use of chlormequat on crops like wheat, oats and barley decreases stem height of the plants

By **Daniella Genovese** | **FOXBusiness** |

Illinois Personal Injury Lawyer Blog

Toxic Chemical Chlormequat Found in Oat-Based Food and Humans, Threatens Reproductive Harm

FEBRUARY 20, 2024 | Margaret Collins

For years, the big cereal companies have been telling us that a bowl of whole grain oat cereal for breakfast is a healthy way to start our day. Turns out maybe it isn't.

A recent study by the Environmental Working Group (EWG) has uncovered a toxic chemical, chlormequat, in popular oat cereals like Cheerios and Quaker Oats.

Chlormequat should not be in our food supply. It is an agricultural chemical used to limit

CONTAMINANTS IN HERBAL RAW MATERIALS AND THEIR ANALYTICS

MYCOTOXINS

MYCOTOXINS – GENERAL INFORMATION

- In the cultivation, harvesting and storage of plant-based raw materials, fungal infections (e.g. ergot in the case of cereals) or mould infestation (*Aspergillus, Penicillium, Fusarium, Alternaria*) can lead to contamination with mycotoxins (e.g. aflatoxin, ochratoxin A, fumonisins, zearalenone, deoxynivanenol).
- Mycotoxins are secondary metabolic products of moulds and are toxic even in very small quantities (carcinogenic, mutagenic, teratogenic, neurotoxic, organ-damaging (e.g. hepatotoxic, nephrotoxic))
- Depending on climatic conditions (temperature, humidity), contamination can occur in the field or during transport, processing and storage. An increase in these problems is to be expected as a result of global warming.
- Types of contamination
  - Primary: The food raw material (e.g. grain) has already been infested by the mould in the field
  - Secondary: Food is stored for too long and possibly under conditions favourable to the fungus and is infested with mould during storage or transport
  - Carry over: Livestock ingest mould-infested food and pass on the spores via products such as meat, eggs or milk

Mycology and toxicology are now aware of over 200 mycotoxins produced by 300 mould species

MYCOTOXINS – GENERAL INFORMATION

The ingestion of mycotoxins can have various consequences for the organism:

- irreversible damage to the embryo
- Triggering of the most severe allergic reactions up to anaphylactic shock
- Damage to DNA and thus potentially carcinogenic effects
- Damage to the central nervous system
- Negative influence on the immune system leads to failure of an appropriate immune response
- Disruption of enzymatic processes
- Triggering of the most severe metabolic imbalances
- Causes severe skin damage on contact with the body surface; in extreme cases up to necrosis

5.5.2023 EN Official Journal of the European Union L 119/103

COMMISSION REGULATION (EU) 2023/915

of 25 April 2023

on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

(Text with EEA relevance)

The EU Contaminants Regulation (EU) 2023/915 currently regulates limit values for 15 different mycotoxins. These include

- aflatoxins B1, B2, G1 and G2
- ochratoxin A
- patulin
- citrinin
- and numerous fusarium toxins.

AFLATOXINS
REQUIREMENTS IN PHARMACOPOEIA

PhytoLab

Monograph 2.8.18: Determination of aflatoxin B_1 in herbal drugs

- Aflatoxins are naturally occurring mycotoxins that are produced mainly by Aspergillus flavus and Aspergillus parasiticus
- These fungi are common and widespread in nature and are most often found when certain cereals are grown under stressful conditions such as drought.
- The mould is found in soil, rotting vegetation, hay and grain
- It penetrates all types of organic substrates whenever the conditions are favourable for its growth (high moisture)
- Aflatoxins are very toxic and carcinogenic, Aflatoxin B_1 is considered to be the most toxic aflatoxin
- Unless otherwise specified in the individual monograph, herbal drugs contain not more than **2 µg/kg** of **aflatoxin B_1**
- The competent authority may also set a limit of **4 µg/kg** for the **sum of aflatoxins B_1 , B_2 , G_1 and G_2**

AFLATOXINS – REQUIREMENTS FOR ANALYSIS

- Methods for aflatoxin analysis must be validated
- Monograph 2.8.18 describes an example of a method that is considered suitable for devil's claw root, ginger and senna.
- For other drugs, either the suitability of this method must be verified, or another method validated for the specific matrix must be used

The principle of the described method is:

Chromatography using LC with fluorescence-detection, immunoaffinity column and post-column derivatisation by photochemically or electrochemically generated bromide (KOBRA-cell); identification and quantification of aflatoxin **B_1 , B_2 , G_1 and G_2** with external reference standards.

AFLATOXINS – DATA SITUATION

TOP LIST: ...at least 10 samples analysed:

		Aflatoxin B1		Aflatoxin sum of (B1,B2,G1,G2)		Aflatoxin B1		Aflatoxin sum of (B1,B2,G1,G2)	
Product	No. of samples analysed	No of positive samples	% positive samples	No of positive samples	% positive samples	No of samples > ML	% samples > ML	No of samples > ML	% samples > ML
Senna, Pods (C. angustifolia)	122	81	66%	81	66%	67	55%	52	43%
Ginger, rhizome	574	243	42%	293	51%	142	25%	160	28%
Chaste tree, fruit	82	30	37%	30	37%	17	21%	15	18%
Cubeb pepper, fruits	15	5	33%	5	33%	2	13%	0	0%
Senna, Pods (C. acutifolia)	154	40	26%	40	26%	19	12%	14	9%
Ignatius bean, seeds	12	3	25%	4	33%	0	0%	2	17%
Rauvolfia, root	12	3	25%	3	25%	3	25%	3	25%
Guar, gum	15	3	20%	4	27%	0	0%	0	0%
Belladonna, leaves	16	3	19%	3	19%	3	19%	3	19%
Cayenne Pepper, fruit	55	9	16%	10	18%	2	4%	0	0%
Senna, leaves (C. acutifolia)	192	25	13%	25	13%	5	3%	4	2%
Tea (Camellia sinensis)	32	3	9%	3	9%	0	0%	0	0%
Apple, fruit	225	19	8%	23	10%	6	3%	5	2%
Florence Fennel, seeds	25	2	8%	2	8%	1	4%	1	4%
Peanut, seeds	13	1	8%	1	8%	1	8%	0	0%
Passion Flower, herb	691	48	7%	67	10%	24	3%	26	4%
Almond, nuts	15	1	7%	1	7%	1	7%	1	7%
Horse-Chestnut, bark	15	1	7%	1	7%	0	0%	0	0%
Curcuma, root	31	2	6%	2	6%	0	0%	0	0%
Cardamom, fruit	17	1	6%	1	6%	1	6%	1	6%
Sheep's bane, herb	18	1	6%	2	11%	1	6%	1	6%
Strophantus, seeds	18	1	6%	1	6%	1	6%	1	6%

