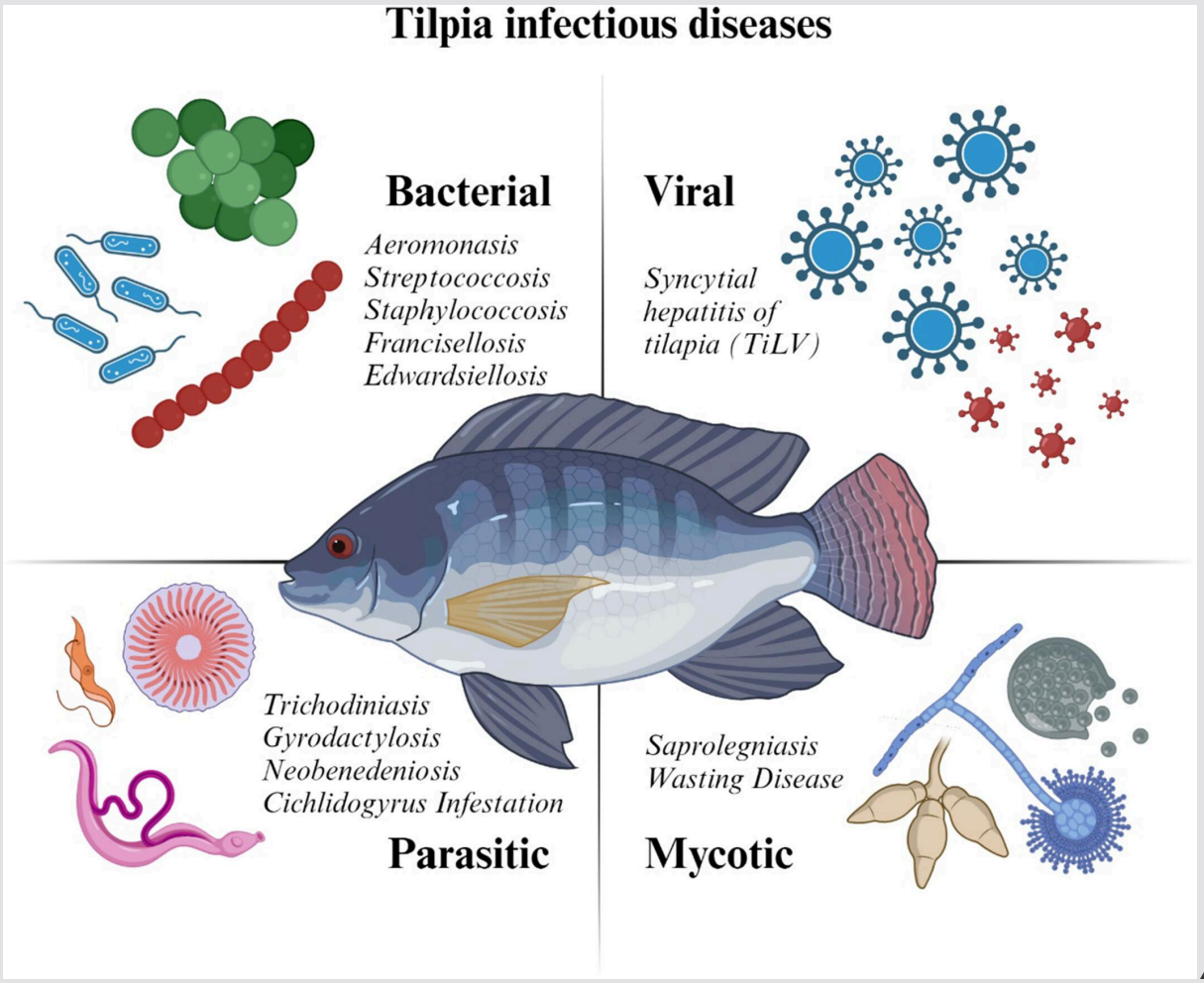


***ACT RX* WILL BE MADE INTO TEA SPRAYED ON ALL ANIMAL & FISH FOOD**. For example, stopping

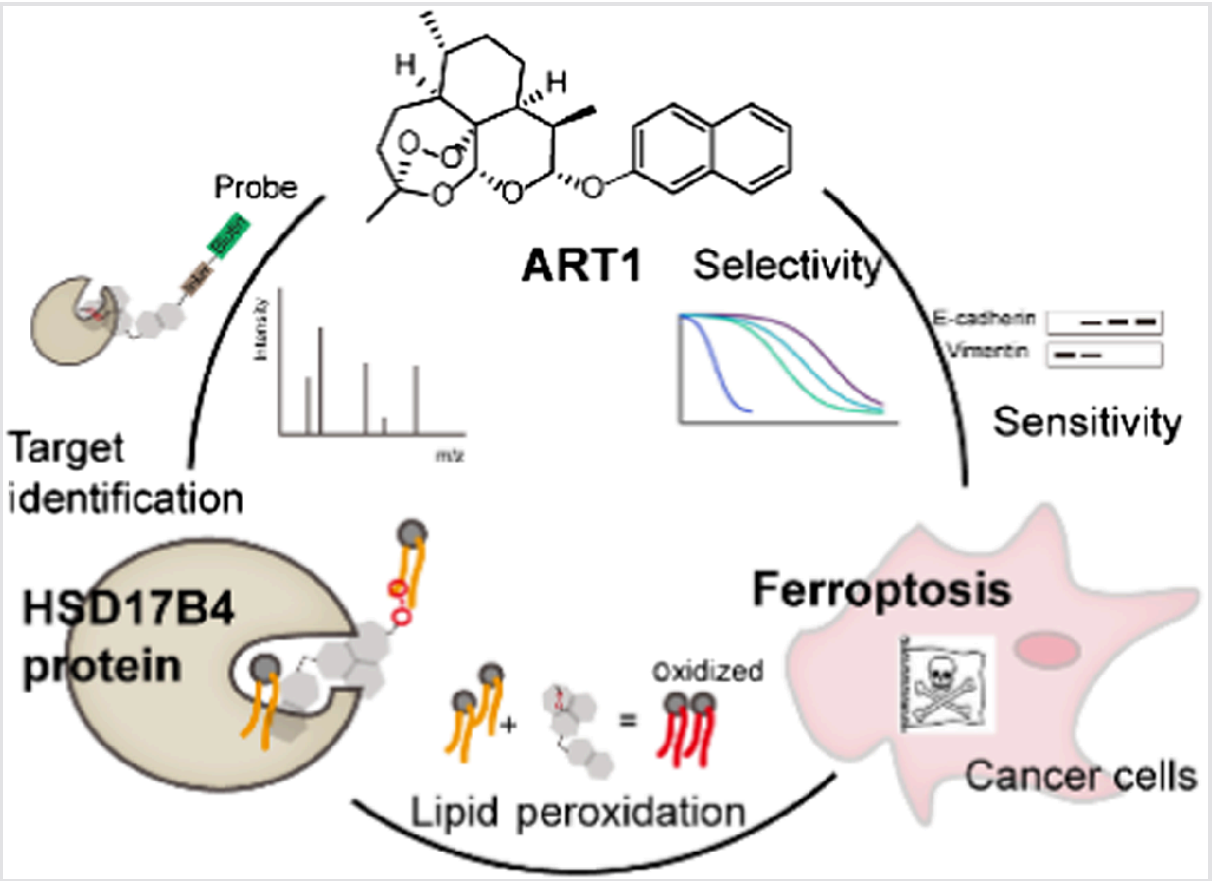
all four viral, fungal, bacterial and plasmoidal fish diseases; and; blocking viral insertion and replication by blocking RNA reverse polymerase in all viruses, which stops replication of RNA viruses by blocking manufacture of virus proteins inside cells in mammals and reptiles for all RNA viruses, including ***Influenza A***, ***Covid***, ***Sars***- ***Covid***, ***Herpes***, ***Hepatitis***, ***AIDs***, etc.; plus binding spike proteins to prevent virus insertions to healthy cells. ACT RX works in nine additional ways to prevent infections from all four disease vectors shown in the fish example pictured above. ***ACT Rx's*** animal trade name ***Nano-Peroximide*** is sprayed-on ***Act Rx*** tea comprising less than 2% by dry weight of finished medicated animal food. This medicated food is trade named ***Dr J's Pet Shield***; and; legally falls under **GRAS (Generally Regarded As Safe)** because Act Rx's three 1000-year old, highly tested, ***India Ayush***- approved artemisinin, artesunate synthesized from it, and ***Ayush-*** approved berberine are all well tolerated and safely used for thousands of years! By **GRAS** statutes, no further approvals are needed under 5%! And; it's optional whether we put ***Act Rx*** ingredients on the label, so it can stay a trade secret. Of course, later on (6 months) EGG Pharma gets ***FDA*** / ***DOH certificate***/ ***license after testing through Department Of Ag***, and; it will be the greatest selling factor: curing your cow, chicken, cat, goat, fish, etc. for just a dollar extra per kg of food for a month!!

