

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CHEWING GUM BASE

Issue

Members are asked whether the applicant company's response to their earlier comments and objections to the marketing of REV-7 chewing gum base as a novel food ingredient provide the necessary reassurance that the product meets the necessary criteria for authorisation as a novel food ingredient.

Background

1. The substance REV-7 is a reaction product of the polymers polyisoprene-graft-maleic anhydride (PIP-g-MA) and monomethoxy-polyethylene glycol (MPEG). REV-7 has been developed for use as a component of chewing gum base<sup>1</sup> with a view to making used gum easier to remove from a variety of surfaces. It has been developed solely for incorporation into chewing gum base at levels not exceeding 15%.
2. In April 2009, the European Commission forwarded to Member States the Dutch Competent Authority (CA)'s initial opinion on the application, which had been submitted by Revolymer made under Article 4(1) of Regulation (EC) No 258/97, for the authorisation of REV-7 as a novel food ingredient for use in chewing gum base.
3. The Committee considered the application and the Dutch CA initial opinion by post (ACNFP/94/1/P). Members were unable to agree with the positive opinion of the Dutch CA and concluded that additional information is required before the assessment of the safety of the NI can be concluded. Members raised a number of comments and objections which formed the basis of the UK response to this application (attached at **Annex 1**). Concerns related to a significant underestimation of the consumption of chewing gum (and as a consequence the novel ingredient) and a lack of human studies to determine its fate during transit through the human gastrointestinal (GI) tract. Members also expressed concern that the new ingredient would not be identified on food labels.
4. Members were informed at the September 2009 meeting that the applicant intended to carry out additional work to investigate the fate of ingested chewing

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<sup>1</sup> **Chewing Gum Base** 'is the raw material used in the manufacture of chewing gum and bubble gum, and consists essentially of a mixture of natural/ synthetic gums and resins. The base functions as a primarily inert repository for the sweetening, flavouring and chewing components.

gum base containing REV-7. The applicant indicated that they intended to use a validated *in vitro* model which simulated the environment of the human gastrointestinal tract as they did not expect to be able to obtain ethical approval to carry out an *in vivo* study as this would require subjects to swallow relatively large quantities of chewing gum.

### **Applicant's response**

5. The applicant has now carried out this study and the results, together with their responses to the Committee's other concerns, are attached at **Annex 2** and summarised below.
6. **Intake Assessment** The applicant has acknowledged that their original estimation of chewing gum consumption was based on 'all user' data and as such significantly underestimated consumption levels by consumers of the product. The applicant has provided a revised exposure assessment which indicates that high level consumption is in the region of 6-14g per day, in line with the estimates carried out by the Secretariat (see ACNFP/94/1P). The applicant notes that, even if it is assumed that all chewing gum consumed (up to 14.5 grams/day) were to be swallowed then the results of their 28 day rat feeding study indicates that there would be a 188 fold safety margin for the REV-7 component.
7. **Toxicology** The applicant carried out an additional *in vitro*<sup>2</sup> study to determine the effect of differing environmental stresses that gum containing REV-7 it would encounter during transit through the human GI tract. This study evaluates the visco-elastic properties of chewing gum containing REV-7, compared with a number of commercial chewing gum products, and uses an *in vitro* simulator of the human intestinal microbial ecosystem. The results indicate that there is a widespread variation in the results seen for the different test materials, and that the values for the products containing REV-7 fall within the same range as the commercial products.
8. **Labelling** The applicant has acknowledged that there is no requirement for the labelling of individual components of chewing gum base, but they have indicated that they would support the inclusion of a statement 'with REV-7 ' if it were legally permitted.

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<sup>2</sup> *In vitro* studies in the application dossier modelled conditions in the upper GI tract only.

### **Committee Action Sought**

9. The Committee is asked whether the applicant's responses are sufficient to adequately address their earlier comments and objections.
10. The Committee's comments will be used to inform the Agency's position in future discussions regarding this novel ingredient at meetings of the Standing Committee on the Food Chain and Animal Health.

**Secretariat  
January 2010**

### **Annexes attached:**

- Annex 1** Letter to the Commission with the ACNFP's comments on the Dutch Competent Authority's Initial opinion
- Annex 2** Applicant's response to the UK's comments



**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

Letter to the Commission with the ACNFP's comments on the Dutch Competent Authority's Initial opinion.