MYCOTOXINS: ALTERNARIA TOXINS

L 107/90 EN Official Journal of the European Union 6.4.2022

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/553

of 5 April 2022

on monitoring the presence of *Alternaria* toxins in food

- Recommendation (EC) 2022/553 on the monitoring of *Alternaria* toxins in food, the following food products are mentioned in the Regulation:
    - processed tomato products, paprika powder, sesame seeds, sunflower seeds, sunflower oil, nuts, dried figs, cereal-based baby food.
- Screening of various products, including those not described in the Regulation, is recommended by the EU.
- EFSA findings: dried fruits, herbs, cereal products, nuts, spices
- Findings PhytoLab: elder, lemon balm, sage, other herbs, dried fruits, extracts

MYCOTOXINS: FUSARIUM TOXINS

- Regulation (EU) 2023/915 regulates maximum levels for Fusarium toxins for cereal products and cereals:
    - Deoxynivalenol, Zearalenone, Fumonisins

- **Planned** updates to (EU) 2023/915 (not yet accepted):
    - PLAN 2017/1539
        - Lower limits for Deoxynivalenol in various products, e.g.
            - Baby food
            - Food for special medical purposes
    - PLAN 2017/1196
        - Introduction of MRL für T-2 and HT-2 toxins
            - Mostly for oat grains, cereals, barley, maize, pasta, bakery products, but also:
            - Baby food
            - Food for special medical purposes

MYCOTOXINS: FUSARIUM TOXINS

PhytoLab

Based on our many years of experience in the analysis of herbal products, we can make the following statements:

- frequently positive findings in products regulated Regulation (EU) 2023/915, such as maize, oats, barley, wheat, millet - but also in
    - fruits (apple) or plant extracts from ivy, passion flower, milk thistle, horse chestnut, ginger, ginkgo, curcuma.

➔ **We highly recommend a monitoring of the named pharmaceuticals in order to get a better picture BEFORE a possible change in the legal situation**

FOOD ADDITIVES & CONTAMINANTS: PART B
https://doi.org/10.1080/19393210.2024.2332516

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Mycotoxins and pyrrolizidine alkaloids in herbal dietary supplements

Zane Berzina[a,b], Romans Pavlenko[a], Elena Bartkiene[c], and Vadims Bartkevics[a,b]

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https://doi.org/10.1080/19393210.2024.2332516

ABSTRACT

The market demand for herbal dietary supplements is rapidly growing and such products are becoming more common and accessible to consumers. However, the knowledge about their safety remains incomplete. Herbal dietary supplements are one of the food groups that can contribute significantly to human health concerns arising from chronic exposure to pyrrolizidine alkaloids and mycotoxins. This study aimed to simultaneously determine 79 natural contaminants, including mycotoxins, as well as pyrrolizidine and tropane alkaloids in herbal dietary supplements in one analytical run. Exposure assessment and human health risks were assessed for all compounds included in this study. The total concentration of naturally occurring contaminants in herbal dietary supplements reached 5.3 mg kg^{-1} and the most frequently detected mycotoxins were tentoxin and alternariol monomethyl ether. The latter was detected with the highest frequency, reaching concentrations up to 2.5 mg kg^{-1}. The obtained results indicate a potential risk to public health related to herbal dietary supplement consumption.

ARTICLE HISTORY
Received 18 September 2023
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KEYWORDS
Herbal dietary supplements; mycotoxins; pyrrolizidine alkaloids; tropane alkaloids; risk assessment

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Mycotoxins and pyrrolizidine alkaloids in herbal dietary supplements

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- Herbal dietary supplements are one of the food groups that can contribute significantly to human health concerns arising from chronic exposure to pyrrolizidine alkaloids and mycotoxins. An additional concern is that the recommended duration of use for such herbal dietary supplements may be up to several months, as amounting to a long-term exposure.
- The current Regulation (EU) 2023/915 of the European Commission (2023) sets maximum levels of mycotoxins in various foodstuffs, but for herbal dietary supplements or their ingredients only the content of citrinin and PAs is regulated. As a result of that, many studies focus only on the prevalence of regulated mycotoxins like aflatoxins, ochratoxin A, trichothecenes, zearalenone and fumonisins. However, emerging mycotoxins such as the enniatin group and *Alternaria* mycotoxins can occur in herbal dietary supplements and constitute a significant part of the total toxin burden.
- With the obtained data of 47 samples from Latvian retail market a preliminary safety assessment of some of these was carried out, to demonstrate that its consumption substantially contributes to total mycotoxin exposure.
- The Estimated Daily Intake (EDI) levels of mycotoxins and PA were calculated and compared with the Tolerable Daily Intake (TDI) or other safety threshold values obtained from the available toxicology data in order to assess the food safety risks associated with the identified contamination.
- Hazard quotient (HQ) was used to characterise the risk associated with the mycotoxin content in herbal dietary supplements. HQ values were calculated by HQ = EDI/TCC x 100%, where TCC is the Threshold of Toxicological Concern. The dietary risk was considered to be acceptable when HQ < 100%, otherwise (HQ > 100%) the contaminant was deemed to present a potential threat to public health.
- Detectable amounts of mycotoxins were found in 74% of the samples (35 of 47). The most frequently detected mycotoxins were alternariol monomethyl ether (AME) and tentoxin from the *Alternaria* mycotoxins group.
- Regulated mycotoxins such as aflatoxins were detected in 3 samples, Ochratoxin A was found in 2 samples deoxynivalenol in 1 sample
- According to EFSA (EFSA on Contaminants in the Food Chain CONTAM 2011), alternariol monomethyl ether is classified as a genotoxic compound.

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Four of the 19 positive samples exceeded the TTC value and 5 samples reached 60% or more of the TTC.

