

TEA & HERBAL INFUSIONS EUROPE

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



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Interpretation of the EU Contaminants Regulation (EU) 2023/915 with regard to herbal infusions (raw materials) and tea (*Camellia sinensis*): an approach to open questions

In Regulation (EU) 2023/915 “herbal infusions“ are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.

The definition of the term “herbal infusions” in Reg. (EU) 2023/915 is different from Reg. (EC) 396/2005: In Reg. (EC) 396/2005 the term “herbal infusions” only covers certain raw materials commonly used as ingredient of herbal infusions; in Reg. (EU) 2023/915 the term „herbal infusions” refers to the category and the final product.

“Herbal infusions” as such are a food listed in Annex I to Reg. (EU) 2023/915.

MLs for spices, herbs and vegetables do not cover spices, herbs and vegetables for use in herbal infusions if not explicitly mentioned in the according entry.

The same applies to “fruit infusions” which are also regarded as a separate category in Annex I to Reg. (EU) 2023/915 and thus this category forms its own independent basis for evaluation.

1. Introduction

The EU Contaminants Regulation (EC) 1881/2006 was replaced by Regulation (EU) 2023/915

- to improve readability and

- to **increase** the references to Annex I to Regulation (EC) 396/2005 for the definitions of the categories (Reason 12).

MLs currently set out by Regulation (EC) 1881/2006 should be **maintained** by the new Regulation (Reason 12).

For **new MLs transitional measures** are foreseen where appropriate (Reason 18).

In addition, the Commission clarified that the replacing Regulation (EC) 1881/2006 by Regulation (EU) 2023/915 is not formally a recast, even though it has always been referred to as a recast throughout the process. If reference is made to Regulation (EC) No 1881/2006, then Regulation (EU) 2023/915 applies today. (see: <https://www.row-minvws.nl/documenten/verslag/2023/06/29/verslag-cwg-milieucontaminanten-29-juni-2023>)

2. Impact for tea and herbal infusions

Under Regulation (EC) 1881/2006 as amended only very few MLs had been set for herbal and fruit infusions raw materials, herbal and fruit infusions (dried) and tea (*Camellia sinensis*). Although the new Contaminants Regulation (EU) 2023/915 in general builds on the former Regulation (EC) 1881/2006 and the ALARA principle and claims to improve readability it highlights **two principles which challenge the interpretation of this Regulation, in**



particular regarding herbal infusions (raw materials) (HFI) and tea (*Camellia sinensis*); these are:

- the **increased** reference to Annex I to Regulation (EC) 396/2005 (Reason 12; Footnote 1 to Annex I); - that food containing contaminants **should not be used as a raw material or as food ingredient** (Reason 3; Art. 2 (1)).

The situation with tea and herbal infusions is a special one as tea and herbal infusions are not consumed as such but only the brew is consumed. And a lot of contaminants present in the dried product do not or only partly diffuse into the brew. When setting MLs for tea and herbal infusions in Regulation (EC) 1881/2006 this has been taken into consideration.

The general rules set under the new Contaminants Regulation give rise to the question of whether this special situation of tea and herbal infusions may continue to be taken into account. This must be clarified against the following background in particular:

While Art. 1 (1) of Regulation (EC) 1881/2006 stated

“The foodstuffs listed in the Annex shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex.”,

Art. 2 (1) of Regulation (EU) 2023/915 reads

“The food listed in Annex I shall not be placed on the market and shall not be used as a raw material in food or as an ingredient in food where it contains a contaminant at a level which exceeds the maximum level set out in Annex I.”

Herbal infusions blends and flavoured teas are compound food which may contain plant parts as ingredients which are also consumed as fruit, as vegetable or as spice. Even single ingredient herbal infusions may consist of a plant material which has a dual use. An example is fennel seed which may be used as spice or as an ingredient of herbal infusions.

The key questions are:

- Does the increased reference to Annex I to Regulation (EC) 396/2005 have influence on ingredients for flavoured tea and herbal infusions?
- Can the fact that only the brew of tea and herbal infusions is consumed be taken into consideration in the interpretation of Art. 2 (1) of the new Contaminants Regulation?

Interpretation

A. Definition of categories

1. “Herbal infusions”

Annex I to Reg. (EU) 2023/915 sets MLs for different contaminants in “herbal Infusions”.