Andreas Klepsch  
DG SANCO  
European Commission

29 June 2009

Reference: NFU 741

**Application under (EC) 258/97 for REV-7 Chewing Gum Base**

Dear Mr Klepsch

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report prepared by the Dutch CA for the above product.

We consulted ACNFP members by post and their comments are provided in the attached document. Due to time constraints this document has not been endorsed by the whole Committee. However, it contains sufficient detail to explain that the UK has reasoned objections to the authorisation of this novel ingredient. Our concerns relate to a significant underestimation of the consumption of chewing gum (and as a consequence the novel ingredient) and a lack of human studies which are required to determine its fate during transit through the human gastrointestinal (GI) tract. We are also concerned about the proposal that the new ingredient should not be identified on food labels.

We also note the argument that REV-7 is intrinsically of low concern because it is a large polymer and EFSA has endorsed an earlier view from the Scientific Committee on Food that polymers derived from food contact materials (FCM) with a molecular weight in excess of 1000 daltons are of little toxicological relevance.<sup>3</sup> However, it is important to differentiate between low level migration of polymers into food from FCM and their intentional addition to food at high levels, which will result in regular intake at much higher levels

In view of these comments, the UK would not be able to support the authorisation of REV-7 until these issues have been addressed.

Yours sincerely,  
*(By email only)*

Dr Chris Jones

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<sup>3</sup> [http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Document/CEF\\_note\\_for\\_guidance\\_FCM\\_evaluation\\_2008.08.07.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/CEF_note_for_guidance_FCM_evaluation_2008.08.07.pdf?ssbinary=true)

## **COMMENTS FROM ACNFP MEMBERS**

### **Intake Estimation.**

The applicant's assessment of consumption of chewing gum used poor quality or old data, and significantly underestimated likely average and high level consumption. UK dietary survey data and figures in two recently published EFSA reports give more appropriate estimates<sup>4</sup>. These figures indicate that consumption of chewing gum is 3-4 times higher than the 4.8g/day figure which was proposed by the applicant. Given that children can consume chewing gum, consumption by children who, by kilogram body weight, would be likely to be amongst the highest consumers and may also be more likely to swallow chewing gum to be of particular concern. Consumption in adults is likely to be particularly high in specific sub-groups, including individuals who regularly consume chewing gum when dieting.

### **Safety Studies.**

Although it is accepted that chewing gum is not intended to be swallowed, Members agreed with the Dutch opinion that the assessment of safety cannot assume this to be always the case.

Even when the higher consumption values for chewing gum are used, the available data provide sufficient margin of safety for low molecular weight materials and other potential contaminants that are associated with REV-7. However, it is questionable whether the 28 day sub-chronic toxicity study provides sufficient safety margins when considering the safety of the polymer at the higher levels of consumption. Also, such a study cannot replicate the effect of transit through the human gastrointestinal tract and, although the applicant had carried out two *in vitro* studies to model the conditions in the human upper GI tract, these studies were limited in scope and did not investigate the effect of digestive enzymes and bacterial degradation that may occur elsewhere in the GI tract and under different pH conditions.

The absence of such data is a particular cause for concern because REV-7 is a novel polymer that has not been consumed elsewhere in the world and has been developed specifically so that the gum exhibits different adhesion properties to existing products. It is necessary to consider the effect of the differing environmental stresses that it will encounter during passage through the entire human GI tract. It is possible that some of these may alter the visco-elastic nature of the polymer leading to an increased risk of intestinal obstruction, particularly in children. There also needs to be reassurance that the consumption of REV-7 does not affect the digestion or absorption of any nutrients or other bioactive components of food.

### **Labelling.**

Although current food labelling legislation does not require that individual components of chewing gum base are identified, Members were of the view that as REV-7 is a novel food ingredient component with no understanding of the effect of prolonged use, it should be clearly identified in the list of ingredients.

**ACNFP June 2009**

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<sup>4</sup> Additional information on this aspects is detailed in Paragraphs 17 – 23 of Committee paper ACNFP/94P/1, available at <http://www.acnfp.gov.uk/meetings/acnfpmeet09/acnfp02jul09/acnfpagendajul09>

**Annex 2 to ACNFP/96/5**

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

Applicant's response to the UK's comments

**Secretariat  
January 2010**