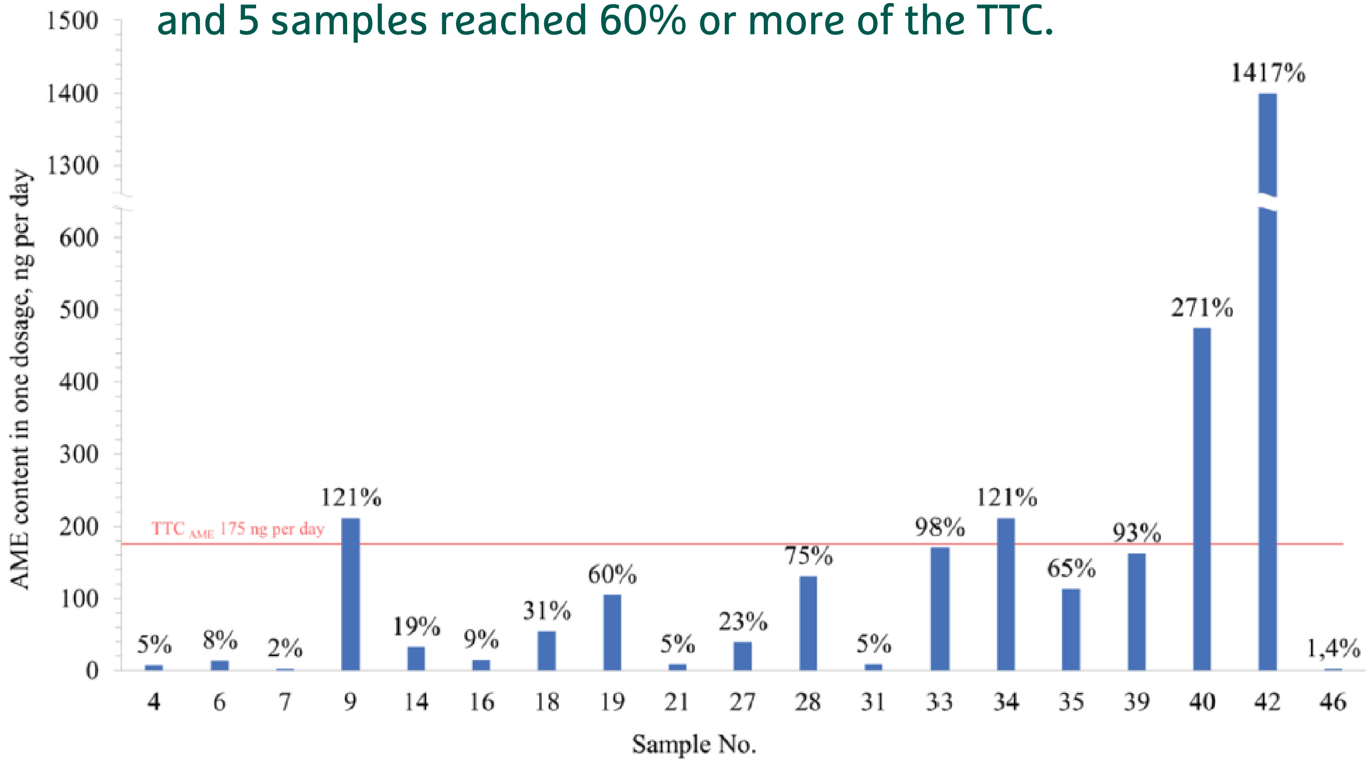

Figure 6. HQ of alternariol monomethyl ether (for samples > LOQ). Red line represents the TTC for an adult of 70 kg bw.

No. 42 was a multi-component HDS, including marjoram, sensitive pea, dry extracts of olive and various fruits and red yeast rice.

Sample No. 40 was ashwagandha powder.

Sample No. 34 was a multi-component mixture, including cereals, fruits and vegetable fibre

Sample No. 9 was a dry extract of milk thistle.

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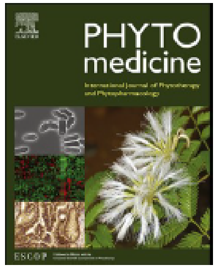

PhytoLab

Original Article

Studies of Mycotoxins in Medicinal Plants Conducted Worldwide over the Last Decade: A Systematic Review, Meta-Analysis, and Exposure Risk Assessment

http://crossmark.cr
.phymed.2024.155

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A R T I C L E I N F O

Keywords:
Mycotoxin contamination
Enniatins
Health risks
Risk characterization

A B S T R A C T

Background: Mycotoxins have been reported to be present in medicinal plants. With the growing usage of medicinal plants, contamination of mycotoxins has emerged as one of the biggest threats to global food hygiene and ecological environment, posing a severe threat to human health.
Purpose: This study aimed to determine the mycotoxin prevalence and levels in medicinal plants and conduct a risk assessment by conducting a systematic review and meta-analysis.
Methods: A thorough search on Web of Science and PubMed was conducted for the last decade, resulting in 54 studies (meeting the inclusion criteria) with 2829 data items that were included in the meta-analysis.
Results: The combined prevalence of mycotoxins in medicinal plants was 1.7% (95% confidence interval, CI = 1.1% – 2.4%), with a mean mycotoxin concentration in medicinal plants of 3.551 µg/kg (95% CI = 3.461 – 3.641 µg/kg). Risk assessment results indicated that aflatoxins and ochratoxin A found in several medicinal plants posed a health risk to humans; additionally, emerging enniatins exhibited possible health risks.
Conclusion: Therefore, the study underlines the need for establishing stringent control measures to reduce the severity of mycotoxin contamination in medicinal plants.

Changing climate, shifting mycotoxins: A comprehensive review of climate change impact on mycotoxin contamination

Alessia Casu[1] | **Marco Camardo Leggieri**[1] | **Piero Toscano**[2] | **Paola Battilani**[1]

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Abstract

Climate change (CC) is a complex phenomenon that has the potential to significantly alter marine, terrestrial, and freshwater ecosystems worldwide. Global warming of 2°C is expected to be exceeded during the 21st century, and the frequency of extreme weather events, including floods, storms, droughts, extreme temperatures, and wildfires, has intensified globally over recent decades, differently affecting areas of the world. How CC may impact multiple food safety hazards is increasingly evident, with mycotoxin contamination in particular gaining in prominence. Research focusing on CC effects on mycotoxin contamination in edible crops has developed considerably throughout the years. Therefore, we conducted a comprehensive literature search to collect available studies in the scientific literature published between 2000 and 2023. The selected

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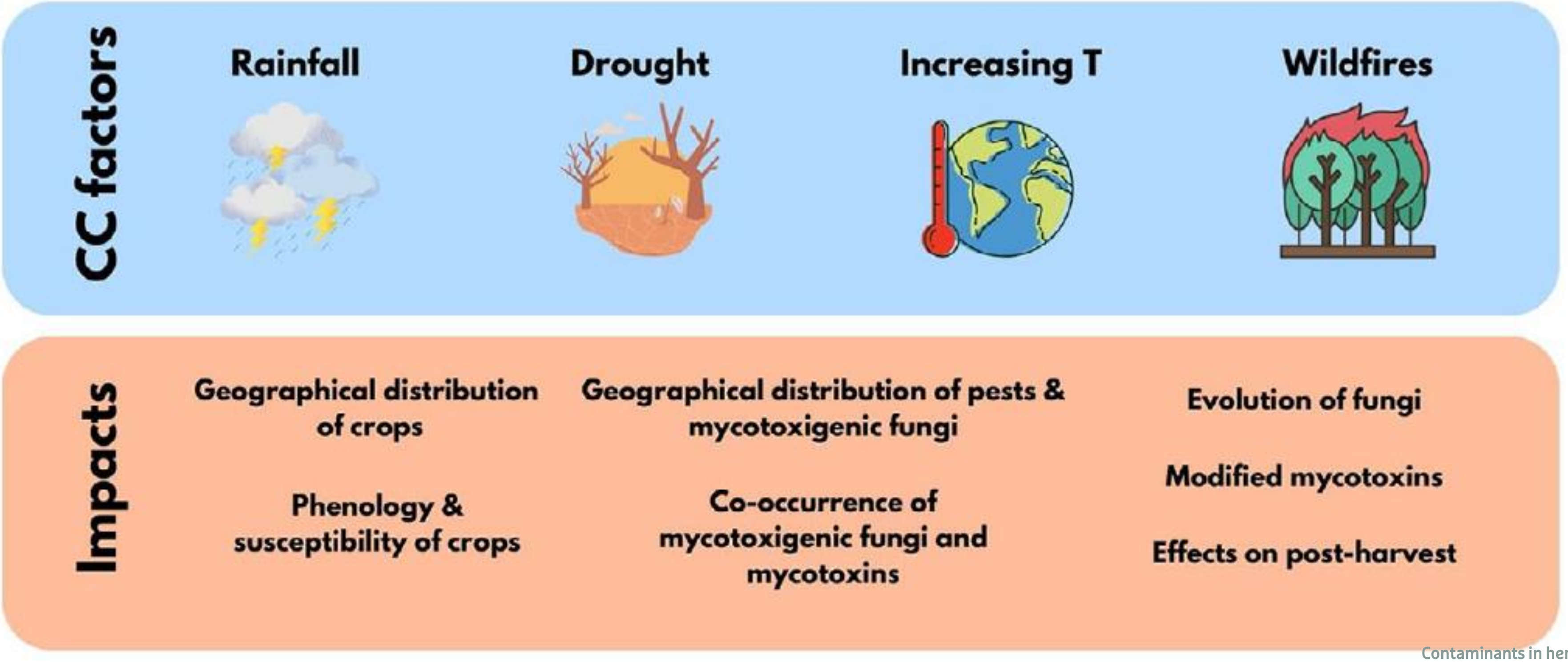

