Superior Health Council

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Novel food ingredients: oils rich in conjugated linoleic acid in food

6 juli 2011

1. INTRODUCTION AND REQUEST

This request for advice was submitted by the Federal Public Service Public Health, Food Chain Safety and Environment (DG 4).
It concerns the opinions issued by the EFSA on two dossiers pertaining to requests for authorisation to market Clarinol® and Tonalin® TG80, i.e. oils that are rich in conjugated linoleic acids (CLA) and are intended for use as an ingredient in different types of food, especially fruit juices, cereals and milk preparations. The recognition as a "novel food ingredient" was requested under Regulation (EC) No. 258/97. CLAs are unsaturated fatty acids, but contain a double trans and a double cis bond.

These two oils are rich (>74 %) in c9t11 and t10c12 CLA isomers (present in comparable concentrations). They were marketed before 1997. However, a safety approval is required in order to use them as an ingredient in food that is commonly consumed. The target market are adults who wish to avoid gaining or wish to lose (truncal) excess weight. The overall intake suggested by the firms is 3 to 3.5 g of the CLA-mixture.

In Spain, CLA has been approved since 2004-2005 as an ingredient in liquid yoghurts, milk, cheese and orange juice.

A first assessment regarding Clarinol was submitted on 9 May 2008 by the *Food Safety Authority of Ireland* (FSAI). It issued a positive opinion, provided that the label mention certain warnings aimed at limiting the intake of this product by children and pregnant and breastfeeding women.

A second assessment was made by the Dutch VNV (*Veiligheidsbeoordeling Nieuwe Voedingsmiddelen*) commission (30 September 2008). It backed the conclusions drawn by the FSAI.

The EFSA *Panel on Dietetic Products, Nutrition and Allergies* (NDA) suggested that the authorisation to market the product be granted for consumption periods up to 6 months, but that the label should mention that it is not recommended for individuals with type 2 diabetes, who will require medical supervision (EFSA, 2010a). The EFSA plans to carry out a new assessment by 2015 of the information provided by the firms on the quantities consumed and potential adverse effects for consumption periods over 6 months.

An "open consultation" carried out by the NHFS working group of the SHC raised a few issues that could result in a more qualified and less positive opinion on these dossiers.

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It should be noted that the *Food Standards Australia New Zealand* (FSANZ) recently published an assessment (13 May 2011) in which it concludes that the potential risks linked to consuming Tonalin TG80 outbalance the potential benefits. As a result, this advisory report recommends that the authorisation to market Tonalin as a novel food and to use it as an ingredient in preparations intended for overweight individuals should be denied. This decision was justified by e.g. the potentially increased cardio-vascular risk as well as the risk of developing or worsening diabetes.

The following questions still need to be addressed:

- Do the opinions of the EFSA contain all the known scientific elements on the public health effects of CLA?
- What are the risks involved in consuming CLA used as an ingredient in various types of food at the suggested dose?
- Are the different restrictive measures proposed in the draft Commission Decisions (food categories, dose, post-marketing monitoring plan) sufficient to limit the risks?

In order to respond to this request, the permanent NHFS (Nutrition and Health, including Food Safety) working group was tasked with this dossier.

2. ADVICE

The two dossiers (regarding Clarinol and Tonalin TG80) are very similar and the draft Decision proposed by the Commission on the basis of the scientific assessment made by the NDA Panel of the EFSA is the same for both of them.
Though this advisory report is mainly concerned with assessing the potential adverse effects of CLA-rich oils, an analysis of the potential benefit/potential risk ratio such as that carried out by the *Food Standards Australia New Zealand* (FSANZ) is fully relevant. As regards the benefits, two meta-analyses (Whigham LD et al, 2007 ; FSANZ, 2011) as well as a review of the recent scientific literature do not find that these products are highly effective in reducing the intra-abdominal fat mass in humans (Gaullier JM et al, 2007 ; Watras AC et al, 2007 ; Larsen TM et al, 2006 ; Norris LE et al, 2009). In actual fact, the NDA Panel of the EFSA refused to authorise the following health claims for the CLA isomers: maintenance or achievement of a normal body weight, increase in lean body mass, increase in insulin sensitivity, protection of DNA, proteins and lipids from oxidative damage, and contribution to immune defences by stimulation of production of protective antibodies in response to vaccination (EFSA, 2010b).

