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Scientific Opinion on the substantiation of a health claim related to Equazen eye q® , a combination of EPA, DHA and GLA, and improving reading ability pursuant to Article 14 of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Equazen eye q[®], a combination of EPA, DHA and GLA, and improving reading ability pursuant to Article 14 of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Vifor Ltd, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Equazen eye q[®] and improving reading ability. The Panel considers that Equazen eye q[®], a combination of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and gamma-linolenic acid (GLA) (at a weight ratio of 9:3:1), which is the subject of the health claim, is sufficiently characterised. Improving reading ability is a beneficial physiological effect. The applicant provided four human intervention studies that investigated the effect of Equazen eye q[®] on reading ability in children. No conclusions can be drawn from three of these studies for the scientific substantiation of the claim. The fourth study does not show an effect of Equazen eye q[®] consumed daily over a period of 20 school weeks, on reading ability in children aged 3–13 years. The Panel concludes that a cause and effect relationship has not been established between the consumption of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children.

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KEY WORDS

Equazen eye q[®], eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), gamma-linolenic acid (GLA), reading ability, children, health claims

¹ On request from the Competent Authority of the United Kingdom following an application by Vifor Ltd, Question No EFSA-Q-2014-00462, adopted on 23 September 2015.

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SUMMARY

Following an application from Vifor Ltd, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Equazen eye q[®] and improving reading ability.

The scope of the application was proposed to fall under a health claim referring to children's development and health. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is Equazen eye q[®], a combination of the n-3 polyunsaturated fatty acids (PUFAs) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), and the n-6 PUFA gamma-linolenic acid (GLA), at a weight ratio of 9:3:1 (EPA:DHA:GLA). EPA and DHA are derived from natural or highly concentrated fish oils, whereas GLA is derived from evening primrose seed oil. EPA, DHA and GLA are well-recognised nutrients, which can be measured in foods by established methods. The Panel considers that Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), is sufficiently characterised.

The claimed effect proposed by the applicant is 'improvement in reading ability'. The target population proposed by the applicant is healthy children from 3 to 13 years of age. The Panel considers that improving reading ability is a beneficial physiological effect.

The applicant provided four human intervention studies that investigated the effect of Equazen eye q[®] on reading ability in children.

The Panel considers that no conclusions can be drawn for the scientific substantiation of the claim from three of the provided studies, owing to different reasons (i.e. uncontrolled design, lack of testing for multiplicity of outcomes, interaction between intervention and schools on reading ability not addressed in the statistical analysis).

In the fourth study, which was a double-blind, placebo-controlled parallel intervention, children were randomised to consume Equazen eye q[®] or placebo for 20 school weeks. Reading ability in children was measured using the Wide Range Achievement Test: Fourth Edition. This study does not show an effect of Equazen eye q[®] consumed daily over a period of 20 school weeks, on reading ability in children aged 3–13 years.

The Panel notes that, in the absence of evidence for an effect of Equazen eye q[®] on reading ability in children, studies on potential mechanisms by which Equazen eye q[®] could exert the claimed effect cannot be used in supporting the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 20/06/2014.
- The scope of the application was proposed to fall under a health claim referring to children's development and health. The application included a request for the protection of proprietary data.
- On 21/07/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 25/07/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 31/07/2014.
- On 15/10/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and the scientific evaluation was suspended on 23/10/2014, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 21/11/2014, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 22/01/2015, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and the scientific evaluation was suspended on 10/02/2015, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 09/04/2015, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 06/05/2015, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and the scientific evaluation was suspended on 11/05/2015, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- On 07/07/2015, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

- During its meeting on 23/09/2015, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Equazen eye q[®] and improving reading ability in children.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: Equazen eye q[®] and improving reading ability.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Equazen eye q[®], a positive assessment of its safety, nor a decision on whether Equazen eye q[®] is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Vifor Ltd, Route de Moncor 10, P.O. Box, CH-1752 Villars-sur-Glâne, Switzerland.

The application includes a request for the protection of proprietary data for three unpublished study reports (Portwood et al., 2005; Balfour et al., 2013; Johnson, 2014).

Food/constituent as stated by the applicant

According to the applicant, Equazen eye q[®] is the food that is the subject of the health claim. Equazen eye q[®] contains a combination of omega-3 and omega-6 polyunsaturated fatty acids: eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and gamma-linolenic acid (GLA) at a ratio of 9:3:1 (EPA:DHA:GLA).

