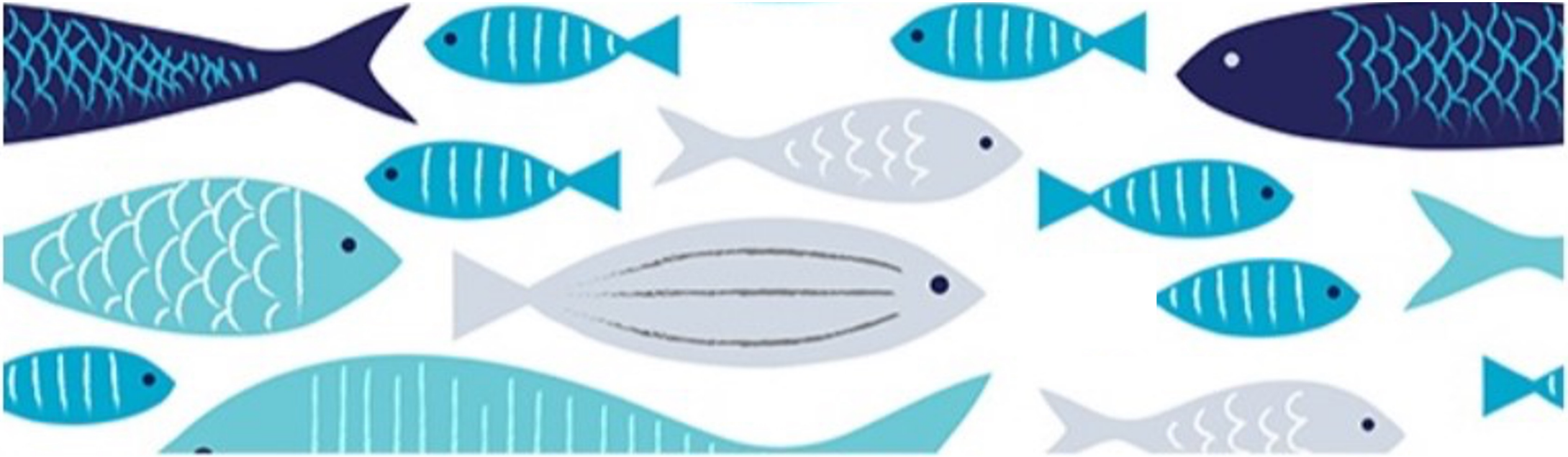
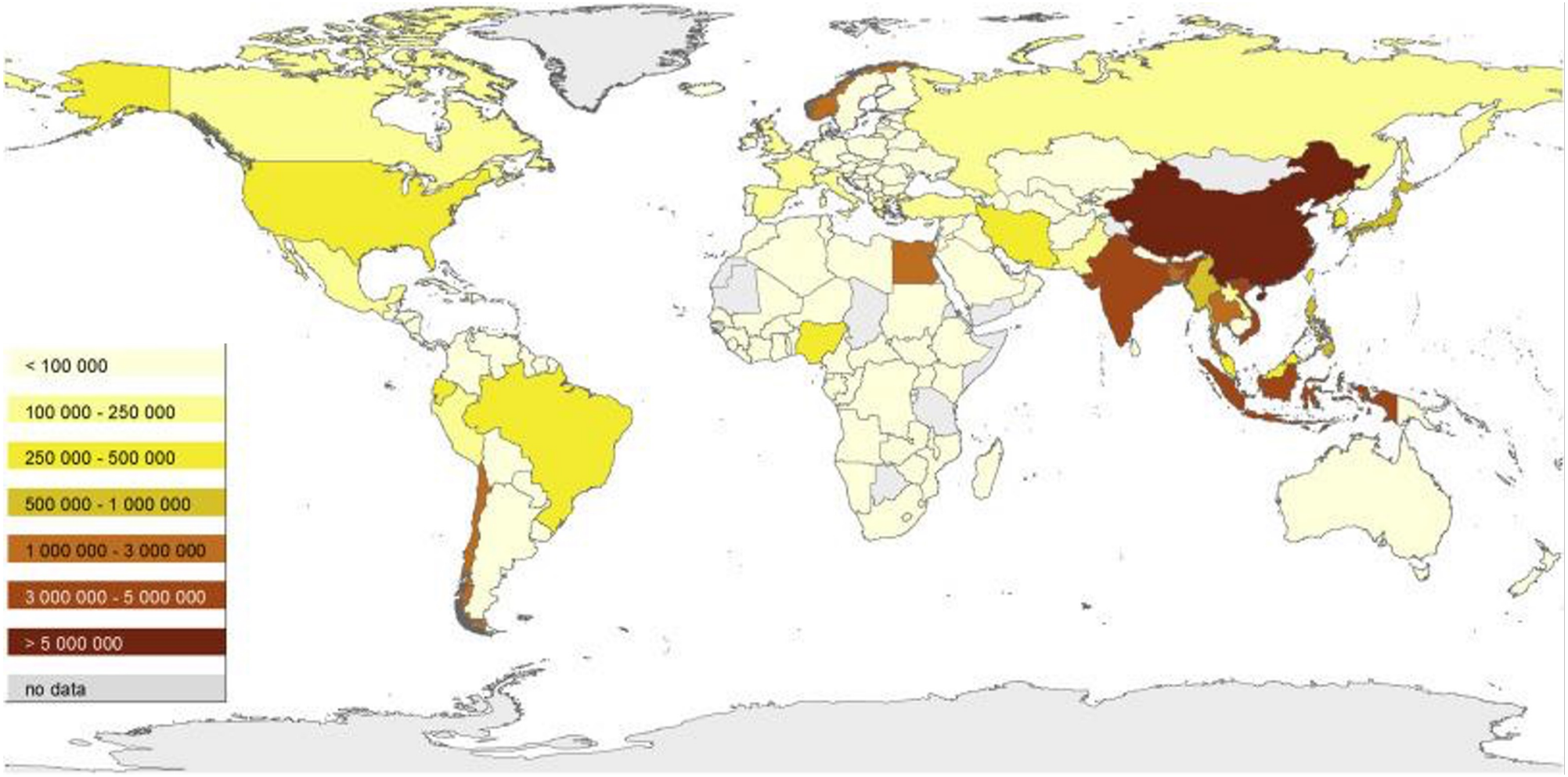
Vaccini stabulogeni in acquacultura: attualità e prospettive future



