



Code of Practice to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Raw Materials for Tea and Herbal Infusions

The European Tea and Herbal Infusions Industry acknowledge its responsibility to ensure that products sold in the market are safe. In recognition of these obligations, THIE developed this Code of Practice (CoP) to prevent and reduce pyrrolizidine alkaloid contamination in agricultural commodities used in the manufacture of tea and herbal infusions to As Low As Reasonably Achievable (ALARA) levels.

This CoP is an addendum to the Codex Alimentarius CoP regarding the prevention and reduction of PA contamination [1] and to general THIE guidelines and guidance notes [2, 3].

Raw Materials for tea and herbal infusions are products that grow widely throughout the world in both developed and developing countries either as cultivated crops or in the wild. The CoP applies in full to cultivated crops. In the case of uncultivated and 'wild collected' crops, the CoP only applies to a limited extent. 'Wild collected' raw materials grow in the wild rather than being cultivated and are harvested in a classical cottage-garden industry format by local smallholders. Such producers tend to sell raw materials daily to local collector, who gathers truckload that is then sold in bulk to buyers representing the processors.

This document provides guidance which is designed to minimize contamination of materials at the primary producer level. It is intended that companies circulate this CoP to producers and distributors of raw materials with a strong recommendation to comply with them. This CoP provides a framework for individual management approaches in companies.

1. BACKGROUND

Pyrrolizidine alkaloids (PAs) are natural toxins occurring in a wide variety of plants, angiosperm families of the *Boraginaceae* (all genera), *Asteraceae* (tribes *Senecioneae* and *Eupatorieae*) and *Fabaceae* (genus *Crotalaria*). Over 6,000 plant species throughout the world are expected to contain PAs. PAs are probably the most widely distributed natural toxins that can affect wildlife, livestock and humans [1].

PAs have a common toxicity profile with the liver being the main target organ of toxicity. Major signs of toxicity in all animal species include various degrees of progressive liver damage (centrilobular hepatocellular necrosis), and veno-occlusive disease. Furthermore, the International Agency for Research on Cancer (IARC) has classified three PAs, lasiocarpine, monocrotaline and riddelliine, as 'possibly carcinogenic to humans' (Group 2B). PAs may differ



in potency, the relative potencies are currently not known due to lack of oral toxicity data on individual PAs, which hampers risk assessment for PAs [1].

PA containing weeds contamination of raw materials for tea and herbal infusions may occur through e.g. spot contamination of fields and unintended harvesting of weeds together with the plants, and are considered as the reason for the findings in tea and herbal infusions.

Dietary exposure to PAs should be as low as possible due to the potential health-threatening effects. To achieve this, management practices aimed at the prevention and reduction of contamination of food and feed with PAs must be undertaken.

Management practices to prevent or reduce PA contamination should comprise weed management (removal/reduction) practices to reduce presence of PAs.

Auditing of growers on site and inspection of the fields showed that PA-containing field weeds are not distributed evenly over the growing areas, but instead they occur in individual “spots”. These may be either in the crop itself, or in the adjacent field borders and non-cultivated areas. Special meadows, left in their natural state by growers and designed to attract bees, evidently also play a part in further dissemination of PA-containing plants such as *Senecio* and *Heliotropium*. That is basically comparable with the occurrence of cornflowers and poppies in cereal fields.

It has to be stressed that the whole issue of PAs has turned out to show a dimension which by far surpasses all previous standards of a good agricultural practice. The amount of PAs in a PA-containing plant itself is very high, tests of *Senecio* and *Heliotropium* plants show result between 1,000 and 13,000 ppm (mg/kg). A small number of plants is sufficient to generate detectable contents of PAs in the harvest, e.g. 6 PA plants with a PA load of 1,310 ppm on an area of one hectare that holds 60,000 peppermint plants results in an amount of 0.1310 ppm of the dried crop.

This CoP focuses on weed management. Deliberate use of naturally PA-containing plants for foods cannot be justified for any reason without appropriate assessment.

It should be emphasized that total eradication of PA-containing plants is not technically possible, not feasible or ecologically desirable as they may be important for the insect population in the area.

This CoP will cover control measures for the management of the PA-containing plants as well as measures for control of plant release and spread to prevent contamination of food with PAs on the one hand and, where contamination cannot be completely avoided, to reduce the PA contamination by weed management.

The most effective way to control PA-containing plants is to follow a combination of agricultural, mechanical and chemical methods (integrated weed management).