Legally: the active ingredient will be between 1% and less than 1.5% by weight; a peroxide moiety- which is the active ingredient. ***EGG Pharma*** is ready to grow ***Artemisia Philipina*** on 10 k ha of the ***Higanon Tribe's*** land, and; the ***Department of Ag*** in region 11 is ready to commence testing on animals; plus; Claveria mayors will give low-cost land and help with transferring to ***EGG Pharma*** their already received government grants dispersed by the mayors for labour and training to grow one

million doses of our ingredients in first year.

Therefore, to make Dr J's Pet Shield we definitely don't need separate year long FDA/ DOH tests. Artemisin, artesunate and Berberine are approved by Ayush and used for thousands of years. They are the best tested and tolerated natural medicine on the planet.

I suggest we start the Lake Laguna -P$2 bn hyacinth job to make our own pet and fish good in jv with Mindanao Univ with Dir Ruby Gonzales, while doing certified tests In fish immediately.



Generally Recognized as Safe (GRAS)

"GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

- Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. General recognition of safety through scientific procedures is based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

Overview

- About the GRAS Notification Program
- How FDA's GRAS Notification Program Works
- FDA's Approach to the GRAS Provision: A History of Processes

GRAS Final Rule

- Federal Register Notice – the GRAS Final Rule (81 FR 54960 – August 17, 2016)
- Federal Register Notice - the GRAS Proposal (62 FR 18937 - April 17, 1997)
- Federal Register Notice - Substances Generally Recognized as Safe; Reopening of the Comment Period (75 FR 81536 - Dec 28, 2010)

Inventory for Human Food

- GRAS Notice Inventory

Related Databases

- GRAS Substances (SCOGS) Database
- Microorganisms & Microbial-Derived Ingredients Used in Food (Partial List)
- Enzyme Preparations Used in Food (Partial List)

Regulatory and Policy Guidance

- Guidance for Industry: Best Practices for Convening a GRAS Panel
- Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act
- Guidance for Industry: Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food
- Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives
- Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements

- Providing Regulatory Submissions to OFAS
    - Centralized Online Submission Module (COSM)
- Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula

Scientific Guidance

- Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices for Enzyme Preparations
- Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions
- Guidance for Industry: Estimating Dietary Intake of Substances in Food
- Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food

Regulations

- 21 CFR 181 - Prior Sanctioned Food Ingredients
- 21 CFR 182 - Substances GRAS in food
- 21 CFR 184 - Substances Affirmed as GRAS in Food
- 21 CFR 186 - Substances Affirmed as GRAS for Use in Food Packaging