New substances: risk assessment, New Substances Notifications 21071, 21072, 21073, and 21074
Schedule 5 of the *New Substances Notification Regulations (Organisms)*

Name of company: GloFish LLC
Notified organisms: Four genetically modified lines of Tiger Barbs (*Puntigrus tetrazona*) known as the GloFish® Electric Green® Barb (GB2011), GloFish® Starfire Red® Barb (RB2015), GloFish® Galactic Purple® Barb (PB2019), and GloFish® Sunburst Orange® Barb (OB2019)
Schedule of the NSNR(O): Schedule 5 - Information Required in Respect of Organisms Other than Micro-organisms
First day of assessment period: 2022/01/22
Last day of assessment period: 2022/05/21
Organism type: Fish
Use: Importation for use as ornamental fish in home aquaria
Anticipated quantity: Importation of 40,000 total adult fish annually from the United States
Assessment level of concern:

- **Human health hazard:** Low
- **Human exposure:** Low to medium
- **Environmental hazard:** Low
- **Environmental exposure:** Low

Assessment conclusion (under section 64 of CEPA): Low risk, not suspected to be toxic
Category: Added to the Domestic Substances List on November 23, 2022
Recommended action: None
Waiver: None

Contents

Synopsis

Puntigrus tetrazona lines GB2011, RB2015, PB2019, and OB2019 (hereafter mentioned as notified organisms) are genetically modified lines of fluorescent Tiger Barb that were notified to the New

Substances program for use as ornamental tropical fish in home aquaria. Other potential uses may include release or culturing in outdoor ponds, mosquito control, scientific research and future manufacture in Canada.

There is no evidence to suggest a potential a risk of adverse environmental and human health effects at the exposure levels predicted for the environment and general population in Canada from production of the notified organisms.

It is determined that the notified organisms are not toxic or capable of becoming toxic according to the criteria under section 64 of the Act as there is no evidence to suggest that the notified organisms may enter the environment in a quantity or concentration or under conditions that:

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity,
- constitute or may constitute a danger to the environment on which life depends, or
- constitute or may constitute a danger in Canada to human life or health.

No risk management is recommended.

This assessment was subject to a scientific expert peer review process (DFO, 2023).

Background information

The notified organisms are genetically modified lines of fluorescent Barb containing genes expressing fluorescent proteins, which make the fish appear green, red, purple, and orange, under ambient light including sunlight. These organisms were each derived from an albino domestic strain of Tiger Barb, which is a tropical freshwater fish species native to Sumatra and Borneo. Tiger barb is commonly used in home aquariums in Canada.

The risk assessment is based on the evaluation of information submitted by the notifier and publicly available literature. The following sections give more details on the hazard and exposure.

Hazard

The environmental hazard potential of the notified organisms is determined to be low because:

1) They are not likely to produce toxins that could affect other species if released in the environment. Other GloFish® lines (e.g. Tetra, Zebra Danio, and Betta) containing similar modifications have been in commercial production in the United States for several years without any reported toxic effects resulting from exposure.
2) The fluorescence transgenes introduced into the notified organisms have been commonly used in a wide range of genetically modified organisms with few reports of harmful effects.
3) There is no direct evidence that the expressed fluorescent proteins would increase the hazard to the Canadian environment relative to domesticated *P. tetrazona*.

4) The *P. tetrazona* species is aggressive both with its own species and with other fish species, particularly if not kept in large groups (five or more). If the notified organisms were released to the environment, they could potentially interact with and impact native fish populations. However, since *P. tetrazona* activity is lower in cooler temperatures, it is unlikely that the notified organisms would have a significant impact on larval and smaller fish populations or their habitats.
5) Data from temperature tolerance tests demonstrated that the notified organisms and their non-modified siblings have similar median lethal dose temperature values of under 12°C.
6) *P. tetrazona* are tropical freshwater fish of the family Cyprinidae that are native to Sumatra, Borneo and other parts of Asia. As Canadian lakes, rivers and other bodies of water do not consistently remain above 7°C throughout the entire year, the notified organisms are not likely to establish in Canadian aquatic environments. Their activities are known to decline in cooler waters, thereby decreasing the likelihood of the notified organisms to have a significant impact on larval and smaller fish populations or their habitats if released into the Canadian environment. Therefore, there is a low potential for them to cause a significant impact through mating with native fish in Canada.
7) Overall, their potential to impact prey and competitor community dynamics through altered appetite, behaviour, and possible habitat use at different life stages if released outside of containment is expected to result in a low impact to biodiversity.
8) There are no known reports of unintended mutations resulting in observable characteristics that may result in harm to other environmental species or the environment itself.