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1. Changes in geographical distribution, phenology, and susceptibility of host crops

- There will be two predominant effects on crops due to climate change:
  - More crops may be produced in currently cool or cold regions (e.g., Northern Europe).
  - As part of the general "movement of crops to the poles," the production of tropical crops, such as coconut, maize, soybeans, coffee, and cocoa, may become optimal in the world's currently subtropical regions.

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2. Changes in geographical distribution of pests and mycotoxin-producing fungi

- The so-called “movement of crops to the poles” is combined with the “movement of pests to the poles.”
- Every fungal species has its own range and optimal environmental conditions— particularly in relation to air temperature and relative humidity and the amount and distribution of rain — for crop infection, host colonization, toxin production, and survival.
- Accordingly, changes in climatic conditions will lead to shifts in fungal populations and mycotoxin patterns, with fungal species migrating to those areas with the best environmental conditions for their growth. Therefore, one of the most anticipated effects of climate change is that warmer temperatures will enable the migration, introduction, or establishment of more thermophilic/thermotolerant species, but in parallel, the higher frequency of extreme weather events will diminish the number of species with low phenotypic plasticity.

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3. Climate change impact on fungal dynamics

- Very hot and dry seasons occurred in northern Italy where maize is largely grown. Drought and elevated temperatures resulted in a switch from *F. verticillioides* and FUM contamination to *A. flavus* and AF contamination.
- The increasing prevalence of *A. flavus* on maize crops was not only identified in Italy but also in the Balkan regions (i.e., Serbia and Croatia) and Hungary. It is predicted that *A. flavus* will outcompete other fungi whose optimal temperatures are lower.
- *A. flavus* was isolated more frequently than *A. ochraceus* in Brazil nuts and pepper from Brazil. Moreover, *A. flavus* may outcompete *A. carbonarius*, with AF then posing a greater risk than OTA, in grapes grown in northern Portugal.
- *F. graminearum* is considered the main DON producer in central and southern Europe, whereas *F. culmorum* is reportedly dominant in Nordic regions. However, a decline in the presence of *F. culmorum* coupled with an increase in that of *F. graminearum* has been reported in some areas of central and northern Europe, like in the Netherlands, Germany, Poland, and the United Kingdom. These two *Fusarium* spp. have different temperature optima for growth, namely, 24–28 °C for *F. graminearum* and 20–25 °C for *F. culmorum*.

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3. Climate change impact on fungal dynamics

- Under certain scenarios, some mycotoxigenic fungal species could go extinct, representing a climate change benefit. For example, temperatures in Pakistan have reached a staggering 53.7 °C; this could drive the extinction of fungal species.
  - but, temperatures of 40◦C or above also pose a challenge to crops' health.
  - And should aflatoxigenic fungi go extinct, yet some crops persist, it does not prevent those aflatoxigenic fungi from being substituted by other more thermophilic fungi.
- The "Parasites Lost Phenomenon" hypothesis, whereby crops could experience a release from their associated pests as they move into new geographical regions, could lead to potential advantages in terms of enemy fungi and mycotoxin contamination. However, if temperatures do not become extremely high and drought conditions recur more often, then a stimulation of AF contamination may ensue. Further, it is plausible that crops will diminish in quality due to the stress related effects of CC and thereby come to harbor more mycotoxins per unit weight of crops.

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4. Climate change impact on mycotoxin dynamics

Aflatoxins

- In the past, serious AF contaminations were detected particularly in the tropical climatic zones of developing countries.
- AFs are increasing in the Mediterranean Basin, especially in crops such as maize and, more recently, in almonds, peanuts, and pistachios grown in southern Europe.
- On the contrary, AFs may be of little or negligible concern in countries with currently very cold climates (e.g., Norway, Canada, and Russia), where even global warming will not result in temperatures warm enough to sustain the growth of *A. flavus* and *A. parasiticus* populations.

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4. Climate change impact on mycotoxin dynamics

Ochratoxin

- Regarding OTA contamination, it is more commonly associated with *A. ochraceus* in warm regions, such as west and central Africa, and with *P. verrucosum* in temperate climates such as northern European countries and Canada
- Given that OTA is optimally produced by *A. ochraceus* between 25 and 30◦C but only at 25 °C by *P. verrucosum*, it is likely the latter will become less prominent in OTA production due to CC, especially in currently warm regions.
- In general AF will tend to supersede OTA as the major mycotoxin found in grapes and coffee, because temperatures will become more suitable for the thermotolerant *Aspergilli* that produce AF.
- Conversely, OTA will increase its presence in currently cold regions because *P. verrucosum* can thrive in those areas as temperatures become warmer. Nonetheless, OTA contamination driven by OTA producing *A. westerdijkiae* and *A. steynii* will probably continue affecting coffee beans grown in tropical regions.

