

10/10/2019

**EHPM Contribution in the context of  
TRIS notification 2019/331/NL:**

***On the Dutch Decree amending the Commodities Act  
Decree on herbal preparations and the Commodities Act  
Decree on administrative penalties regarding the addition  
of certain harmful substances to herbal preparations and  
applying certain technical amendments***

To be submitted by the  
**end of the Standstill period: 23:59 of the 10/10/2019**

Dear Sir/Madam,

The European Federation of Associations of Food Product Manufacturers, hereinafter EHPM, EU stakeholder registered on the EU Transparency Register (No. [65512466920-96](#)) would like to submit a contribution in the context of the TRIS notification number 2019/331/NL submitted by the Dutch Authorities on the Decree amending the Commodities Act Decree on herbal preparations and the Commodities Act Decree on administrative penalties regarding the addition of certain harmful substances to herbal preparations and applying certain technical amendments.

EHPM was created in 1975 and represents 1600 health-product manufacturers in 14 European countries. Through our member associations EHPM aims to provide consumers with safe, science-based, high quality products as well as accurate and helpful information about their nutritional value and use and to assure a fair European regulatory framework for our sector.

As a European Federation representing the food supplement sector, the EHPM would like to join its voice to our Dutch member NPN, who expressed concerns about the Dutch decree that was recently notified.

We would like to stress that our Association is particularly concerned about the fact that the Dutch decree will create substantial barriers to trade, putting at stake the free movement of goods in the European Union.

This is due to the extremely low proposed maximum level for pyrrolizidine alkaloids (1 mcg/kg or litre), which is not in line with the ALARA (as low as reasonably achievable) principle, as it is impossible to be met by the multiple economic operators that will be impacted by such measure. Growers, producers and suppliers will all be seriously damaged in their activities if the Dutch decree is adopted.

Furthermore, we would like to highlight that the maximum level for pyrrolizidine alkaloids suggested by the Dutch Decree (1 mcg/kg or litre) is way below the lowest detectable level identified by EFSA in its 2017 opinion<sup>1</sup>. Such level is of 4.5 mcg/kg, using the liquid chromatography with tandem spectrometry (LC-MS/MS) method.

Therefore, if the Dutch decree is applied, it will not be possible to detect the level set (1 mcg/kg). Besides, a number of products with an amount lower than 4.5 mcg/kg will appear as 0 to the analysis, as the method used is not sensitive enough.

Moreover, the EU Commission has been working on a regulatory proposal that will amend Regulation (EC) 1881/2006 setting maximum levels for certain contaminants in foodstuffs - soon to be voted within the PAFF Standing Committee - introducing a maximum level for pyrrolizidine alkaloids of probably 400 mcg/kg of finished product. We expect the amended regulation to enter into force by spring 2020.

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<sup>1</sup> EFSA, Risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements, EFSA Panel on Contaminants in the Food Chain (CONTAM). European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2017;15(7):4908. p. 16

Therefore, considering that the EU decision on maximum levels for pyrrolizidine alkaloids is imminent, and in line with the Principle of Precedence of European Law, the Dutch measure will be overruled once the EU regulation will enter into force. Thus, it would not constitute a preferable legal construction to adopt a law that will be likely overruled. However, the Dutch decree would still constitute a substantial barrier to trade during the period preceding the application of the EU amended regulation.

We would like also to highlight that the EHPM considers fundamental to guarantee the consumers' safety and in case of concerns to take the relevant measures. Our Association is aware of the potential risk posed by pyrrolizidine alkaloids (PAs) and supports appropriate actions and measures to ensure the safety of the consumers.

Those actions should be proportionate: limits should be set only for those products with plants that can contain PAs, not for all plants in all products, like the Dutch decree foresees.

Moreover, the actions should take into account the potential risk for the consumers, the most recent reliable scientific evidence<sup>2</sup> and at the same time the impact on the availability of herbal products to consumers and on the market sector, allowing sufficient time for market operators to adapt to the new limits.

Livia Menichetti  
Head of Policy & Administration

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<sup>2</sup> In the European Court of Justice (ECJ) ruling of 27 April 2017 in [Case C 672/15, Noria Distribution SARL](#), the ECJ stated that: there should be coherence between the risk assessments and regulatory measures; the scientific risk assessment should be based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups and should be appropriate and proportionate.