



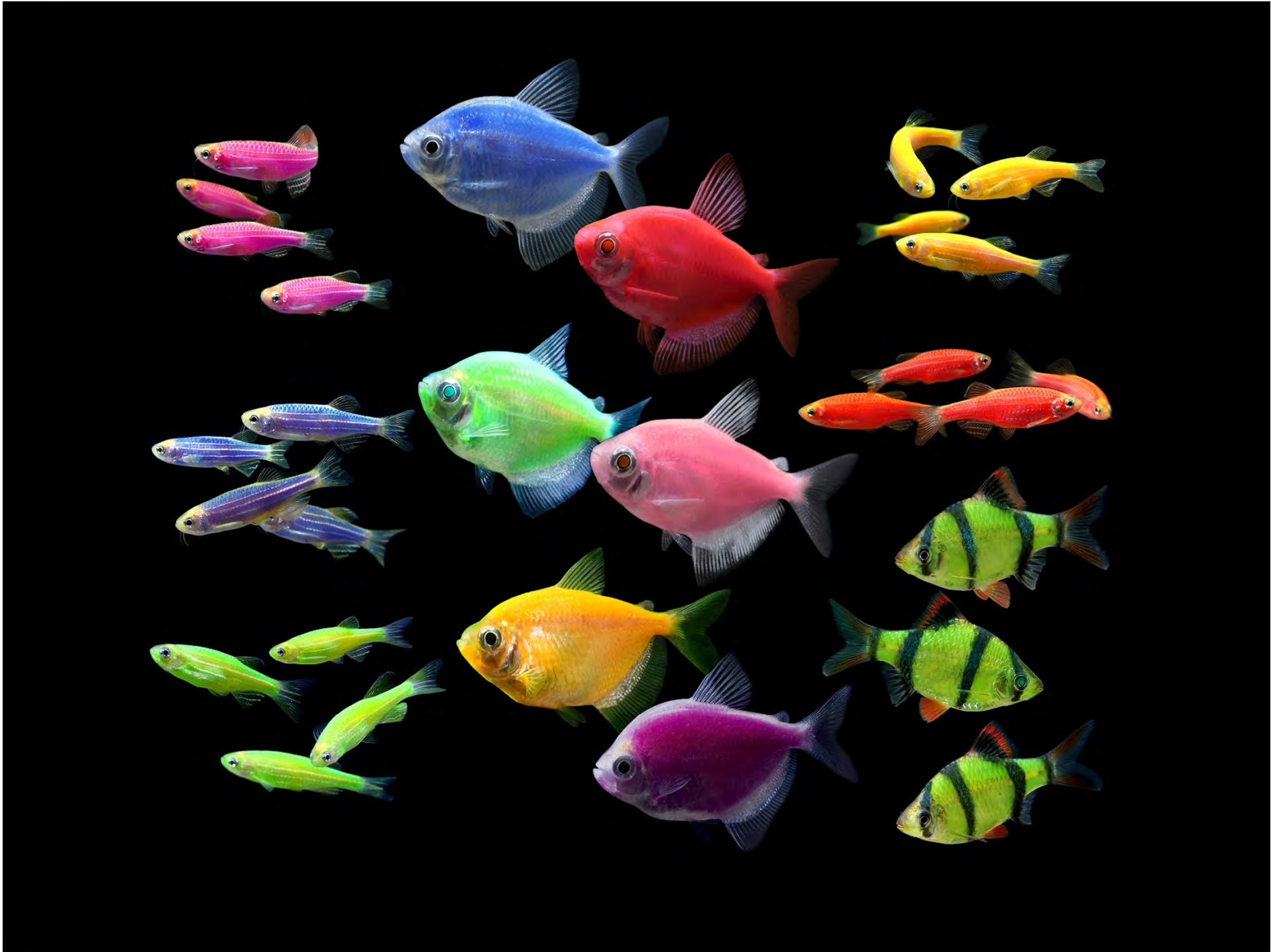
GloFish<sup>®</sup>

Experience the Glo!<sup>®</sup>

# About GloFish

- 🐟 World's first widely available biotech animal
- 🐟 Tropical aquarium fish that express fluorescent proteins, available in 3 species and 12 lines
- 🐟 First line developed by Zhiyuan Gong at National University of Singapore to detect water toxins
- 🐟 Each line has been reviewed by FDA as described in Guidance 187





# Pre-Market Ethical Considerations





- 🐟 Would there be any ecological consequences?
- 🐟 Would there be any fish health or well-being impact?
- 🐟 Are there any human health concerns?
- 🐟 Is the technology used within accepted norms?
- 🐟 What potential benefits exist for humans and fish?

