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ADULTERATION UPDATE: How YOU can help stop the resale of irreparably defective ingredients and products

Show Announcements:

- Download the Mobile App to view the Exhibitor List, Show Schedule, Floor Plan and our Sponsors.
 - Thank you to our Mobile App sponsor: **Epicor (Booth 4465)**
- Wi-Fi – Sponsored by **Cactus Botanicals (Booth 4237)**
 - Select network: **SupplySideWest23**
 - On the splash page, agree to terms & conditions
 - Enter access code: **cactus4237** (access code is case sensitive)
- Please place all devices on silent mode
- The Expo Hall is open today from 10am – 5:30pm.
- There is an LGBTQ + Allies Networking reception tonight from 5:30-7:30pm in South Pacific Ballroom F.
This reception is in partnership with the Naturally Proud Network.

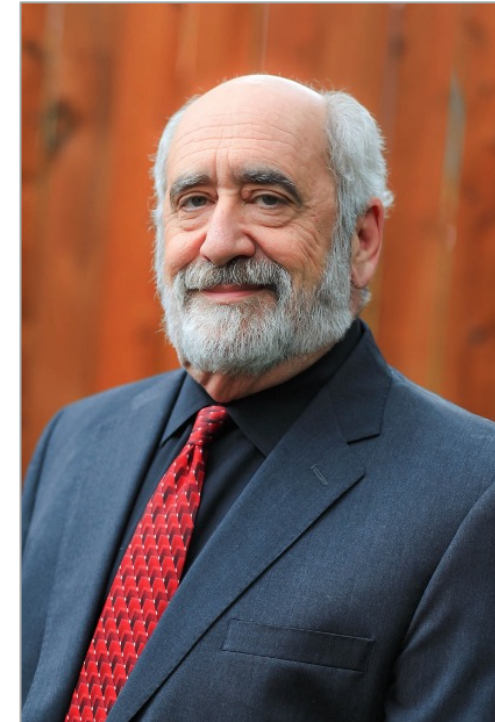




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ABC AHP NCNPR
**Botanical Adulterants
Prevention Program**



THE UNIVERSITY of
MISSISSIPPI
NATIONAL CENTER FOR NATURAL
PRODUCTS RESEARCH



AMERICAN HERBAL PHARMACOPOEIA®


A BRIEF
HISTORY
OF

ADULTERATION

OF
HERBS, SPICES, AND
BOTANICAL DRUGS
BY
STEVEN FOSTER



Echinacea Echinacea purpurea. Photo ©2011 Steven Foster



The botanical supply chain is global; adulteration is a global challenge.



Many responsible, ethical companies in both the supply chain and in the manufacture and marketing of herbs and finished herbal products provide reliable high-quality ingredients and consumer goods.





Top-selling Herbal Supplements US Mainstream Multi-outlet Channel, 2021

Rank	Primary Ingredient
1	Elder berry
2	Psyllium
3	Apple cider vinegar
4	Horehound ^a
5	Turmeric ^b
6	Cranberry
7	Ashwagandha
8	Ivy leaf
9	Ginger
10	Fenugreek
11	Echinacea ^c
12	Garlic
13	St. John's wort
14	Wheatgrass / barley grass
15	Beta-sitosterol ^d
16	Valerian
17	Ginkgo
18	Saw palmetto
19	Flax seed or oil
20	Black cohosh

Primary Ingredient Subject to Adulteration

- 1. Elder Berry
- 5. Turmeric
- 6. Cranberry
- 7. Ashwagandha
- 11. Echinacea
- 13. St. John's Wort
- 17. Ginkgo
- 18. Saw Palmetto
- 20. Black Cohosh

= 45%

Source: Source: Smith T et al. US Sales of Herbal Supplements Increase by 9.7% in 2021. *HerbalGram* 136 (2023):42-69.



Top-selling Herbal Supplements US Natural Channel, 2021

Rank	Primary Ingredient
1	Cannabidiol (CBD)
2	Turmeric ^a
3	Elder berry
4	Ashwagandha
5	Wheatgrass / barley grass
6	Quercetin ^b
7	Mushrooms (other)
8	Aloe
9	Flax seed or oil
10	Milk thistle
11	Psyllium
12	Oregano ^c
13	Spirulina
14	Apple cider vinegar
15	Echinacea ^d
16	Cranberry
17	Saw palmetto
18	Chlorophyll / chlorella
19	Garlic
20	Maca

Primary Ingredient Subject to Adulteration

1. CBD
2. Turmeric
3. Elder Berry
4. Ashwagandha
8. Aloe
10. Milk Thistle
12. Oregano
15. Echinacea
16. Cranberry
17. Saw Palmetto
20. Maca

= 55%

Source: Source: Smith T et al. US Sales of Herbal Supplements Increase by 9.7% in 2021.
HerbalGram 136 (2023):42-69.