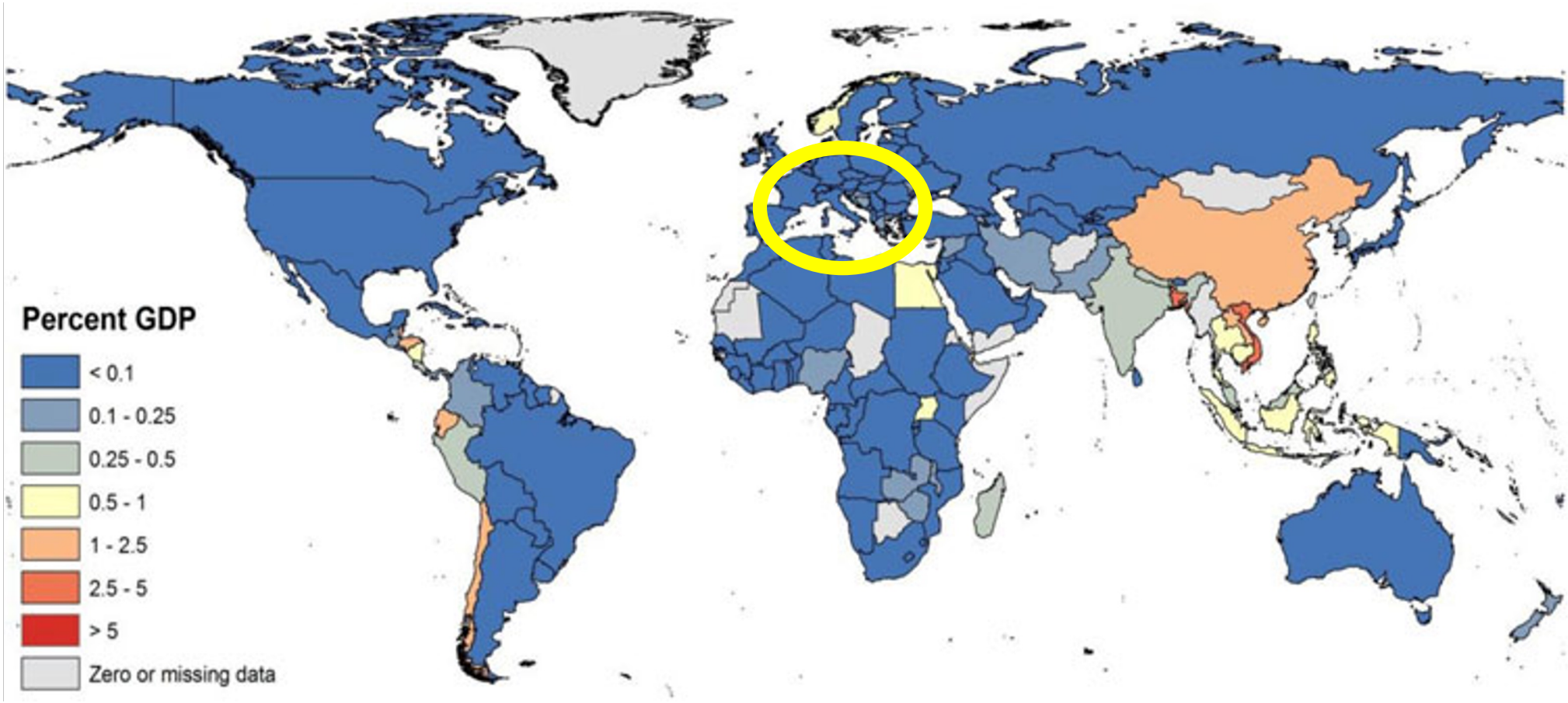
SIPI - Verona - 10 Novembre 2023

Giulio Severi - DVM PhD IZSUM - g.severi@izsum.it

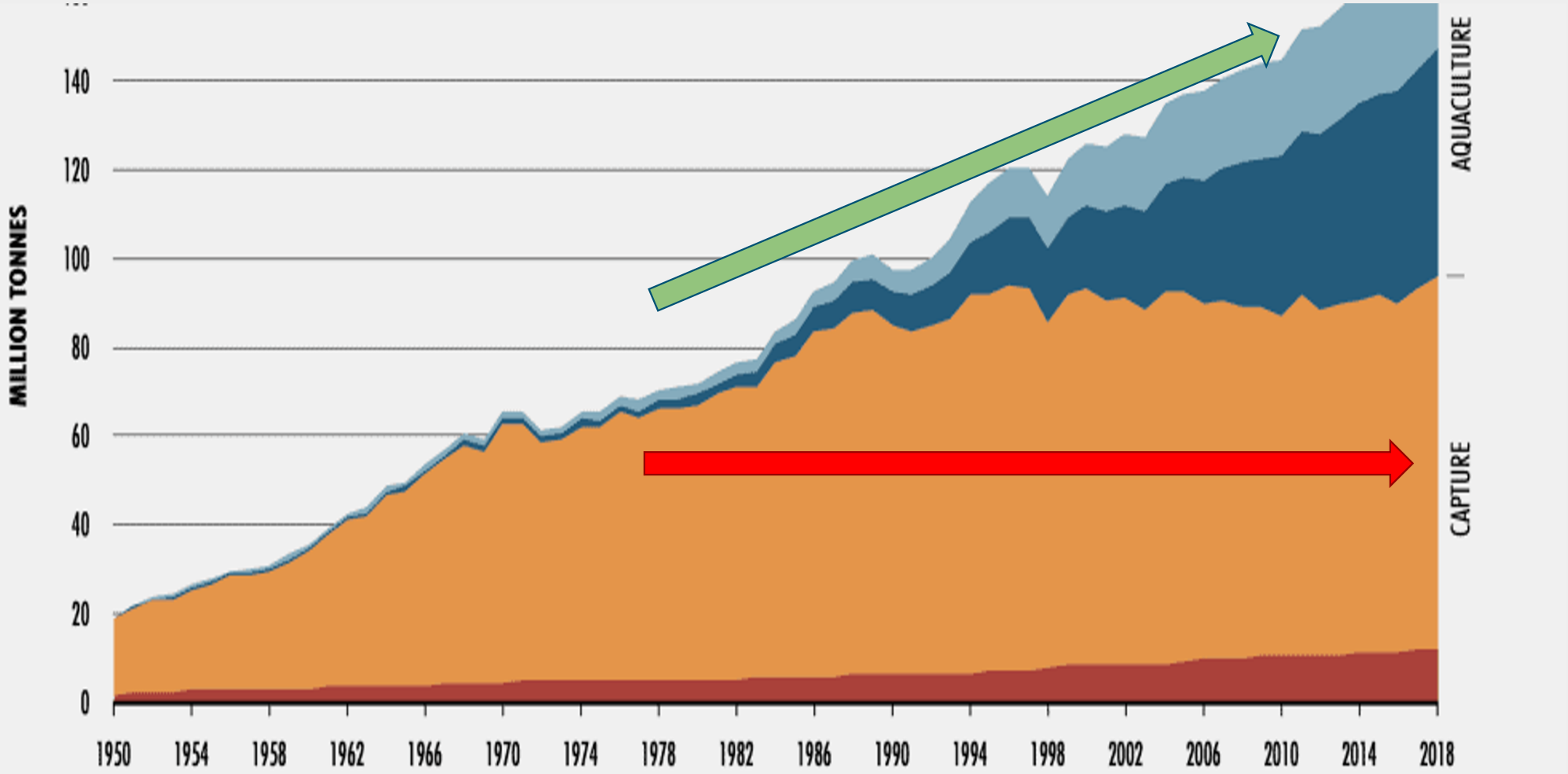
Total aquacolture production in tonnes



Aquacolture: Global contribution of aquaculture to gross domestic product (GDP) by country



Why aquaculture?



Aquaculture - Feed Conversion Ratio (FCR), Water Consumtion and Carbon Footprint

Farmed salmon is one of the most eco-efficient and sustainable forms of protein

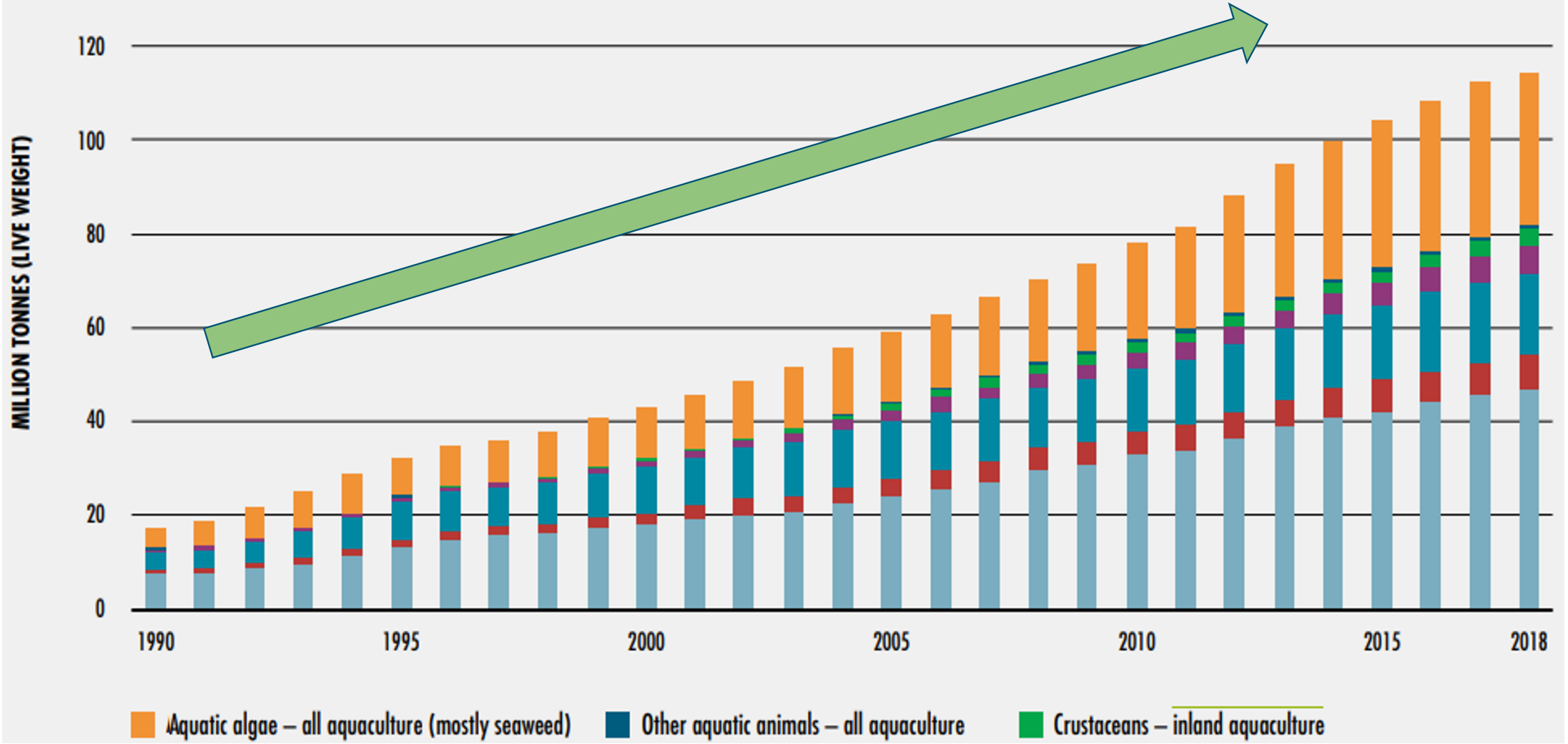
Feed Conversion Ratio[1]	1.2–1.5*	1.7–2	2.7–5	6–10
Water Consumption[2] (liter / kg edible meat)	2,000**	4,300	6,000	15,400
Carbon Footprint[1] (grams CO_2-equivalent / typical serving of 40 g edible protein)	0.6*	0.9	1.3	5.9

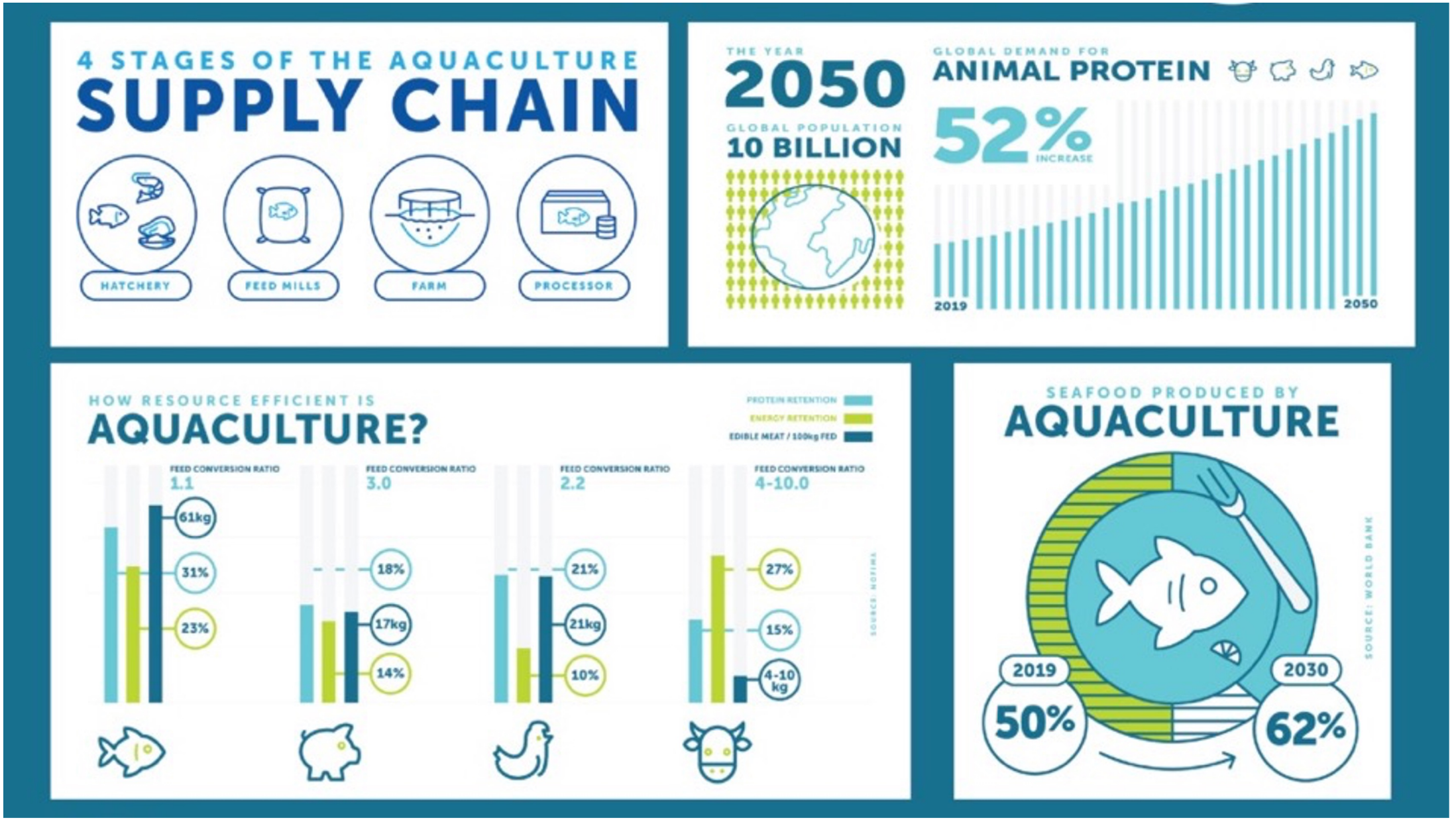
[1] Global Salmon Initiative (GSI) Sustainability Report. Available at: https://globalsalmoninitiative.org/en/sustainability-report/. Last accessed October 2019.
[2] Mowi. Salmon Farming Industry Handbook 2019. Available at: http://hugin.info/209/R/2246047/887370.pdf. Last accessed October 2019.

