

**Press release**  
**2 September, 2024**

## **Solar Foods obtains self-affirmed GRAS status for Solein® in the United States**

Solein® has obtained the so-called *independent conclusion of GRAS status* (Generally Recognized as Safe) also referred to as *self-affirmed GRAS status* in the United States. Solar Foods has made a conclusion as an end result of this regulated procedure that Solein® is “Generally Recognized as Safe” for its intended use. Solar Foods sees the *self-affirmed GRAS status* as a major step towards Solein’s commercialization and entry onto the US market. Solein received a novel food regulatory approval that allows for the sale of food products containing Solein in Singapore in September 2022.

*“Obtaining self-affirmed GRAS status is the first step towards entering the United States. We will shortly be able to launch commercial activities in this significant new market, including marketing and sales operations, and drive our growth. So far this has been possible only in Singapore,”* says Chief Commercial Officer **Juan Benitez-Garcia** at Solar Foods.

Solein, produced by Solar Foods, is a novel food that requires regulatory approval in most markets before it can be sold and used in food and beverages. In the United States, obtaining *self-affirmed GRAS status* is one of the procedures available for introducing new foods to the market. In order to obtain *self-affirmed GRAS status*, Solar Foods has conducted large-scale scientific research, and the results pertaining to food safety have been published in peer-reviewed scientific journals. Additionally, a qualified panel of experts has compiled a statement on the product’s safety and intended use based on determined food categories and Solein®-concentrations.

The next steps in Solein’s commercialization in the US are to register the Solar Foods production facility Factory 01 with the U.S. Food and Drug Administration (FDA), which requires a food safety plan fulfilling the specific requirements, and to fulfill any other applicable requirements. This will enable Solar Foods to start food export from Factory 01 to the United States. Solar Foods estimates sales could start by the end of this year.

After this, Solar Foods aims to obtain the so-called *notified GRAS status*, which means receiving the so-called *No Questions Letter* from FDA. To this end Solar Foods is required to make a notification with necessary reports on safety of the product for

evaluation by the FDA. This status may widen the possibilities for sale of Solein® as some potential customers may require the go-through of this procedure. Solar Foods estimates it will obtain the *No Questions Letter* by the end of 2026.

*"The United States will be a significant market for us. GRAS status in the US will contribute to advancing Solein's expansion into other markets that do not grant specific novel food approvals, such as Japan,"* Benitez-Garcia adds.

Solar Foods has also filed for novel food regulatory approvals for Solein in the UK and the EU.

### **What is Solein?**

Solein is an all-purpose protein grown with the air we breathe: The unique bioprocess takes a single microbe, one of the billion different ones found in nature, and grows it by fermenting it using air and electricity. Solein is a nutritionally rich and versatile ingredient which can replace protein virtually in any food. Solein can also be used as a fortifier to complement the nutritional profile of various foods: it can be a source of iron, fiber and B vitamins, and it can also bring different techno-functionalities into food products. Learn more about Solein at [www.solein.com](http://www.solein.com).

### **Additional information:**

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Images for editorial use: [www.solarfoods.com/media](http://www.solarfoods.com/media)

### **About Solar Foods**

Solar Foods produces protein using carbon dioxide and electricity. Solein® production, independent of weather and climate conditions, liberates global protein production from the constraints of traditional agriculture. Solar Foods was founded in Finland in 2017. [solarfoods.com](http://solarfoods.com)



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