Total BAPP Publications, October 9, 2023

- Botanical Adulterant Prevention Bulletins 27
- Laboratory Guidance Documents 16
- Articles on adulteration (*HerbalGram* etc.) 11
- “Botanical Adulterants Monitor” newsletters 28
- Best Practices SOP for Disposal / Destruction
for Irreparably Defective Articles 1

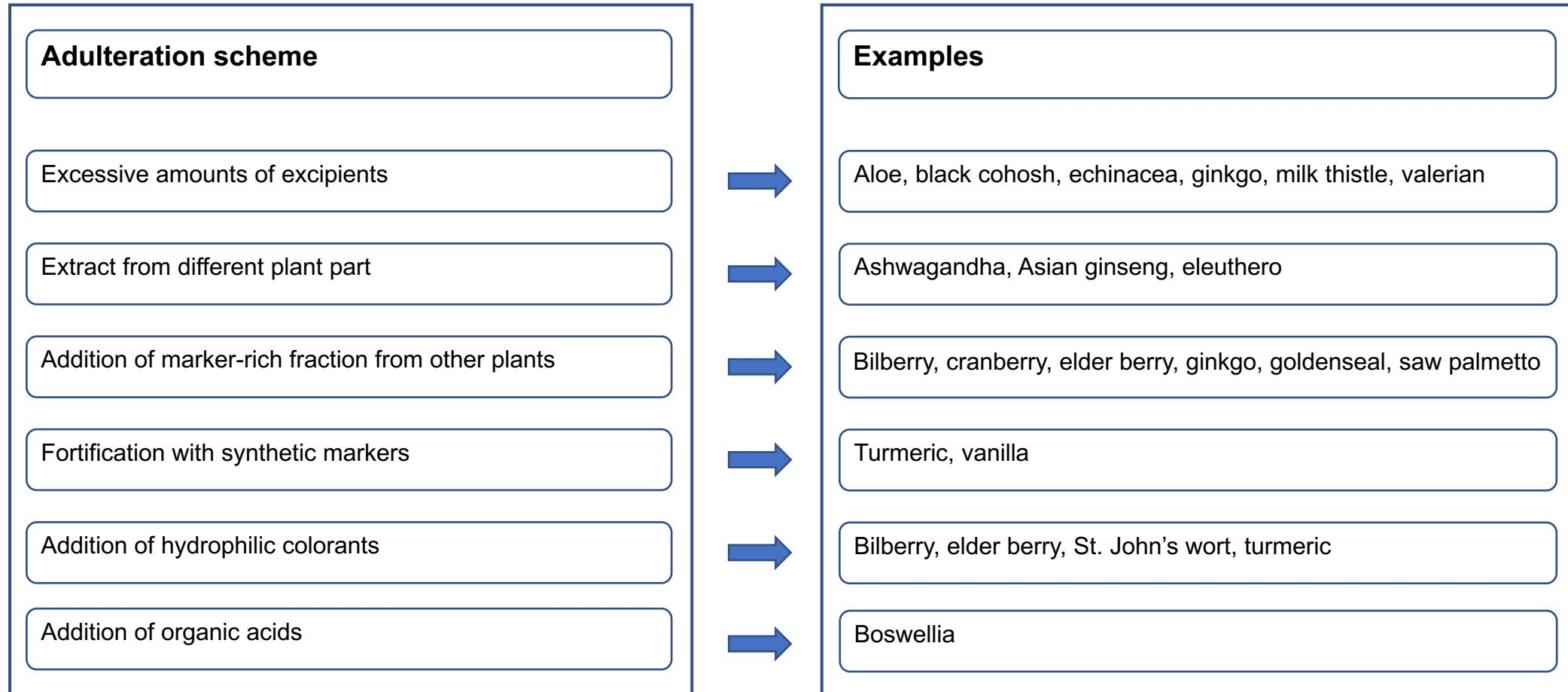
Total

83

ALL PUBLICATIONS ARE FREE ACCESS:

www.herbalgram.org/resources/botanical-adulterants-prevention-program/

Common Ways to Adulterate Botanical Ingredients



BAPP Review on Fooling Analytical Laboratory Methods Used to Authenticate Botanicals

Botanical Ingredient Forensics: Detection of Attempts to Deceive Commonly Used Analytical Methods for Authenticating Herbal Dietary and Food Ingredients and Supplements

Stefan Gafner,* Mark Blumenthal, Steven Foster, John H. Cardellina, II, Ikhlas A. Khan, and Roy Upton

