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<u>Possible maximum levels for pyrrolizidine</u> <u>alkaloids as discussed at Working Group</u> <u>Agricultural Contaminants for targeted</u> <u>consultation of stakeholder organisations</u>

## 1) The possible maximum levels under discussion relate to the sum of 21 individual pyrrolizidine alkaloids

The maximum levels under discussion refers to the sum of the following 21 pyrrolizidine alkaloids:

- intermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide,
- senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide,
- seneci(o)phylline, seneciphylline-N-oxide,
- retrorsine, retrorsine-N-oxide,
- Echimidine, echimidine-N-oxide,
- lasiocarpine, lasiocarpine-N-oxide,
- Senkirkine
- europine, europine-N-oxide,
- heliotrine and heliotrine-N-oxide.

However, it is known that with the use of the most habitual analytical method for the analysis of pyrrolizidine alkaloids, i.e. high-performance liquid chromatography – tandem mass spectrometry (HPLC-MS/MS), other pyrrolizidine alkaloids might co-elute with one or more of the above identified 21 pyrrolizidine alkaloids. In case of co-elution of the following 12 pyrrolizidine alkaloids with one or more of the above identified 21 pyrrolizidine alkaloids, they are included in the sum of 21 pyrrolizidine alkaloids but they are not to be quantified separately.

Indicine (possible co-elution with lycopsamine/intermedine) Indicine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermedine-N-oxide) Echinatine (possible co-elution with indicine) Echinatine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermedine-N-oxide) Rinderine (possible co-elution with indicine) Rinderine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermedine-N-oxide) Integerrimine (possible co-elution with senecivernine) Integerrimine-N-oxide (possible co-elution with senecivernine) Heliosupine (possible co-elution with echimidine) Heliosupine (possible co-elution with echimidine) Spartioidine (possible co-elution with seneciphylline) Spartioidine-N-oxide (possible co-elution with seneciphylline)

## 2) Possible maximum levels under discussion relating to the sum of individual pyrrolizidine alkaloids are set as lowerbound concentrations.

The possible maximum levels as discussed are lowerbound concentrations. Lowerbound concentrations are calculated on the assumption that all the values of the different individual pyrrolizidine alkaloids (or "co-eluted" pyrrolizidine alkaloids) below the limit of quantification are equal to zero.

For tea, herbal infusions, herbs, food supplements containing herbal ingredients, pollen based supplements, pollen and pollen products the Limit of Quantification to be achieved for the individual pyrrolizidine alkaloids (or co-eluted pyrrolizidine alkaloids) is  $5 \mu g/kg$ .

(For honey, the Limit of Quantification to be achieved for the individual pyrrolizidine alkaloids (or co-eluted pyrrolizidine alkaloids) is  $2 \mu g/kg$ .)

## 3) Possible maximum levels under discussion

	µg/kg (product)
- Herbal infusions – Rooibos	400
- Other herbal infusions	200
- Herbal infusions – mixtures of rooibos with other herbs (*)	300
- Tea (Camellia sinensis)	100
- Herbal tea for infants and young children (solid or dried	75
product)	
- Herbal tea for infants and young children (liquid)	1.0
- Food supplements containing herbal ingredients excluding	400
oils	
- Pollen based food supplements	
- Pollen and pollen products	
- Herbs (fresh, frozen and dried)	400
- Cumin seeds (seed spice)	400

(\*) The maximum level of 300  $\mu$ g/kg is applicable to mixtures where the relative proportion of the ingredients is not known. In case the relative proportion of the ingredients is known, Article 2 (1) (c) of Regulation (EC) 1881/2006 applies

The possible maximum levels under discussion are based on the occurrence data referred to in the EFSA scientific report "<u>Dietary exposure assessment to pyrrolizidine alkaloids in the European</u> <u>population</u>" and more recent data made available to the EFSA database after the publication of the abovementioned scientific report.

Based on these data, the suggested maximum levels for herbal infusions reflect about the 80<sup>th</sup> to 90<sup>th</sup> percentile of the available data. For tea, the suggested maximum level is above the 95<sup>th</sup> percentile of the available data. Taking into account the available information, it is considered that the suggested possible maximum levels are achievable by applying good practices.

In herbs, sometimes very high levels of pyrrolizidine alkaloids are observed in certain herbs such as borage, lovage, majoram and oregano. Not considering these very high values the possible maximum level under discussion for herbs reflects the 95<sup>th</sup> percentile of the available data.