
SUSTAINABLE
LOCAL
HEALTHY
VENTURA
SHELLFISH ENTERPRISE
Promoting healthy oceans with sustainable shellfish aquaculture
Aerial Photography Los Angeles

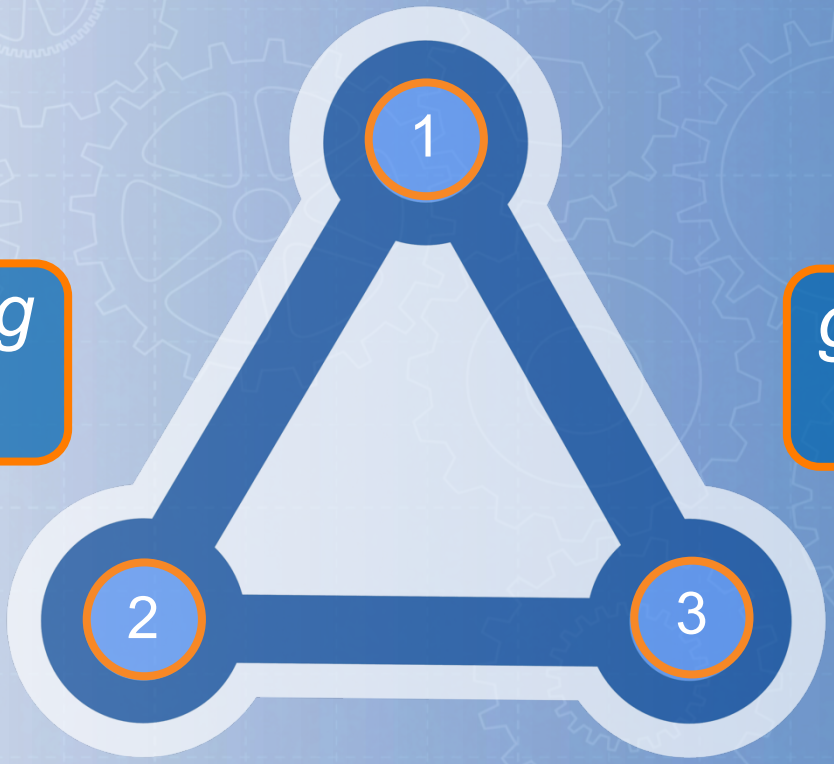
Outreach Program

Feb to Jun	Jul 11,13 | Aug 9	TBD
General Information	Site Planning	Training Program needs assessment

Project Innovation

Lowering barriers for future growers

pre-permitting farming sites



grower training and support

growing water certification

Food Quality & Safety

WS1

global food security

WS3

WS6

food commodity

WS7

food safety

Shellfish Regulation

National Shellfish Sanitation Program

Guide for the Control of Molluscan Shellfish | 2015 Revision

Shellfish Regulation

CA State Shellfish Sanitation Program

CDPH
California Department of
PublicHealth

Shellfish Control Authority for CA

Shellfish Regulation

CA State Shellfish Sanitation Program

Shellfish Control Authority for CA

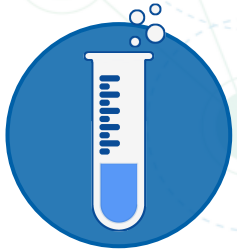
CDPH California Department of PublicHealth

- *Environmental Management* — *regulates* → ***pre**-harvest elements of NSSP*
- *Food and Drug* — *regulates* → ***post**-harvest elements of NSSP*

Growing Water Certification

Sanitary Survey (VSE)

assess actual and potential pollution sources near area



test water quality at sampling stations in area

Grower Requirements

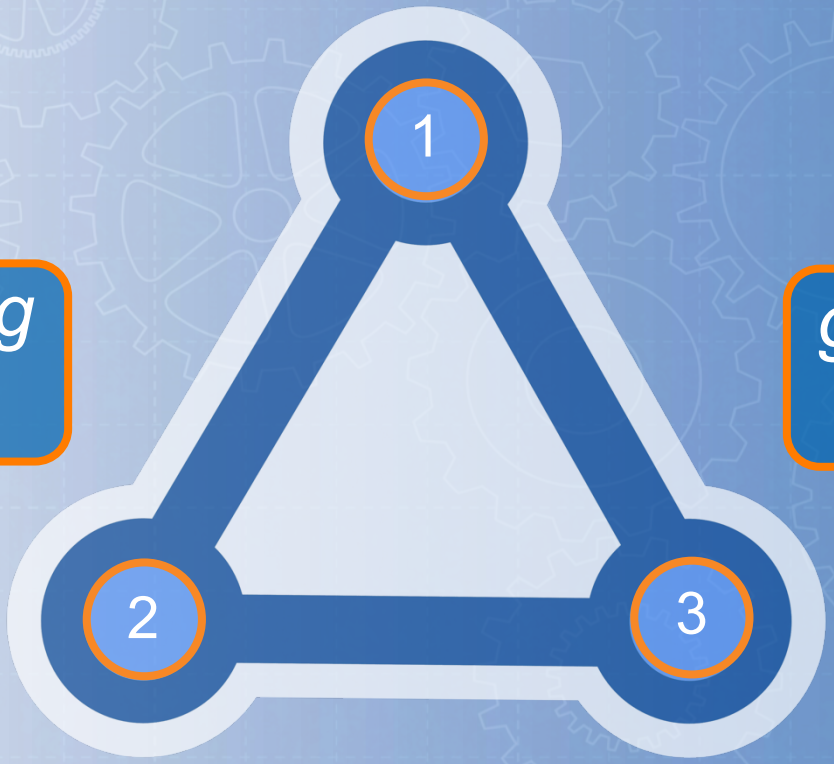
implement sampling plan for routine water quality monitoring