**Will marketing GloFish set a good example for the use of animal biotechnology with the public, our industry, the media, as well as scientific, regulatory, and business stakeholders?**





# Ecological Safety Review


## Wild-type and fluorescent zebrafish safety

-  Wild-type zebrafish sold for nearly 100 years without incident
-  USGS records demonstrate inability to establish populations
-  Analyzed using Net Fitness Model pioneered by Muir & Howard
-  Fluorescent fish slightly less ecologically fit than wild-type

## Discussions with leading experts

-  Included conversations with state agency officials
-  Establishment of Scientific Advisory Board

## Broad consensus of no ecological risk

-  Fitness change would lead to fluorescence gene elimination even where fish are native



# Fish Health & Well-Being

🐟 No discernible health or well-being impact

🐟 Fluorescent fish long used in research

🐟 General behavior unchanged

🐟 Fluorescent fish exhibit no unique signs of stress

🐟 Life-cycle, including life expectancy, unchanged

🐟 Fluorescent fish live a fish's life

🐟 Fluorescence genes naturally derived

🐟 Non-toxic & widely used as marker genes

🐟 Extremely common in marine organisms

🐟 Fluorescence genes derived from sea coral

🐟 180 species of naturally occurring fluorescent fish



# Human Health Considerations

- Added protein not toxic or allergenic
- Minimal direct human interaction
- Not intended for use as food
- No risk to the food supply
- Modification poses no known human health risks



# Technology Norms

- 🐟 Creation of fluorescent fish commonplace
  - 🐟 Water pollution detection
  - 🐟 Developmental modeling
  - 🐟 Cancer research
  - 🐟 Ecological risk assessment
- 🐟 Is “entertainment” use inherently problematic?
  - 🐟 Original line already existed
  - 🐟 Ignores potential benefits
  - 🐟 Dismisses owners’ fulfillment
  - 🐟 Long history of companion animals





# Potential Benefits

- 🐟 Support positive use of biotechnology
  - 🐟 Proceeds help fund beneficial research at NUS
  - 🐟 By-product commercialization helps to make research viable
- 🐟 General test case for biotechnology
  - 🐟 Shows that public acceptance is possible
  - 🐟 Necessary for continued technology development
- 🐟 Reduce demand for dyed & injected fish
  - 🐟 Extremely controversial process
  - 🐟 Substantial animal welfare concern
- 🐟 Great for educational purposes
  - 🐟 Develop complementary GloFish lesson plans
  - 🐟 Explore merits, ethics, responsibilities of biotech



# Potential Benefits Cont'd

- 🐟 Companionship and emotional tranquility
  - 🐟 Helps create connection to nature
  - 🐟 Teach responsibility & care
  - 🐟 Well-being through stress reduction
- 🐟 Supports industry
  - 🐟 Helps to create jobs and economic opportunities
  - 🐟 Benefits tax base, supports local government
- 🐟 Allows for charitable initiatives
  - 🐟 Possible with longer-term success

**Achieving these benefits would require a long-term ethical commitment, which we shared on our website through our guiding ethical principles.**



## GloFish™ Fluorescent Fish Guiding Ethical Principles



The providers of GloFish™ fluorescent fish realize that the enormous potential of genetic technology carries with it an important responsibility. To help ensure that we use this technology appropriately, we dedicate ourselves to the following guiding ethical principles:

**Environmental Safety First.** We believe it is of paramount importance that all the fluorescent fish we offer for sale be safe for the environment. To ensure that we are successful, stringent testing will be performed before any fish is made available to the public, with specific emphasis placed on analyzing growth rates, temperature sensitivities, and mating success. Any line of fluorescent fish demonstrating increased strengths or successes in these areas relative to non-fluorescent fish of the same species, or otherwise displaying any characteristic that poses an environment concern, will not be offered for sale.

**Humane Treatment of Fish.** We are committed to humane breeding practices, and the distributors of GloFish™ fluorescent fish will make every effort to provide an exemplary, healthy environment for our fish throughout their life cycle. We encourage our customers to remember that, while unique, beautiful, and interesting, these fish are living creatures and not toys, and should be treated with the utmost care. For more information about the proper care for these fish, please visit our [GloFish™ Fluorescent Fish Care](#) section of our website.