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4. Climate change impact on mycotoxin dynamics

Fumonisins

- FUM contamination has a production peak at ca. 30 °C. Therefore, a general increase in the FUM contamination of crops is anticipated, namely, maize, wheat, rice, and soybeans. Yet displacement by AFs is also possible in certain areas. *Fusarium* spp. are in fact tolerant of higher temperatures but they are not as xerotolerant as *A. flavus*; hence, in areas where relative humidity is predicted to decrease, FUM may be replaced by AF. Depending on the year and climatic conditions that develop, AFs and FUMs could alternate in dominance, as AFs thrive during hotter seasons and FUMs thrive during wetter seasons, even if their co-occurrence is the most likely outcome. Therefore, unlike for OTA, FUM contamination seems capable of withstanding adverse climatic conditions brought about by climate change.
- An important effect tied to climate change that cannot be overlooked is a possible switch in dominant mycotoxins produced to other related compounds, which could then become the predominant toxic contaminants. It is known that *F. verticillioides* is able to produce different FUM toxins (FUM B1, B2, B3, and B4); under a climate change scenario the ratio of these toxins can significantly change.

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4. Climate change impact on mycotoxin dynamics

Alternaria toxins

- Moreover, it is worth mentioning *Alternaria* toxins. These toxins may become more common in currently cold regions such as Poland, less prevalent in currently warm regions such as Spain. This geographical shift is expected to occur because the environmental conditions of southern European countries will become too extreme for the fungi to grow and produce toxins, whereas the conditions in central and northern European countries will become progressively optimal for that.

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5. Co-occurrence of mycotoxigenic fungi and mycotoxins

- In the past, the contamination of food commodities, and therefore its effect on human and animal health, was studied by examining one fungus at a time. However, fungi are members of fungal communities and are subjected to their dynamics. The presence of more fungi in the same environment can influence the growth of a single member species or strain and eventually mycotoxin contamination. Moreover, most fungi are not specialized in the production of a sole type of mycotoxin but rather can produce several mycotoxins. It follows that the co-occurrence of mycotoxins would be an obvious consequence.
- The co-occurrence ofmycotoxins can cause additive and eventually synergic effects, resulting in a modification of their toxicity to humans and animals in a not well-defined manner.

CONTAMINANTS IN HERBAL RAW MATERIALS AND THEIR ANALYTICS

PLANT TOXINS

PYRROLIZIDINE ALKALOIDS, TROPANE ALKALOIDS

PYRROLIZIDINE ALKALOIDS (PA) GENERAL INFORMATION

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Pyrrolizidine alkaloids (PA) are a large group of natural substances that are mainly produced by plants, but also by fungi and bacteria. The compounds are presumably produced by plants in particular to protect them from predators.

So far several hundred PAs and their N-oxides are known. In plants, PAs have so far been detected in more than 350 species worldwide, but based on chemotaxonomic considerations, PAs are thought to occur in over 6,000 plant species.

The ability to form PAs is found in representatives from at least 13 plant families, in particular in representatives from the families *of Asteraceae, Boraginaceae, Fabaceae, Apocynaceae, Ranunculaceae* and the *Scophulariaceae* family.

Native PA-forming plants in Central Europe include, for example, ragwort, common ragwort and viper's bugloss.

Chemically speaking, PAs are esters of a necin base and aliphatic mono- or dicarboxylic acids (necin acids).

PYRROLIZIDINE ALKALOIDS (PA)

HOW CAN PA GET INTO FOOD, FOOD SUPPLEMENTS AND PHARMACEUTICALS?

PhytoLab

According to current knowledge, there are four ways in which 1,2-unsaturated PAs can contaminate plant products:

1. PA-forming plants that grow on the cultivation areas of crops and contaminate the food at harvest. For example:
    - contamination with ragwort/grass weed in salads
    - Contamination in wheat due to strong spread of plants of Heliotropium in wheat fields
    - Contamination of tea and herbal tea as well as herbs/spices with PA-forming plants during harvesting
2. bee products such as honey and pollen can be contaminated with 1,2-unsaturated PAs. The main sources of contamination are wild plants such as *Echium, Senecio* and *Borago* species, from which bees collect pollen.
    - Raw honeys from certain countries in Central and South America are less contaminated than raw honeys from some European countries.

PYRROLIZIDINE ALKALOIDS (PA) – REQUIREMENTS FOR ANALYSIS

The PA analytic is very complex due to the many naturally occurring individual compounds and their occurrence in different matrices

Due to their structure and chemical properties, 1,2-unsaturated PAs are easy detectable using liquid chromatography in combination with mass spectrometry

The results of many interlaboratory tests have shown that laboratories produced satisfactory results

- the **method must be validated**, for not validated matrices, the suitability of the method **must be verified**, or another method validated for the specific matrix must be used
- **Calibration using individual primary standards** (Highest accuracy through the use of certified reference standards (phyproof))
- **Separation of stereoisomers** during the measurement and quantified individually to obtain more accurate results

Comparison between different laboratories – separation of pyrrolizidine alkaloid isomers

