



Risikovurdering af hyaluronsyre (produceret via fermentering) i kosttilskud

Poulsen, Morten

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Fødevarestyrelsen
Kemi og Fødevarekvalitet
Stationsparken 31-33
2600 Glostrup

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Risikovurdering af hyaluronsyre (produceret via fermentering) i kosttilskud

Bestilling

DTU Fødevareinstituttet er af Fødevarestyrelsen, Kemi og Fødevarekvalitet, blevet bedt om at foretage en risikovurdering af hyaluronsyre (fermenteret af *Streptococcus equisubsp. Zooepidemicus*) i kosttilskud.

Der er tale om en ny kilde til hyaluronsyre end den, der allerede er godkendt i Danmark.

Virksomheden oplyser i sin ansøgning, at der er tale om en tilsætning af 64 mg hyaluronsyre pr. anbefalet daglig dosis.

DTU bedes undtage aldersgruppen 0-12 år i vurderingen.

Konklusion

DTU Fødevareinstituttet vurderer at indtag (64 mg pr. anbefalet daglig dosis) af hyaluronsyre, fermenteret af *Streptococcus equisubsp. Zooepidemicus*, i kosttilskud ikke udgør en sundhedsmæssig risiko.

Baggrund og Vurdering

The hyaluronic acid in the present application is obtained from fermentation by *Streptococcus equisubsp. Zooepidemicus*, and is thereby considered as a new source of hyaluronic acid in Denmark. Hyaluronic acid is a non-sulphated glycosaminoglycan. Its basic unit is a disaccharide of D-glucuronic acid and N-acetyl-D-glucosamine linked by a β -1,3-glycosidic bond; these disaccharides are polymerized via β -1,4-glycosidic bonds. Due to the

nature of these bonds, hyaluronic acid will most likely only be digested to a limited extent by the human enzymes in the upper tract.

In 2013 hyaluronic acid was assessed by EFSA as a constituent from rooster combs and rooster comb extract (RCE).

The risk assessment from EFSA concluded that a daily dose of 80 mg RCE was safe for adults. The hyaluronic acid assessed constituted 60-80% of the RCE, which corresponds to 48-64 mg hyaluronic acid per person per day. This is based on the outcome of the animal studies and due to the nature of, and the natural occurrence and previous consumption of RCE constituents. In the EFSA opinion, the target population was the general population, with the exception of pregnant women, children and people with adverse reactions to sodium hyaluronate and/or avian protein. However, due to the nature of hyaluronic acid and the of adverse effects observed, no complications for pregnant women and children above 12 are expected

In their opinion, EFSA considered the nature of hyaluronic as well as data on nutrition, microbiology, toxicology, and allergenicity.

No information on a possible difference between the new source of hyaluronic acid (present application) and the hyaluronic acid from rooster comb has been identified, and there are no indications that the two types of hyaluronic from different sources should have different toxic potential.

Human studies

EFSA included two randomised placebo-controlled human studies where RCE has been tested. The studies included a few endpoints on safety and tolerability but were primarily designed to study possible beneficial effects of the RCE. EFSA concluded that due to the relatively low dose, the number of safety endpoints studied, and the limited information on these safety endpoints, no conclusions about the safety of RCE from the human studies could be drawn.

Toxicological studies

In their opinion, EFSA referred to repeated dose studies in rodents ranging from 14 days to 13 weeks in duration. In these studies, rats were orally administered doses of 5 to 600 mg Rooster comb extract/kg body weight/day, and no compound-related adverse effects were reported. Based on these results, the NOAEL for the rooster comb extract was found to be 600 mg/kg body weight, which was the highest dose tested.

In the present application, the company applies for addition of 64 mg hyaluronic acid to a food supplement (corresponding to 0.91 mg/kg bw/day). This amount is in range with 48-64 mg hyaluronic acid per person per day, which was assessed as safe by EFSA.

Conclusion

This assessment is mainly based on the EFSA opinion and the supporting material in the application, and it is assumed that the hyaluronic acid in the present application is similar to the hyaluronic acid obtained from rooster comb.

DTU Fødevareinstituttet finds that intake of 64 mg hyaluronic acid per person per day through a food supplement will lead to no adverse health effects.

The uncertainty of this conclusion is considered as low to medium. The medium uncertainty is due to use of animal studies in the assessment.

Referencer

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on Rooster Combs Extract. EFSA Journal 2013;11(6):3260, 22 pp. doi:10.2903/j.efsa.2013.3260

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