

Dr Andreas Klepsch
European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium

23 November 2007

Reference: NFU 630

Dear Andreas,

Application for the approval of ferric sodium EDTA (Ferrazone®) as a source of iron under the EC Novel Foods Regulation (258/97)

Further to my letter sent to you on 11 September 2006 regarding this application from Akzo Nobel Chemicals GmbH, I am writing to inform you that the company has extended their request to include fortified foods and has provided an updated dossier.

We note that this use requires assessment and authorisation under Regulation EC No.1925/2006. This does not effect our conclusions that this application requires additional assessment, as foreseen in Article 6(3) of the EC Novel Foods Regulation (258/97).

Under our national procedures, this application will be published on the FSA website. Any comments received will be forwarded to you. We understand that the applicant will provide you with a copy of the updated dossier.



We note that the dossier has been amended in the following places to reflect the extended use; sections 1.1.3, 2.6.2, 2.6.3, 2.7.2, and 2.2.3.3.

Also, the applicant has inserted references to a recent JECFA evaluation (section 2.8) and a new clinical study (Table 3.1-1).

Yours sincerely,

(By email)

Dr Sandy Lawrie

Novel Foods, Additives and Supplement Division