



## Risikovurdering af hyaluronsyre i kosttilskud - risikovurdering af nyt næringsstof til kosttilskud

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## Risikovurdering af hyaluronsyre i kosttilskud

### risikovurdering af nyt næringsstof til kosttilskud

#### Bestilling

Fødevarestyrelse anmoder om en risikovurdering vedrørende tilsætningen af stoffet hyaluronsyre fra hanekamsekstrakt til kosttilskud.

Virksomheden oplyser i sin ansøgning, at der er tale om en tilsætning af 48 mg hyaluronsyre pr. anbefalet daglig dosis.

#### Konklusion

På baggrund af bl.a. EFSA's vurdering fra 2013 "Scientific Opinion on Rooster Combs Extract" vurderer DTU Fødevareinstituttet, at et indtag på 48 mg hyaluronsyre per person per dag via kosttilskud ikke udgør en sundhedsmæssig risiko.

#### Risikovurdering

Hyaluronic acid is derived from rooster combs using mild enzymatic hydrolysis. Rooster combs are obtained from authorized European slaughterhouses. The process of removing combs from poultry's head takes place under hygienic measures once poultry has been sacrificed. Afterwards, combs are cleaned in order to avoid the presence of any adjacent bone or other tissues such as skin of the head, fat or feathers. After that, combs are frozen and later processed. It is not clear whether the present product is produced via this process but it is likely.

Rooster comb extract (RCE) was in 2013 assessed by EFSA. The conclusion from the EFSA risk assessment was 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. 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. These population groups are therefore not covered by the present assessment.

In their opinion, EFSA considered the nature, the natural occurrence and previous consumption of RCE constituents including hyaluronic as well as data on nutrition, microbiology, toxicology, and allergenicity.

#### Human studies

EFSA included two randomised placebo-controlled human studies where RCE has been tested. The studies included some 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 48 mg hyaluronic acid to a food supplement (corresponding to 0.69 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.

On the basis of the EFSA opinion and the supporting material in the application, DTU Fødevareinstituttet finds that intake of 48 mg hyaluronic acid per person per day through a food supplement will not lead to any adverse health effects.

#### **Benyttet litteratur**

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

Canut et al., (2012) Genotoxicity, acute and subchronic toxicity studies in rats of a rooster comb extract rich in sodium hyaluronate. Regulatory Toxicology and Pharmacology, 62, 532-541.