

WRITTEN QUESTION P-3594/03
by Wolfgang Kreissl-Dörfler (PSE)
to the Commission

Subject: Novel Foods Regulation EC No 258/97, marketing of noni products in the EU

Pursuant to Article 1(2)(e) of Regulation EC No 258/97¹, foods and food ingredients consisting of or isolated from plants and obtained by traditional propagating or breeding practices and having a history of safe food use do not fall within the scope of that Regulation. Pursuant to Article 3(4) of the Regulation, a simplified notification procedure as set out in Article 5 of the Regulation applies to foods or food ingredients that are judged to be substantially equivalent to foods or food ingredients already authorised. The EU has authorised the placing on the market by the company Morinda of noni juice as a novel food. For other products produced from noni fruit, however, the basic possibility of their being regarded as substantially equivalent to the authorised juice has to date always been refused.

The costly authorisation procedure under the Regulation prevents small and medium-sized companies from introducing new natural products into the EU. In effect, this creates a monopoly for large groups, as only big companies have sufficient resources to carry out such procedures.

1. According to what criteria is 'having a history of safe food use' defined in this connection, and which institution decides whether a food or food ingredient has a history of safe food use?
2. What legal remedies are available to a distributor seeking to establish that a food or food ingredient has a history of safe food use?
3. What requirements are laid down by the Commission in respect of evidence that a food or food ingredient has a history of safe food use?
4. What legal remedies are available to a distributor where the competent national body referred to in Article 4(3) of the Regulation refuses to deliver an opinion declaring that a food or food ingredient is substantially equivalent to a food already authorised?
5. What is the basis for the EU working party's conclusion that only another juice may be regarded as substantially equivalent to authorised noni juice?

¹ OJ L 43, 14.2.1997, p. 1