The NHFS working group wishes to draw attention to the following issues:

1) Both oils contain comparable ratios (~1 :1) of the two CLA isomers c9t11 and t10c12. The former is commonly ingested in dairy products and ruminant meat, whereas only minimal amounts of the latter are naturally found in food. This (1 :1) mixture supplementation therefore results in a much more significant increase in the average relative intake of t10c12 than of c9t11.
2) The literature suggests that these two isomers do not have similar metabolic effects. Indeed, when these two isomers are administered on their own at relatively high doses, the t10c12 isomer can lead to more metabolic complications (insulin resistance and impaired carbohydrate regulation) than the c9t11 isomer (Tricon S et al, 2004 ; Tricon S et al, 2005 ; Toomey S et al, 2006).
3) Consuming CLAs (polysunsaturated fatty acids) at high doses (20g/day) for 3 weeks can increase the LDL-/HDL-cholesterol ratio (Wanders AJ et al, 2010), which is a significant cardiovascular risk factor. A recent analysis of all good-quality intervention studies has revealed that the effect on the LDL/HDL-cholesterol ratio is almost as marked for the (1:1) CLA isomer mixture as it is for monounsaturated trans fatty acids produced by the

industry. It also shows that no clear threshold has been identified under which its intake does not appear to have this effect (Brouwer IA et al, 2010). The LDL-/HDL-cholesterol ratio increase caused by a CLA supplementation of 3 g/day, i.e. the recommended dose that is suggested to have a positive effect on the body composition, could amount to a 3 to 12 % increase in the cardiovascular risk.

4) Studies among diabetic subjects find alterations in the carbohydrate regulation, which are not out-balanced by any other positive effects. Reviews of human studies usually advise caution, especially as regards individuals with risk factors for diabetes and cardio-vascular disorders (Salas-Salvado J et al, 2006). These aspects, which were highlighted in the EFSA assessment (2010a), raise particular concern in view of the proportion of individuals at risk of developing diabetes or with undiagnosed diabetes (Dunstan DW et al, 2002).
5) Increased blood and urinary concentrations of F2-isoprostanes were reported in healthy or overweight individuals who received 4.2 or 4.5 g/day CLA supplementation for 12 weeks (Iannone A et al, 2009). Other studies confirm these data, which they attribute to the t10c12 isomer, and show an increase in the biological markers of inflammation (Smedman A et al, 2005). Though the higher isoprostane concentrations are usually considered to reflect increased oxidative stress, they could also result from a slower catabolism.
6) These products are aimed at individuals suffering from excess weight, yet the recommended intake (3 to 4,5 g/day) amounts to an additional intake of 30 to > 40 kcal/day. Whilst this may appear to be a low energy supplement compared to the overall intake, a simple calculation shows that it may be linked to a weight increase of approximately 1.2 to 1.6 kg after one year, which is not insignificant.

In conclusion, the opinion of the NDA panel of the EFSA does not appear to take sufficiently into account recent studies that show that the CLA Novel Food may have adverse effects in humans, especially an increased cardio-vascular risk and altered glucose homeostasis in overweight individuals, who are in fact their target market.

In this context, it is not possible to set safe intake limits. As a result, the SHC takes the view that CLA-enriched products cannot be authorised.

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3. FURTHER DETAILS AND ARGUMENTATION

List of abbreviations used

CLA : Conjugated linoleic acid
DNA: Deoxyribonucleic acid
EFSA: European Food Safety Authority
FSAI : Food Safety Authority of Ireland
FSANZ : Food Standards Australia New Zealand
HDL : High density lipoprotein
LDL : Low density lipoprotein
NDA: Dietetic Products, Nutrition and Allergies
NHFS : Nutrition and Health, including Food Safety
SHC : Superior Health Council

3.1 Methodology

This advisory report is based on an analysis of the dossier provided by the applicant firm, but also on a critical review of the scientific and gray literature as well as on the examination of various expert reports.

