1 September 2026

RE: Discussion on pyrrolizidine alkaloids at the next Working Group Meeting on Agricultural Contaminants in Food of 3 September

Dear Members of the Working Group,

During the next meeting of the Commission Working Group, the discussions on a proposal to increase the maximum levels (ML) for Pyrrolizidine Alkaloids (PA) in dried herbs and food supplements will continue.

We understand that the proposal contains the following elements:

1. No change for most herbs for which the ML remains at 400 µg/kg.
2. An increase of the ML from 400 µg/kg to 700 or 1000 µg/kg for a limited number of dried herbs for which rejection rate data show that the current low limit is not achievable.

   It is noted that for the same reason an increased level of 1000 µg/kg is already accepted before for some other herbs (e.g. for borage, lovage, marjoram and oregano).

   We note that two herbs are missing from the proposed ML of 1000 µg/kg, even though they are listed in the proposal: Feverfew (*Tanacetum parthenium*) and St. John's Wort (*Hypericum perforatum*). We would ask Member States to include these in 2.4.3.
3. No change of the current ML of 400 µg/kg for food supplements containing those herbs to which a maximum limit of 400 µg/kg applies.
4. An increase of the ML from 400 µg/kg to 800 µg/kg for food supplements containing those herbs for which an increase to 700 or 1000 µg/kg is proposed and extracts (Option 2).

   We note that there is still discussion on whether the limit for food supplements should be increased. We believe this is necessary for the following reasons:

   - PA contamination is unpredictable, despite massive efforts of the sector to implement mitigation measures. The increase of the ML for the dried herbs is based on a solid Europam/ITEIPMA database[1] of raw occurrence data, on the basis of which, following the request by the Working Group, 28 herbs have been identified as particularly vulnerable and for which European growers and processers are consistently facing difficulties in complying with the current ML with a high rejection rate as a result.
   - It is consistent that when the ML for dried herbs is increased, the same level also applies to food supplements containing these dried herbs as such. Otherwise this increase would remain ineffective and still lead to a high rejection rate.
   - In addition, most of these dried herbs are used for extraction. This results in unavoidable concentration (likewise as the concentration that has already been recognized for powdered extracts for instant herbal infusions).

     The proposed increased ML for food supplements accounts for this factor. Not accepting the proposed increased ML means that, to be acceptable for extraction, the PA level in the raw materials must be a factor 2-4 lower than 400 µg/kg, which results in an even higher rejection rate. In fact, to be consistent, the ML for food supplements should be increase to 1600 µg/kg, rather than to the currently proposed 800 µg/kg.

We therefore ask Member States to support this increase (Option 2) as it is consistent and well-justified by data and in line with the Alara principle.

In addition, the proposed increase does not lead to increased risk for consumers because of the nature and use of the products concerned:

- The proposed levels are maximum levels, which means that, in reality, most products will contain lower values. They also do not apply to the whole category of products but only to selected herbs and food supplements.

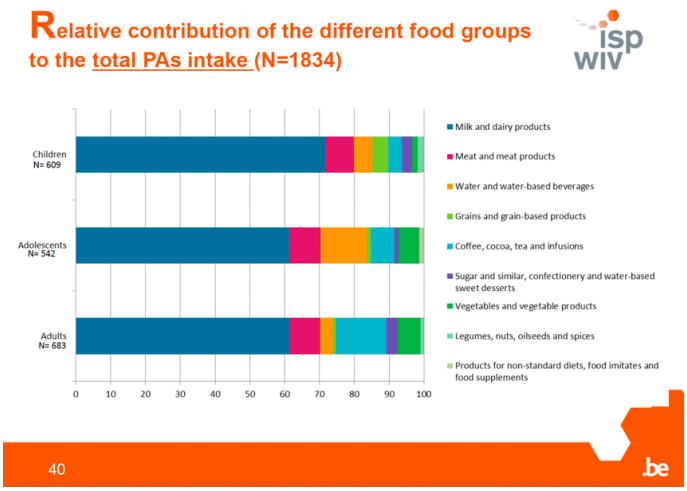
  An increase of the ML will not lead to all products containing PA at the ML. The data on which the proposal is based shows a rejection rate > 5%, which means that typically > 90% of all batches already comply with the current ML. Given the mitigating measures put in place by the growers and collectors over the past years, a change of this situation is not expected. Rather, the increase of the ML would enable to minimize the losses caused by the batches that do not comply with the current ML, because of the unpredictability of PA contamination.

- The increase of the ML results in a potential but limited increase of exposure, given that botanical food supplements are consumed in very small doses.

  EFSA confirms that the majority of supplement based on herbal formulations and/or plant extracts correspond to capsules and tablets and the average unit weight is 0.7 grams[2]. Given that additives (e.g. fillers, binding agents, capsule material) are required to manufacture tablets and capsules, the plant extract content of such products is likely to be less than 50%, i.e. 0.35 g. Such products are typically consumed only by adults and on a 1 per day basis and it is a legal requirement to state on the label of any food supplement that the recommended daily amount must not be exceeded, which limits the intake to what is recommended on the label.

  At the current legal ML of 400 µg/kg for food supplements, the exposure from such a food supplement results in an intake of PA of 0.14 µg/day. At the proposed ML of 800 µg/kg, this increases to 0.28 µg/day.

  Data from Siensano[3] show that 85% of PA exposure comes from dairy products, meat and meat products and other foods, because, although occurrence levels are in the ng/kg range, their consumption is significant.



