





Mr Michael Flueh Head of Unit - DG SANTE, unit E3 European Commission B-1049 Brussels

Murcia, 17th February 2016.

Dear Mr Flueh,

Setting of processing factor for cold pressed lemon oil

On 23 June 2015, Ailimpo has met with your services to discuss the issue that cold pressed lemon oil industry faces due to changes in the levels of pesticide residues caused by processing fresh lemons.

The European lemon processing industry produces cold pressed lemon oil (CPLO) from fresh lemons as raw material using common technology based on JBT Food Tech extraction systems. Considering that CPLO is obtained from the oil glands located in the very external peel of fresh lemons, a higher concentration of pesticide residues is expected in the final product.

CPLO is not consumed directly as it is an ingredient used in a very low quantities in the composition of other food products, mainly soft drinks and beverages. For this reason, in pesticide presence terms, the impact on the final product for consumer is very limited. When assessing the safety of CPLO the MRLs for pesticides in processed product have to be derived from the MRLs for raw lemons, taking into account the concentration caused by processing (processing factor) as described in Regulation (EC) No 396/2005, article 20 (1).

In 2015 Ailimpo has conducted a study in order to assess the concentrations of pesticides maximum residues in lemon oil. This processing study was designed:

- a) Supported by 3 trials
- b) Carried out at industrial scale, not pilot plant nor laboratory scale
- c) Using JBT Food Tech technology (the most common in the lemon processing industry)
- d) Without considering spiked samples

An initial point of the study was a theoretical approach based on 2 factors:

- A Processing Factor of 1000 as indicated in the OCDE guidance document on magnitude of pesticide residues on processed commodities ENV/JM/MONO (2008)23, and:
- A theoretical Processing Factor of 333, considering a yield of 0,3% (1 ton of fresh lemons is needed to obtain 3 kilos of cold pressed lemon oil), following the criteria used for olive oil, with a generic PF of 5 considering a yield of 20% - Regulation (EC) No 1274/2014.

Apart from the theoretical data, a practical approach has been considered in order to be realistic and achieve secured and completed data, following BfR Criteria and DG AGRI Guideline Doc- 7035/VI/95 rev.5.







The industry would like to ask the European Commission services to consider setting a generic processing factor for a product as such - cold pressed lemon oil, instead of for each individual pesticide detected in the product. AILIMPO, representing the Spanish lemon industry has derived the proposal of a generic processing factor considering the conclusions of a processing study conducted in 2015 in order to have a harmonised MRL assessment. The results of the study in a format of excel file can be found enclosed in the e-mail together with this letter.

Moreover, setting of a generic processing factor for CPLO would ensure harmonized interpretation of safety of product across MS's avoiding distortions of the internal market, to support international trade, and to eliminate uncertainty and B2B disputes.

Conclusions of the study allows to propose a generic processing factor equal to 30 as a commitment from the private sector to guarantee the minimum pesticide residues following ALARA principle during pre- and postharvest treatments as well as developing the implementation of good practices, but considering the unavoidable concentration in the cold pressed lemon oil. Indeed, this processing factor is deemed to be also applicable when limit of determination (LOD) is set for fresh lemons as in many cases the pesticide residues are not detectable in the raw commodity but are in fact concentrated in the final processed product.

The processing factor indicated in this proposal (PF = 30) should be applied in such a way that the pesticide MRL fixed in the Regulation (EC) No 396/2005 for fresh lemons should be multiplied by the processing factor. Such formula should be used when judging the safety of cold pressed lemon oil.

We kindly ask the European Commission to have an exchange of views with other member states on this issue at the Standing Committee meeting on Pesticide Residues. Consequently, to consider a temporary enforcement guideline with a generic PF of 30, making an appropriate statement in the minutes of the meeting. As a next step the Commission should request EFSA to deliver a scientific opinion if needed, in order to set a permanent processing factor.

We are fully open to share with you all the detailed information if needed. We are also eager to meet you or your colleagues once again to explain the results of the studies and look for ways of better cooperation.

In Annex of this letter: a complete dossier of information on the background, the processing study carried out and its results

José Antonio García Director

In cc: Almut Bitterhof, Roberto Manos. DG SANTE. Brussels.

César Casado de Santiago, Victorio Teruel Muñoz. Spanish Ministry of Health.

AECOSAN, Madrid.









AILIMPO is the Spanish Lemon and Grapefruit Interbranch Association representing all economic activities related to the production, trade and processing of these citrus products in Spain with an average annual turnover of 700 million €.

Ailimpo was founded in 1998 and is officially recognised by the European Commission according to Regulation (EU) no 1308/2013, formerly Regulation (EC) no 2200/96 (OJ C 190/7 7.7.1999).

Ailimpo focuses on:

- · improving knowledge and the transparency of production and the market;
- helping to coordinate better the way the products are placed on the market, in particular by means of research and market studies;
- drawing up standard forms of contract compatible with Union rules;
 exploiting to a fuller extent the potential of the fruit and vegetables produced;
- providing the information and carrying out the research necessary to adjust production towards
 products more suited to market requirements and consumer tastes and expectations, in
 particular with regard to product quality and protection of the environment;
- seeking ways of restricting the use of plant-health products and other inputs and ensuring product quality and soil and water conservation;
- developing methods and instruments for improving product quality at all stages of production and marketing;
- exploiting the potential of organic farming and protecting and promoting such farming as well as designations of origin, quality labels and geographical indications;
- promoting integrated production or other environmentally sound production methods.