# Executive Overview of the BAPP Best Practices SOP for the Disposal / Destruction of Irreparably Defective Articles

Thank you for agreeing to read the "BAPP SOP Best Practices Executive Overview" and possibly endorsing and/or underwriting this historic and voluntary Best Practices Standard.

History bears repeating: There are no regulations that instruct a company what to do with adulterated, contaminated, and potentially dangerous ingredients or products upon their receipt. The regulations in United States and elsewhere simply say: "You cannot use these ingredients in your products or sell adulterated products. If adulterated ingredients are used in a finished product, that product is, by definition, adulterated."

**Why does this matter?** Adulterated ingredients and/or products are sometimes returned to their supplier, who might resell those ingredients to another company. Defects (also known as "out of spec", or non-conforming "articles") could represent minor or trivial problems, and, therefore, would be "reparably defective," i.e., lawfully remediated, resold, or otherwise reconditioned.

Or, defects might be of such a degree that they can render ingredients and all products containing them to be deemed "irreparably defective articles" ("IDAs") and "adulterated" as defined by law[1], and unable to be lawfully consumed by humans or animals, anywhere. Examples may include certain biological contamination, chemical contamination, and economically motivated adulteration (EMA). (EMA could also include undisclosed spiking with pharmaceutical drugs).

**Our Objective**: To help stop the resale of irreparably defective articles as ingredients or components in dietary supplements, foods, finished products, OTC drugs, and cosmetics, into global commerce. This consumer protection initiative supports the promise and potential of safe, natural products intended to improve the public health.

**What Is an IDA?** In plain language, an "IDA" – a new term created in this SOP -- could be an ingredient that is fraudulent and/or adulterated and, in some cases, potentially dangerously contaminated beyond lawful repair for its intended use.

Examples include economically motivated adulteration (EMA) in which an undeclared, lower-cost ingredient "dilutes" a more expensive ingredient *and is fraudulent but not necessarily dangerous to health* (e.g., palm oil in saw palmetto oil or extract; lower-cost vegetable oil(s) in olive oil; vitamin B12 in CoEnzymeQ10; magnesium sulfate in MSM).

[1] https://www.law.cornell.edu/uscode/text/21/342

However, in what we believe to be comparatively rare cases, some adulterants are potentially or sometimes actually dangerous to human health and therefore must be certified to have been destroyed, instead of returned to the supplier for possible resale to another customer.[2]

A very lamentable, recent historical example is the concealed substitution of melamine in protein powder. DEG (di-ethylene glyco) is another classic example of a deadly economic adulterant in glycerin, which prompted the 1938 revision to the US Food, Drug, and Cosmetic Act of 1938, which required premarket approval for drugs based on safety and efficacy. DEG in sulfanilamide solution killed 105 people in the United States. Despite that fact, FDA never instructed industry to destroy DEG-contaminated glycerin. This same economic adulterant continues to harm or kill people around the world to this day.[3]

Another example is the adulteration of skullcap (*Scutellaria lateriflora, Lamiaceae)* with American germander: A persistent problem, ingestion of germander is potentially hepatotoxic and can be lethal. An extensive review of this problem, authored by Steven Foster, appeared in issue 93 of *HerbalGram*.( https://www.herbalgram.org/resources/herbalgram/issues/93/table-of-contents/feat_skullgerm/)

**Context: Guardians at the Gate**

Buyers are obligated under cGMPs to develop specifications. Each company develops its own ingredient specifications and defines the testing methods to assure those specifications are met. A company's Buyer's Quality Unit, therefore, is the "Guardian at the Gate." Specifications contractually define (and affirm) the buyer's quality requirements for each SKU. Specifications are foundational to quality.

This flexibility in specifications also explains why the quality of one brand may greatly differ from another in efficacy and price. The Quality Unit is the final barrier against fraud and has the responsibility to establish specifications and testing practices to protect consumers from adulterated and possibly hazardous ingredients. Some leading companies simply do a much better job than others at building specifications to verify and validate their ingredients. Quality begins with appropriately robust and routinely updated ingredient specifications.

