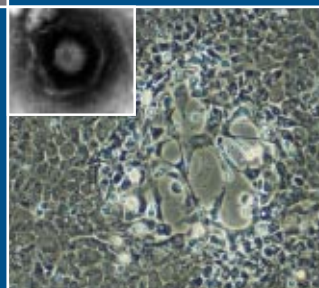




Fish vaccine and veterinary medicine product evaluation

Research and technical services

- Fish vaccines
- Veterinary medicines
- Pesticides
- Feed additives





CEFAS has been a Member of the UK GLP Compliance Monitoring Programme since 1997. We have extensive experience of European registration procedures, the demand of licensing authorities and related experimental requirements for the testing of aquatic medicinal products.

CEFAS is an agency partly funded by the UK government. We are independent of any manufacturer or retailer, have a detailed knowledge of relevant regulations and registration procedures, and a **long established track record for the quality, integrity and impartiality of our work.** We recognise and respect the need for absolute client confidentiality.

Fish vaccine and veterinary medicine product evaluation

Research and technical services

- Fish vaccines ● Veterinary medicines
- Pesticides ● Feed additives



The Centre for Environment, Fisheries and Aquaculture Science, (CEFAS) is a long established research organisation with a thorough knowledge and skills base in fish cultivation, fish health and disease, fish stock assessment and fisheries management. We operate in over 30 countries world-wide, providing training, advice, research, consultancy and project management.

The CEFAS Product Evaluation Group comprises a **dedicated group of scientists**, experienced in *in vivo* and *in vitro* testing, the diagnosis of fish pathogens and the development and use of disease challenge models. Direct expertise within the group includes microbiology, virology, veterinary medicines, fish diseases and vaccines.

CEFAS staff at the Weymouth Laboratory have world class expertise in fish molecular biology, epidemiology, pathology, physiology, parasitology as well as expertise in regulatory aspects of product registration and UK/EU legislation on fish disease and fish movement. This gives **CEFAS a broad based authoritative approach** to its work, advice and recommendations, and puts CEFAS in a strong position to **advise on dossier production and strategy.**

The CEFAS track record consists of:

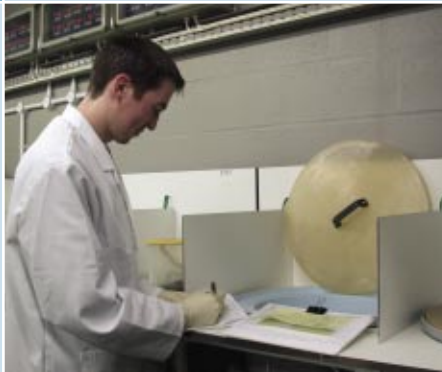
- Over 25 years of research into fish medicines.
- Medicine testing since the early 1990's.
- Salmonid disease challenge models available since the 1970's.
- Sea bass and turbot disease challenge models available since the mid 1990's.



For vaccine and pharmaceutical manufacturers

- trials and high quality data for regulatory approvals
- longer term research collaborations

CEFAS provides world-class chemotherapeutant and vaccine evaluation and assessment competencies based on a wealth of experience, a wide range of expertise, modern facilities and internationally recognised disease reference resources. We have extensive experience of UK/EU registration procedures, the demands of licensing authorities and related experimental requirements for antibiotics and other medicines.



We are also keen to develop closer links with the industry and value the opportunity for close collaborations. We have active externally-funded research programmes which can accommodate longer term research collaborations.

We specialise in efficacy and safety trials and assessments for regulatory approval portfolios.

- Assessments of therapeutants and vaccines against diseases from around the world
- Intra-peritoneal, intra-muscular, bath and co-habitant challenge protocols for a wide range of pathogens and fish species

A range of in vitro and in vivo protocols for the testing of various products:

- Vaccines
 - control of starting materials: cell line, virus seed and bacterial seed testing,
 - assays for licensing authority approvals: dose response, shelf-life testing, stability, duration of immunity, depletion, safety and efficacy testing,
 - finished product: routine batch safety and potency testing.

- Chemotherapeutants, disinfectants and feed additives:
 - safety, dose titration, efficacy, residue depletion testing, radio-labelled metabolism studies.
- Review of data package and expert report:
 - advice on registration procedures and experimental requirements,
 - design, monitoring and evaluation of large scale field trials for data packages for licensing purposes,
 - expert assessment of safety and efficacy dossiers for product registration.