For certain crops Reg. (EU) 2023/915 refers to Annex I to the Pesticide Residue Regulation (EC) 396/2005 in order to align the definitions of the terms. For “herbal infusions” this is not the case as “herbal infusions” are not mentioned in Footnote 1 to Annex I of Reg. (EU) 2023/915. This reference was deliberately omitted. In the revised draft of the new Contaminants Regulation the proposal for footnote (1) stated as follows: “...in case of maximum levels established for the category oilseeds, herbs, spices and **herbal infusions** as listed in the relevant category as defined in that [Reg. (EC) 396/2005] Regulation”. But this reference did not fit into the system of the Contaminants Regulation: e.g. there is an ML for Ochratoxin A (OTA) set under 1.2.19.1. for liquorice root as an ingredient in herbal infusions, but liquorice root is regarded as a spice



according to Code No. 0840010 of Annex I to Reg. (EC) 396/2005 and not as a herbal infusion according to Code No. 0630000.

Accordingly, the definition of “herbal infusions” as mentioned in Annex I to Reg. (EU) 2023/915 differs from “herbal infusions” as listed under Code No. 0630000 in Annex I to Reg. (EC) 396/2005. The crops listed under Code No. 0630000 are commonly used as ingredients in herbal infusions, but they are not the only ones. There are further materials allocated to different Code Numbers. These crops have different uses and may also be used as ingredient in herbal infusions.

In the Contaminants Regulation “herbal infusions” does not just refer to a list of raw materials which may be used as ingredient in “herbal infusions” but to the final product, dried. This becomes clear when looking at the different entries mentioning “herbal infusions” in Annex I to Reg. (EU) 2023/915: they read e.g. “Ginger roots (dried) for use in herbal infusions” or “Herbal infusions (dried product) and ingredients used for herbal infusions (dried products)”. Thus, the term “herbal infusions” refers to the category as such and not to single ingredients.

- In Regulation (EU) 2023/915 “herbal infusions” are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.
- The definition of the term “herbal infusions” in Reg. (EU) 2023/915 is different from Reg. (EC) 396/2005.
- In Reg. (EC) 396/2005 the term “herbal infusions” only covers certain raw materials commonly used as ingredient of herbal infusions.
- In Reg. (EU) 2023/915 the term „herbal infusions” refers to the category and the final product.

2. Dried Spices

Different spices are also commonly used as ingredients for tea and herbal infusions. MLs are set for the following contaminants in “dried spices” or certain dried spices: Aflatoxins, OTA, lead and PAHs. For “spices” footnote 1 to Annex I of the new Contaminants Regulation refers to “spices” in Annex I to Regulation (EC) 396/2005. Accordingly, the question is whether these MLs also apply to spices used as ingredients in tea and herbal infusions.

The wording of the entries “dried spices” as well as the examples specified in the new Contaminants Regulation are in line with Annex I of Regulation (EC) 396/2005. This suggests that the MLs for “dried spices” shall apply independent of the use.

In contrast, the history of the ML for PAHs in “dried spices” supports that at least this ML does not apply to “dried spices” used as ingredient for tea and herbal infusions. When establishing MLs for PAHs in plant materials MLs for “tea” and “herbal infusions” were in discussion besides MLs for “dried herbs” and “dried spices” (see [Summary Report of the SC PAFF, 28/11/2014](#) - Section Toxicological Safety of the Food Chain; [MVWS Report of the CWG on Environmental and Industrial Contaminants 08/01/2015](#)). Due to the information that PAHs do not diffuse into the brew the legislator deliberately abstained from setting MLs for PAHs in tea and herbal infusions. The [MVWS Report of the CWG Meeting held on 02/03/2015](#) states: “*Er zijn studies die aangeven dat PAHs in (kruiden)thee niet in het zetsel terecht komen. De lidstaten concluderen dat MLs voor PAHs in (kruiden)thee het niet nodig zijn.*” Accordingly, the draft Regulation voted in the SC PAFF on 10/03/2015 did not foresee MLs for tea and herbal infusions anymore (see [Summary Report of the SC PAFF, 10/03/2015](#) -Section Toxicological Safety of the Food Chain).