Analytes	PhytoLab	Lab 1	Lab 2	Lab 3	Lab 4 (Isomere ohne Trennung)	Lab 5
Echimidin	Echimidin	Echimidin/Heliosupin	Echimidin/Heliosupin	Echimidin	Echimidin/Heliosupin	Echimidin/Heliosupin, Summe
Echimidin N-Oxid	Echimidin N-Oxid	Echimidin N-Oxid	Echimidin N-Oxid	Echimidin N-Oxid	Echimidin N-Oxid	Echimidin-N-oxid
Echinatin	Echinatin	Echinatin/Rinderin/Indicin/Lycopsamin	Echinatin/Rinderin/Indicin/Lycopsamin	Echinatin	Echinatin/Rinderin	Rinderin/Echinatin, Summe
Echinatin N-Oxid	**Echinatin N-Oxid**	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	MISSING	Echinatin-N-oxid
Erucifolin	Erucifolin	Erucifolin	Erucifolin	Erucifolin	Erucifolin	Erucifolin
Erucifolin N-Oxid	Erucifolin N-Oxid	Erucifolin N-Oxid	Erucifolin N-Oxid	Erucifolin N-Oxid	Erucifolin N-Oxid	Erucifolin-N-oxid
Europin	Europin	Europin	Europin	Europin	Europin	Europin
Europin N-Oxid	Europin N-Oxid	Europin N-Oxid	Europin N-Oxid	Europin N-Oxid	Europin N-Oxid	Europin-N-oxid
Heliosupin	Heliosupin	Echimidin/Heliosupin	Echimidin/Heliosupin	Heliosupin	Echimidin/Heliosupin	Echimidin/Heliosupin, Summe
Heliosupin N-Oxid	Heliosupin N-Oxid	Heliosupin N-Oxid	Heliosupin N-Oxid	Heliosupin N-Oxid	Heliosupin N-Oxid	Heliosupin-N-oxid
Heliotrin	Heliotrin	Heliotrin	Heliotrin	Heliotrin	Heliotrin	Heliotrin
Heliotrin N-Oxid	Heliotrin N-Oxid	Heliotrin N-Oxid	Heliotrin N-Oxid	Heliotrin N-Oxid	Heliotrin N-Oxid	Heliotrin-N-oxid
Integerrimin	Integerrimin	Senecionin/Integerrimin	Senecionin/Integerrimin	Integerrimin	Senecionin/Integerrimin/Senecivernin	Senecivernin/Integerrimin, Summe
Integerrimin N-Oxid	**Integerrimin N-Oxid**	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Integerrimin-N-oxid/Senecionin-N-oxid, Summe
Intermedin	Intermedin	Intermedin	Intermedin	Intermedin	Intermedin	Intermedin
Intermedin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid	Intermedin-N-oxid/Indicin-N-oxid, Summe
Indicin	Lycopsamin/Indicin	Echinatin/Rinderin/Indicin/Lycopsamin	Echinatin/Rinderin/Indicin/Lycopsamin	Indicin	Lycopsamin/Indicin	Lycopsamin/Indicin, Summe
Indicin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid/Echinatin N-Oxid	Intermedin N-Oxid/Indicin N-Oxid	Intermedin-N-oxid/Indicin-N-oxid, Summe
Jacobin	Jacobin	Jacobin	Jacobin	Jacobin	Jacobin	Jacobin
Jacobin N-Oxid	Jacobin N-Oxid	Jacobin N-Oxid	Jacobin N-Oxid	Jacobin N-Oxid	Jacobin N-Oxid	Jacobin-N-oxid
Lasiocarpin	Lasiocarpin	Lasiocarpin	Lasiocarpin	Lasiocarpin	Lasiocarpin	Lasiocarpin
Lasiocarpin N-Oxid	Lasiocarpin N-Oxid	Lasiocarpin N-Oxid	Lasiocarpin N-Oxid	Lasiocarpin N-Oxid	Lasiocarpin N-Oxid	Lasiocarpin-N-oxid
Lycopsamin	Lycopsamin/Indicin	Echinatin/Rinderin/Indicin/Lycopsamin	Echinatin/Rinderin/Indicin/Lycopsamin	Lycopsamin	Lycopsamin/Indicin	Lycopsamin/Indicin, Summe
Lycopsamin N-Oxid	Lycopsamin N-Oxid	Lycopsamin N-Oxid	Lycopsamin N-Oxid	Lycopsamin N-Oxid	Lycopsamin N-Oxid	Lycopsamin-N-oxid
Monocrotalin	Monocrotalin	Monocrotalin	Monocrotalin	Monocrotalin	Monocrotalin	Monocrotalin
Monocrotalin N-Oxid	Monocrotalin N-Oxid	Monocrotalin N-Oxid	Monocrotalin N-Oxid	Monocrotalin N-Oxid	Monocrotalin N-Oxid	Monocrotalin-N-oxid
Retrorsin	**Retrorsin**	Retrorsin/Usaramin	Retrorsin/Usaramin	Retrorsin/Usaramin	Retrorsin	Retrorsin/Usaramin, Summe
Retrorsin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin-N-oxid/Usaramin-N-oxid, Summe
Rinderin	Rinderin	Echinatin/Rinderin/Indicin/Lycopsamin	Echinatin/Rinderin/Indicin/Lycopsamin	Rinderin	Echinatin/Rinderin	Rinderin/Echinatin, Summe
Senecionin	Senecionin	Senecionin/Integerrimin	Senecionin/Integerrimin	Senecionin	Senecionin/Integerrimin/Senecivernin	Senecionin
Senecionin N-Oxid	**Senecionin N-Oxid**	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Senecionin N-Oxid/Integerrimin N-Oxid	Integerrimin-N-oxid/Senecionin-N-oxid, Summe
Seneciphyllin	Seneciphyllin	Seneciphyllin/Spartiodin	Seneciphyllin / Spartioidin	Seneciphyllin	Seneciphyllin	Seneciphyllin
Seneciphyllin N-Oxid	Seneciphyllin N-Oxid	Seneciphyllin N-Oxid/Spartiodin N-Oxid	Seneciphyllin N-Oxid/Spartiodin N-Oxid	Seneciphyllin N-Oxid	Seneciphyllin N-Oxid	Seneciphyllin-N-oxid
Senecivernin	Senecivernin	Senecivernin	Senecivernin	Senecivernin	Senecionin/Integerrimin/Senecivernin	Senecivernin/Integerrimin, Summe
Senecivernin N-Oxid	Senecivernin N-Oxid	Senecivernin N-Oxid	Senecivernin N-Oxid	Senecivernin N-Oxid	Senecivernin N-Oxid	Senecivernin-N-oxid
Senkirkin	Senkirkin	Senkirkin	Senkirkin	Senkirkin	Senkirkin	Senkirkin
Spartiodin	Spartiodin	Seneciphyllin/Spartiodin	Seneciphyllin / Spartioidin	Spartiodin	MISSING	Spartiodin
Spartiodin N-Oxid	Spartiodin N-Oxid	Seneciphyllin N-Oxid/Spartiodin N-Oxid	Seneciphyllin N-Oxid/Spartiodin N-Oxid	Spartiodin N-Oxid	MISSING	Spartioidin-N-oxid
Trichodesmin	Trichodesmin	Trichodesmin	Trichodesmin	Trichodesmin	Trichodesmin	Trichodesmin
Usaramin	**Usaramin**	Retrorsin/Usaramin	Retrorsin/Usaramin	Retrorsin/Usaramin	MISSING	Retrorsin/Usaramin, Summe
Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Usaramin N-Oxid	Retrorsin N-Oxid/Usaramin N-Oxid	Retrorsin-N-oxid/Usaramin-N-oxid

42 analytes, relevant for food/pharma regulations: The PhytoLab method has the hightest separation power

PYRROLIZIDINE ALKALOIDS (PA) – REGULATIONS – MAXIMUM LIMITS

PhytoLab

Pharmaceuticals:
Monograph 2.8.26:

Limits:
Patient exposure to PAs from medicinal products should be as low as possible and must not exceed the maximum daily intake agreed by the competent authority.

Food and Foodsupplements:
Reg. (EC) 2023/915:

- The EU Contaminants Regulation (EU) 2023/915 currently regulates Maximum limits for "sum of 21+14" PA and Isomers
- Limit related to the "ready-to-eat" product
- The sum of PAs should be specified according to the **"lower bound"** approach, i.e. results <LOQ for individual PAs are included in the sum with zero

PYRROLIZIDINE ALKALOIDS (PA) – DATA SITUATION - SUM OF 28 PA

PhytoLab

TOP LIST: ...at least 50 samples analysed:

Product	% positive samples	% > 100 µg/kg
Blond Psyllium, seeds	87%	71%
Senna, leaves	87%	67%
Blond Psyllium, husk	84%	48%
Fumitory, herb	83%	75%
Lemon Verbena, herb	81%	32%
Rooibos, leaves	78%	10%
Cowslip, Oxslip, root	65%	47%
Golden Rod, herb	61%	34%
Tea (Camellia sinensis)	60%	16%
Sage, leaves	58%	37%
Common Wormwood, herb	55%	25%
Pelargonium, root	55%	9%
Sweet Orange, leaves	55%	17%
St. John's wort, herb	48%	27%
Stevia, herb	48%	31%
Raspberry, leaves	46%	19%
Horsetail, herb	44%	14%
Sweet Blackberry leaves	43%	16%
Dandelion, herb	43%	26%
Stinging Nettle, Dwarf Nettle, herb	43%	21%