* Figures reflect feed conversion ratio and carbon footprint of farmed Atlantic salmon.
** Total water footprint for farmed salmon fillets in Scotland, in relation to weight and content of calories, protein and fat.

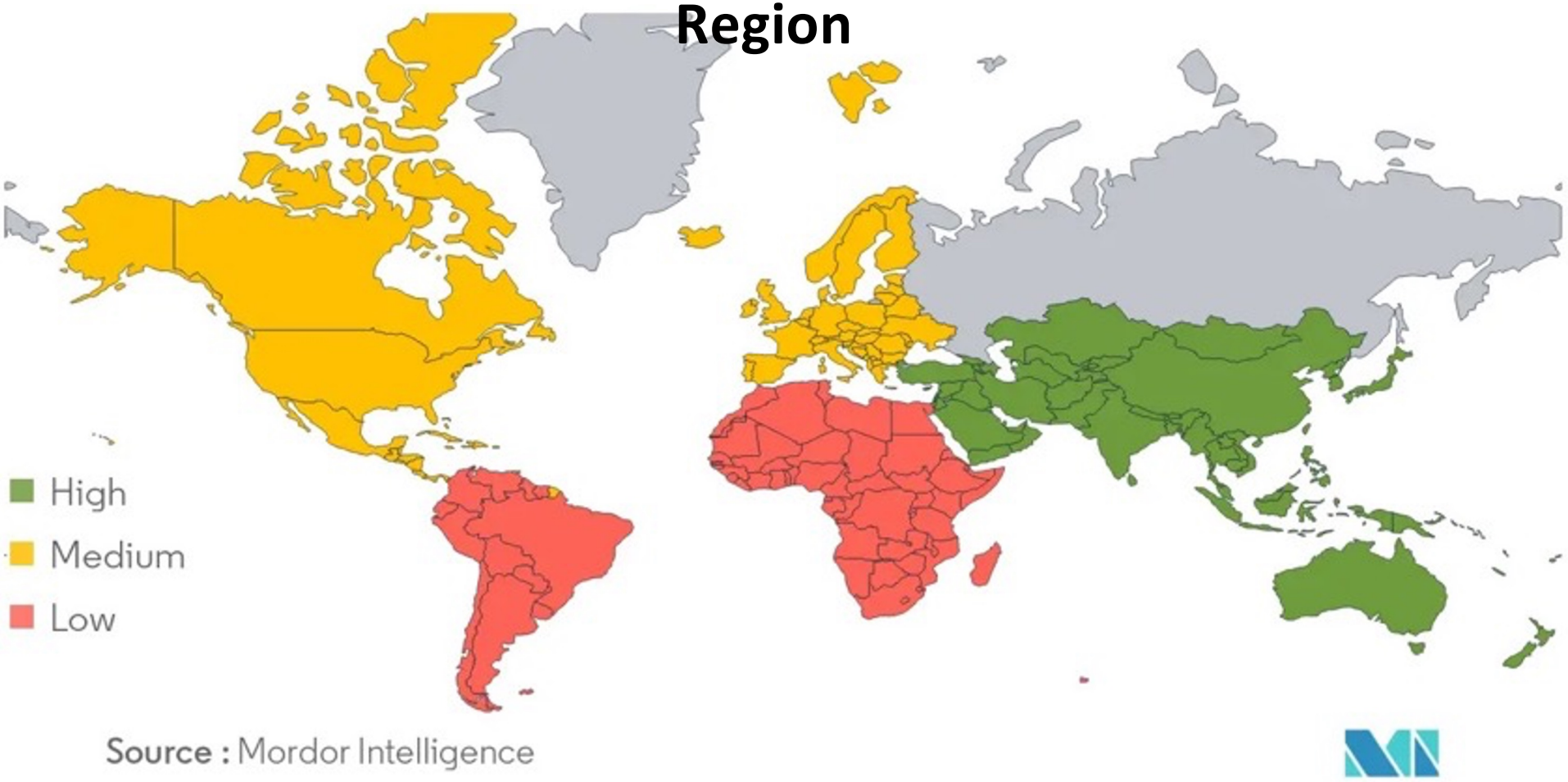

PRESENT
FUTURE
PAST

WORLD AQUACULTURE PRODUCTION OF AQUATIC ANIMALS AND ALGAE, 1990–2018




4 STAGES OF THE AQUACULTURE
SUPPLY CHAIN
HATCHERY
FEED MILLS
FARM
PROCESSOR
THE YEAR
2050
GLOBAL POPULATION
10 BILLION
GLOBAL DEMAND FOR
ANIMAL PROTEIN
52%
INCREASE
2019
2050
HOW RESOURCE EFFICIENT IS
AQUACULTURE?
PROTEIN RETENTION
ENERGY RETENTION
EDIBLE MEAT / 100kg FED
FEED CONVERSION RATIO
1.1
61kg
31%
23%
FEED CONVERSION RATIO
3.0
18%
17kg
14%
FEED CONVERSION RATIO
2.2
21%
21kg
10%
FEED CONVERSION RATIO
4-10.0
27%
15%
4-10 kg
SOURCE: NOFIMA
SEAFOOD PRODUCED BY
AQUACULTURE
2019
50%
2030
62%
SOURCE: WORLD BANK

Aquacolture Vaccines Market - Growth Rate by Region



AQUACULTURE VACCINES MARKET

Global Market Insights

CAGR (2021-27): 4.4%

2020: >$200 MN

2027: >$265 MN

Regional Analysis

1 NA — CAGR (2021-27): 4.7%

2 EUROPE — Market Share (2027): >47%

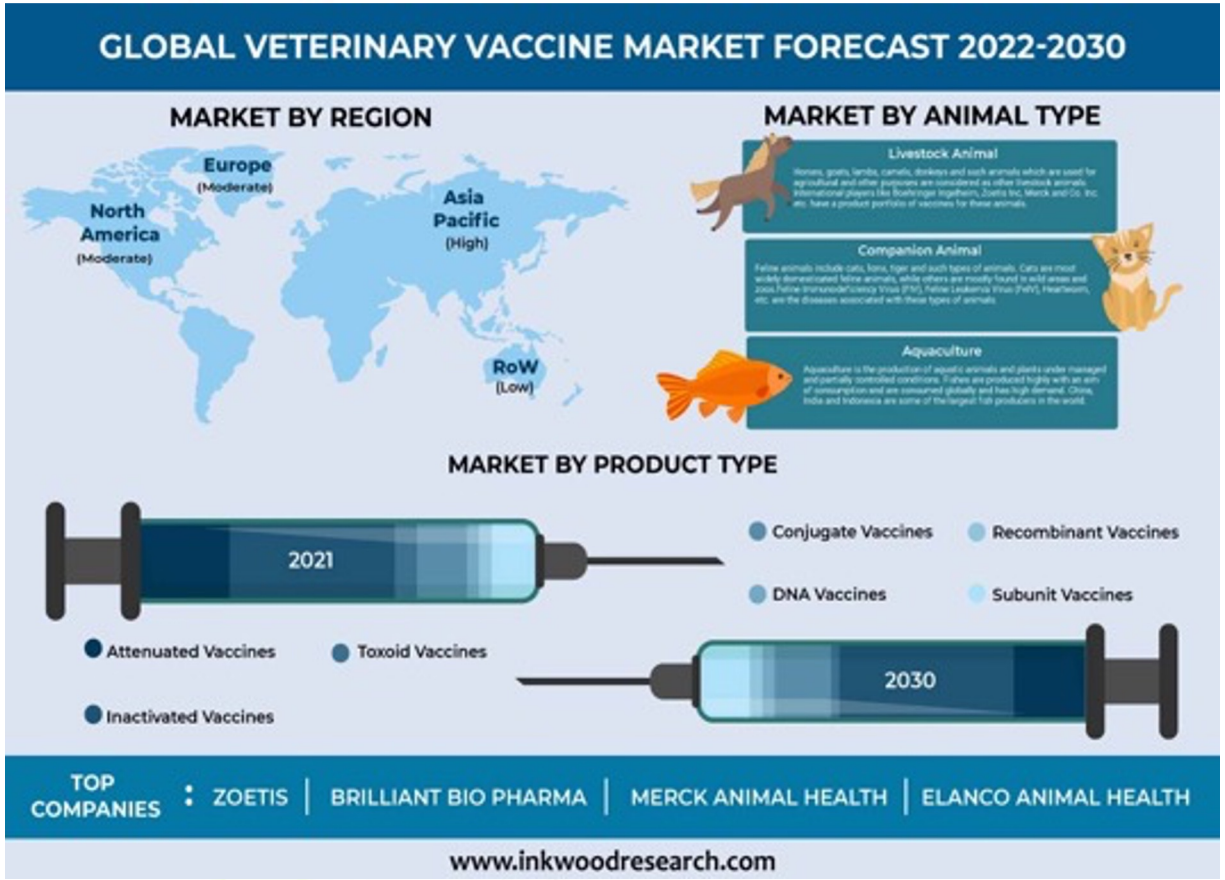
Market Value (2020):

Inactivated vaccines segment	Trout segment	Viral infection segment
$163.1 MN	$39.8 MN	$31.9 MN