[2] DEG in glycerin: DEG, a lethal solvent used to prepare a sulfanilamide elixir, killed 105 Americans and was the impetus for the 1938 Federal Food, Drug and Cosmetic Act. This economic adulterant used to dilute or replace glycerin remains a threat in personal care products; in 2020, 66 people died from a cough and cold syrup manufactured in India that contained this adulterant. https://en.wikipedia.org/wiki/Diethylene_glycol

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-glycerin-propylene-glycol-maltitol-solution-hydrogenated-starch-hydrolysate-sorbitol

When ingredients are received by a Buyer for manufacturing and do not meet specifications, they cannot be released into manufacturing without approval by the Quality Unit. These "non-conforming ingredients" (or "out-of-spec" ingredients) may be "irreparably defective." Some companies simply return these ingredients to their suppliers, who may resell them to another customer. At present, there is no regulation or guidance that mandates their destruction, hence, this BAPP Best Practices SOP.

**Four Essential Supply Contract Principles**

To solve this conundrum, these BAPP Best Practices rely upon expressly stated supply contract language containing these four essential principles:

1. Buyer specifies and Supplier warrants that every lot delivered will be lawful for intended use and not be adulterated or misbranded.

2. Buyer must provide Supplier with specifications as required under cGMPs.

3. If an article received is determined by Buyer and Supplier to be Irreparably Defective ("IDA" – ref: Definitions, below), the parties agree to lawfully destroy that article to prevent its resale into domestic or international commerce. In the case of dispute, the parties agree to abide by the Dispute Resolution Process outlined in the SOP (or as notification terms modified by the parties).

4. The parties agree to the reciprocal notification, recordkeeping, and certified destruction process described for irreparably defective articles.

**Selected Definitions from the BAPP Best Practices SOP Contract Language Template**

**"Adulterated."** Adulterated foods, dietary ingredients, and dietary supplements are defined in 21 US Code Subchapter 342. Adulterated cosmetics are defined in 21 US Code Subchapter 361**.**

**"Defective"** describes any Article that does not fully meet the Buyer's currently approved specifications and/or does not comply with applicable laws (e.g., adulterated and/or misbranded with an undeclared ingredient(s); the adulteration could be deliberate (e.g., economic adulteration of glycerin with DEG) or accidental (e.g., contamination with an unlawful pesticide). Whereas BAPP previously focused only on economically adulterated botanical products, this language is expanded in scope to now include all contaminated ingredients in foods, supplements, OTC drugs, and cosmetics; this deliberate expansion is an effort to contractually stop the resale of irreparably and potentially dangerous defective articles into the supply chain.

**"Disposal" and** "**Destruction."** Any Article that is not approved for use by the Buyer's Quality Unit must remain quarantined to prevent its release into manufacturing. Under cGMPs and in a manner fully compliant with the Company's SOPs, the disposition of the quarantined Article will be determined by the Quality Unit (for dietary supplements examples, see 21 CFR 111.87 and 111.90). After consultation and agreement is reached with the Supplier, when the material review determines that the final disposition does not include lawful reprocessing OR lawful return to Supplier, the quarantined article will be labeled for Disposal. Articles labeled for Disposal must be lawfully destroyed by Buyer, Supplier, or a licensed third party as approved by the parties hereto. The parties hereto agree that evidence of all instances of lawful remediation, lawful export, and lawful Destruction will be provided to and retained by both Buyer and Supplier and in compliance with the notification requirements in the SOP.

**"Reparably Defective"** describes any Article that is non-conforming with Buyer's complete set of specifications associated with the purchase order, shows evidence of improper storage or transportation conditions, has damage to the product or product containers, or is otherwise "adulterated" or "misbranded" as defined [FD&C Act, sec. 301(a) and (d); 21 U.S.C. 331(a) and (d)]. It may be possible for the Supplier to lawfully remediate a Reparably Defective Article or lawfully export it to a foreign country where the Article would fully comply with all locally governing regulations.

**"Irreparably Defective"** describes an Article that is Defective and cannot be lawfully remediated by Supplier or any third party for any use, anywhere. For avoidance of doubt, this description can apply to "components" (used in dietary supplements [DS]), "ingredients" (used in cosmetics), and/or "food" (used in foods). An Irreparably Defective Article that cannot be lawfully remediated for any use (example: used as a cosmetic ingredient instead of a DS component) must be disposed of and/or destroyed to prevent its re-entry into commerce.