The human hazard potential of the notified organisms is determined to be low because:

1) They are genetically modified tropical fish with no indication that any of the inserted genetic material or expressed proteins can cause adverse effects (toxicity, pathogenicity or allergenicity) in humans.
2) While the potential for unintended effects from genetic modifications remains unknown, the methods used to produce these organisms do not raise any indirect human health concerns.
3) While there are reported cases of zoonotic infections transmitted to humans from tropical aquarium fish, particularly in immunocompromised individuals and children, no such reports are attributed to wild-type species of Barbs or any of the commercially available lines of GloFish®. The notified organisms are not expected to be any different than the commercially available wild-type Tiger Barbs.
4) There is a history of safe use for the notified organisms (limited for OB2019 and PB2019 due to only being commercially available since 2020) in the United States and the wild-type species has been safely used as an ornamental aquarium fish since the 1950s. In addition, there is a history of safe use for the other lines of GloFish® commercially available in Canada since 2018.

Exposure

The environmental exposure potential of the notified organisms is assessed to be low because:

1) The intended use of the notified organisms is in the ornamental aquarium trade. Therefore, these genetically modified Barbs are intended to be contained and maintained in indoor aquaria.

2) Should any of these fish be released accidentally or intentionally into the Canadian environment, the temperatures of Canadian lakes and rivers are not consistently above 7°C for the entire year and will therefore limit the ability and the capacity for the fish to establish themselves.
3) Isolated opportunities for reproduction may occur in a few Canadian lakes that have temperatures in the mid 20°C for a short period during the summer months. The ideal recommended temperatures for Tiger Barb rearing ranges from 21.1°C to 26.7°C and from 23°C to 28°C while breeding, therefore they are not expected to persist where water temperatures are below optimal for their survival and reproduction.
4) Although freshwater surface temperatures in Canada are rising because of global climate change and are projected to increase by 1.5 to 4.0°C by 2063 (DFO, 2013) they would remain well below the required temperatures for the organisms to establish themselves.

The human exposure potential of the notified organisms is determined to be low to medium because:
1) The primary sources of human exposures would result from the proposed import of adult fish through unidentified points of entry in Canada and distribution through about 500 retail outlets.
2) The sole intended use of the notified organisms is as ornamental tropical aquarium fish, thus limiting potential exposure primarily to persons living in Canada that have a home aquarium.
3) Like other aquarium fish, human exposure may include immunosuppressed individuals, children, those with underlying medical conditions, or other individuals who may be more susceptible.
4) Typical human exposure to live or dead aquaria fish in the home is most often related to maintenance activities such as tank cleanings and water changes. Low temperatures in Canadian waters during the winter and low cold tolerance of the tropical notified organisms limits human exposure through the environment, in scenarios of accidental release.
5) No significant increase in human exposure is expected from other potential uses of the notified organisms such as for mosquito control or research purposes.

Risk characterization

Owing to the low potential hazard and the low potential exposure, the environmental risk associated with the use of the notified organisms for use as ornamental tropical fish in home aquaria are assessed to be low.
Owing to the low potential hazard and the low to medium potential exposure, the human health risk associated with the use of the notified organisms for use as ornamental tropical fish in home aquaria are assessed to be low.

Risk assessment conclusion

There is no evidence to suggest a potential a risk of adverse environmental and human health effects at the exposure levels predicted for the environment and general population from the use of *P. tetrazona* GB2011, RB2015, PB2019, and OB2019 as ornamental tropical aquarium fish, nor from any uses that may result in introduction of the fish into the Canadian environment. The risk to the environment and human health associated with the notified organisms are not suspected to meet the criteria in

paragraphs 64(a), (b), or (c) of the *Canadian Environmental Protection Act, 1999*. No further action is recommended.

References

Barik, M., Bhattacharjee, I., Ghosh, A., and Chandra, G. (2018). Larvivorous potentiality of *Puntius tetrazona* and *Hyphessobrycon rosaceus* against *Culex vishnui* subgroup in laboratory and field based bioassay. BMC Res Notes 11(1): 804.

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DFO. 2013. Risk-based assessment of climate change impacts and risks on the biological systems and infrastructure within Fisheries and Oceans Canada's mandate - Freshwater Large Aquatic Basin. DFO Can. Sci. Advis. Sec. Sci. Resp. 2013/011

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