High Quality work and facilities

Chemotherapeutant, vaccine and feed additive regulatory approval portfolios require high quality safety and efficacy assessments. CEFAS has the staff, facilities and QA systems to provide experimental evidence of the very highest scientific quality for registration of a new product or changed formulation.

The CEFAS Weymouth Laboratory offers:

- Precise control of water temperature, salinity and illumination in our **state-of-the-art aquaria** ensure reproducible data with minimal spurious results due to "tank effects".
- As a **National Reference Laboratory** we are uniquely placed to ensure the quality and health status of all test fish. We have also developed close links with a number of sources of specific pathogen free fish for use in specific protocols.
- The **OIE Collaborating Centre for Information on Aquatic Animal Diseases**, the aim of which is to propose and develop procedures that will facilitate the harmonisation of international regulations applicable to the surveillance and control of animal diseases.
- We have developed **novel challenge protocols** which closely reflect the way fish acquire and develop infection in the fish farm environment ensuring that product evaluation will be relevant to conditions of use.
- Our diagnostic work and media preparation services are in the process of **ISO/IEC 17025 standard accreditation**.
- We have developed testing protocols that comply with relevant EU regulations, CVMP & EMEA guidelines, European Pharmacopoeia monographs and other regulatory requirements, as required.
- **Our work is conducted to Good Laboratory Practice** standard by highly trained professional staff. All our in vivo work complies with national legislation and EU directives on **animal welfare** and experimentation.

Responsiveness

The unique versatility of our automated facilities and our knowledgeable experts backed up by fully trained and flexible technical staff mean that we can meet client needs for complex product assessments to demanding deadlines.



For further information contact

Product Evaluation Group

CEFAS
Weymouth Laboratory
Barrack Rd, The Nothe
Weymouth, Dorset DT4 8UB, UK
Tel: +44 (0) 1305 206 600
Fax: +44 (0) 1305 206 601
E-mail: Prod.Eval.Gp@cefass.co.uk

Dr. Stephen Irving:
Customer Relationship Manager
Email: s.irving@cefass.co.uk

Myriam Algoët, DVM:
Product Evaluation Group Leader
Email: m.algoet@cefass.co.uk

Business Development Unit

CEFAS
Lowestoft Laboratory
Pakefield Road
Lowestoft, Suffolk NR33 0HT
Tel: +44 (0) 1502 524 579
Fax: +44 (0) 1502 524 569
Email: marketing@cefass.co.uk

Dr Geoff Tingley:
Business Development Manager
Mobile +44 (0) 7769 670 965
Email: g.a.tingley@cefass.co.uk
Tel: +44 (0) 1502 524 345
Fax: +44 (0) 1502 524 569

Modern GLP compliant aquarium facilities

More than 30 years of experience in holding fish under experimental conditions is reflected in the design of the aquarium suite. **A dedicated aquatic services team** of staff experienced in all aspects of fish husbandry maintain the facility.

The extensive aquarium facilities at the CEFAS Weymouth Laboratory are run in compliance with the OECD principles of Good Laboratory Practice and The Good Laboratory Practice Regulations, Statutory Instrument 1999 No. 3106.

Excellent flexibility to accommodate all trial requirements

- Over 220 tanks, in 14 isolation suites, including high disease security units. Three tank sizes (140 x 50 litres, 58 x 350 litres and 30 x 1000 litres) for work on fish of all sizes.
- Additional large stock holding facilities available for long-term studies.
- Marine and freshwater supply for work on a wide range of fish species.
- Freshwater from dechlorinated potable borehole source supply.

- Seawater from Weymouth Bay of defined quality at 35‰ salinity and filtered to 15 µm allowing a salinity range from 0 to 35‰.
- Sub-polar to tropical water temperatures (5°C to 30°C ± 0.1°C).
- Programmable illumination.

Precise control of the test environment

- All tanks fitted with independent computer control of water temperature and illumination for precise and reproducible conditions.
- Experimental conditions stored and accessed electronically.
- Ozone and UV sterilisation of all effluents.
- Aquarium facilities in compliance with the UK advisory committee on dangerous pathogens (ACDP) containment level 2 requirements.
- Independently controllable tanks for simultaneous studies.
- 100% flow through.