Examples of Irreparably Defective Articles include, but are not limited to, the following:

a. Articles containing illegal, undeclared drugs, unlawful levels of biological or chemical contaminants
b. Articles containing botanical ingredients adulterated with one or more undeclared species, undeclared dyes, and other economically motivated adulterants that cannot be removed and lawfully remediated
c. Irreparable failure to meet all Buyer specifications for identity, purity, strength, composition, and limits on contaminants for specific ingredients: e.g., melamine in protein powder, DEG in glycerin, palm oil and/or animal fats in saw palmetto, sodium alginate and alginate sulfate di-ester in chondroitin, etc. Reference 21 CFR 111.70(b)

**"Misbranded."** A food shall be deemed to be misbranded in accordance with the definitions provided in 21 USC Subsection 343. A cosmetic shall be deemed to be misbranded if it meets the standards defined in 21 USC Subchapter 362.

**"Non-Conforming Article"** is any Article that does not fully meet the Buyer's specifications. A non-conforming Article may be determined after inspection by the parties to be either Reparably Defective or Irreparably Defective; if the latter, the Article will be scheduled for Disposal or lawful Destruction.

**"Qualified Laboratory"** means a laboratory used for analytical and/or microbiological testing that, at minimum, satisfies FDA and all other applicable regulations, is compliant with Buyer's supplier qualification SOPs, and is compliant with 21 CFR Part 111.

Additionally, a Qualified Laboratory uses testing methods that are appropriate and fit for purpose or published compendial methods that have been verified as such within the laboratory; all methods used are scientifically valid, statistically sound, and fit for purpose in the matrix. Unless otherwise prescribed by local regulation, a Qualified Laboratory's compliance with ISO/IEC 17025:2005 or equivalent is recommended but not mandatory.

**Selected Excerpt from Section 4.D: General Representations, Warranties, and Covenants**

> "Supplier represents that every lot of Component, Food, or Ingredient delivered to Buyer will (a) meet Buyer's then current specification (on record) for such Article, (b) meet signed certificate of analysis (COA) that accompanies shipment of such Article, and (c) be lawful for its intended use and not be adulterated or misbranded."

