

## CLIENT ALERT

### The European Commission Is Not Bound by EFSA's Approval of Food Health Claims

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On March 16, 2016, the General Court of the European Union (the GC) delivered a [judgment](#) (Case T-100/15 – *Dextro Energy v Commission*, not yet available in English) that, despite approval of a food health claim by the European Food Safety Authority (EFSA), the European Commission (the Commission) is entitled under Regulation (EC) 1924/2006 to reject the health claim on the basis of generally accepted scientific advice.

More specifically, the GC upheld the decision of the Commission that health claims related to the beneficial effects of glucose on energy metabolism were ambiguous and misleading, even though scientifically correct, because they encouraged the consumption of sugar contrary to generally accepted scientific advice recommending a reduction in sugar consumption.

#### The Case

The German company Dextro Energy is a manufacturer of energy tablets made almost entirely of glucose sugar. In accordance with the provisions of Regulation (EC) 1924/2006, Dextro Energy requested EFSA approval for the following health claims in relation to its energy tablets:

- **Two claims targeted at the population in general:** that 'glucose is metabolised within the body's normal energy metabolism' and that 'glucose contributes to normal energy-yielding metabolism.'
- **Three claims targeted at healthy men and women well trained for sport activities and endurance:** that 'glucose supports physical activity', that 'glucose contributes to normal energy-yielding metabolism during exercise' and that 'glucose contributes to normal muscle function during exercise.'

The EFSA approved these claims and stated that, on the basis of the information submitted by Dextro Energy, a cause-and-effect relationship had been established between the consumption of glucose and an increase in human energy-yielding metabolism.

However, despite EFSA's approval, the Commission, whose authorization is required pursuant to Regulation (EC) 1924/2006, refused to authorize Dextro Energy's health claims. In particular, in Recital 14 of Regulation 2015/8, the Commission noted that the use of Dextro Energy's "health claim would convey a **conflicting and confusing message to consumers**, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced" (emphasis added). The Commission relied on Article 3 of Regulation 1924/2006, which provides that claims should not be ambiguous or misleading.

Dextro Energy lodged an action with the GC seeking annulment of Regulation 2015/8, and argued that the Commission had erred by disregarding EFSA's prior approval and had infringed the principle of proportionality by not permitting a warning label or dosage restrictions instead of rejecting the health claim.

The GC dismissed Dextro Energy’s action entirely, after finding that Article 18(4) of Regulation 1924/2006 allows the Commission to base its decision on whether or not to authorize a health claim not only on (i) the advice of EFSA but also on (ii) “any relevant provisions of [EU] law **and (iii) other legitimate factors relevant to the matter under consideration.**” The GC found that the Commission has discretionary power to determine the nature and the weight of each of these elements in its assessment. The GC concluded that health claims that highlight only the beneficial effects of glucose for the energy-yielding metabolism are likely to increase the consumption of sugar and, consequently, increase the risks to consumer health caused by the excessive consumption of sugar. As a result, the health benefit claims are ambiguous and misleading even though they are scientifically correct.

The GC also agreed with the Commission’s position that imposing restrictive conditions of use or additional warnings would not be sufficient to alleviate consumer confusion. The GC found that providing warnings or maximum usage levels on a sugar-based product while, at the same time, making health benefit claims, would *per se* be contradictory and would not sufficiently respect the generally accepted nutritional and health principles that focus on reducing sugar consumption.

As a result, scientifically accurate health claims can be rejected notwithstanding EFSA approval if they are inconsistent with generally accepted nutritional and health principles.

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