

**Question for written answer E-003334/2026
to the Commission**
Rule 144
Gerald Hauser (Pfe)

Subject: Termination of the novel food procedure for lithium orotate dihydrate
(NF/2024/30250)

On 27 March 2026, the Commission issued C(2026)1964, terminating the procedure for authorising lithium orotate dihydrate (NF/2024/30250) as a novel food, without updating the Union list. The specific justification for this has not been published on the Commission's website. The information available to us suggests that the procedure was not terminated on the basis of a final scientific assessment, but because the application did not contain the full information requested as regards the identity of the novel food, the production process, the exact composition of the novel food and the scientific evidence demonstrating its safety. In 2025, Aron et al. reported in 'Lithium deficiency and the onset of Alzheimer's disease', *Nature* 645, 712-721, that lithium homeostasis is already disrupted in the human brain in cases of mild cognitive impairment and Alzheimer's. Experimental lithium deficiency exacerbated pathology and cognitive deficits in mouse models of Alzheimer's disease; low-dose lithium orotate prevented or reduced several of these changes.

1. What specific information regarding identity, the production process, composition and safety was deemed to be missing or insufficient?
2. What were the scientific safety concerns – if any – about lithium orotate dihydrate, irrespective of any lack of completeness from a formal or documentation-related point of view?
3. Was the *Nature* paper by Aron et al. ('Lithium deficiency and the onset of Alzheimer's disease') taken into account? If not, is the Commission or EFSA intending to take it into account if the application is resubmitted, in particular the effects of very low doses of lithium orotate in the Alzheimer's mouse model that are reported in the paper?

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