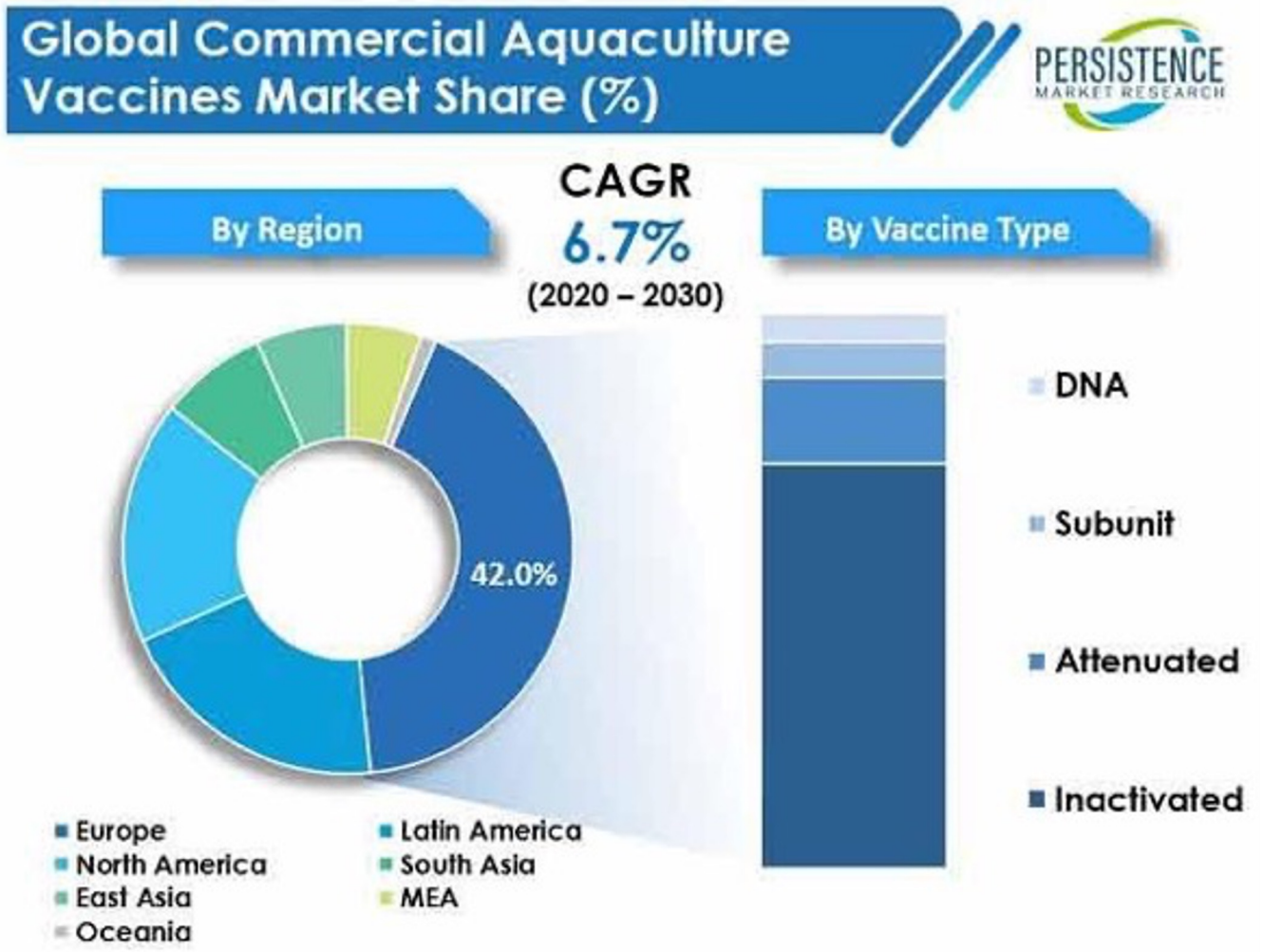
Major Players

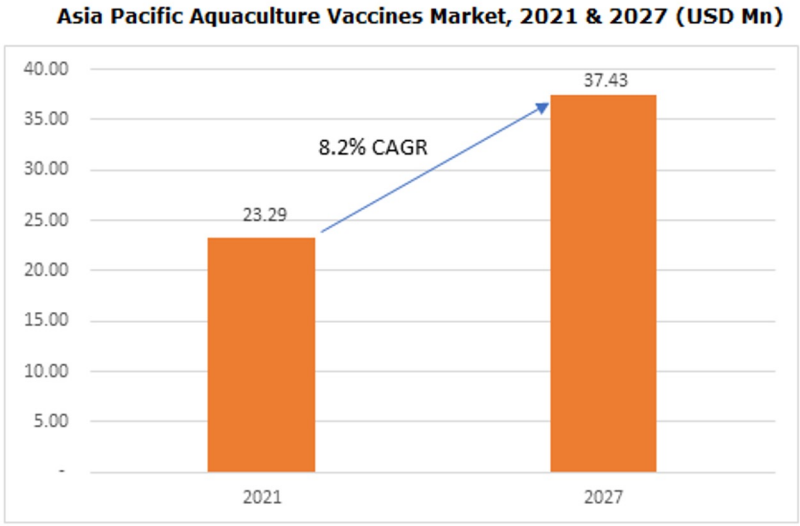
1. Merck & Co. Inc. (Intervet International B.V.)
2. Pfizer Inc. (PharmaQ)
3. Hipra
4. Tecnovax
5. Ictyogroup

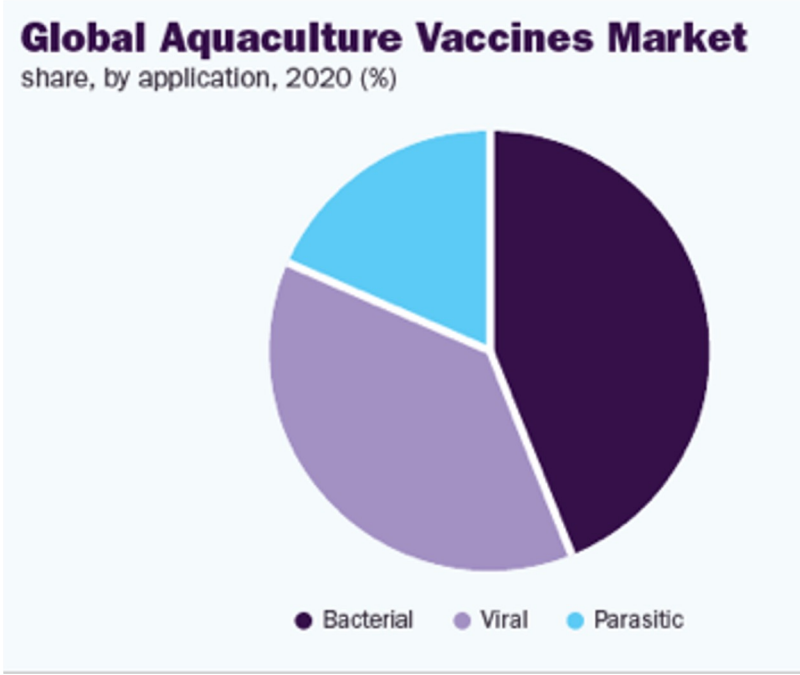
Market Concentration



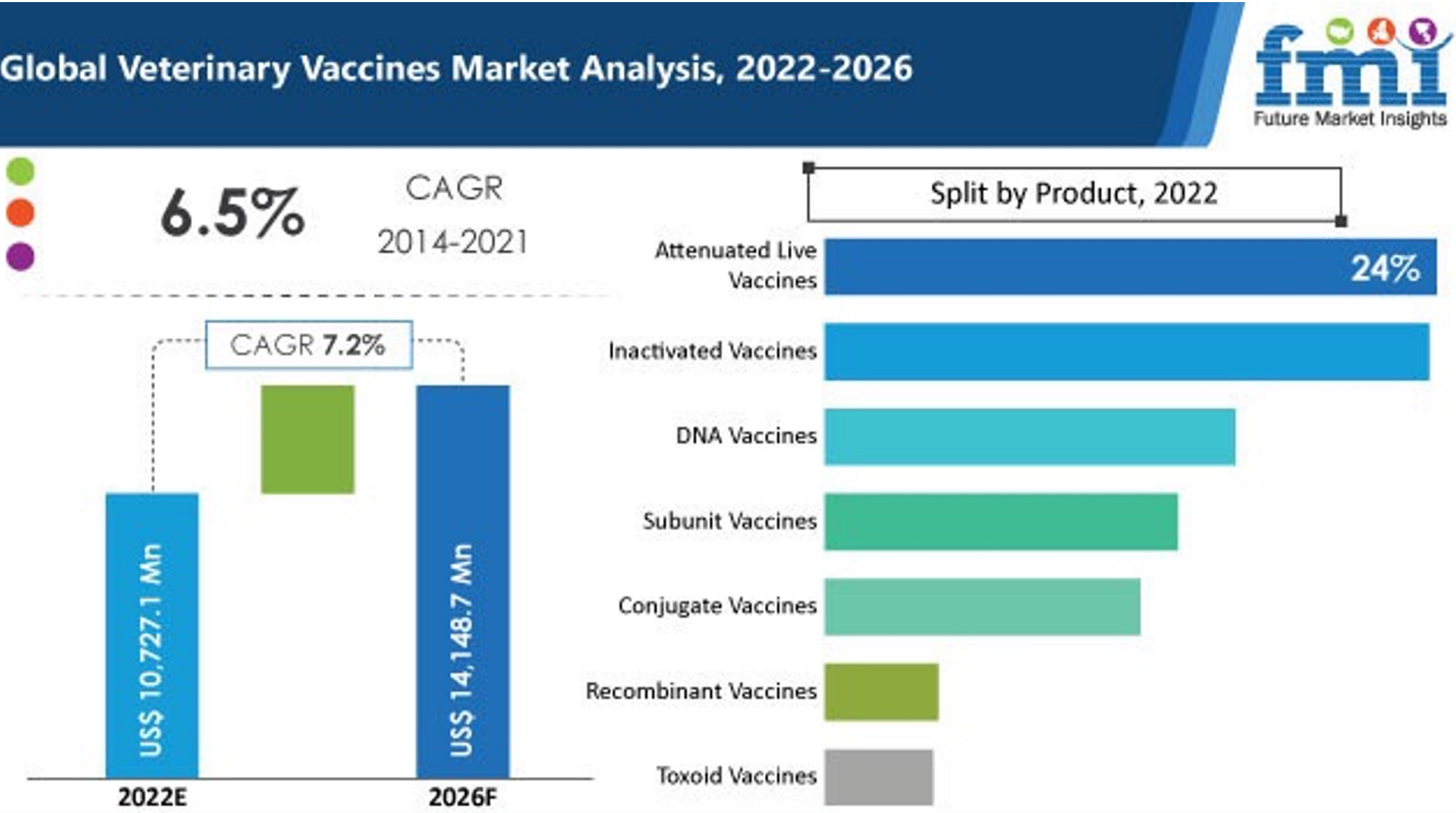
Source: Mordor Intelligence


Global Commercial Aquaculture Vaccines Market Share (%)
PERSISTENCE MARKET RESEARCH
By Region
CAGR
6.7%
(2020 – 2030)
By Vaccine Type
42.0%
Europe
North America
East Asia
Oceania
Latin America
South Asia
MEA
DNA
Subunit
Attenuated
Inactivated


