

Technical Alert

Adulteration risk & TGA Testing of Listed Medicines

Launch of International Atlas of HPTLC Methods for Identification of Herbal Drugs

The following listed medicine ingredients are at risk of adulteration or contamination issues:

- Turmeric (AHN: *Curcuma longa*)
- Black Cohosh (AHN: *Actaea racemosa*)
- Green lipped mussel (ABN) – also known as *Perna canaliculus*

The TGA may request samples of listed medicines with the above ingredients for testing as part of the laboratories testing program. Turmeric testing is in progress.

Outcomes of laboratory testing are published biannually in the TGA Database of Laboratory Testing Results:

<https://www.tga.gov.au/ws-labs-index>

Turmeric (*Curcuma longa*) – Adulteration with other substances and heavy metals

Turmeric is likely one of the spices most frequently adulterated because of its widespread use and high cost. The American Botanical Council (ABC) released a [bulletin](#) in May 2018 which reports that *Curcuma longa* may be adulterated with:

- Synthetic curcumin
- Other *Curcuma* species including *Curcuma zedoaria*
- Starches
- Chalk powder
- Cassava
- Yellow soapstone powder
- Synthetic dyes including Metanil yellow, **lead chromate**, acid orange 7, & Sudan Red G.
- Heavy metals, especially lead.

The ABC bulletin reports a 2016 food recall of 172,000kg of Curcumin due to elevated lead levels.

TGA Testing

Items that may be the focus of TGA testing:

- Chromatographic profiling to confirm the presence of *Curcuma longa*;
- Synthetic dyes as listed above;
- Heavy metals, particularly lead.

Lead & other heavy metals

Please be aware that the TGA are using the [ICH-Q3D](#)¹ as a reference standard for heavy metals limits. The Q3D provides for the following “Permitted Daily Exposures” or PDEs, which is the maximum amount of heavy metals that a medicine can deliver per maximum daily recommended dose for oral medicines:

Lead:	5ug per day
Cadmium:	5ug per day
Arsenic:	15ug per day
Mercury:	30ug per day

Black Cohosh (*Actaea racemosa*) – adulteration with other species

Adulteration of *Actea racemosa* (Black Cohosh) has been the subject of investigation and research since it became a popular herbal medicine. An ABC [bulletin](#) suggests that the concern is ongoing. Common adulterants (both deliberate and accidental) include different plants from the same genus:

- *Actaea cimicifuga* (syn: Cimicifuga foetida)
- *A. dahurica* (syn: C. dahurica)
- *A. heracleifolia* (syn: C. heracleifolia)
- *A. simplex* (syn: C. simplex)
- *A. brachycarpa* (syn: C. brachycarpa)

TGA Testing

Herbal adulteration could be targeted through chromatographic profiling, combined with the presence/absence of specific herbal marker compounds.

Note that in 2015 the [Botanical Adulterants Program](#) published a laboratory guidance document that provides a review of the various analytical technologies used to differentiate between authentic *A. racemosa* and its potentially adulterating species.

Green lipped mussel – heavy metal, bacteria, and shellfish toxins

There is potential for heavy metal contamination and bacterial contamination in Green lipped mussel products, which have undergone testing.

The TGA may conduct a testing program to establish safe limits for shellfish toxins in Green lipped mussel products. Currently, Schedule 19 of the Australian New Zealand Food Standards Code applies limits for maximum levels of Amnesic shellfish poisons (20mg/kg), Diarrhetic shellfish poisons (0.2mg/kg), Neurotoxic shellfish poisons (200MU /kg and Paralytic shellfish poisons (0.8mg/kg) in bivalve molluscs.

Please forward identified issues to Lucy.Lang@cmaustralia.org.au for attention by CMA Secretariat.

¹ INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE; ICH HARMONISED GUIDELINE GUIDELINE FOR ELEMENTAL IMPURITIES - Q3D

Launch of free HPTLC Atlas (International Atlas of HPTLC Methods for Identification of Herbal Drugs)

As foreshadowed at CMA Innovation day, the HPTLC Association has launched the pilot phase of the “International Atlas of HPTLC Methods for Identification of Herbal Drugs” ([HPTLC Atlas](#)), an on-line collection of HPTLC reference standards (fingerprints) intended to assist in the quality control of herbal medicines. Information is free to download.

The International Association for the Advancement of High Performance Thin Layer Chromatography ([HPTLC Association](#)) promotes the use of the HPTLC method in plant analysis. The association comprises of representatives from academia, industry, research, regulatory and standard setting bodies.

The HPTLC Atlas is a free searchable resource which clearly shows which entries are complete and which are under development. Each monograph contains the botanical name, synonyms, related species, the HPTLC method used, images of the chromatographs and links to related national formularies and pharmacopeial monographs. It is a dynamic database that is supplemented weekly.

Honey fingerprinting project

As an example of the work utilised, and for those that had questions in relation to the presentation at the CMA Innovation day, the below link is a podcast with the research head Dr Connie Locher from UWA School of Pharmacy, which explains the Honey project and the fingerprinting of the botanical sources using the raw material/end Honey product and possible investigation into medicinal properties.

<http://www.crchoneybeeproducts.com/sticky-science-episode-4/>

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