If spices for use as ingredient in herbal infusions should be regulated, this is always mentioned explicitly. This is shown e.g. by the entry 1.2.19.2 for OTA which lists "Liquorice root (dried), including as an ingredient in herbal infusions". If the entry "spices" in Annex I to Reg. (EU) 2023/915 would cover spices independent from their use it would be superfluous to mention "as an ingredient in herbal infusions". This is also in line with the entries for tropane alkaloids (TA) and pyrrolizidine alkaloids (PA) which read "herbal infusions (dried product) and ingredients used for herbal infusions (dried products)".

Eventually, this interpretation is based on the general rules as stated in Article 2: According to paragraph 1 of this Article "**Food listed in Annex I** shall not be placed on the market and shall not be used as a raw material in food or as an ingredient in food ...". The food listed in Annex I is "herbal infusions" and this entry refers – as explained before – to the final product. Thus, if ingredients of herbal infusions shall be regulated in Annex I by exemption this needs to be stated explicitly, as has been done in the cases mentioned before.

That herbal infusions are regarded a category of its own under Annex I to Reg. (EU) 2023/915 is because herbal infusions (dried) are not consumed as such but the infusion is consumed. Several contaminants are hardly or only partly water soluble so that herbal infusions do not contribute considerably to the intake of these contaminants although they are present in the dried matter. In comparable cases the Contaminants Regulation also foresees exemptions for other cases: according to reason (14) the exemption for cadmium in malt is extended to all cereals used for the production of beer or distillates because cadmium mainly remains in the cereal residues and therefore the content of cadmium in the beer is very low. According to reason (15) the MLs for PAHs for infant formulae, follow-on formulae and young-child formulae and for food for special medical purposes intended for infants and young children continue to apply to the products ready to use. Thus, the use of a certain material makes a difference if it has an influence on the ready to use product.

- In Regulation (EU) 2023/915 "herbal infusions" are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.
- "Herbal infusions" as such are a food listed in Annex I.
- MLs for spices do not cover spices for use in herbal infusions if not explicitly mentioned in the according entry.

2. "Herbs"

A lot of herbs are typical ingredients of "herbal infusions". As Annex I to Reg. (EU) 2023/915 sets MLs for different contaminants in "herbs" it needs to be considered what is meant by the term "herb".

In the revised draft of the new Contaminants Regulation footnote (1) stated as follows: "...in case of maximum levels established for the category oilseeds, **herbs**, spices and herbal infusions as listed in the relevant category as defined in that [Reg. (EC) 396/2005] Regulation";

In the final draft of the new Contaminants Regulation the amended wording reads as follows: "Fruits, treenuts, vegetables, oilseeds, **herbs** and spices as listed in the relevant category as defined in Annex I to Regulation (EC) 396/2005...."

THIE commented that there is no clear definition for "herbs" in Annex I to Regulation (EC) 396/2005. This was accepted and accordingly "herbs" were no more mentioned in the final version of the footnote.



There is no explanation given for the deletion of “herbs” in the footnote; in particular, the Summary Report from the Standing Committee on Plants, Animals, Food and Feed - Section Novel Food and Toxicological Safety of the Food Chain – of 19 October 2022 does not provide any reason. The deletion can have been made because “herbs” shall not be covered or because it is not necessary to name them separately as they are already covered by “vegetables” (subgroup “Fresh herbs and edible flowers”).

In order to clarify this question, the different provisions foreseen for the different contaminants and their wording in Annex I to Regulation (EU) 2023/915 need to be considered in the light of the general provisions and targets of the new Contaminants Regulation.

“**Dried herbs**” are mentioned in entry 1.2.5. OTA, 2.4.2. and 2.4.3. PAs and 5.1.3. PAHs.

Neither the entry for OTA nor the entry for PAs give any hint on the definition of the term “dried herbs” and whether it shall refer to dried herbs used as ingredients in tea and herbal infusions.

The entries for PAs in tea and herbal infusions carry a remark which also mentions “dried herbs” and states that Art. 3 applies. Art. 3 provides rules for dried, diluted, processed and compound food. As the MLs set for PAs already refer to dried materials the remark can only refer to the rule for compound food in Art. 3. Thus, this entry is of no help regarding the definition of “dried herbs”.

But for the entry 5.1.3. PAHs in “dried herbs” the same arguments apply as for the entry 5.1.10. PAHs in “dried spices”. As MLs for “dried herbs” have also been considered besides MLs for tea and herbal infusions this indicates that the term “dried herbs” does not refer to dried herbs which are used as ingredients for tea and herbal infusions.