Asia Pacific Aquaculture Vaccines Market, 2021 & 2027 (USD Mn)
40.00
35.00
30.00
25.00
20.00
15.00
10.00
5.00
-
23.29
37.43
8.2% CAGR
2021
2027


Global Aquaculture Vaccines Market
share, by application, 2020 (%)
Bacterial
Viral
Parasitic

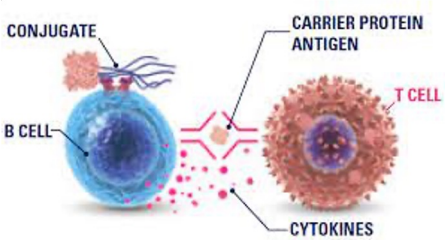
Global Veterinary Vaccines Market Analysis, 2022-2026

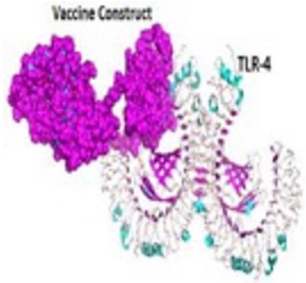


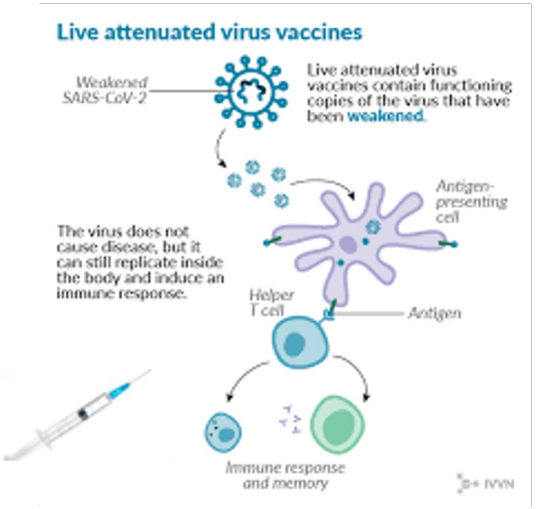
Vaccine types... but how many there are?

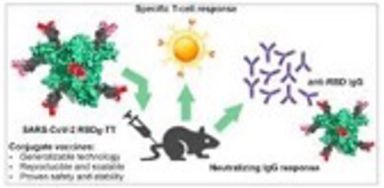
- Live attenuated
- Inactivated
- Sub-unitary
- Toxoid
- From edible plants

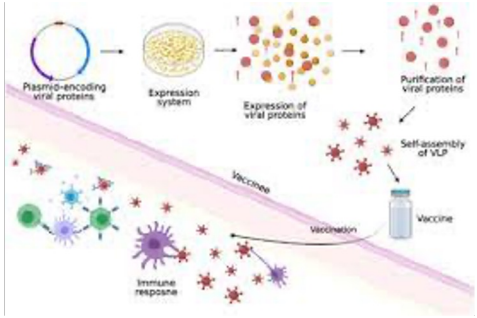
- Conjugate
- Marker
- Deleted
- DNA/RNA
- Vector