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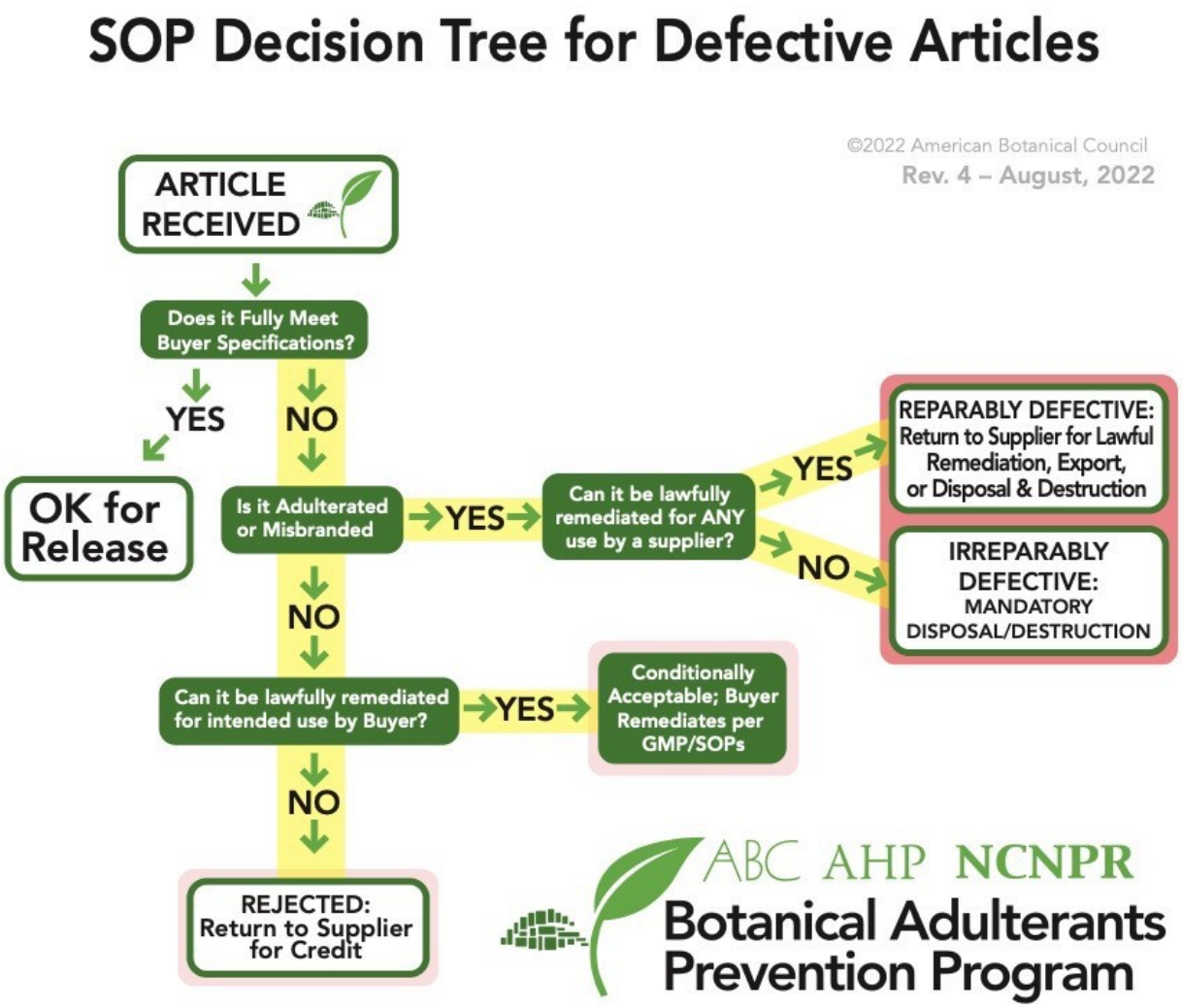
**The BAPP Best Practices Table of Contents includes the following:**

The **SOP Decision Tree**: This flowchart graphically depicts decisions related to quality control of all material receipts.




**Contract Language** that industry members can customize and deploy t fit their specific needs. Modular in design, it can be appended to existing supply contracts or referenced via a standalone memorandum of understanding. To achieve the goal of mandatory Destruction of "irreparably defective articles," we anticipate the definitions, dispute resolution process, and notification and recordkeeping process to be widely adopted by companies committed to defect-free, quality ingredients in their finished products.

**A draft SOP template**, with two supporting document templates, for recordkeeping and to explain the process by which Buyer and Seller agree to document to each other the certified Destruction of irreparably defective articles.

**A three-party Nondisclosure Agreement (NDA)** among Buyer, Seller, and analytical laboratory to protect the confidentiality of data and define the specific process by which dispute resolution might occur. This fairly protects the economic interests of all parties, including the labs. (When asked in an interview, "Who pays for the testing in the event the supplier disagrees with the buyer? Who rejects an ingredient—based on the assessment of irreparably defective?" Michael D. Levin, primary BAPP SOP author, answered, "The loser." Buyer and Seller agree upfront which lab to use and how to test, and the lab has financial guarantees contractually obligated while confidentiality is appropriately preserved.

The **Frequently Asked Questions (FAQs)** section addresses numerous comments received during two rounds of public comment and team review. The FAQs are in very plain language and provide the reasoning behind the choices for specific language and the final recommendations taken.

**Will you help us stop adulteration?**

To read the BAPP Best Practices SOP for the Disposal/Destruction of Irreparably Defective Articles, please visit: https://abc-media.mcnines.net/media/0pucgdy4/bapp_sop_final_10112022.pdf

To endorse the BAPP SOP and grant the American Botanical Council (who manages BAPP) permission to disclose your company name as Endorsers of the BAPP SOP in all communications, please visit: https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/laboratory-guidance-documents/bapp-sop/

Thanks in advance for your vigorous support of this important consumer protection effort!