

February 12, 2026

オリザ油化株式会社

## Food with Function Claims Accepted Under PRISMA 2020 Guidelines for "Lutein-20FA"! – Three Health Claims: Visual Function, Sleep, and Cognition –

Oryza Oil & Fat Chemical Co., Ltd. (Headquarters: Ichinomiya City, Aichi Prefecture; President: Hiromichi Murai; hereinafter "Oryza Oil & Fat Chemical") announces that its Food with Function Claims product, "Oryza Lutein EX 2020" (Notification Number: K611), formulated with Lutein-20FA (Lutein 20 mg, Zeaxanthin 4.08 mg), has been accepted based on a systematic review (SR) compliant with the PRISMA 2020 guidelines. This acceptance follows the new format required for submissions as of April 1, 2025; accordingly, SR documentation is now ready for immediate application by our clients.

Regarding the intake dosage and displayable functionality: an intake of 10 mg/day of Lutein and 2 mg/day of Zeaxanthin allows for claims regarding the improvement of visual function and cognitive function. Furthermore, an intake of 20 mg/day of Lutein and 4.08 mg/day of Zeaxanthin allows for claims regarding the improvement of sleep quality.

### ■ Notification Details (Formulated Material: "Lutein-20FA")

**Product Name:** Oryza Lutein EX 2020

**Notification Number:** K611

**Functional Substances:** Lutein 20 mg, Zeaxanthin 4.08 mg (*For claims limited to visual function and cognitive function improvement: Lutein 10 mg, Zeaxanthin 2 mg*)

**Functional Labeling:** This product contains lutein and zeaxanthin. It has been reported that lutein and zeaxanthin function to maintain eye health by increasing macular pigment levels in the retina, reducing light stress such as ultraviolet rays and blue light (from televisions, computers, and smartphones), and supporting glare recovery (visual recovery from brightness) and contrast sensitivity (the ability to identify color gradations and see things clearly by improving blurriness and haziness). Additionally, it has been reported to reduce temporary mental stress and eye fatigue, thereby improving sleep quality. Furthermore, it has been reported to maintain decision-making (the ability to respond appropriately to changing situations and to reason) and attentiveness (the ability to focus on one thing or direct attention to multiple things), which are parts of cognitive function that decline with age.

■ Regarding the PRISMA Statement (2020)

Currently, when submitting a notification for Food with Function Claims based on a systematic review (SR), it must be conducted in accordance with the PRISMA Statement (Preferred Reporting Items for Systematic Reviews and Meta-analyses Statement), an international guideline for SR reporting. Since the inception of the Food with Function Claims system, documentation compliant with the “PRISMA Statement (2009)” has been mandatory. However, as the “PRISMA Statement (2009)” has been updated to the “PRISMA Statement (2020),” new notifications for Food with Function Claims starting from April 1, 2025, must be based on SRs compliant with the “PRISMA Statement (2020).”

While this change does not alter the underlying academic papers, it requires a more detailed evaluation of the quality of scientific evidence to be compiled as SR documentation.

■ Oryza Oil & Fat Chemical’s Initiatives for “PRISMA Statement (2020)” Compliance

Oryza Oil & Fat Chemical offers 14 materials compatible with Food with Function Claims, covering 23 health claims. We provide application support for these materials. We are sequentially updating our documentation for all materials to ensure they are available in the new format compliant with PRISMA 2020.

**ORYZA'S FFC PRODUCTS**  
14 products 23 health claims ACCEPTANCE !

|  |  |  |   |   |
|--|--|--|---|---|
| <p><b>EYE FUNCTION</b><br/>Increased macular pigment, protection from light stress, improvement of contrast sensitivity and glare recovery)</p> <p><b>CONGNITIVE FUNCTION</b><br/>(enhancement, maintain attentional) Improve sleep quality (improve eye fatigue, mental stress and sleep quality)</p> <p><b>LUTEIN (free)</b><br/>Protects eyes from light irritation</p> <p><b>LUTEIN (esters)</b></p> | <p>Decrease in visceral fat body weight and BMI</p> <p><b>FUCOCANTHIN</b></p>                  | <p>Lower uric acid levels<br/>Reduce eye discomfort</p> <p><b>KIKU FLOWER EXTRACT</b></p>            | <p>Decrease in visceral fat, body weight, and BMI<br/>Suppression of rise in postprandial blood sugar level</p> <p><b>COFFEE BEAN EXTRACT</b></p> | <p>Liver function (Decrease in blood ALT level)</p> <p><b>BRUSSELI SPROUT EXTRACT</b></p> |
| <p>Maintain skin elasticity</p> <p><b>TOMATO SEED EXTRACT</b></p>  | <p>LDL cholesterol level and blood pressure lowering effect</p> <p><b>PERILLA SEED OIL</b></p> | <p>Moisturizing the skin<br/>Moisture content of skin (lips, arms)</p> <p><b>ORYZA CERAMIDE®</b></p> | <p>Moisturizing eye support<br/>Reduced Eye fatigue/discomfort/ burden on shoulders</p> <p><b>Maquifright®</b></p>                                | <p>Maintenance of walking function</p> <p><b>BLACK GINGER EXTRACT</b></p>                 |
| <p>Suppression of blood pressure elevation<br/>Improve sleep quality<br/>skin elasticity<br/>Anti stress/anti fatigue<br/>Maintaining muscle mass</p> <p><b>ORYZA GABA®</b></p>  | <p>Improved vitality</p> <p><b>PASSIONFLOWER EXTRACT</b></p>                                   | <p>Blood triglyceride and total cholesterol lowering effect</p> <p><b>ORYZA RICE BRAN OIL</b></p>    | <p>Improve sleep quality</p> <p><b>Safleep®</b></p>   | <p>Coming soon</p>  |
| <p>Coming soon</p>   | <p>Coming soon</p>   | <p>Coming soon</p>   | <p>Coming soon</p>  |   |

Up date: February, 10, 2026

<Supplement>

“Lutein-20FA” was launched in 2022 as an eye-care material standardized to contain at least 20.0% free lutein and at least 4.0% zeaxanthin. Lutein specifically accumulates in the macula, located at the center of the retina, and is known for its ability to improve visual function through blue light absorption and strong antioxidant effects.