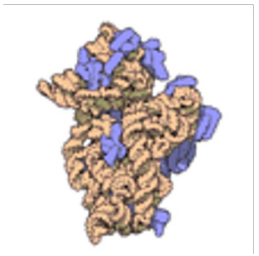




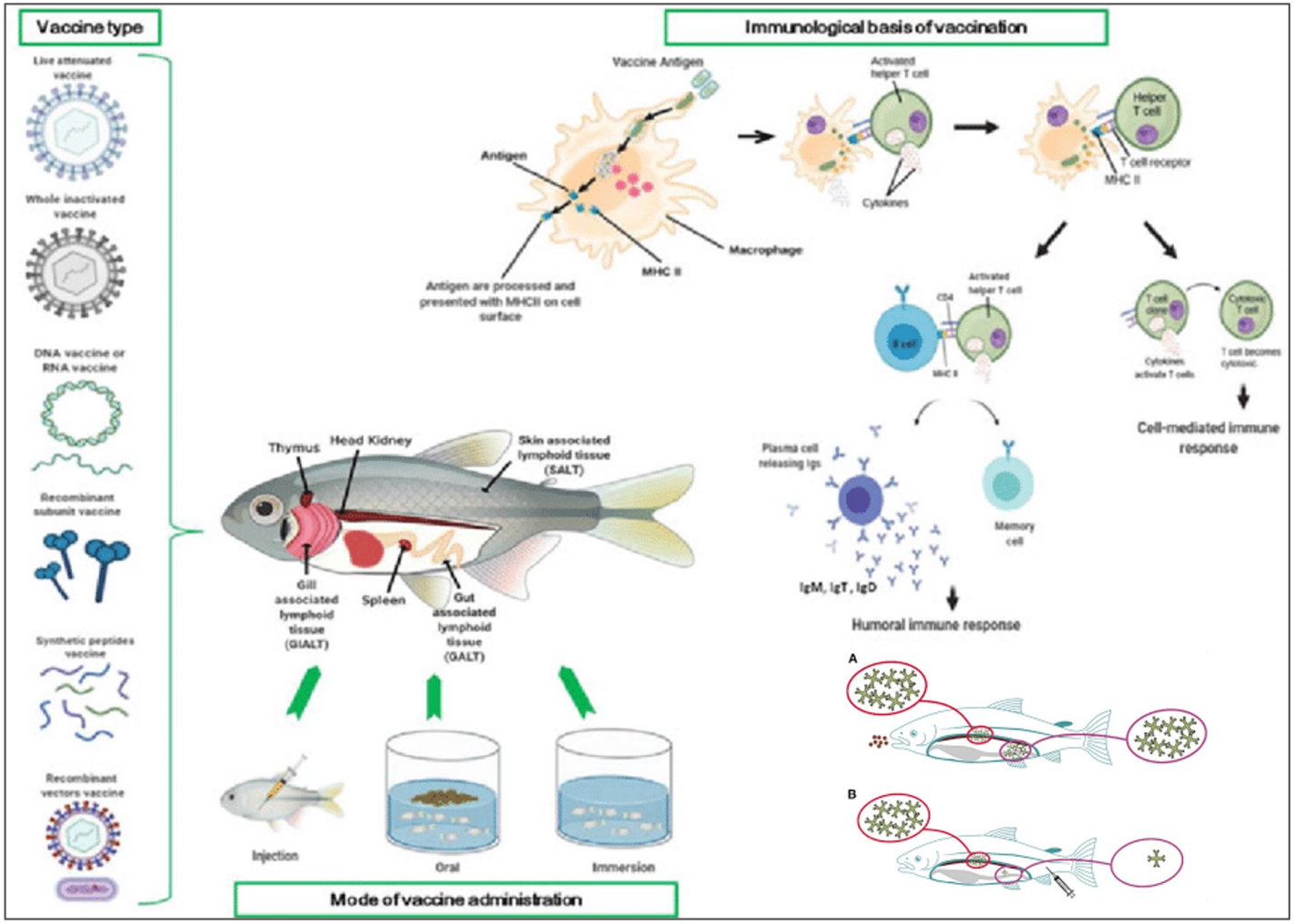




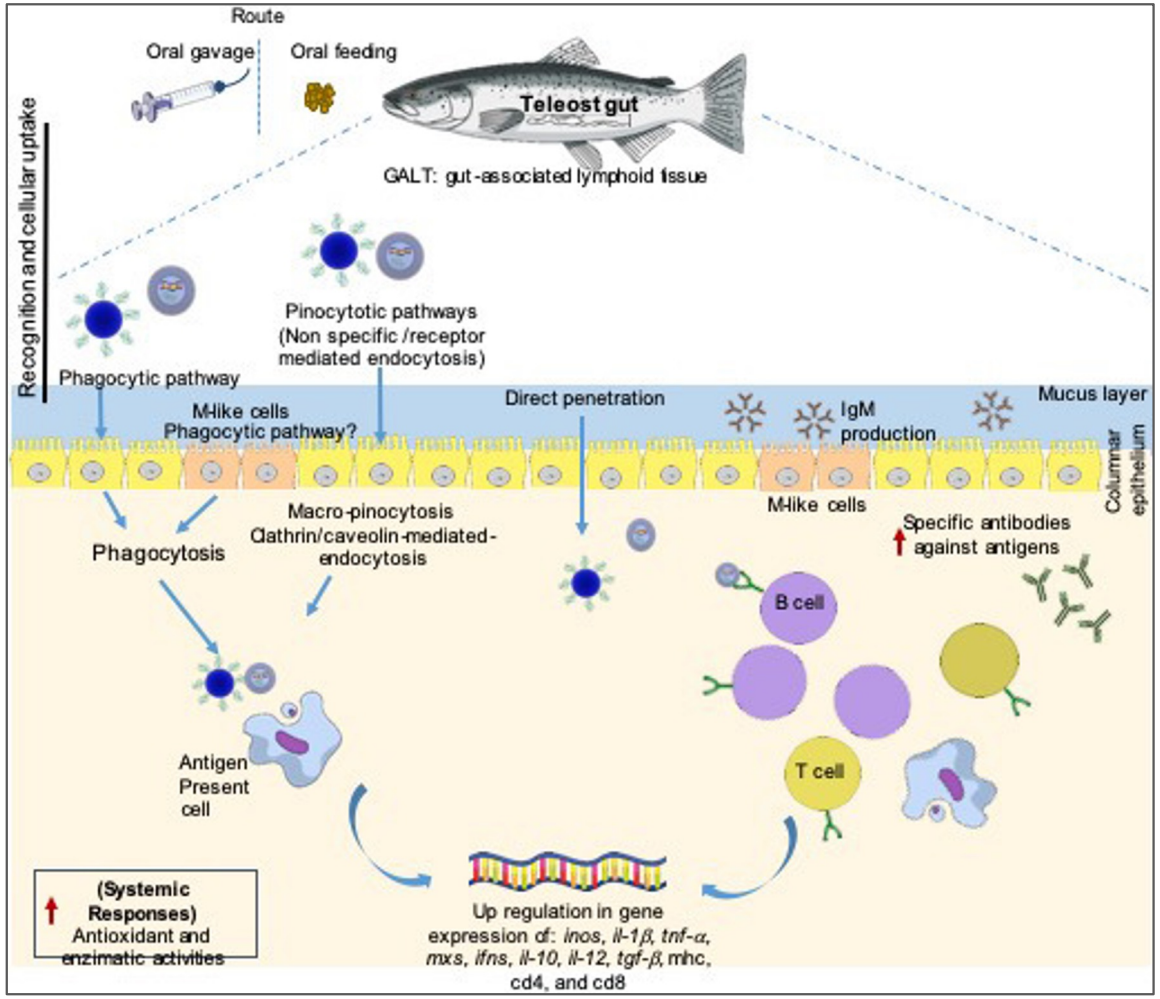


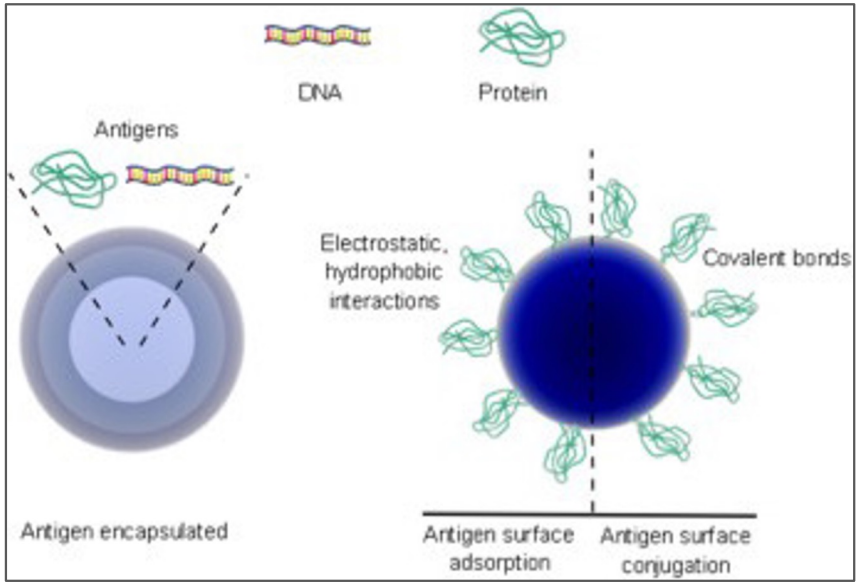


VACCINES AND VACCINATION STRATEGY



PREVENTION IS BETTER THAN CURE





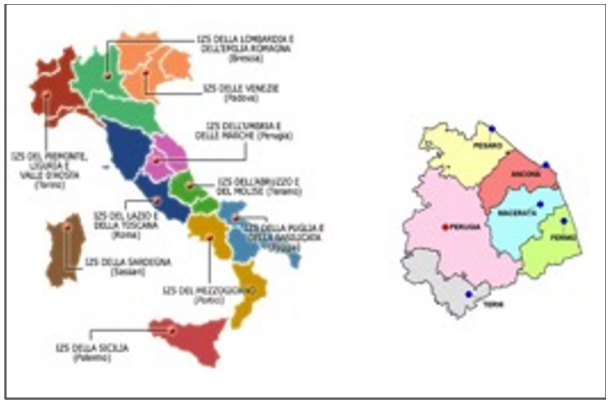
REVIEWS IN Aquaculture
Reviews in Aquaculture (2021) 13, 1172–1192
doi: 10.1111/raq.12518

Developing oral nanovaccines for fish: a modern trend to fight infectious diseases

Carlos Angulo[1], Marlene Tello-Olea[1], Martha Reyes-Becerril[1], Elizabeth Monreal-Escalante[1,2], Luis Hernández-Adame[1,2], Miriam Angulo[1] and José M. Mazon-Suastegui[1]

https://doi.org/10.1111/raq.12518

II.ZZ.SS. - ITALY



1. DIAGNOSIS
2. PREVENTION
   a. BIOSAFETY
   b. VACCINATION STRATEGIES
   c. RESEARCH AND DEVELOPMENT OF NEW VACCINES
   d. PRODUCTION AND CONTROL OF AUTOGENOUS VACCINES
3. SURVEILLANCE and CONTROL
4. MONITORING
5. COLLABORATION and COOPERATION

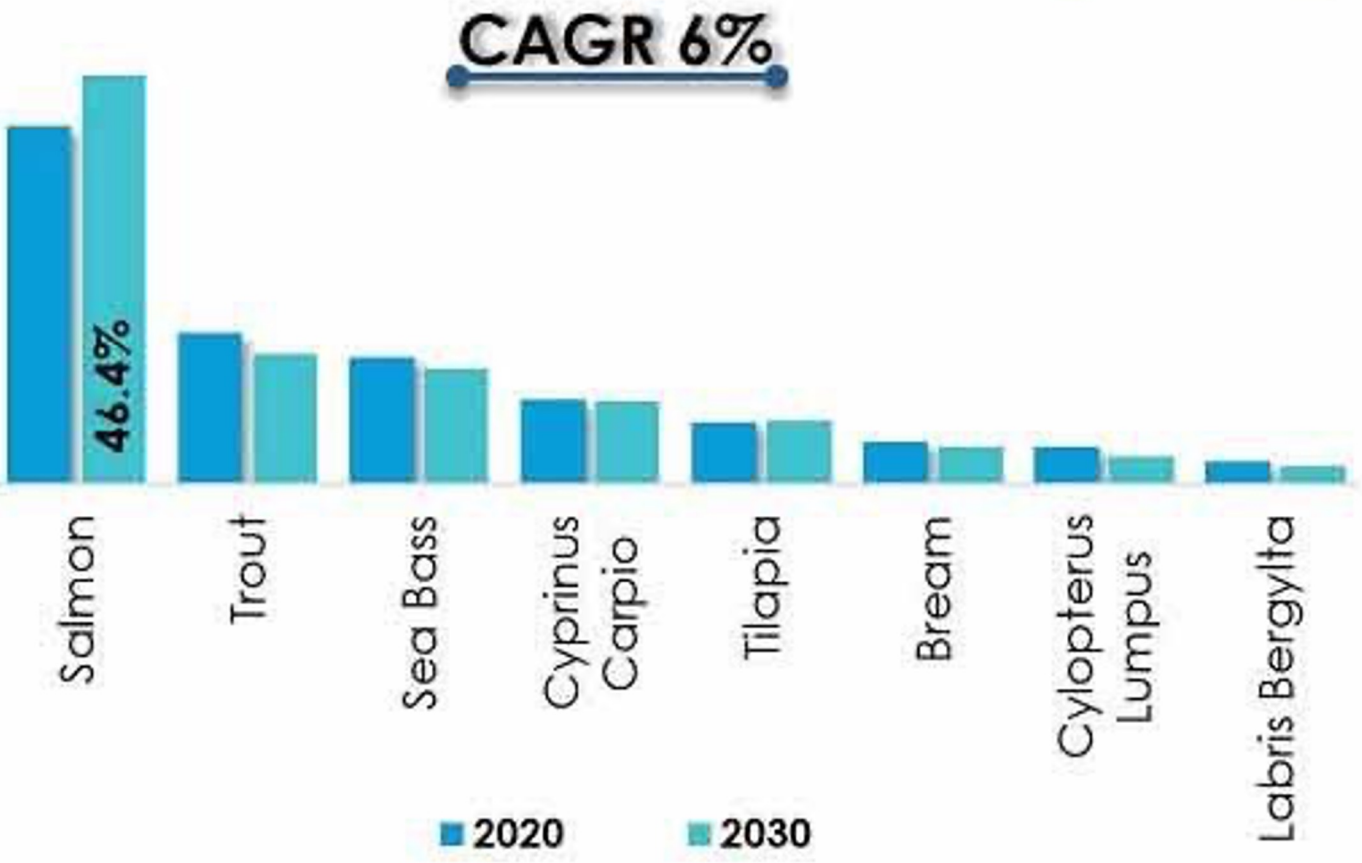
Pharmaceutical Laboratory

ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE "TOGO ROSATI"

Autogenous Vaccine for Aquaculture Market

By Fish Species- Global value Share Analysis 2020 & 2030

PERSISTENCE MARKET RESEARCH

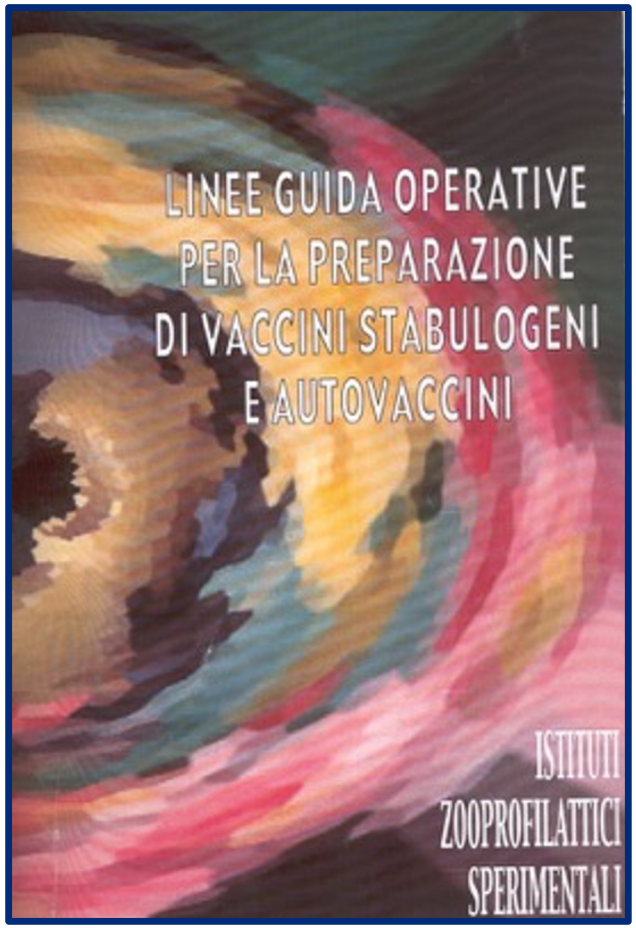


Production

Authorized only in the Experimental Zooprophylactic Institutes laboratories (pharmaceutical laboratories) after permission of the Ministry of Health and under control of ISS