3.2 Further details

Based on the opinions issued by the EFSA *Panel on Dietetic Products, Nutrition and Allergies* (NDA), the Commission proposed draft Decisions on two dossiers pertaining to requests for authorisation to market CLA-rich oils intended for use as an ingredient in various types of food (especially fruit juices, cereals and milk preparations), as well as their recognition as a "Novel Food Ingredient".

The two dossiers were submitted by the firm Cognis Deutschland GmbH & Co KG (one directly, the other indirectly). They apply for recognition of the Tonalin® TG 80 and Clarinol® preparations as new ingredients to be used in a series of foodstuffs under Regulation EC No. 258/97 : milk- or fermented-milk based beverages, soy milk, yoghurt-based products.

Clarinol and Tonalin TG80 are two CLA-rich oils (> 74 %) that contain comparable ratios of the two isomers c9t11 and t10c12. They were marketed before 1997 but a safety approval is required in order to use them as an ingredient in food that is commonly consumed.
The target market are adults who wish to lose or avoid gaining excess weight, especially a truncal fat mass accumulation. The overall daily intake suggested by the firms is 3 to 3.5 g of the CLA-mixture, which amounts to 4.5 g/day for Tonalin and 3.75 g/day for Clarinol.

The Commission suggests that the products be recognised as “novel food ingredients” that may be used in food. It requires the firm Cognis Deutschland GmbH & Co KG to mention on the label that diabetic individuals need medical supervision; the firm Cognis should also set up an information programme on the amounts of CLA provided to their European customers and the quantities ingested in the various types of food and produce assessments on the potential adverse effects linked to consuming this preparation for over 6 months. The EFSA is believed to plan a new assessment of the information provided by the firm by 2015, which will enable the Commission to issue a new opinion on this subject by 2016 at the latest.

In Spain, CLA has been approved since 2004-2005 as an ingredient in liquid yoghurts, milk, cheese and orange juice.

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A first assessment on Clarinol was submitted on 9 May 2008 by the *Food Safety Authority of Ireland* (FSAI). It issued a positive opinion, provided that the label mention certain warnings aimed at limiting the intake of this product by children and pregnant and breastfeeding women.
A second assessment was made by the Dutch VNV (*Veiligheidsbeoordeling Nieuwe Voedingsmiddelen*) commission (30 September 2008). It backed the conclusions drawn by the FSAI (21 August 2008).

However, the *Food Standards Australia New Zealand* (FSANZ) recently published an assessment which goes in the opposite direction, concluding that the potential benefits (low weight loss, low loss of or redistributed fat mass) linked to the use of Tonalin are outbalanced by the potential risks due to an increased cardio-vascular risk and a higher risk of developing or worsening type 2 diabetes. It refused to grant the authorisation to market Tonalin as a novel food and to use it as an ingredient in preparations intended for overweight individuals. The FSANZ also did not believe that this risk could be modulated by reducing the intake of the CLA-mixture to an acceptable level, as the suggested benefit can only be obtained at the dose recommended by the applicant firm.
This analysis of the potential benefits/potential risks ratio is interesting and goes beyond a strict assessment of the potential adverse effects of CLA-rich oils.
It is therefore important to emphasise that the recent scientific literature finds that these CLA isomer mixture products are effective to a limited extent only (at best!) in reducing the fat mass in humans and that, in all likelihood, it has no such effect on intra-abdominal fat. The supplementation studies have yielded conflicting results, yet there are two meta-analyses that suggest that there is a moderate effect on the fat mass and that, strangely, this effect is not linked to any improved insulin action, on the contrary. Finally, whether or not including CLA-rich oils in food is at all effective remains unknown. In this respect, the NDA Panel of the EFSA refused to authorise the following health claims for the CLA isomers: maintenance or achievement of a normal body weight, increase in lean body mass, increase in insulin sensitivity, protection of DNA, proteins and lipids from oxidative damage, and contribution to immune defences by stimulation of production of protective antibodies in response to vaccination.

Chemical and toxicological safety, safety from bacterial contamination:
As regards these different user safety issues, the data provided in the dossier seem reassuring.