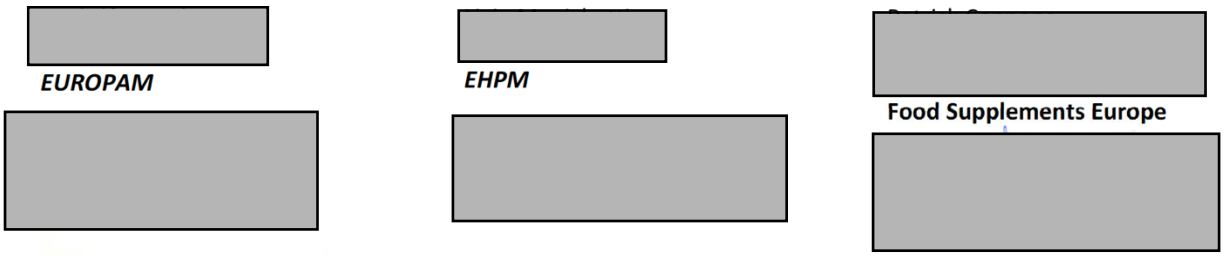
These are unavoidable sources, and exposure from these sources is not likely to change over time. The legal ML for tea, infusions, honey and food supplements have already ensured a significant reduction of the exposure to PA. The proposed increase of the ML for food supplements is therefore not likely to have a material impact on overall exposure from the diet.

- In addition, an intake of 0.28 µg/d from a food supplement is still significantly lower than the maximum limit of intake of 1 µg/day that has been established by the European Medicines Agency[4] based on a toxicological evaluation for traditional herbal medicinal product which have a comparable format and consumption pattern as food supplements.

We therefore believe that the proposal to increase the ML to 700/1000 µg/kg for dried herbs and a concomitant increase of the ML for food supplements to 800 µg/kg does not lead to an increased risk for consumers, is fully justified in the context of the ALARA principle and absolutely necessary to address the current excessive rejection rate of whole harvests.

To help the practical feasibility for operators, a further reduction of this ML should not be agreed, as even with these increased ML, the rejection rate will remains high for certain herbs (see annex).

We ask the Member States to support this at the next meeting of the Working Group and remain available for any further clarification.



References

1 Europam/ITEIPMA data shared with the European Commission

2 EFSA 2018. Internal report on the quantification of food supplements units to be used in the assessment of dietary exposure. https://zenodo.org/records/1346209

3 Sciensano (Belgian Scientific Institute for Human, Animal and Environmental Health) PASFOOD Project 2016-2017.

4 EMA 2021 Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal medicinal products with pyrrolizidine alkaloids - Revision 1 https://www.ema.europa.eu/en/use-herbal-medicinal-products-containing-toxic-unsaturated-pyrrolizidine-alkaloids-pas-scientific-guideline

Annex

Scientific name	Common name	Part of the plant	Percentile 90th	N. of samples	ML < 400 ppb Rejection rate	ML < 700 ppb Rejection rate	ML < 1000 ppb Rejection rate
Aloysia citrodora Paláu	Lemon verbena	Leave	905.40	3	67%	67%	67%
Artemisia dracunculus L.	Tarragon	Leave	1406.60	87	30%	23%	17%
Ballotta nigra L.	Black horehound	Aerial part	4554.63	3	67%	33%	33%
Centella asiatica (L.) Urb.	Centella	Leave	704.99	12	17%	17%	0%
Cuminum cyminum L.	Cumin	Seed	1408.80	3	67%	67%	67%
Cynara cardunculus L. and C. scolymus L.	Cardoon/ Artichoke	Leave	843.02	39	15%	15%	8%
Echinacea purpurea (L.) Moench.	Purple coneflower	Herb	522.00	45	18%	9%	4%
Equisetum arvense L.	Horse tail	Aerial part	572.96	40	23%	10%	10%
Eschscholzia californic a Cham.	California poppy	Aerial part	11058.44	65	62%	54%	49%
Hypericum perforatum L.	St. John's wort	Aerial part	6684.62	18	56%	50%	44%
Matricaria chamomilla L.	Chamomile	Flower	536.50	1378	13%	8%	6%
Melilotus officinalis (L.) Lam.	Melilot	Aerial part	1021.40	20	25%	15%	10%
Melissa officinalis L.	Lemon balm	Leave	648.05	196	15%	9%	5%
Mentha × piperita L.	Peppermint	Leave	735.70	1190	13%	10%	9%
Nasturtium officinale W.T. Aiton	Watercress	Herb	4749.40	10	60%	60%	60%
Ocimum basilicum L.	Basil	Aerial part	3494.08	7	43%	43%	43%
Passiflora incarnata L.	Passionflower	Aerial part	856.40	22	18%	14%	9%
Petroselinum crispum (Mill.) Fuss	Parsley	Aerial part	2059.60	13	54%	54%	46%
Pimpinella saxifraga L.	Burnet saxifrage	Root/Leav e/Herb	3838.25	6	67%	50%	50%
Rubus fruticosus L.	Blackberry	Leave	6058.00	71	18%	14%	13%
Rubus idaeus L.	Raspberry	Leave	8176.8	28	56%	46%	37%
Salvia officinalis L.	Sage	Leave	10516.00	135	41%	38%	32%
Sisymbrium officinale (L.) Scop.	Hedge mustard	Aerial part	828.77	12	25%	17%	8%
Solidago canadensis L.	Goldenrod	Aerial part with flower	542.18	9	22%	0%	0%
Tanacetum partheniu m (L.) Sch. Bip.	Feverfew	Aerial part	8879.60	17	59%	59%	59%
Taraxacum officinale F. H. Wigg.	Dandelion	Leave	2291.56	18	39%	28%	28%
Urtica dioica L.	Nettle	Herb	3468.00	247	29%	26%	23%