Product	% positive samples	% > 100 µg/kg
Lavender, flowers	43%	20%
Florence Fennel, seeds	39%	8%
Aniseed	38%	27%
Camomile, flowers	37%	15%
Rest Harrow, root	37%	11%
Lemon Balm, leaves	36%	17%
Gesamtergebnis	35%	17%
Blackberry, leaves	34%	12%
Thyme, herb	34%	13%
Ladies Mantle, herb	34%	13%
Globe Artichoke, leaves	32%	15%
Java Tea, leaves	30%	11%
Peppermint, leaves	30%	16%
Senna, Pods	29%	4%
Strawberry, leaves	28%	12%
Oats, straw, green	27%	12%
Mallow, leaves	26%	14%
Yarrow, herb	26%	9%
Ribwort, herb	24%	6%
Holy basil, herb	23%	10%

Monograph 2.8.26:

Limits:

Patient exposure to PAs from medicinal products should be as low as possible and must not exceed the maximum daily intake agreed by the competent authority.

PhytoLab
SAFEGUARDING BOTANICAL QUALITY

CONTAMINANTS IN HERBAL RAW MATERIALS AND THEIR ANALYTICS

PAH
POLYCYCLIC AROMATIC HYDROCARBONS

POLYCYCLIC AROMATIC HYDROCARBONS (PAH) – GENERAL INFORMATION

PhytoLab

- PAH = polycyclic aromatic hydrocarbons, PAHs are natural components of coal and crude oil
- High proportion in coal tar (road construction) - banned since 1984
- PAHs are formed during the incomplete combustion of various organic materials, such as coal, heating oil, fuels, tobacco, wood, etc.
- Another source of PAH pollution is the production of coke and gas from coal
- The majority of PAH pollution is due to anthropogenic processes, but also of natural origin, such as forest fires or condensation reactions from humic acids (peat, lignite)
- Occurrence in tobacco smoke, in smoked, grilled or roasted meat, accumulation in house dust on busy roads. Present all over the world as particles in soil and air or dissolved in seepage and groundwater
- In economically less developed countries, mainly wood, coal or straw are burnt, but also waste. If these fires are used to dry plants such as teas or herbs, PAHs can get onto the plants and ultimately into the food supplements via the smoke.
- In the **European Rapid Alert System** (RASFF), there are repeated reports of food supplements containing matcha, turmeric, ginkgo, garlic, green coffee, propolis powder, rice, spices, paprika powder, Spirulina and olive oil, especially raw materials from Asia.

POLYCYCLIC AROMATIC HYDROCARBONS (PAH) – EXCEEDANCES PHYTOLAB SINCE 2010

PhytoLab

Limit values according to Regulation (EC) 2023/915 for food supplements containing herbal substances and preparations thereof:

- **10 µg/kg (benzo[a]pyrene)**
- **50 µg/kg (total PAH 4)**

Total	Benzo[a]pyren: % > 10µg/kg	Total PAK 4: % > 50µg/kg
All analysed products	**8%**	**9%**

Top List Products % > ML
(at least 20 analysed)

Products from	Benzo[a]pyren: % > 10µg/kg	Total PAK 4: % > 50µg/kg
Quince extract	57%	69%
other roots extract	57%	61%
Mate	50%	47%
Lime	48%	52%
Elderberry	43%	43%
Valerian extract	37%	45%
Spirulina	28%	32%
Dandelion	24%	20%
Vervain	23%	33%
Orthosiphon	21%	23%
Cardamom	21%	29%
Tea (camellia sinensis)	16%	17%
Nettle extract	16%	23%
Valerian	14%	13%
Nettle	13%	13%
Seaweed	10%	5%
Pennywort	9%	30%
Ginseng	6%	22%
Echinacea extract	6%	8%
Arnica	5%	5%
Echinacea	4%	4%

POLYCYCLIC AROMATIC HYDROCARBONS (PAH) – EXAMPLE OF RISK ASSESSMENT

PhytoLab

no findings	0
few findings	x
Frequent findings (>10%):	xx
Frequent findings and >MRL:	xxx
No sufficient data available:	?

no analysis →
no data →
no risk assessment

Product English	Plant Latin	PAH	remark
Alder Buckthorn, bark	Rhamnus frangula	xxx	
Aniseed	Pimpinella anisum	x	
Arnica, flowers	Arnica montana	x	
Arnica, root	Arnica montana	?	High risk based on similar products
Bearberry, leaves	Arctostaphylos uva-ursi	xxx	
Birch, leaves	Betula pendula, B. pubescens	xxx	
Boldu, leaves	Peumus boldus	x	
Caraway, seeds	Carum carvi	xx	
Centaury, herb	Erythraea centaurium	x	
Chaste tree, fruit	Agnus castus	xx	
Clove, buds	Eugenia caryophyllata	xxx	
Common Ivy, leaves and herb	Hedera helix	xxx	
Dandelion, root	Taraxacum officinale	xxx	
Echinacea, herb	Echinacea spec.	xx	see also root
Echinacea, root	Echinacea spec.	xxx	see also herb

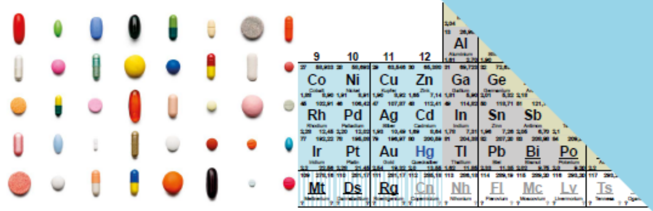
Product English	Plant Latin	PAH	remark
Elder, flowers	Sambucus nigra	xxx	see also leaves, fruit
Elder, fruit	Sambucus nigra	xx	see also flowers, leaves
Elder, leaves	Sambucus nigra	xxx	see also flowers, fruit
Eucalyptus, leaves	Eucalyptus globulus	x	
Fennel, seeds	Foeniculum vulgare	xx	
Feverfew, herb	Pyrethrum parthenium	?	
Garlic, bulb	Allium sativum	xxx	
Ginkgo, leaves	Ginkgo biloba	xxx	
Hops	Humulus lupulus	xxx	
Horse-Chestnut, seeds	Aesculus hippocastanum	xxx	
Horsetail, herb	Equisetum arvense	xx	
Juniper, flower	Juniperus communis	?	see also fruits
Juniper, fruit	Juniperus communis	x	see also flowers
Lemon, peel (C. limon)	Citrus limon	0	
Liquorice, root	Glycyrrhiza glabra	xx	
Lovage, herb	Levisticum officinale	xx	
Marjoram, herb	Origanum majorana	xx	
Milk Thistle, fruit	Silybum marianum	x	
Nasturtium, herb	Tropaeolum majus	xx	
Oat pressed juice	Avena sativa	?	Increased risk depending on the processing factor?
Oats, straw, green	Avena sativa	x	
Onion, bulb	Allium cepa	0	