Furthermore, “**herbs**” and “**fresh herbs**” are mentioned in Annex I to Reg. (EU) 2023/915 in different occasions. In particular, an ML is set for Perchlorate in “Leaf vegetables and herbs” in entry 6.3.1.2. Besides this entry an ML applies for Perchlorate in “Tea (*Camellia sinensis*) (dried product), herbal and fruit infusions (dried product) and ingredients used for herbal and fruit infusions (dried products)” according to entry 6.3.2. As regards Herbal infusions a remark clarifies that the ML refers to “herbal infusions (dried product) from flowers, leaves, stalks, roots, and any other parts of the plant (in sachets or in bulk) used for the preparation of herbal infusion (liquid product)”. The wording clearly shows that entry 6.3.2. covers all ingredients of herbal infusions independent of whether they can also be used as spice or dried herb. Thus, the ML for perchlorate in herbal infusions is a *lex specialis* compared to the entry for “herbs”.

These examples confirm that “herbal infusions” are a category of its own in the Contaminants Regulation. MLs for herbs (“dried herbs”, “fresh herbs”, “herbs”) do not apply to ingredients of “herbal infusions”. “Herbs” refers to materials intended for use as culinary herbs.

- In Regulation (EU) 2023/915 “herbal infusions” are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.
- “Herbal infusions” as such are a food listed in Annex I.
- MLs for herbs do not cover herbs for use in herbal infusions if not explicitly mentioned in the according entry.

3. “Vegetables”

This interpretation is also underlined by other entries referring to vegetables:



Entry 1.2.6 sets an ML for OTA in “Ginger roots (dried) for use in herbal infusions” and entry 1.2.7 in “dandelion roots (dried) ... for use in herbal infusions”. Ginger roots as well as dandelion roots are regarded as vegetables according to Code No. 0213040-006 and Code No. 0213040-001 of Annex I to Reg. (EC) 396/2005. Both entries mention explicitly that the use as ingredient of herbal infusions shall be covered. This suggests that use of vegetables as an ingredient in herbal infusions is only covered if explicitly mentioned.

- In Regulation (EU) 2023/915 “herbal infusions“ are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.
- MLs for Vegetables do not cover vegetables for use in herbal infusions if not explicitly mentioned in the according entry

4. “Fruits”

For “fruits” the situation is more difficult:

With regard to fruits footnote I to Annex I to Reg. (EU) 2023/915 refers to the definition of Annex I to Reg. (EC) 396/2005.

Annex I to Reg. (EU) 2023/915 only mentions “herbal infusions”, not “fruit infusions”. Furthermore, there are no entries which explicitly mention the use of “fruits” as ingredient for herbal and fruit infusions. The only exemption is entry 6.3.2. which specifies a ML for perchlorate in “Herbal and **fruit infusions** (dried product) and ingredients used for herbal and fruit infusions (dried products)”. In addition, entry 2.4.4. and entry 2.4.5. on PAs in flavoured teas (*Camellia sinensis*) mention “dried fruits” as ingredients: “For teas with dried fruits and dried herbs, Article 3 applies.”. As explained before this remark does not allow interpretation of the term “dried fruits”.

Accordingly, the mentioning of “fruit infusions” in entry 6.3.2. is the only anchor which allows the interpretation for spices, herbs and vegetables to be mirrored on fruits as well. As there is no objective reason for not doing so the logic explained above should also apply to “fruits” and “fruit infusions”.

- In Regulation (EU) 2023/915 “herbal and fruit infusions“ are regarded as a separate category alongside herbs, spices, etc. and thus this category forms its own independent basis for evaluation.

B. Conclusions

In order to avoid that different case-by-case interpretation is done by FBOs, laboratories analysing contaminants in HFI and tea, enforcement authorities and local courts which will lead to disturbances in trade **a consistent approach of the industry to the Contaminants Regulation is needed**. A misinterpretation of the Regulation would force FBOs to spend a lot of money in analysing foodstuffs for irrelevant contaminants only to prove compliance of foodstuffs. This would contradict the purpose of the Regulation to protect public health and concentrate on relevant contaminants (see title of the Regulation: “certain contaminants”).

A consistent logic approach to Annex I of Reg. (EU) 2023/915 shows that herbal infusions are regarded as a separate category and that ingredients of herbal infusions only have to fulfil the requirements of the categories spices, herbs, vegetables or fruits if explicitly stated in Annex I.