Health relationship as claimed by the applicant

According to the applicant, the claimed effect concerns improvement in reading ability and related cognitive functions. The primary outcome measurement to assess reading ability in the pivotal pertinent study was the LOGOS test battery. Other measurements used to evaluate reading performance were the Wechsler Objective Reading Dimensions and the Wide Range Achievement Test: Fourth Edition. Each of these tests assessed skills related to decoding and/or linguistic comprehension. In addition, the culture-free Draw-A-Person test was used to assess non-verbal cognitive skills in Aboriginal Australian children whose native language was not English.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'Equazen eye q[®] (composition of EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability and related cognitive functions in children'.

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is healthy children from 2 to 18 years of age.

According to the applicant, to obtain the claimed effect, healthy children should receive the recommended daily dosage of Equazen eye q[®] providing 558 mg EPA, 174 mg DHA and 60 mg GLA. Such an amount may be consumed in a balanced diet that includes sufficient oily fish and certain vegetable oils.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Equazen eye q[®], a combination of the n-3 polyunsaturated fatty acids (PUFAs) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), and the n-6 PUFA gamma-linolenic acid (GLA), at a weight ratio of 9:3:1 (EPA:DHA:GLA). EPA and DHA are derived from natural or highly concentrated fish oils (EPA from sardine, mackerel and anchovy oils; DHA from anchovy, sardine and tuna oils). GLA is derived from evening primrose (*Oenothera biennis*) seed oil.

Equazen eye q[®] is presented in different formulations:

- capsules or chewable capsules: 93 mg EPA, 29 mg DHA, 10 mg GLA per capsule;
- triple strength capsules: 279 mg EPA, 87 mg DHA, 30 mg GLA per capsule;
- liquid formulation: 186 mg EPA, 58 mg DHA, 20 mg GLA per 5 ml.

EPA, DHA and GLA are well-recognised nutrients, which can be measured in foods by established methods.

The Panel considers that Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is ‘improvement in reading ability and related cognitive functions’. Upon a request by EFSA for clarification of the claimed effect, the applicant indicated that the claimed effect is ‘improvement in reading ability’. Upon a request by EFSA for clarification of the target population, the applicant indicated that the target population is healthy children from 3 to 13 years of age.

The following tests have been proposed by the applicant to assess reading ability in children: LOGOS test, Wechsler Objective Reading Dimensions (WORD), Wide Range Achievement Test: Fourth Edition (WRAT4) and the Draw-A-Person (DAP) test.

The Panel considers that the WORD and WRAT4 tests are appropriate for assessing reading ability in children, whereas the DAP test does not measure reading ability. Upon a request by EFSA for clarification of the LOGOS test, the applicant provided information on how this test was validated in children, how it compares to the WORD and WRAT4 tests and a list of studies that used the LOGOS test to assess reading ability in children. The Panel considers that the following subtests of LOGOS, comprising 17 subtests on several domains, are appropriate to assess reading ability in children: reading speed, reading comprehension, phonologic reading time, phonologic reading number correct, orthographic reading time, and orthographic reading number correct.

The Panel considers that improving reading ability is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed to identify intervention studies on an effect of EPA, DHA and GLA on reading ability, learning, and other related cognitive functions in children. The following combination of key words was used: (human clinical trial AND (polyunsaturated fatty acids OR fish oil) AND children AND (reading OR cognition OR learning) NOT (infant)). The following exclusion criteria were applied to the search strategy: studies in children younger than 2 years of age or in adults; non-fish oil sources of DHA; subjects with a history of attention deficit hyperactivity disorder (ADHD), dyslexia, dyspraxia and/or major physical or mental conditions such as epilepsy, diabetes mellitus, depression, chronic fatigue syndrome, autism or retardation, or medication use for any of these conditions.

The applicant provided four human intervention studies (Portwood et al., unpublished, 2005; Sinn et al., 2011; Parletta et al., 2013; Johnson, unpublished, 2014), which investigated the effect of Equazen eye q[®] on reading ability in children by using appropriate tests for this outcome measure (i.e. WORD, WRAT and LOGOS tests).

In the single-arm, uncontrolled study by Sinn et al. (2011), 47 children aged 3–14 years consumed Equazen eye q[®] for 12 weeks and were assessed for their reading ability using the WRAT test. The Panel considers that no conclusions can be drawn from this single-arm, uncontrolled study for the scientific substantiation of the claim.