Potential adverse effects:
Older publications suggest that consuming the CLA isomer t10c12 (virtually absent from common diets) has significantly more adverse effects than consuming the c9t11 isomer, which is naturally found in milk and ruminant meat. Consuming oils that contain these 2 industrially produced isomers results in a much more substantial increase in the relative intake of t10c12.

1. Plasma lipoproteins

Two recent publications from the same Dutch group (Wanders et al., 2010 ; Brouwer et al., 2010) analyse the impact of consuming CLA-mixtures on the profile of cholesterol-rich lipoproteins in humans. The first study compares the effects of consuming 20 g/day of a CLA-mixture (80 % c9t11 and 20 % t10c12) for 3 weeks on the one hand and those of consuming industrial trans fatty acids on the other, with the same intake of oleic acid (control). As it turns out, the trans fatty acids increase the LDL-/HDL-cholesterol ratio by 11%, whereas the CLA-mixture leads to a 10 % increase of this ratio. The second study compares the effect on the LDL-/HDL- cholesterol ratio of consuming smaller amounts of industrial trans fatty acids and CLA for a lengthy period of time with that of consuming oleic acid, based on all the serious studies available. If we exclude the study mentioned above and only consider those using a (~1 :1) mixture of the 2 CLA isomers, the increase in LDL-cholesterol and the decline in HDL-cholesterol are comparable to those observed with industrial trans fatty acids. The increased LDL-/HDL-cholesterol ratio amounts to a 3 to 12% increase in the cardio-vascular risk and there does not seem to be any threshold under which their intake does not lead to any observable alterations in the lipoproteins. These results are in

keeping with those of the FSANZ group, which estimates that the increase in the cardio-vascular risk linked to the 3.5 g/day intake of CLA in the form of Tonalin amounts to 5%.

2. Glucose homeostasis

Eight studies have been published which measure the effects of supplementation with a (~1 :1) mixture of CLA isomers on the markers of glucose homeostasis. These studies do not allow to conclude that supplementation has any positive effect on glucose homeostasis, as would have been expected as a result of the reduced fat mass. On the contrary, there are studies which raise the question whether it may have an adverse effect on the general population: one of them in particular shows a rise in proinsulin and an increased proinsulin/insulin ratio, which are two markers that are considered to be linked to the risk of developing diabetes and to a cardio-vascular risk.
Two studies involving diabetes patients show that it has a significant adverse effect on glucose homeostasis, which suggests that the intake of CLA entails a risk for these patients.

3. Inflammation and oxidation markers

Whilst the dossier submitted by the applicant firm suggests that there may be an anti-inflammatory effect, human studies show elevated plasma and urinary concentrations of F2-isoprostanes: these are lipid peroxidation markers that are indicative of oxidative stress. In addition, two other studies report an increase in some markers of subclinical inflammation.
As mentioned above, the NDA Panel of the EFSA did not respond favourably to the request for authorisation to use the claim that CLA-rich oils have an anti-inflammatory effect.

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5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group ***in a private capacity***. The names of the members and experts of the Superior Health Council are indicated with an asterisk*.

The following experts were involved in drawing up this advisory report:

BRASSEUR Daniel *	Paediatric nutrition	ULB
CARPENTIER Yvon *	Nutrition, pathological biochemistry	ULB
DE BACKER Guy *	Preventive medicine, public health, epidemiology	UGent
FONDU Michel	Chemistry, additives, contaminants	ULB
MAGHUIN-ROGISTER Guy *	Foodstuff analysis	ULg
MERTENS Birgit	Toxicology, novel foods	ISP
PAQUOT Michel *	Chemistry, technology	Gembloux Agro-Bio Tech
PUSSEMIER Luc *	Residues and contaminants, chemical risks	CERVA
RIGO Jacques *	Paediatric nutrition	ULg

The Administration was represented by:

RADEMAKERS Eline	*Novel foods*	FPS Public Health, DG4

This working group was chaired by Mr. Yvon CARPENTIER, the scientific secretaries were Ms. Liesbeth PEETERS and Ms. Michèle ULENS

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Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, a referring committee) and 4) the final endorsement of the advisory reports by the Board (ultimate decision-making body). This coherent set of procedures aims at allowing the SHC to issue advisory reports based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

These advisory reports are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

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