Cite This: <https://doi.org/10.1021/acs.jnatprod.2c00929>

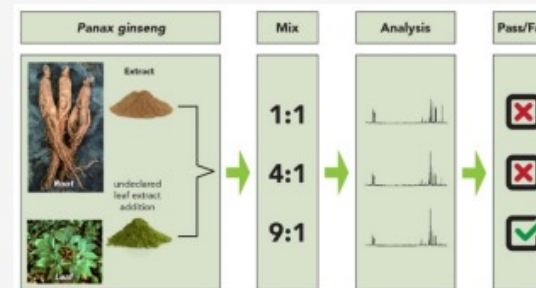
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ABSTRACT: Botanical ingredients are used widely in phytomedicines, dietary/food supplements, functional foods, and cosmetics. Products containing botanical ingredients are popular among many consumers and, in the case of herbal medicines, health professionals worldwide. Government regulatory agencies have set standards (collectively referred to as current Good Manufacturing Practices, cGMPs) with which suppliers and manufacturers must comply. One of the basic requirements is the need to establish the proper identity of crude botanicals in whole, cut, or powdered form, as well as botanical extracts and essential oils. Despite the legal obligation to ensure their authenticity, published reports show that a portion of these botanical ingredients and products are adulterated. Most often, such adulteration is carried



out for financial gain, where ingredients are intentionally substituted, diluted, or "fortified" with undisclosed lower-cost ingredients. While some of the adulteration is easily detected with simple laboratory assays, the adulterators frequently use sophisticated schemes to mimic the visual aspects and chemical composition of the labeled botanical ingredient in order to deceive the analytical methods that are used for authentication. This review surveys the commonly used approaches for botanical ingredient adulteration and discusses appropriate test methods for the detection of fraud based on publications by the ABC-AHP-NCNPR Botanical Adulterants Prevention Program, a large-scale international program to inform various stakeholders about ingredient and product adulteration. Botanical ingredients at risk of adulteration include, but are not limited to, the essential oils of lavender (*Lavandula angustifolia*,

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Summary of Elder Berry Product Investigations

Reference	Samples analyzed	Number of adulterated samples	Adulteration (%)
Galetti 2016	30	9	30
Gafner et al. 2021	532	58	11
Güzelmeriç et al. 2021	11	9	82
Hänni et al. 2021	73	18	25
Avula et al. 2022	31	21	68
Crawford et al. 2022	18	4	22
Total	695	110	17

Summary of Echinacea Product Investigations

Reference	Samples analyzed	Number of adulterated samples	Adulteration (%)*
Gilroy et al. 2003	55	24	44
Mudge et al. 2011	9	0	0
Agatonovic-Kustrin et al. 2013	3	2	67
Sandasi et al. 2014	20	6	30
Harnly et al. 2017	19	7	37
Raclariu et al. 2018	53	5	9
Waidyanatha et al. 2020	18	6	33
Frommenwiler et al. 2022**	23	3	13
Total	200	53	27

*Includes products with no or very low amounts of echinacea and mixtures of echinacea species

Estimated Extent of Adulteration of Ginkgo biloba Extracts

Summary of 28 investigations into the authenticity of commercial extracts from 2003-2023

	Sample number*	Adulterated samples**	Adulteration [%]
All samples***	533	304	57.0
Asia/Australia/New Zealand	49	15	30.6
Europe***	245	157	64.0
Europe (herbal medicine)	27	0	0
Europe (food supplement)	98	60	61.2
North America	137	85	62.0
South America	26	20	76.9
2003 - 2010	111	39	35.1
2011 - 2020	399	246	61.7
Post 2020	23	19	82.6

*Includes multiple analysis of products from same manufacturer

**Based on the assessment of the study authors

***Some authors did not detail the origin of the analyzed products, or distinguish among food supplements and herbal medicine

Challenges in Assessing Adulteration Extent

- No comprehensive studies published
- Published data lack information on brands tested, sales volume
- Analytical approaches and criteria for adulteration vary
- Adulteration schemes change over time
- Samples of the same brand subject to multiple analysis
- Author bias may impact results



Purchasing Drivers & Consumer Concerns

Adult consumers take supplements to address their health concerns, but ...

Consumers fear:

- False or misleading claims (~50%, a major concern in US)
- Undetected Contaminants (~50%, a major concern in US)
- Adulterated Products or substituted ingredients (~40%, a major concern in US)
- Lack of FDA enforcement (~40%, a major concern in US)

Results from an extensively detailed, recent study (N=3,500 consumers in 6 countries)

Source: Highlights from the 2023 ITC Consumer Insights, used with permission, courtesy of Len Monheit

Adulteration is Real AND Preventable

Fit for Purpose (FFP) Analytical Methods evolve over time. Specs are dynamic.