It must be emphasized that the requirements of good agricultural and collection practices are significantly higher with regard to PA than for any other issue relating to tea and herbal infusions.

The scope of implementation of the CoP may vary and depends on the raw material and country of origin. This will mean continued efforts to reduce contamination, adjust measures and develop this CoP according to improvements.

In addition to the measures at agricultural level as described in this CoP, every producer has to assess raw material and supplier specific risks and act accordingly within its food safety management system.

PAs in food are a spot contamination roughly comparable to mycotoxins. Therefore, appropriate sampling is of major importance to obtain representative results.

Tests should be performed on 28 PAs, based on the method published by the Federal Institute for Risk Assessment (BfR) [4]. The limit of quantification (LOQ) for each substance is at least 10 ppb ($\mu\text{g}/\text{kg}$).

2. SCOPE

To ensure adequate prevention of the spread of PA-containing plants, and to lower the costs of control measures, early detection and identification of these plants is essential followed by action to prevent contamination of food.

To achieve early detection, raising awareness by providing good information is critical, e.g. information with an overview and description of the most important PA-containing plants and their ecology. Once PA-containing plants are detected, an integrated weed management plan should be implemented. In this respect, it must be recognized that the different PA-containing plants may react in a different way to a particular management measure. Therefore, it is important to keep the ecology of the specific plant in mind. Additionally, influences of weather or climate must be taken into account.



3. EVALUATION OF THE NEED TO PROCEED TO ACTION

Before considering any action, the need to proceed to action should be established by identifying the risks posed by the presence of PA-containing plants. This could be done by setting up a tiered risk characterization approach based on:

- proximity of the PA-containing plants to arable fields and meadows/pastures/grasslands;
- botanical identification;
- level of infestation;
- local circumstances;
- climate;
- soil type;
- vegetation cover;
- harvesting technology and post-harvest technology.

The likelihood of PA-containing plants spreading to land used for agricultural purposes should be the determining factor for assessment of the risk, e.g.

- high risk: PA-plant is present and flowering/seeding within 50 m
- medium risk: PA-plant is present within 50 m to 100 m
- low risk: the land on which PA-plant is present is more than 100 m away

In a “high risk” situation immediate action should be taken to control the spread of PA-containing plants using appropriate control techniques. In case of a medium risk, a control policy has to be established to ensure that when the situation changes from a medium to a high risk of spread, it is identified and dealt with in a timely manner using appropriate control techniques. In case of a low risk, no immediate action is required.

4. RECOMMENDED PRACTICES

For managing the reduction of PA-containing plants, preferably a toolbox with non-chemical and chemical methods, *i.e.* integrated weed management, should be applied to obtain the most effective results.

The use of an integrated weed management plan could reduce the use of and reliance on herbicides, thereby lowering the chance of herbicide resistance, and allows weed management in most environments. An integrated weed management plan should be accompanied with practices to reduce the spread of PA-containing plants thereby preventing infestations to spread.



5. PERSPECTIVES

This CoP focuses on weed control with the aim to reduce the PA contamination in tea and herbal infusion finished products. The tea and HI industry needs to implement measures "from field to cup" to reduce the PA content in the finished products and to ensure safe products for consumers.

In order to achieve this, goal measures have been implemented to gather and improve information about PA weeds, their occurrence and typical PA pattern.

The European Tea and Herbal Infusions Industry is collecting PA data, under the roof of THIE, to have a sound database on PAs in tea and herbal infusion products. This informs the industry about the current PA situation in raw materials and tea and herbal infusion products and allows the industry to review the effectiveness of their weed management plans.

To be more effective on the weed management, a database of PA plants with their typical PA pattern related to the origin or region and photos of all growth stages, including the seeds should be established.

The industry supports different research projects in the field of PA, e.g. on the development of a faster PA detection method based on ELISA (Enzyme-linked Immunosorbent Assay). This will allow the industry to get a quick qualitative result about the presence of PA in the sample, but provides only a semi-quantitative information.

At the moment, there are no legal maximum limits for PA in the EU. Currently, so-called action levels for PAs in teas and herbal infusions ready for consumers have been set up in Germany to ensure a consistent approach by enforcement authorities. In the meantime, the Austrian authorities have also joined in this approach.

