

Report

Title: Assessment of the public health risks of beeskin wraps containing jojoba-oil

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Summary

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Background

Beeskin GmbH in Berlin markets wraps for sausages containing beeswax and jojoba oil. The German food authority (BfR, Bundesamt für Risikobewertung) has issued a warning of jojoba-oil in beeswax wraps. The reason is that the jojoba oil may contain the natural constituent “simmondsin“, which is reported to have adverse effects.

Food Safety & Nutrition Consultancy (Prof.Dr. Hans Verhagen) was asked to deliver a short risk assessment of simmondsin in jojoba oil as per the use of jojoba oil in these wraps.

Safety information of simmondsin

There is little safety information in the literature. A simple search on internet refers to Wikipedia as the most ‘abundant’ albeit limited source of information: <https://en.wikipedia.org/wiki/Simmondsin>:

“Simmondsin is a component of [jojoba](#) seeds ([Simmondsia chinensis](#)). While it had been considered toxic due to jojoba seed meal causing weight loss in animals, in recent years its [appetite suppressant](#) effect has also been researched as a potential treatment for obesity. It is thought to reduce appetite by increasing levels of [cholecystokinin](#).”

Estimated intake of simmondsin

BfR has calculated that the exposure to jojoba oil via the above use is 67 microgram per person per day.

The content of simmondsin in the jojoba oil has been analysed at 2,5 mg / 100 g of oil.

Hence, the potential intake of simmondsin via the jojoba oil can be estimated at: $(2,5 / 100\ 000) * 67$ microgram = 0.0017 microgram simmondsin per person per day = 1.7 nanogram simmondsin per person per day.

Risk assessment of simmondsin contained in jojoba-oil in beeswax wraps

Regulation (EC) No. 1935/2004 on Food Contact Materials states under General requirements in Article 3 that:

“1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or
- (c) bring about a deterioration in the organoleptic characteristics thereof.”

For the purpose of this document only the first requirement is of relevance: the constituents should not endanger human health.

Whereas there is very little information on the safety profile of simmondsin it is still possible to execute a toxicological risk assessment of its exposure at the above intake estimate. Even, in case there are no data available on genotoxicity or from sub-chronic toxicity (typically established via OECD Guidelines such as 471, 487 and 408), a toxicological risk assessment is possible:

When toxicity information is recognized to be insufficient, then the Threshold of Toxicological Concern (TTC) approach can be applied based on the component category in Cramer Classes. For each Cramer Class of chemicals, the corresponding TTC level is taken from the EFSA 2019 Guidance¹:

Type of chemical	Limit of daily* intake (µg/kg bw)	Max. daily intake per person of 70 kg (µg)
Cramer Class I	30	2100
Cramer Class II	9	630
Cramer Class III	1.5	105
DNA reactive	0.0025	0.18

*: considering life-time exposure

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/5708>

As the potential genotoxicity of simmondsin is not known, a worst-case approach is taken: simmondsin is treated as if it were a DNA-reactive chemical. Such chemicals are without appreciable health risk at daily lifetime intake levels of 0.18 microgram per person (180 nanogram per person).

The calculated intake by BfR is 1.7 nanogram simmondsin per person per day, a factor of two orders of magnitude below the insignificant intake level as per the TTC approach, i.e. certainly without public health risk in the most conservative approach.

It goes without saying that if simmondsin is not even a DNA reactive chemical the concomitant Margin of Safety is even far larger.

Conclusion

The established intake of simmondsin as per the BfR estimate is at least two orders of magnitude below the intake level that is without health risks as per the TTC approach, i.e. it is without concern for public health.

Concomitant safety of jojoba oil

Whereas the safety of simmondsin as a constituent of concern of jojoba-oil in beeswax wraps has already been established above, the safety of jojoba-oil *per se* can be approached in the same way. Indeed, there are little safety data on jojoba-oil which justifies the worst-case consideration as per the TTC approach. Jojoba-oil is essentially an oily/waxy material, the risk profile of which would be compatible with Cramer Class I. The calculated intake of jojoba-oil is 67 microgram per person per day, which is also one to two orders of magnitude below the level without concern. Hence also the intake of jojoba-oil *per se* is without concern for public health.