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Attention: European Union TBT Enquiry Point

Subject: *Comments on the TBT/WTO Notification G/TBT/N/EU/826 - Reclassification of reproductive toxicity of 2-ethylhexanoic acid by the European Union*

Elekeiroz S.A. (Elekeiroz), the sole producer of 2-ethylhexanoic acid (2-EHA) in Brazil and an exporter to the EU, would like to thank the European Union authorities for the above-mentioned notification and appreciates the opportunity to comment on the new risk classification for the 2-ethylhexanoic acid (2-EHA) as notified to the World Trade Organization (WTO).

We refer to the changes made to Part 3 of Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures (CLP), specifically to the entry corresponding to index number '607-230-00-6, which introduces a stricter classification of reproductive toxicity to 2-EHA, from Repr. 2 to Repr. 1B.

Elekeiroz recognizes the need for adequate risk classification for substances allowed to be imported into the European Union, as a measure of protection of human health and safety and of the environment. Therefore, we call attention to the flaws identified in the procedure for re-evaluation of the substance, which lead to incorrect technical conclusions and incompatibilities with the EU commitments before international trade rules.

First, we note that the study which serves as basis for the new classification used read-across methodology with valproic acid when reaching the toxicity conclusion for 2-EHA. As it is known, the proper use of read-across depends on the assumption that, due to the presence of close chemical aspects, the substances in question will have similar effects when exposed to the same tests, and thus, will reveal the same toxicity. That was not the case, since valproic acid and 2-EHA don't share similar reproductive toxicity profiles, especially regarding fetal developmental toxicity, the key element to the present reclassification. Therefore, the studies carried out directly with 2-EHA make up the best technical knowledge to inform the European authorities on the correct risk classification for the substance, that is, Repr. 2.

The new risk classification is incompatible with 2-EHA's actual reproductive toxicity. This understanding is similar to that of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), of which the European Union is in violation by introducing a stricter toxicity classification for 2-EHA. We recall that the CLP is the domestic implementation of GHS

by the EU and therefore should include the system's standards, in order to facilitate the global trade of chemicals.

The situation presents a series of incompatibilities with international trade rules, in particular Articles 2.2, 2.4 and 2.5 of the Agreement on Technical Barriers to Trade (TBT Agreement). The new classification is a trade barrier more restrictive than needed for reaching the desired goal, i.e., protection of human health and safety and protection of the environment. It also does not consider the relevant international standard present, i.e., GHS, and creates adaptation costs which are not aligned with the real toxicity of the product, unjustifiably harming 2-EHA importers, and, in turn, exporters around the globe.

Elekeiroz welcomes all initiatives to strengthen the protection of human health and safety and of the environment, as well as the principles of open trade and transparency. Accordingly, it believes the 2-EHA re-classification is not aligned with such principles. It is an obstacle to trade more restrictive than necessary, and therefore, should be reconsidered by the competent authorities.

Consequently, considering that the most reliable information regarding reproductive toxicity for 2-EHA indicates a less rigid classification for reproductive toxicity, Elekeiroz proposes a postponement of the adoption of the new reproductive toxicity classification for 2-EHA until the competent authorities can analyze the private sectors' comments on the read-across studies, the GHS standards for 2-EHA, and therefore reaffirm Repr. 2 as the adequate reproductive toxicity classification.

Elekeiroz would be grateful if its comments could be considered and replied to, according to WTO procedure.