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Writer's Direct Access
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September 7, 2018

Via Electronic and U.S. Mail

Mr. Tom Inglis
General Manager
Bi-Ax International, Inc.
596 Cedar Avenue
P.O. Box 848
Wingham, Ontario N0G 2W0
Canada

**Re: EU Status of Evlon PLA Film in Food-Contact Applications;
Our File No. BI13632-01**

Dear Mr. Inglis:

The purpose of this letter is to respond to your request for our opinion regarding the status, under the laws and regulations in place in the European Union (EU), of Bi-Ax International, Inc.'s (Bi-Ax) Evlon polylactide (PLA) heat seal and plain films for use in food-contact applications. Specifically, we understand that the Evlon PLA films are coextruded, three-layer structures consisting of a top skin, core, and bottom skin.

Based on the information you have provided regarding the composition of the Evlon PLA films (heat seal and plain), together with the information we received from your suppliers regarding the regulatory status of some of the individual components, it is our opinion that the Evlon PLA films at the maximum thickness described to us, when used in contact with all food types under all temperature conditions, may properly be said to comply with the Plastics Regulation (Commission Regulation (EU) No 10/2011, as amended) and the safety requirement set forth in Article 3.1(a) of the Framework Regulation (Regulation (EC) No 1935/2004), provided that the finished articles in which the Evlon heat seal and plain films are used meet an overall migration limit (OML) of 10 mg/dm², except if the articles are intended for use in holding food to be consumed by infants and young children, in which case the OML may not exceed 60 mg/kg.¹

¹ It is the legal responsibility of the manufacturer of the finished food-contact article to ensure compliance with the OML. Based on worst-case migration calculations, we can confirm
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Our opinion with regard to the marketing and use of the Evlon PLA films in the Netherlands and Spain, *i.e.*, those Member States with applicable “positive lists” for polymer production aids, and Austria, which technically requires pre-market authorization, is based on the principle of mutual recognition. Thus, the Evlon PLA heat seal and plain films should be marketed first in another EU Member State before being imported into Austria, the Netherlands, or Spain.

The Evlon heat seal and plain films contain lactic acid (E 270), which is a dual use additive (*i.e.*, an additive that is also an authorized food additive). Lactic acid is permitted in certain foodstuffs *quantum satis* (meaning it may be used in accordance with good manufacturing practice at a level not exceeding the amount needed to achieve the intended purpose), as well as in meat preparations at a maximum level of 5,000 mg/l.

Finally, we note that it is the responsibility of the manufacturer of the final food-contact material or article in which the Evlon heat seal and plain films are used to ensure that it meets the requirements of Article 3 §1(b) and 3 §1(c) of the Framework Regulation (*i.e.*, it must not bring about an unacceptable change in the composition of the food or a deterioration in the organoleptic characteristics of the food).

We trust that you will find this letter fully responsive to your request for our opinion. Should you have any questions regarding this matter, or if we may be of assistance in any other way, please do not hesitate to contact us.

Cordially yours,



George G. Misko

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that this product complies with all applicable specific migration limits (SMLs) under the Plastics Regulation.