As PAs occur as spot contaminations, the incoming batches are probably inhomogeneous. So far, several different methods have already been tested for their suitability. It turned out that there is no optimal sampling method, but that depending on the situation certain procedures are more suitable than others. Defining a sampling procedure that is representative of all possible eventualities remains a major challenge.

This CoP is meant to be a support for all stakeholders to take appropriate measures for the prevention and reduction of PA in finished tea and herbal infusion products.

Processors are recommended to provide this CoP to their suppliers to enable improvement in all steps of the process resulting in an elimination of PA contamination peaks and a gradually lowering of PA levels to a best possible extent following the ALARA-principle.



REFERENCES

- [1] Codex Alimentarius, *Code of Practice for Weed Control to prevent and reduce Pyrrolizidine Alkaloid Contamination in Food and Feed*, CAC/RCP 74-2014 (online available: http://www.fao.org/fao-who-codexalimentarius/download/standards/13794/CXP_074e_2014.pdf).
- [2] Tea & Herbal Infusions Europe (THIE), *Guidelines for Good Agricultural and Hygiene Practices for Raw Materials used for Herbal Infusions* (online available: http://www.thie-online.eu/fileadmin/inhalte/Publications/HFI/2_2014-06_PU_GAHP_Version_6.pdf).
- [3] Tea & Herbal Infusions Europe (THIE), *HACCP Guidance Notes for European Tea Packers and Processors in the Country of Origin* (online available: http://www.thie-online.eu/fileadmin/inhalte/Publications/Tea/2_2012-09_HACCP_Guidance_Notes_Website_.pdf).
- [4] Federal Institute for Risk Assessment (BfR), *Determination of pyrrolizidine alkaloids (PA) in plant material by SPE-LC-MS/MS – Method Protocol – BfR-PA-Tea-2.0/2014* (online available: <http://www.bfr.bund.de/cm/349/determination-of-pyrrolizidine-alkaloids-pa-in-plant-material.pdf>).

TEA & HERBAL INFUSIONS EUROPE

Formerly: European Tea Committee (ETC) and European Herbal Infusions Association (EHIA)



Annex

Procedures and precautionary measures to reduce the risk of PA contamination of tea and HFI raw materials intended for human consumption



Compilation of procedures and precautionary measures to reduce the risk of PA contamination of tea and HFI raw materials intended for human consumption. Depending on the type of botanical and process step the appropriate actions have to be applied.					
Process step	Hazard	Probability	What to do?	Comments	Who is responsible?
Prior to cultivation	PA weeds on field and areas bordering the field. PA weeds in various phases of growth	high	<ul style="list-style-type: none"> Identify PA weeds in various phases of growth Determine the best time to remove PA weeds and way of removing/pulling Check for improvement by agricultural practices like crop rotation Train staff Pull and destroy weeds, avoid contamination, e.g. burn the weeds If necessary use herbicides registered for this application 	<p>Create a Database with description and pictures of PA weed in various phases of growth and how to handle the weed</p> <p>Destroy weeds immediately. Some plants are able to form viable seeds within a very short period of time, so-called "premature ripening"</p>	Farmer Support by research departments and institutes
	Contamination of crop seeds with weed seeds	Depending on the kind of crop	<ul style="list-style-type: none"> Check the crop seeds on foreign seeds Clean the seeds if necessary Train staff 		Farmer Support by research departments and institutes
During cultivation	PA weeds on field and areas bordering the field. PA weeds in various phases of growth	high	<ul style="list-style-type: none"> Identify PA weeds in various phases of growth Determine the best time to remove PA weeds and way of removing/pulling Train staff Pull and destroy weeds, avoid contamination, e.g. burn the weeds If necessary use herbicides registered for this application 	<p>Create a Database with description and pictures of PA weed in various phases of growth and how to handle the weed</p> <p>Destroy weeds immediately. Some plants are able to form viable seeds within a very short period of time, so-called "premature ripening"</p>	Farmer Research departments and institutes



