Published on *The National Law Review* https://natlawreview.com

EU Parallel Trade Permit: Who Has Burden of Proof that Plant Protection Products and Biocides Are Identical?

Article By:

Sabine Naugès

On 15 December 2020, the French administrative court specified who bears the responsibility to prove that two plant protection products are deemed identical, even in their packaging boxes, in the context of submitting an extension of a parallel trade permit.

Gritche, a French cooperative company specialised in the wholesale of chemical products, has been entitled to a parallel trade permit since 13 December 2014. The permit allows it to import a wheat and barley fungicide called “Tipi” from the United Kingdom. On 27 June 2017, the company filed an application for an extension to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) in order to be able to import Tipi from Hungary. The product to be imported under the name “Tipi” holds a marketing authorisation on the Hungarian market under the name “D.” granted to Syngenta AD. Gritche considered that this product D. (which would be imported from Hungary under the Tipi name) was identical to the fungicide D. that Syngenta France SAS is allowed to sell on the French market.

On 31 July 2018, the ANSES reached its conclusions regarding the extension request for Tipi’s trade permit. The ANSES estimated that the active ingredients found in the Hungarian product D. and the one authorised in France under the reference D. had the same origin, and that both products’ composition was identical. However, the ANSES stated that the information at its disposal did not make it possible to ascertain whether the packaging was identical. Thus, the origin extension request of the trade permit had not met the requirements under article 52 of EU regulation No 1107/2009 or under French regulations. The ANSES therefore denied the French cooperative its extension request for the Tipi permit.

On 5 October 2018, the Association of Users and Distributors of Agrochemicals in Europe made an appeal to the administrative court on behalf of Gritche against the ANSES’s refusal.

The administrative court considered that “article 52(3) of EU regulation No 1107/2009 states that Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request.”

However, “Gritche argues that the ANSES failed to observe the provisions under article 52 of the above-mentioned regulation. The claimant states that it cannot be held responsible for missing

information on the packaging boxes since the ANSES should have gathered these information from the Hungarian authorities."

On the other hand, "it follows from some documents in the file that, subsequent to the reception of the application to the permit's extension, the ANSES sent a letter requesting explicit information regarding the packaging's size, volume and type of material for the D. product. Hungary sent the related information to the ANSES, including the packaging box's composition, but did not mention the exact material which had been used, instead only writing "plastic". In response, even without being required to do so, the ANSES sent a letter to the Hungarian authorities asking them to precisely state the plastic material used for the packaging boxes. Their response did not bring any additional information. Considering all these elements, the ANSES did not make any illegal decision by relying only on "the available elements," nor by not registering a new information request under article 52(2) of regulation No 1107/2009."

Contrary to the company's claims, the procedure for granting a parallel trade permit was interrupted from the day the request for information was sent to the competent authority of the Member State of origin. In addition, the company was not able to prove that the materials used in both products were identical or equivalent. The burden of proof is the company's responsibility. By considering all these elements, the ANSES had the right to deny extending the Tipi's parallel trade permit to Hungary, based on article 52 of EU regulation No 1107/2009, and for reasons relating to the safety of human and animal health and the environment.

National Law Review, Volumess XI, Number 41