Protocols

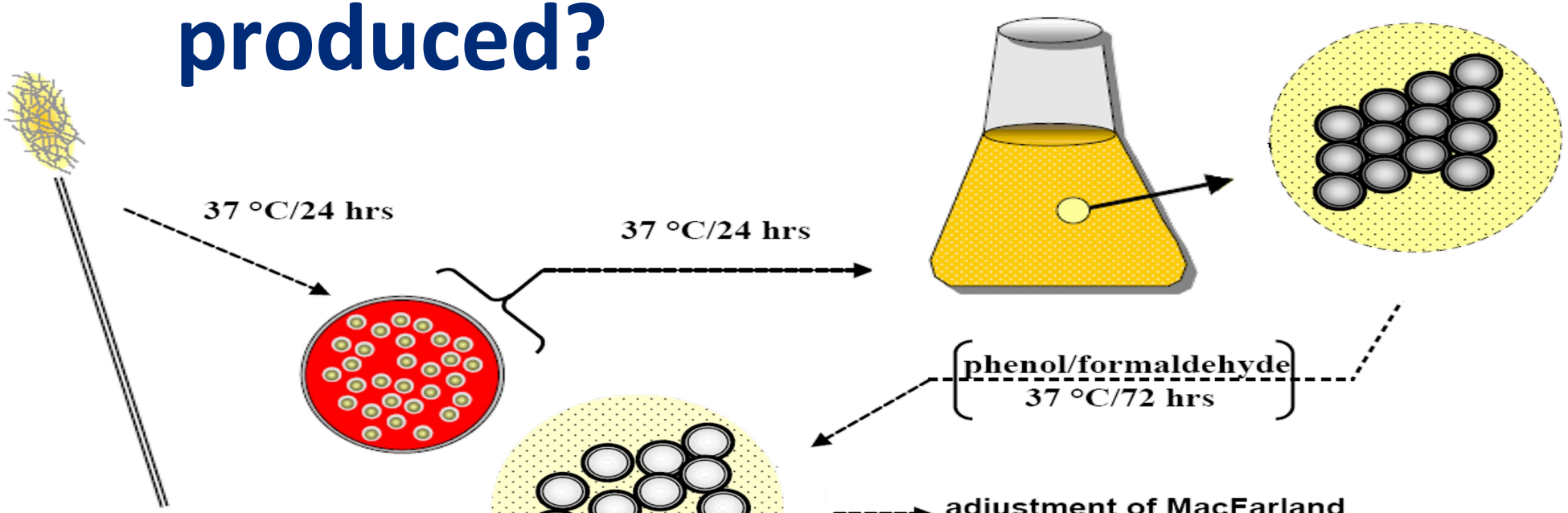
Operational guidelines agreed to harmonize and standardize the production of autogenos and autologus vaccines in the IZS laboratories



Autogenous vaccine

The autogenous vaccine is a **veterinary immunological drug** prepared with pathogens and/or antigens isolated from subjects affected by infectious form (dominant in a particular farm) and **used for the treatment of the same farm animals or the animals of the same "country"** if the DVM believe it appropriate for evident epidemiological reasons.

How is the autogenous vaccine produced?



ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE "TOGO ROSATI"

killed but still intact micro-organisms are in the autovaccine

- Inactivation (growth media)
- Sterility (growth media)
- Toxicity (LAL Test and/or lab. animals)
- Formaldehyde % (residual/free)

ISTITUTO ZOOPROFILATTICO
SPERIMENTALE
DELL'UMBRIA E DELLE MARCHE
"TOGO ROSATI"

44

Regulatory Affairs…

- Definition
- Request
- Protocols
- Production
- Distribution

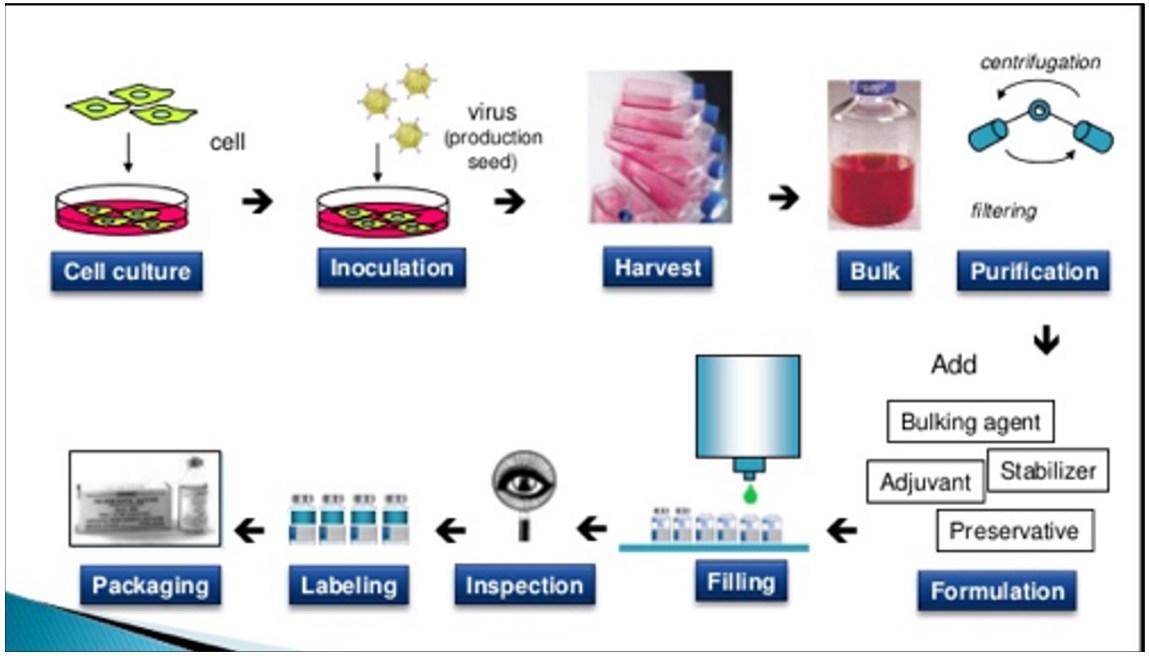
Operational guidelines agreed to harmonize and standardize the production of autogenous and autologous vaccines in the IZS laboratories…but in a short time…

CMDv
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

London, 20 March 2017
EMA/CMDv/452656/2016
REC-002-01

Recommendations for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA


Public
II.ZZ.SS.
Private
Private Companies &
Pharma Industries


cell
virus
(production
seed)
centrifugation
filtering
Cell culture
Inoculation
Harvest
Bulk
Purification
Add
Bulking agent
Adjuvant
Stabilizer
Preservative
Formulation
Filling
Inspection
Labeling
Packaging


Personnel Training & Competency
Management Commitment and Continual Improvement
Risk Management and Mitigation
Quality Management Systems
Site, Equipment, & Facilities Management
Product Control
GMP

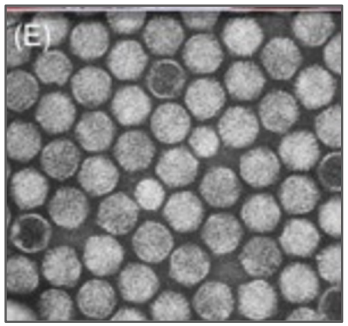
Quality Assurance and Quality Control

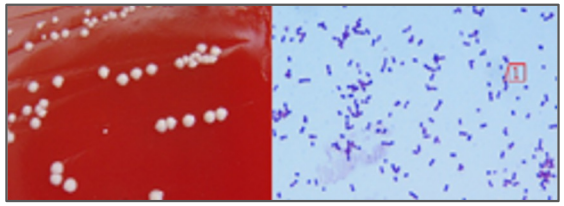
QA

- Is defined as the sum total of organized arrangements made with the objective of ensuring that the products are of quality required for their intended use.

QC

- It is the part of GMP which is concerned with sampling, specifications, testing, documentation and release which ensures that necessary and relevant tests are carried out and that materials/products are released For use/ sale only after their quality is judged to be satisfactory.


(E)



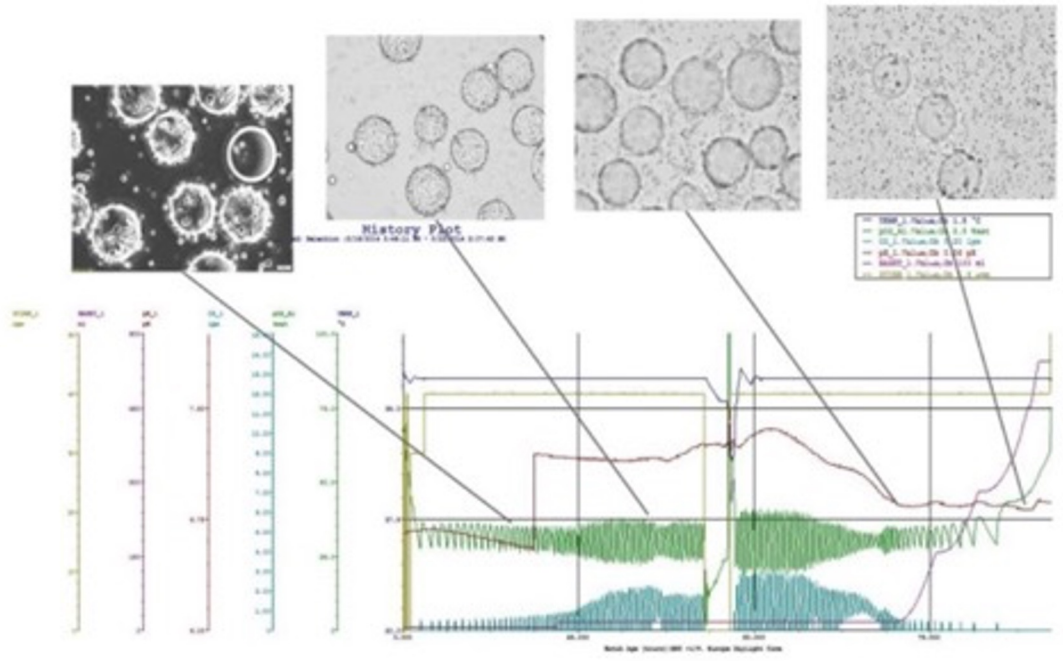

Fast selection of cell line and cultivation medium
Monitoring and control of process development
Industrial systems supporting operation in cGMP environments
Small Scale
Bench Scale
Pilot/Production Scale

