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Practicable approach to drying factors for herbal and fruit infusions raw materials and composed products

Herbal and fruit infusion (HFI) raw materials are plants or parts of plants that do not originate from the tea plant (*Camellia sinensis* (L.) O. Kuntze) and are intended for food use by brewing with freshly boiling water, except for specially designed products. HFI also include blends with tea as a minor component. HFI on the European market are made from more than 400 plant parts obtained from over 300 plant species and varieties. Plants and parts of plants commonly used in HFI are listed in the THIE Inventory List of Herbals Considered as Food in its current version available under www.thie-online.eu.

Dried ingredients of herbal and fruit infusions are subject to the requirements of *Regulation (EC) 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.*

Per definition, pesticide maximum residue levels (MRL) specified in annex I code No. 0250000 (leaf vegetables, herbs and edible flowers) of the regulation refer to fresh materials. For fruit based HFI ingredients, e.g., rose hips, code No 010000 (fruit, fresh or frozen; tree nuts) applies accordingly. Art. 20 of the regulation provides that where MRLs are not set out in annex II or III for processed and/or composite food the MRLs specified in Art. 18 (1) for the relevant product covered by annex I shall apply taking into account the influence of processing or mixing steps. In addition, Art. 20 (2) stipulates that specific concentration or dilution factors for certain processing or dilution steps may be included in annex VI.

Annex I of Regulation (EC) 396/2005 specifies MRLs for several plant materials referring to their dried form under Code No. 0630000. However, for many important ingredients of HFI, e.g., peppermint leaf, MRLs have been specified so far only for the fresh produce while no processing factors applicable for the respective dried HFI ingredients have been included in annex VI.

Considering the huge number of HFI ingredients and the similarly abundant number of active substances – most of which are never actively applied to but may occur in these ingredients due to immission from their application in other crops - the absence of both specific MRLs in annex II or III and of generic processing factors in annex VI leads to legal uncertainty for food business operators and enforcement authorities equally.

The most relevant processing step which has a significant effect on pesticide levels in HFI ingredients is the drying. Drying typically leads to a relative increase of pesticide levels from the fresh to the dried material. Cleaning, cutting, sifting or sighting steps either in the fresh or dried state may have additional impact on pesticide residue levels, however not necessarily in the same magnitude and direction.

Due to the fact that only very few authorisations exist for the use of specific active substances in specific HFI plants in the EU Member States, establishing specific processing factors for

particular plant-active substance combinations via the experimental route is practically impossible. This has also been acknowledged by the legislator: by way of derogation from the usual procedure of setting MRLs based on field trials temporary MRLs for herbal infusions can be set based on monitoring data according to Art. 16. Even in those rare cases of authorised plant-active substance combinations such factors would be branded with a high uncertainty given the huge number of different species, varieties used as well as high variability of origins, cultivation conditions, plant parts used, pre- and post-harvest treatments and processing equipment typical for many HFI plants.

For these reasons it is obvious that processing factors for HFI ingredients can be established via a generic approach only, i.e., as default drying factors (DF). This approach of establishing default processing factors in annex VI of regulation (EC) 396/2005 however has not been implemented so far by the Authority (EFSA) and the European Commission. This is due not least to the fact that this procedure would require commonly agreed methodologies and acceptance criteria.

In attempting to fill the gaps left in the EU regulation and make their enforcement authorities capable of acting, several national institutions from EU Member States, e.g., the German Federal Institute for Risk Assessment (BfR), the Spanish Agency for Safety and Nutrition (AESAN) or the Dutch National Institute for Public Health and the Environment (RIVM) have compiled lists or databases with processing factors, both specific commodity-substance combinations and default processing factors, typically drying factors for the latter. However, these sources suffer from the fact that binding methodologies and acceptance criteria for processing studies have not been established. A detailed view confirms this problem: RIVM suggests a staged approach to select suitable drying factors in its database. The first choice would be a substance-specific processing factor for the dried commodity. Where this is not available a commodity-specific drying factor should be applied. Where this isn´t provided either, a default drying factor is recommended. For default drying factors, the RIVM instructions refer to the OECD Guidance document on magnitude of pesticide residues in processed commodities. This document however provides no factors at all for HFI ingredients (OECD 2008; RIVM 2020). In 2018 the German Federal Institute for Risk Assessment (BfR) published a revised version of its data collection on processing factors (BfR 2018, BfR 2019). For establishing the revised database, the BfR reviewed more than 2,600 processing studies on 193 active substances and identified 6,500 processing factors. For this purpose, the BfR defined and applied acceptability criteria. Only 2,800 (43%) of the 6,500 factors met the minimum quality requirements and were rated "acceptable". 17% of the reported factors were rated "not acceptable" and another 40% as "indicative". These figures underline the lack of standards for processing factor studies as pointed out by the authors (Scholz et al 2018). While the factors listed in the updated BfR database provide a much higher reliability (or, in case, transparent lack of reliability), HFI ingredients are not represented in the database.

Another database of processing factors has been established by EFSA in 2018. Not identical but largely redundant with the updated BfR database the EFSA database also contains only scarce processing factors applicable to HFI ingredients. Of note, in its explanatory document *Compendium of Representative Processing Techniques investigated in regulatory studies for pesticides (EFSA 2018)* EFSA stipulates that *"No processing study on the magnitude of the residue was available for any kind of fresh herbs. It is noted that in some of the crop field trials residues were reported for fresh and dried samples in parallel – however without much detail on the drying process"* and that *"In the absence of specific data, generic figures on water content of fresh and dried may be used as a surrogate."* In the absence of suitable data for HFI ingredients in the database EFSA refers to default drying factors such as suggested, e.g., by the European Spice Association (ESA) (Weber 2008).

