

# Removing Irreparably Adulterated Products from the Global Supply Chain

An Update on the BAPP Best Practices SOP for the Disposal / Destruction  
of Irreparably Defective Articles (“IDAs”)

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# BAPP Best Practices SOP Solution Fixes a Universal Regulatory Gap

- ▶ International Regs ignore what to do when a dangerously adulterated product is received by a buyer. Some simply return to supplier, who resells it.

**Our Solution Combines regulatory law with contract law**

- ▶ When buyer and supplier agree that a receipt is irreparably defective for its intended use and cannot be lawfully remediated for that intended use (an “IDA”), *they contractually agree it must be removed from commerce and certified to be destroyed.*
- ▶ Why?: Burn it, Don't Return It! Returned defective, and possibly dangerous products are being resold into the global marketplace. This must stop.
- ▶ Examples of IDAs:
  - ▶ Spiked with undeclared drugs (PD5 inhibitors, antihistamines, NSAIDs, etc)
  - ▶ Food Fraud (misbranded with intent to deceive the buyer, e.g. melamine in protein)
  - ▶ Is economically adulterated (e.g., colors, botanical dilution, mixed species)
  - ▶ Has biological pathogens above acceptable levels.



# Four BAPP Best Practices SOP Supply Contract Principles

- 1) **Purchase Order:** Buyer specifies and Supplier warrants that every lot delivered will be lawful for intended use in intended markets and not be adulterated or misbranded.
- 2) **Specifications:** Buyer must provide supplier with approved specifications as required under cGMPs.
- 3) **Dispute Resolution:** In the case of dispute, the parties agree to abide by the dispute resolution process outlined in the SOP (or as modified by the parties).
- 4) **Audit Trail.** The parties agree to the reciprocal notification, recordkeeping, and certified destruction process described for irreparably defective articles.

# “Implementation of BAPP SOP Can Reduce Costs of GMPs”\* ANS Case Study



Dubinski noted that ANS and the supplier modified existing purchase agreements to include the SOP language. Now, that supplier is one of ANS’ “more reputable” and “more trustworthy” suppliers, he said.



For ANS, Dubinski added, “hundreds of thousands of dollars” are being saved in “lab testing, the amount of time to test, getting new samples in, purchasing teams, having to source new materials, whatever it may be. [The BAPP SOP] made a huge impact.”

\* HerbalGram Issue 142-2025

# “Implementation of BAPP SOP Can Reduce Costs of GMPs”<sup>\*</sup> Xymogen Case Study



The SOP has certainly saved us a lot of time and helped us financially because it provides a clear roadmap for what to do and when,” Routier-Rogers said. “



While on the front end you have to do a bit of work so that you can make sure that you and your suppliers align and understand that you’re on the same page, **in in the end, it saves so much time and so much effort.**”



Levin, who also discussed SOP implementation details, noted that purchase order specifications are the heart and soul of the program.

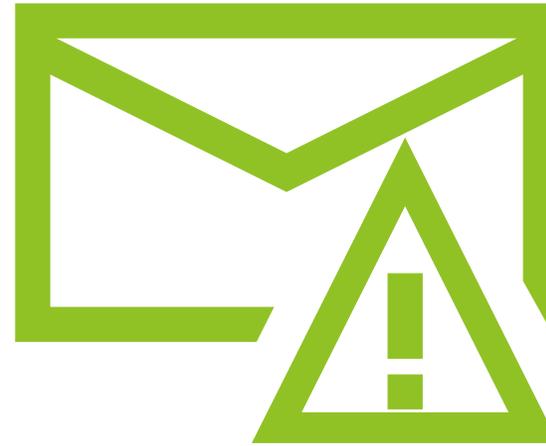
<sup>\*</sup> HerbalGram Issue 142-2025

# Informa Markets & BAPP SOP

- ▶ In summer 2024, Informa Markets, the producer of the two annual SupplySide conferences and tradeshow in the United States, **suggested that “every company buying or selling ingredients should endorse and implement” the BAPP SOP as a voluntary standard.**
- ▶ **Informa also added BAPP to its SupplySide Compliance Program**, which “provides tools to gain a greater understanding of some of the most common compliance issues within the industry and help support self-regulatory efforts.”
- ▶ See handouts for reports from endorsers and Industry Leaders

# Next Steps

- ▶ Third party qualified auditing program for BAPP SOP compliance has been requested by BAPP supporters. Under active consideration.
- ▶ Pros: this independent certification would separate those who walk the talk from those who don't.
- ▶ Your thoughts?



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<https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/>

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