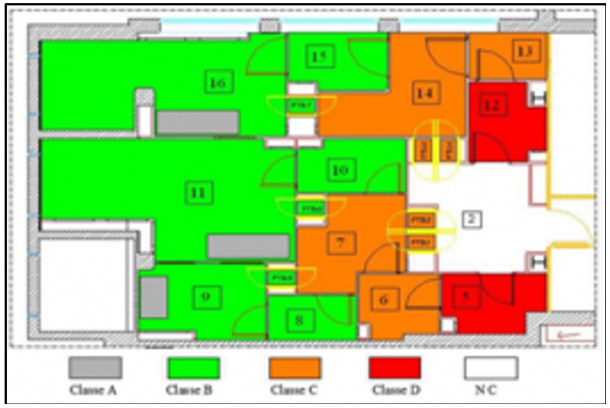

1 mL
100 mL
1 L
10 L
100 L
1000 L

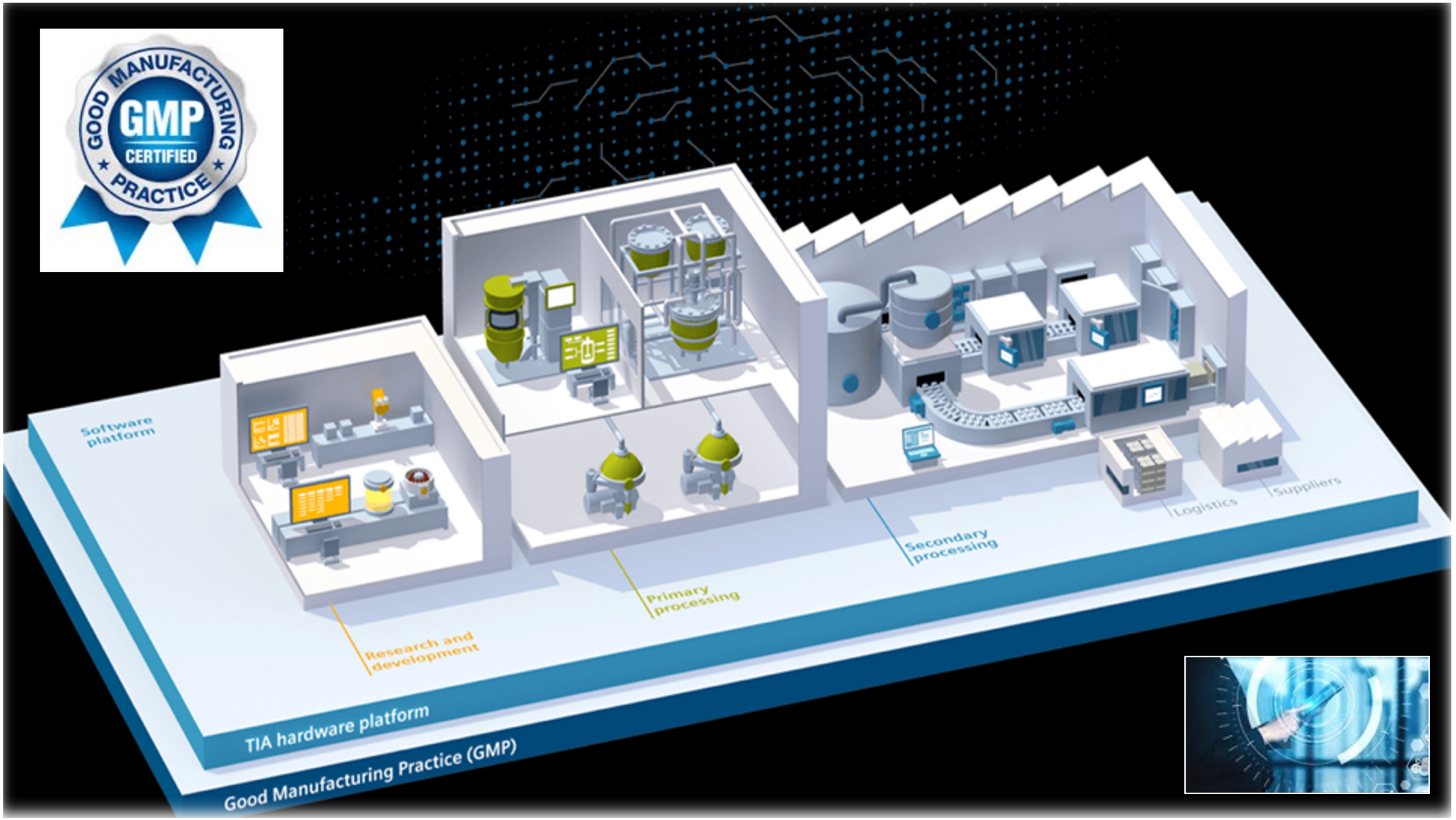

2-10 L
50 L
200L


Desired Product Performance
(Product Specifications)
Quality by Design
rocess Design
rocess Parameters)


CERTIFIED
GMP
AUDIT
QUALITY ASSURANCE
COMPLIANCE
GMP FACILITIES

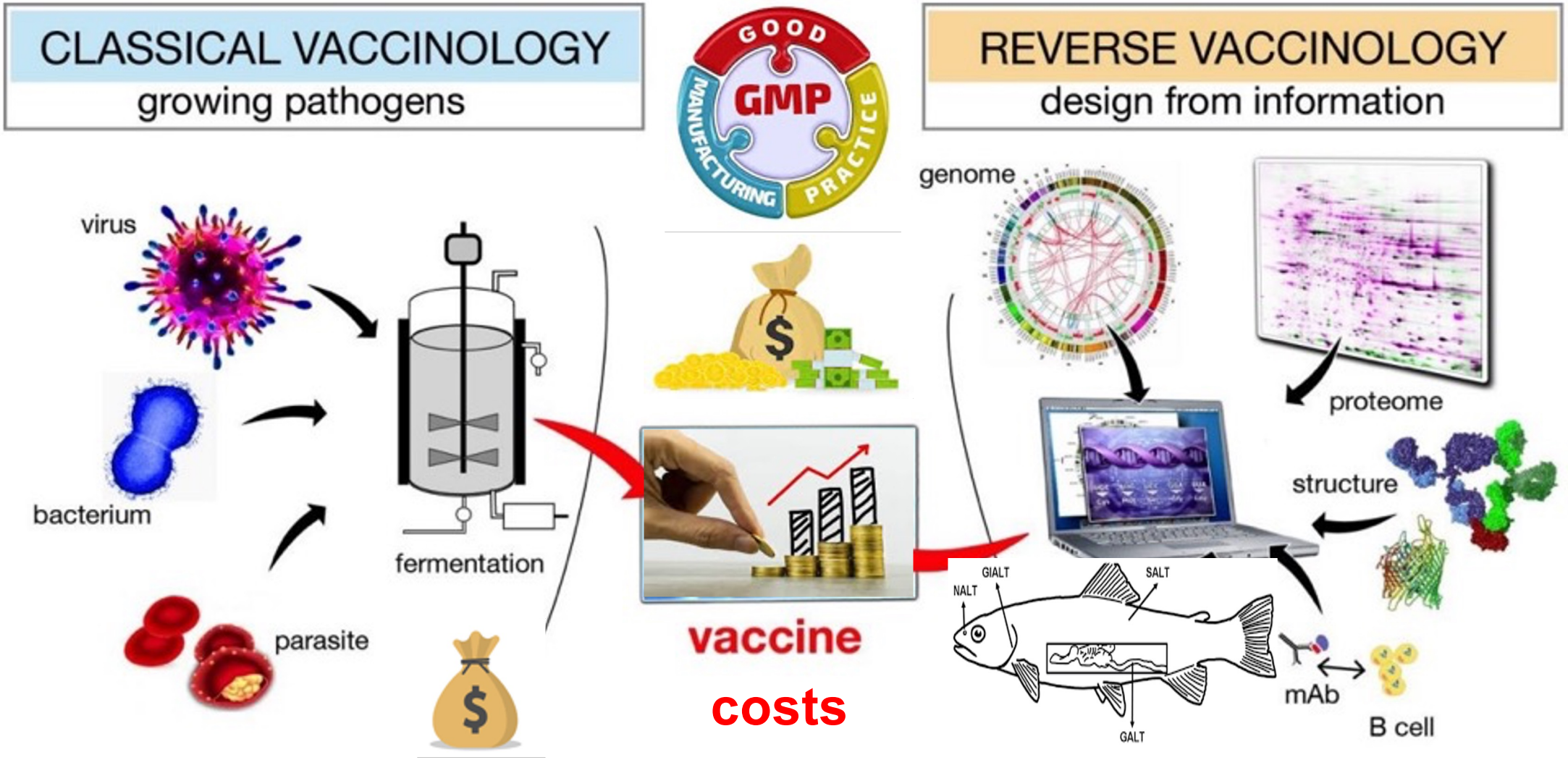

History Plot

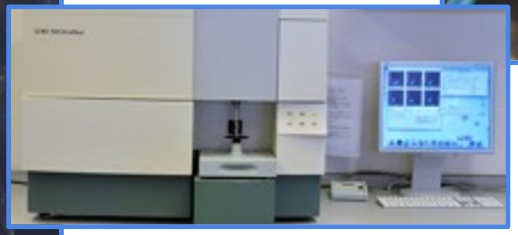

Classe A
Classe B
Classe C
Classe D
N C

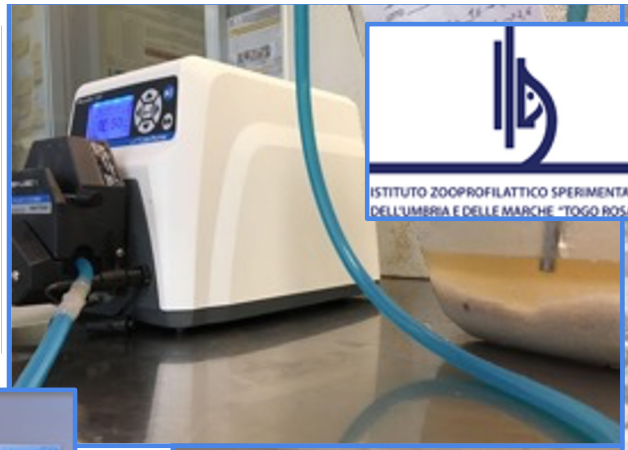

GOOD MANUFACTURING
GMP
CERTIFIED
PRACTICE
Software platform
Research and development
Primary processing
Secondary processing
Logistics
Suppliers
TIA hardware platform
Good Manufacturing Practice (GMP)


BANKROTT
SCHULDEN-
GRIECHENLAND


VACCINOLOGY, NEW VACCINES, GMP and COSTS







ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE "TOGO ROSATI"

Istituto Zooprofilattico Sperimentale delle Venezie

H K N O W

IZS Lazio e Toscana


KNOW
HOW

g.severi@izsum.it

+39 075.3433063

Grazie del tempo che ci siamo