The unpublished study by Portwood et al. (2005) is a randomised, double-blind, placebo-controlled parallel intervention that investigated the effect of Equazen eye q[®] on reading ability in children aged 6–12 years. A total of 241 children from seven primary schools in Middlesbrough (UK) were randomised to consume daily six capsules of Equazen eye q[®] (n = 120) or a control oil (n = 121; olive oil) for 3 months. In the following 3 months, all participants consumed Equazen eye q[®]. The Panel notes that no conclusions can be drawn from the second 3-month, uncontrolled, phase of this study for the scientific substantiation of the claim. Subjects were excluded if they consumed fatty acid supplements 3 months before taking part in the study, or if they had significant neurological, psychiatric or medical problems, including ADHD or autism.

At baseline and at 3 months, children underwent the WORD test, among other tests (i.e. Wechsler Intelligence Scale for Children digit span subtest, Conners' Parent Rating Scales—Long Version, and Conners' Teacher Rating Scales-Long Version). Upon a request by EFSA for clarification on how the WORD test was administered, the applicant indicated that children completed the 'basic reading' and 'spelling' subtests of the WORD test under the supervision of a practitioner. The same practitioner also evaluated the results of these subtests.

The primary outcomes of the study were between-group differences in 'reading age' and 'working memory' changes over 3 months. 'Reading age' is the average level of reading ability achieved by children of a particular age. 'Reading age' indicates delayed or improved reading ability when it differs from children's chronological age. A sample size of 250 children was chosen, based on the sample size calculation of another study (Richardson and Montgomery, 2005), to detect a difference of four 4 in mean 'reading age' between groups, with 80 % power and an α -level of 0.05.

Upon a request by EFSA for clarification on how potential confounding factors were handled, the applicant indicated that supplementation with fatty acids was an exclusion criterion, that participants came from a variety of socioeconomic and ethnic backgrounds and that none of the differences seen at baseline between groups (e.g. mean age, possible signs of fatty acid deficiency, reading and digit span score) was found to be statistically significant or of clinical relevance.

A total of seven children withdrew from the study, as they were unable to take the capsules (n = 2 in the intervention group) or did not wish to continue the study (n = 4 in the intervention and n = 1 in the control groups). The compliance, which was checked by counting the remaining capsules and by record forms completed by teachers and parents, was 93.1 % and 91.4 % in the control and intervention groups, respectively.

Between-group differences in 'reading age' changes during the study were tested by using a t-test for independent samples. The mean increase in 'reading age' was significantly higher in the intervention group than in the control group in children with available data on 'reading age' (n = 109 in the intervention and n = 111 in the placebo groups). Following a request by EFSA for clarification, the applicant provided an additional analysis of the results of the WORD test by using the ANCOVA test with baseline WORD scores as covariate. The Panel notes that this analysis of the WORD test indicated an interaction between intervention and schools on reading ability. The Panel notes that the interaction between intervention and schools was not addressed in the statistical analysis or taken into account in the interpretation of the results. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The unpublished study by Johnson (2014) is a randomised, double-blind, placebo-controlled parallel intervention that investigated the effect of Equazen eye q[®] on reading ability in school children aged 9–10 years. A total of 154 children were randomised to consume daily two capsules of Equazen eye q[®] (n = 78) or a control oil (n = 76; palm oil) for 3 months. In the following 3 months, all participants consumed Equazen eye q[®]. The Panel notes that no conclusions can be drawn from the second 3-month (uncontrolled) phase of the study in relation to the claimed effect. Subjects were excluded if they consumed n-3 or n-6 PUFA supplements for more than 1 month in the previous year, if they were

diagnosed with ADHD or if they used ‘psychoactive’ medications. At screening, baseline and 3-month visits, children performed the LOGOS test battery with a psychologist or a special education teacher. Children were also assessed for ADHD symptoms through the ADHD-Rating Scale-IV, which comprised the 18 symptom criteria for ADHD from the diagnostic criteria of Diagnostic and Statistical Manual, Fourth Edition. Upon a request by EFSA for clarification on the number of children with or without ADHD symptoms, the applicant indicated that none of the participants had ADHD symptoms.

Upon a request by EFSA for clarification of the outcome measures on which the calculation of the sample size was based, the applicant indicated that a sample size of 90 or 118 would be needed to detect a Cohen’s medium effect size of 0.6 for any of the LOGOS subtests, at an α -level of 0.05 and a power of 0.80 or 0.90, respectively.