- Adulteration includes EMA on which BAPP has been focused; as a regulatory term of art, it also includes physical, chemical and biological contamination of ALL ARTICLES (not just botanicals). Hence, the BAPP SOP.
- Ingredients components and finished product specifications, created by each company, can detect and protect consumers from adulterated products

APPROPRIATE SPECIFICATIONS + FFP TESTING + cGMP COMPLIANCE = EVIDENCE-BASED QUALITY (EBQ)

Defective Articles

Suppliers and Buyers can detect and protect consumers from adulterated products

- **“Defective”** – Does not fully meet the Buyer’s currently approved specifications and/or does not comply with applicable laws
- **“Reparably Defective”** – May be possible for the Supplier to lawfully remediate or lawfully export it to a foreign country where the Article would fully comply with all locally governing regulations
- **Irreparably Defective”** – Cannot be lawfully remediated by Supplier or any third party for any use anywhere ... must be disposed of and/or destroyed to prevent its re-entry into commerce

BAPP Best Practices SOP

OBJECTIVE: to prevent the resale of IDAs into domestic and international commerce via the use of mutual supplier/buyer agreements that includes certified destruction of IDAs.

BAPP SOP 'Best Practices' Principles

1. Buyer specifies and Supplier warrants that every lot delivered will be lawful for intended use, meet buyer specifications, and not be adulterated or misbranded
2. Buyer must provide revision-controlled specifications (per cGMPs) to which Supplier must agree
3. In case of dispute, the parties agree to abide by the dispute resolution process as outlined in the SOP and three-party NDA (or as may be modified by the buyer, seller, and lab)
4. The parties agree to the auditable, reciprocal notification, recordkeeping, and certified destruction process defined in the contract and SOP templates

Examples of IDAs

EMA by reason of added dyes and/or additives to fool ID tests

Botanical: dyes in SJW, Bilberry, several others as reported by BAPP and others

Non-Botanical: Melamine in protein powder, DEG in glycerin, sodium hexametaphosphate in glucosamine

EMA by reason of undeclared pharmaceutical drugs to enhance the desired physiological effect (spiking)

Botanicals: Warfarin, DES, steroids, metformin, NSAIDs, PDE-5 inhibitors,

Non-Botanical: PDE-5 inhibitors (ED drugs), steroids

Adulterated by reason of chemical or biological contamination (all articles)

Chemical: Heavy metals, pesticides, fungicides

Micro: Aflatoxins, pathogenic mold, Cronobacter sakazakii, E. coli 0157, staph, others, many of which cannot be lawfully remediated (ref: “FDA Bad Bug Book”)

How You Can Implement the BAPP SOP

1. Assign product leader to draft implementation plan. Include Operations, Sourcing, Quality Unit, Marketing/Sales, and Legal
2. Plan must include communication, collaboration, and communication with suppliers
3. One new SOP will need to be created, others may require modification; (we've provided templates for your use and integration into your Quality Unit/SOP programs)
4. The four essential elements of the BAPP SOP can be implemented via:
 - ADDENDUM TO EXISTING SUPPLIER AND/OR QUALITY CONTRACTS
 - INTEGRATED INTO TERMS AND CONDITIONS ON PURCHASE ORDERS AND BUSINESS DOCUMENTS
 - DEFINE AS A REQUIREMENT IN YOUR VENDOR VERIFICATION SOPs, MAKING IT A CONDITION FOR DOING BUSINESS
 - OR ANY COMBINATION OF THE ABOVE
5. Your team, including legal advisors, should review the options to decide what is best for your organization

What this Best Practices SOP is NOT!!

These auditable controls protect both parties on many levels,
*including the introduction of adulterated products
into interstate commerce*

The BAPP SOP is not ...

- An excuse for a buyer to destroy any “out-of-spec” article
- An opportunity for a bad actor (supplier) to agree to destroy, receive a returned IDA, but simply resell

How you and your company /organization can support the BAPP SOP

- Read the Executive Overview and the SOP
- Become an Endorser of the BAPP SOP
- Adopt the SOP Principles in your purchasing agreements and contracts
- **Become a BAPP Underwriter through a financial contribution**

BAPP SOP Resources

To learn more, endorse and engage, please visit:

herbalgram.org/resources/botanical-adulterants-prevention-program/

Click on:

BAPP SOP for Irreparably Defective Articles

Fast, free registration required



ABC AHP NCNPR

Botanical Adulterants Prevention Program

Thank you!

Contact: BAPPSOP@Herbalgram.org; MLevin2016@icloud.com