Contributions from growers' and producers' associations

Besides ESA, other organisations have as well suggested default drying factors for a variety of herbal ingredients commonly used in HFI, e.g., the European Herb Growers Association (EUROPAM), the German Bundesverband Naturkost Naturwaren

Table 1: Overview of DF

Category Default DF - All plants except where otherwise specified	THIE 5	EUROPAM 5	ESA	BNN 4-5
Spices		n.a.	5-7 for 15 out of 20 important spices 3, 9, 10 (2x), 13 for 5 out of 20 spices	4 Except: Vegetables, Fungi (7) Garlic (3) Apiaceae fruit (2), Vanilla, Cumin (1)
MAP1) with DF <<5		2 12 MAP (fruit/seed, few with HFI relevance)		
MAP with DF >>5		10 39 MAP (of which ca. 10 of market relevance)		

1) MAP: Medicinal and Aromatic Plants

2) The DF of 1 proposed by BNN for, e.g., fennel fruit, cannot be considered representative for all fennel qualities/uses. Data available from THIE members suggest a DF of 5 for fennel fruit used as HFI ingredient.

(BNN) and, not least, the Tea and Herbal Infusions Association (THIE) (BNN 2021; NOVAK 2018; THIE 2018). *(See Table 1 Overview of DF)*

In its Compendium of Guidelines for Herbal and Fruit Infusions as of 22nd June, 2018, THIE recommends a default drying factor of 5 for HFI/HFI ingredients based on the experience from member companies. This default drying factor of 5 has been applied by the industry for more than 20 years and formed part of information on residues in HFI shared with national and European authorities. Very similarly, BNN arrives at default drying factors of 5 for Dried Fruits and 4 for Green and Black Tea, Spice Herbs, Medicinal Herbs and HFI Herbs for HFI ingredients and tea. The lower drying factor of 4 proposed by BNN in comparison with a factor of 5 as suggested by both THIE and EUROPAM for the same group of commodities may be motivated by the fact that consumer expectations with regard to organic products and the absence of pesticides are even stricter than for conventionally grown products." ESA, in contrast, has assigned individual drying (dehydration) factors for 20 prominent spices, many of which are also used in HFI. These factors are based on a literature survey performed prior publication (2008) and data from ESA members. The factors range between 3 and 13 with a factor of 5-7 for 15 out of 20 listed spices. Overall, ESA factors are somewhat higher than THIE and BNN factors. Very well in conformity with THIE and BNN, EUROPAM recommends a general default drying factor of 5 for Medicinal and Aromatic Plants (MAP). For certain plants, EUROPAM allocates a factor of 2 or 10, respectively. EUROPAM is an organisation predominantly of herb growers, thus covering a very broad spectrum of plants/target products/market segments including HFI, spices and also herbal medicinal products. Thus, it is comprehensible that the EUROPAM proposal includes exceptions for a considerable number of plants at first sight, however most of these are of no significant relevance for HFI use.

As long as legally established binding drying factors are not available, a pragmatic approach including default drying factors established by consensus would be extremely helpful for all involved parties, i.e., growers/collectors, producers and enforcement authorities. Unlike growers/collectors, producers and enforcement authorities have to cope with an additional level of complexity and variability–composed products. Where limits are set for fresh produce only, drying factors have to be considered in the assessment of results from pesticide analyses. Drying factors are never identical for different herb/fruit ingredients. Ideally, specific drying factors of each ingredient would have to be considered as well as the weight per cent of each ingredient in composed products. However, the quantitative composition is not included in the labelling of food. While it may be justified in particular cases from either producers' or the enforcement authorities' perspective to try and consider both quantitative composition and ingredient-specific drying factors this is apparently no practicable routine approach and a tangible orientation is necessary in such cases. Composed HFI typically contain up to 10 or even more different ingredients. As a consequence, the contribution of ingredients with relatively high (>> 5) or relatively low (<< 5) drying factors will be levelled in most cases.

Considering that composed products account for the largest part of the HFI market, application of a conventional default drying factor would be a favourable proceeding sufficiently robust for most routine situations – still leaving the option for an in-depth assessment where appropriate.

Summary and conclusion

Herbal and Fruit Infusions (HFI) on the European market cover a range of several hundred plant species. Only a fraction of these is sourced by cultivation. Also cultivated HFI plants originate from a wide variety of geographic origins. The dry matter and water content at the moment of harvest are subject to a plethora of influencing factors and thus may vary from origin to origin, from year to year and from grower to grower (implicating, e.g., different cultivars), to mention but a few factors. It is evident that this results in a considerable variability of the raw agricultural commodities.

For obvious reasons it is not practicable at all to establish specific drying factors even for the empirically most common commodity-active substance combinations observed in industry and enforcement practice. Therefore, default drying factors are the only practicable and appropriate approach both for single ingredient- and composed products. Considering the experience of its members as well as the available published evidence, THIE recommends a default drying factor of 5 for HFI ingredients/products.

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THIE – Tea & Herbal Infusions Europe
Sonninstrasse 28
20097 Hamburg
Germany
Tel: +49 40 236016-21
Fax: +49 40 236016-10
www.thie-online.eu