To the Minister of Social Affairs and Employment Mr Koolmees PO Box 90801 NL-2509 LV THE HAGUE, The Netherlands

SUBJECT Advice on exposure limits for soy allergens

THE HAGUE31 March 2021OUR REFERENCE21.73252ENCLOSURE(S)2

E-MAIL EXTENSION NUMBER

Dear Mr Koolmees,

As part of the exposure limit system, the Social and Economic Council's Subcommittee on Occupational Exposure Limits (GSW)¹ advises you on the introduction of legal exposure limits for genotoxic carcinogenic and allergenic substances for which no safe threshold value can be established.

This advisory letter addresses the issue of allergens from soybeans (*Glycine hispida or Glycine max*) processed into flour after de-hulling and grinding. Soy flour contains about 15 allergenic glycoproteins of heavy molecular weight, the most significant of which are beta-glycinin, glycinin, and trypsin inhibitors, enzymes necessary for the plant's metabolism.

The advisory letter was prompted by the Health Council's report of 16 June 2016 on flour dust from finely ground and de-hulled soybeans.² The Health Council concluded that no safe threshold value can be established for inhalation exposure to allergenic glycoproteins from soy flour. Inhalation of soy flour dust (which contains these allergens) in the workplace can lead to sensitisation and subsequently chronic allergic respiratory conditions, rhinitis and occupational asthma. These are conditions that cause relatively frequent absences and may necessitate retraining. This is especially a risk for workers in bakeries, confectionery manufacturers and soy flour production or processing plants.

The Health Council recommends a reference value for occupational exposure to dust from finely ground and de-hulled soybeans of 0.1 micrograms of soy allergen per cubic metre (0.1 i g/m³), as a time-weighted average concentration in the air over an eight-hour working day (8-hour TWA). At this concentration, workers have an additional 1% risk of sensitisation to this dust compared to the general population, which is in line with the SER's earlier advisory report from 2009³.

In the Netherlands, there is currently no legal exposure limit for allergens in soy flour dust. This letter takes into account the aim of protecting workers and the reality that there are major differences in exposure levels between sectors. Exposure levels are especially high in bulk soybean processing.

¹ Details of the membership of the GSW subcommittee are appended to this letter as Enclosure 2.

² Health Council of the Netherlands (2016) *Flour dust from processed, de-hulled soybeans. Health-based recommendation on occupational exposure limits.* The Hague: Health Council of the Netherlands, Publication No. 2016/07.

³ SER (2009) Advisory Report *Aanpak inhaleerbare allergene stoffen op de werkplek*, [Dealing with respirable allergens in the workplace], Publication No. 6, The Hague, 21 July 2009

This sector in particular will have to make the greatest effort to achieve a safe and healthy working environment.

Process

The subcommittee has tested the technical, operational and economic feasibility of the reference value recommended by the Health Council.⁴ Enclosure 1 of this letter gives details of the responses received and how the process was conducted.

Findings of feasibility test

The SER's GSW subcommittee notes that gaining control of soy flour dust is an important factor in managing the risks of soy allergens. This applies in particular to companies processing soybeans and companies in the animal feed industry. Action must be taken over the coming period by investing in measures that are higher up the hierarchy of the occupational hygiene strategy.

For this reason, the SER's GSW subcommittee recommends provisionally managing the risk from soy allergens by applying an exposure limit for respirable soy flour dust (rather than an exposure limit for soy allergens). The quantity and risk of soy allergens present in the dust have been taken into account when formulating an advisory report on the exposure limit for respirable soy flour dust. The introduction of an exposure limit for soy flour dust has the great advantage, compared to monitoring soy allergens, that exposure to soy flour dust can be assessed in a simple and cost-effective manner.

In this context, the SER's GSW subcommittee considers it desirable to adhere as far as possible to the existing exposure limit for flour dust from wheat, rye, oats and barley of 1.2 mg of respirable wheat flour dust per cubic metre as an average concentration in the air over an eight-hour working day (1.2 mg/mm³ 8-hour TWA).

For the bakery sector, it is worth considering not introducing a separate exposure limit to manage the soy flour issue, but sticking to the current exposure limit, which entered into force on 1 January 2020, of 1.2 mg/m³ 8-hour TWA for respirable wheat flour dust. For the bakery sector, a value of 1.2 mg/m³ (8-hour TWA) of respirable flour dust is achievable with the necessary effort, given the current measured dust load.

The flour dust standard of 1.2 mg/m³ 8-hour TWA is also a realistic target for Nevedi over the coming years.

However, for companies processing soybeans in bulk (VERNOF), the value of 1.2 mg/m³ of respirable flour dust as the 8-hour TWA is not achievable due to the current limits for exposure to dust combined with the relatively high allergen content of the dust. For VERNOF, a value of 4 mg/m³ of respirable flour dust as the 8-hour TWA is feasible, subject to the necessary effort being made.

Recommendation

The starting point for the subcommittee for the long-term is the advisory value of 0.1 i g/m^3 of soy allergens in the air derived by the Health Council as the 8-hour TWA. To ensure unambiguous communication and consistent standardisation and enforcement, the subcommittee chooses, for the time being, to recommend one exposure limit for all sectors, i.e. for flour dust rather than an exposure limit for soy allergens. This makes it easier and less expensive to carry out measurements.

The recommended exposure limit is 4 milligrams of respirable flour dust per m³ of air as an average concentration in the air over an eight-hour working day (4 mg/m³ 8-hour TWA). This value applies to

⁴ As described in the advisory report *Aanpak inhaleerbare allergene stoffen op de werkplek* published by the SER Committee on Working Conditions on 21 July 2009 (SER Publication No. 09/06).

flour dust from all sources and can be introduced directly in addition to the exposure limit for flour dust from rye, oats and barley (1 January 2020).

The sectors (bakery sector and Nevedi) that are already able to comply with 1.2 mg/m³ as the 8-hour TWA are strongly recommended to include this lower value in their occupational health and safety catalogue (arbocatalogus) and/or risk inventory and evaluation (RI&E).

Pragmatism and the desire to guide the most problematic sectors towards better risk management have prompted the SER's GSW subcommittee to decide to conduct another feasibility test after a period of three years following the introduction of the exposure limit to ascertain:

- a. whether it will then be possible to set the exposure limit at $1.2 \text{ mg}/\text{m}^3$ as the 8-hour TWA, and
- b. how far the efforts of companies will have progressed towards achieving the Health Council's advisory value, and
- c. when the feasibility test should be repeated.

The process towards further reducing the exposure limit should be guided by measurements that companies should carry out, identifying the most frequent sources and times of exposure. When setting up and carrying out the measurements, companies should seek advice from the Social Affairs and Employment Inspectorate and/or another expert party.

In order to minimise damage to health, a health monitoring system should be put in place and the use of personal protective equipment should be actively pursued in tasks involving short-term high exposure to dust and allergens.

Finally, the subcommittee believes that exposure to soy allergens can be further reduced by improving risk communication in the supply chain by, for example, labelling preparations from ingredient suppliers with information on their content of soy and other allergens in sectors where this is an issue, such as the bakery sector.

Yours sincerely,

Prof. S. Klosse *Chair*