A total of 32 children ($n = 14$ in the intervention group and $n = 18$ in the control group) dropped out, mainly because of difficulties in swallowing capsules. Compliance (93 % overall) was assessed at each visit and through interviews in biweekly telephone calls with the parents.

Upon a request by EFSA for clarification on how potential confounding factors were handled, the applicant indicated that the background diet was recorded by questionnaires at baseline and at month 3, that there was no need to control for the children’s socioeconomic status, as they were from the same area, and that the randomisation would minimise the effect of confounding factors.

Statistical analyses of the results of the LOGOS test were carried out by using Wilcoxon two-sample tests.

During the evaluation procedure, EFSA requested that the applicant provide a statistical analysis of the LOGOS test for the intention-to-treat (ITT) and the per-protocol (PP) populations, taking into account the multiplicity of outcomes. In reply, the applicant provided a principal component analysis of the results of 13 subtests of the LOGOS test, which does not take into account the multiplicity of outcomes. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The study by Parletta et al. (2013) is a randomised, double-blind, placebo-controlled parallel intervention that investigated the effect of Equazen eye q[®] on reading ability in children (3–13 years old) from four schools in Northern Territory (Australia). Children with completed ‘initial baseline assessment’, which consisted of the DAP test, WRAT4 test and Conners’ Behaviours Rating scales for teachers, were enrolled in this study. A total of 408 children were randomised to consume daily six capsules of Equazen eye q[®] ($n = 206$) or a control oil ($n = 202$; palm oil) on school days for 20 school weeks. In the following 20 school weeks, all participants consumed Equazen eye q[®]. The Panel notes that no conclusions can be drawn from the second 20-week (uncontrolled) phase of the study in relation to the claimed effect.

Literacy (reading and spelling) and cognitive development, which were the primary outcomes of this study, were assessed at baseline and at week 20 through the WRAT4 test and the DAP test, which were run by multiple assessors who were trained and given a verbatim protocol. A minimum of 60 subjects per group was calculated through the Cohen’s power analyses to detect a Cohen’s medium effect size of 0.5 for the primary outcomes. Upon a request by EFSA for clarification on the reason for enrolling a greater number of participants than those calculated to be required, the applicant indicated that all children who were willing to participate in this study were given this opportunity.

At baseline, the reading standardised scores for children older than 5 years ($n = 394$) were not different between the intervention and control groups.

A total of 98 children ($n = 59$ in the intervention group and $n = 39$ in the control group) dropped out mainly because they left schools or because of difficulties in swallowing capsules. Compliance was

assessed by a teaching assistant who ticked off the names of children who received the study products before morning recess.

Statistical analyses were carried out by using generalised linear mixed modelling. No effect of the treatment was observed on reading or spelling in the ITT or PP populations (i.e. children who took 200 or more capsules).

The Panel considers that this study does not show an effect of Equazen eye q[®] consumed daily over a period of 20 school weeks, on reading ability in children aged 3–13 years.

The applicant provided two human intervention studies, one animal and one *in vitro* study in support of a mechanism by which Equazen eye q[®] could exert the claimed effect.

The Panel notes that, in the absence of evidence for an effect of Equazen eye q[®] on reading ability in children, human studies, animal studies and *in vitro* studies on potential mechanisms by which Equazen eye q[®] could exert the claimed effect cannot be used in supporting the scientific substantiation of the claim.

Weighing of the evidence

The Panel took into account that one human intervention study does not show an effect of Equazen eye q[®] consumed daily over a period of 20 school weeks, on reading ability in children aged 3–13 years.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is ‘improvement in reading ability’. The target population proposed by the applicant is healthy children from 3 to 13 years of age. Improving reading ability is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children.

DOCUMENTATION PROVIDED TO EFSA

1. Health claim application on Equazen eye q[®] and improving reading ability pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0419_UK). June 2014. Submitted by Vifor Ltd.

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ABBREVIATIONS

ADHD	attention-deficit-hyperactivity disorder
DAP	Draw-A-Person
DHA	docosahexaenoic acid
EPA	eicosapentaenoic acid
GLA	gamma-linolenic acid
ITT	intention-to-treat population
PP	per protocol population
PUFAs	polyunsaturated fatty acids
WRAT4	Wide Range Achievement Test: Fourth Edition
WORD	Wechsler Objective Reading Dimensions