**Advancing Scientific Research.** We value the potential of the technology that brought us fluorescent fish, and we will work to support additional medical and scientific applications that utilize this technology. GloFish™ fluorescent fish were originally developed to detect pollutants in our water, one of many discoveries with roots in the recent biotechnology revolution. This revolution promises to aid in the fight against countless diseases and significantly improve peoples' lives and environments. We will work to promote and support this research; a portion of the proceeds from the sale of every GloFish™ Fluorescent Fish will go towards this effort.

**Open & Informed Discussion:** We recognize that new opportunities available through increased scientific understanding must be weighed against potential risks. We will regularly consult with leading experts through our Scientific Advisory Board and with appropriate state and federal agencies in support of comprehensive scientific research. We encourage an engaged and informed public discussion surrounding these issues, and provide information about our fish to enlighten that debate. To become a part of this dialog, we invite you to visit the [GloFish™ Fluorescent Fish FAQ](#) section of our website and [send us](#) your comments or questions anytime

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# Initial Reception

- 🐟 Tremendous worldwide media coverage
- 🐟 Generally well-received across marketplace
- 🐟 90% of emails unrelated to biotech nature of fish
- 🐟 FDA issued statement consistent with internal and SAB risk assessment
  - 🐟 Widely misreported to suggest no review or jurisdiction
- 🐟 Media reports often ignored or confused easily accessible information
- 🐟 Activist group sued FDA in federal court



# Early Post-Launch Developments

- 🐟 Additional state agencies reached formal safety findings, including California and Florida
- 🐟 Unanimous consensus from qualified experts regarding ecological safety
- 🐟 Activist lawsuit dismissed on summary judgment
- 🐟 Market interest was tremendous, but demand relatively low due to perceived weak color

**Revisiting our pre-market assessment with the latest information, there were no material changes that suggested developing new lines would be inconsistent with our original conclusion.**



# Twelve Years Later

- 🐟 Many additional GloFish lines available
  - 🐟 All species have long history of non-establishment
  - 🐟 Each line has been reviewed by FDA under Guidance 187
  - 🐟 No lines show any fitness advantage or health difference
- 🐟 No incidents of harm associated with GloFish sale
- 🐟 Numerous studies confirmed initial safety assessment
  - 🐟 Fluorescent fish are low ecological risk (Hill et al. 2014)
  - 🐟 Fluorescence trait will not persist in population and there are no long-term health differences (Howard et al. 2015)
    - 🐟 Gene elimination rate matched Net Fitness Model prediction
- 🐟 GloFish used as a model in multiple studies



# Twelve Years Later (Cont'd)

- 🐟 Extremely broad public acceptance
  - 🐟 Available in approximately 8,000 retail locations
  - 🐟 Consumers' primary concern is ensuring fish are not dyed
  - 🐟 Sales of dyed & injected fish dramatically reduced
- 🐟 Substantial well-being and economic value created
  - 🐟 Underpins a category that drives ~10% of all industry sales
  - 🐟 GloFish Clean Water Initiative serving nearly 20,000 people
- 🐟 Dr. Gong at NUS has developed pollution-detecting fish
- 🐟 Widely used GloFish classroom curriculum available

**It is our sincere hope that we have set a good example for a positive use of biotechnology.**



# Looking Ahead: A Holistic Approach









- 🐟 Our goal is to apply what we've learned more widely for human and animal welfare, but there is no broad, public consensus regarding the ethics of using biotechnology.
- 🐟 There is often an inherent assumption that only the *active* use of biotechnology has ethical implications. It is very important that we consider the ethical implications of the *lack of use* of biotechnology as part of any discussion.
- 🐟 Moving the biotechnology debate towards a holistic ethical framework that takes this into consideration would be very helpful in building consensus across different stakeholder groups.
- 🐟 Such an approach would be particularly useful for people who influence direction and evaluate potential applications, but are often not experts in the field, such as journalists and business leaders.








# Urgent Matters for Consideration

## Human Welfare

-  Disease eradication through insect modification
  -  Elimination of malaria and dengue fever
  -  Avian flu resistance in poultry
-  Nutrition support through animal disease resistance
  -  Cattle resistant to sleeping sickness
  -  Goats that produce anti-microbial milk
-  Reduce overuse of antibiotics
-  Organs for transplantation

## Animal Welfare

-  Horn-free (i.e. polled) cattle
-  Sex selection in chickens
-  African swine fever resistance in pigs



# All That We Ethically Can?

**Are we doing all that we ethically can with  
the tools we have available to alleviate  
human and animal suffering?**

**And, if not us, who, if not now, when?**



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