PhytoLab News - Current topics specially prepared for you

PhytoLab

ICH Q3D Elemental impurities

PhytoLab



Elemental impurities in phytopharmaceuticals - Risk assessment and analysis

Background

ICH Guideline Q3D on elemental impurities outlines a process for the evaluation of toxicity data for potential elemental impurities, the establishment of a permissible daily exposure (PDE) level for each element of toxicologic concern, and the application of a risk-based approach to control such impurities in medicinal products. European Pharmacopoeia (Ph. Eur.) monograph Pharmaceutical Preparations (2619) and the statements made in the "Questio & answers on quality of herbal medicinal products/traditional herbal medicinal products" (EMA/HMPC/41500/2010 Rev.6) make it clear that a risk-based control strategy for elemental impurities must also be available for herbal medicinal products. The second revision of ICH Guideline Q3D, with corrections for nickel, gold and silver in Appendices 2 and 3, has been in force since September 2022. Furthermore, the new Appendix 5 has also introduced specific limits for topical and transcutaneous medicinal products with effect from 24 September 2022.

Strategic evaluation

There are two different approaches, which may be adopted for a risk assessment:

1. An evaluation of the components used, including materials, equipment and packaging materials throughout the manufacturing chain.
2. A product-specific approach based on analytical data of representative batches.

If the level of an elemental impurity is not below the threshold of 30% of the PDE consistently, a monitoring strategy must be established to ensure that the level in the daily dose does not exceed the PDE level.

Analysis

ICH Guideline Q3D divides the listed elements into four categories according to toxicity and probability of occurrence. PhytoLab deploys a multi-element method by means of inductively coupled plasma mass spectrometry (ICP-MS) for product-specific screening of these elements and to monitor elements, which have been assessed as being critical. ICH-compliant validation documentation is available and PhytoLab offers product-specific method verification procedures as and when required.

Risk assessment

The experts in our Medical Affairs team perform guidelir compliant risk assessments and give you support for the re-evaluation of your topical medicinal products in accordance with Appendix 5. In this context, particular attention must be given to the sensitising elements nicl and cobalt, for which lower PDE levels have been define than for Oralia.

We would be happy to advise you and create an individual offer for the evaluation and analysis of your products. Contact us:

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Food supplements

PhytoLab

SAFE MARKETING OF FOOD SUPPLEMENTS

Background

More than 20 years have passed since Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements was published on 10 June 2002. Nevertheless, there is still a notable absence of common values for the maximum amounts of vitamins and minerals to be set according to Article 5 of the Directive, as well as a legally sound harmonised basis for the marketing of botanicals. Therefore, the numerous national regulations and recommendations still play an important role in the marketing of food supplements in the EU.

Strategic evaluation

Although the regulation of maximum amounts has been under discussion at European level for years, along with the question of the botanicals to be used and the ways in which they may be advertised, there are no solutions on the horizon for either issue. If a food supplement is to be marketed in several EU countries, an investigation must therefore be carried out to determine whether the formulation meets the requirements imposed in all target markets or whether adjustments need to be made. Ingredients of plant origin pose a particular challenge in this respect.

Regulatory affairs

Positive and negative lists established to regulate the handling of herbal ingredients at national level must be observed, for example, at the same time. As the majority of these only define plants and parts of plants, it is often necessary to clarify whether or not the chosen preparation is a novel food. We keep an eye on legal developments and offer you comprehensive advice regarding herbal and non-herbal ingredients, as well as labelling issues (mandatory information, health and nutrition claims, clean labelling).

Medical affairs

Safety-relevant aspects are also having to be taken into account to an increasing extent in the development and marketing of food supplements containing botanicals. The increasing regulation of plants and ingredients within the framework of Article 8 of Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and certain other substances to foods requires expert evaluation, as do the activities of EFSA and ECHA, which are relevant to many secondary plant substances as well. You can also count on us at PhytoLab, with our many years of expertise, to provide assistance in the context of objections on the part of the authorities.

Analytics

PhytoLab has a broad spectrum of procedures at its disposal for the analysis of vitamins, minerals, trace elements, carotenoids and omega-3 fatty acids, and is playing a leading role when it comes to analysing the increasingly important secondary plant constituents. We also test the microbiological quality and stability of your products on your behalf. In this way, we offer you the best possible means of ensuring that the marketability of your products is assured from a single source.

Need for action

Do you need independent expertise on food supplements, botanicals or issues relating to the definition of boundaries to other product categories? Or are you looking for a laboratory that can offer you reliable customised solutions for your products, from the analysis of raw materials through to the finished product? If so, you have come to the right place!

Our experts will be happy to advise you.

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Alternaria

PhytoLab

Recommendation (EU) 2022/553 on monitoring the presence of Alternaria toxins in foodstuffs

Background

Moulds of the genus *Alternaria* are ubiquitously distributed on plants. The Alternaria metabolite alternariol and its monomethyl ether are classified as being genotoxic (EFSA 2011). In some cases, chronic exposure of certain consumer groups to Alternaria toxins is considerably higher than the reference value of 2.5 µg/kg bw/day (EFSA 2016). With Regulation (EU) 2022/553 of April 2022, the EU Commission is therefore recommending that Alternaria toxins in food are monitored, while specifying guidance values for certain foodstuffs, including tomato products, paprika powder, sesame seeds, sunflower seeds and processed cereal-based foods for infants and young children.

Strategic evaluation

The Commission is calling on Member States and the industry to collect data on the foodstuffs mentioned above, as well as data on other foodstuffs, and prepares an annual report with the results. By asking national authorities to intensify the monitoring of foodstuffs for the presence of Alternaria toxins and to submit the data to EFSA on an annual basis, the Commission is expecting the data situation to improve and it is likely that guidance values will also be established for other foodstuffs. Alternaria toxins are also known to occur in fruits (e.g. apples, grapes), tea, green coffee beans, herbal tea ingredients (e.g. liquorice) and spices. In the medium term, limit values for foodstuffs are expected to be laid down in Regulation (EU) 2023/915.

Analysis

Our high-performance LC-MS/MS method permits the determination of alternariol, alternariol monomethyl ether, altenuene, tentoxin and tenuazonic acid in foodstuffs and medicinal herbs/extracts. The method has been validated for herbs, spices, extracts and other foodstuffs, and accredited in accordance with ISO/IEC 17025.

We would be delighted to advise you and draw up an offer for the determination of Alternaria toxins in your herbal raw materials or preparations.

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30

Gewachsenes
Vertrauen seit
30 Jahren.

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sagt Danke.

THANK YOU!

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