Process step	Hazard	Probability	What to do?	Comments	Who is responsible?
Prior to harvesting	PA weeds on field and areas bordering the field. PA weeds in various phases of growth	high	<ul style="list-style-type: none"> Identify PA weeds in various phases of growth Determine the best time to remove PA weeds and way of removing/pulling Train staff Pull and destroy weeds, avoid contamination, e.g. burn the weeds If necessary use herbicides registered for this application 	<p>Create a Database with description and pictures of PA weed in various phases of growth and how to handle the weed</p> <p>Destroy weeds immediately. Some plants are able to form viable seeds within a very short period of time, so-called "premature ripening"</p>	Farmers Collectors
Prior to wild collection	PA weeds on field and areas bordering the field. PA weeds in various phases of growth	high	<ul style="list-style-type: none"> Identify PA weeds in various phases of growth Train staff 	Create a Database with description and pictures of PA weed in various phases of growth and how to handle the weed	Farmers Collectors
Prior to / during cultivation Prior to harvesting Prior to wild collection	Contamination of tools and machinery Contamination of shoes, clothing, transport vehicles esp. tires	Depending on process	<ul style="list-style-type: none"> Clean tools and machinery Clean shoes, clothing, vehicles Train staff 	Avoid contamination of PA-free areas	Farmers
	Contamination by dead weed		<ul style="list-style-type: none"> Remove the dead weed Avoid contamination of PA-free areas on transport Destroy weeds, avoid contamination, e.g. burn the weeds Train staff 	Destroy weeds immediately. Some plants are able to form viable seeds within a very short period of time, so-called "premature ripening"	Farmers



Process step	Hazard	Probability	What to do?	Comments	Who is responsible?
Harvesting	Harvest accidentally includes PA weeds	high	<ul style="list-style-type: none"> Determine best time to harvest to exclude PA weeds. Determine best way to harvest to exclude PA weeds. Review cutting position Train staff 	Clean the area of PA weeds prior to harvesting.	Farmers
Wild collection	Gathering accidentally includes PA weeds	high	<ul style="list-style-type: none"> Determine best time for gathering to exclude PA weeds Determine best way for gathering to exclude PA weeds Review cutting position Train staff 		Farmers
Harvesting / Wild collection	Contamination of tools and machinery Contamination of shoes, clothing, transport vehicles esp. tires	Depending on process	<ul style="list-style-type: none"> Clean tools, collecting equipment and machinery Clean shoes, clothing, vehicles Train staff 	Avoid contamination of PA-free areas	Farmers
	Contamination by dead weed		<ul style="list-style-type: none"> Remove the dead weed Avoid contamination of PA-free areas on transport Destroy weeds, avoid contamination, e.g. burn the weeds Train staff 		
Collecting point	Parts of PA weeds in crop	Depending on the botanical and previous measures – low to high	<ul style="list-style-type: none"> Check for PA weeds Remove the dead weed Avoid contamination of PA-free areas Destroy weeds, avoid contamination, e.g. burn the weeds Clean tools and machinery Clean shoes, clothing, vehicles Train staff 		Processor



Process step	Hazard	Probability	What to do?	Comments	Who is responsible?
Post-harvest Processing – e.g. drying, cutting, cleaning, screening, packing	Parts of PA weeds in crop	Depending on the botanical and previous measures – low to high.	<ul style="list-style-type: none"> • Check for PA weeds • Remove the dead weed • Avoid contamination of PA-free areas • Destroy weeds, avoid contamination, e.g. burn the weeds • Clean tools and machinery • Clean shoes, clothing • Train staff 		Processor
Transport	Parts of PA weeds in the means of transport	Depending on the botanical and previous measures - low to high	<ul style="list-style-type: none"> • Clean means of transport • Train staff 		



Process step	Hazard	Probability	What to do?	Comments	Who is responsible?
Incoming goods inspection	Parts of PA weeds in raw material	Depending on the botanical and previous measures – low to high	<ul style="list-style-type: none"> Risk assessment for occurrence of PAs in botanicals with regard to prior results, country of origin, supplier, climate etc Test on 28 pyrrolizidine alkaloids, as published in BfR “Determination of pyrrolizidine alkaloids (PA) in plant material by SPE-LC-MS/MS – Method Protocol BfR-PA-Tea-2.0/2014” according to risk assessment. LOQ is 10 ppb Identify PA-profiles occurring in botanicals Train staff Train suppliers and inform about results 	If PA profiles can be identified in particular botanicals, due to e.g. occurrence of specific PA weeds in the country of origin, the number and type of analytes can be adjusted with regard to the PA profile.	Processor - QA
Processing / blending / packing	Parts of PA weeds in raw material	Very low	<ul style="list-style-type: none"> Technical measures for removing parts of PA weeds 		Processor
Finished goods	Parts of PA weeds in finished goods	Very low	<ul style="list-style-type: none"> Check on finished goods to make sure risk assessment and PA test are appropriate. 		Processor - QA