conduct **(at least)** weekly biotoxin analyses

Project Innovation

Lowering barriers for future growers

pre-permitting farming sites



grower training and support

growing water certification

Project Innovation

Lowering barriers for future growers

pre-permitting farming sites

4

harbor-based testing lab

grower training and support

growing water certification

Workshop 7

VSE Shellfish Quality and Safety Assurance

The (Neuro)science of Marine Biotoxins

Ralph Imondi, Ph.D.
Executive Director | Coastal Marine Biolabs
Integrative Biosciences Institute | Ventura Harbor

Workshop 7

VSE Shellfish Quality and Safety Assurance

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting along the California Sea Coast

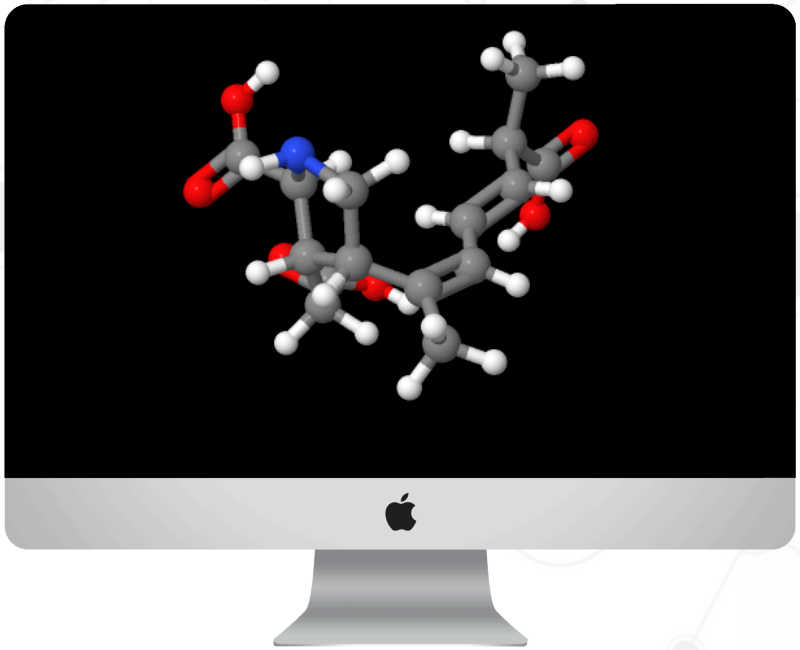
Masaaki Hori
Principal | Mas Hori & Associates

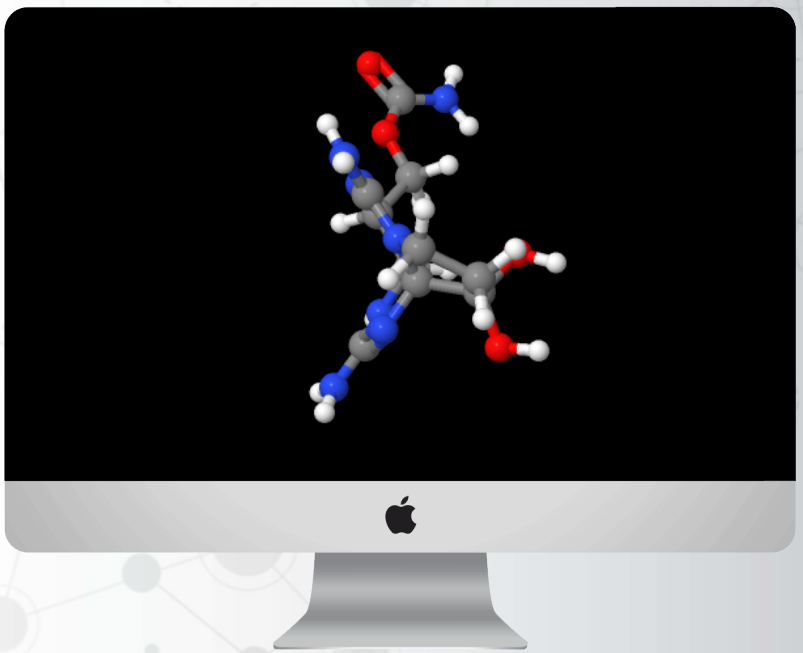
hazard *analysis* *critical* *control* *points*

VSE Workshop 7

The (Neuro)science of Marine Biotoxins

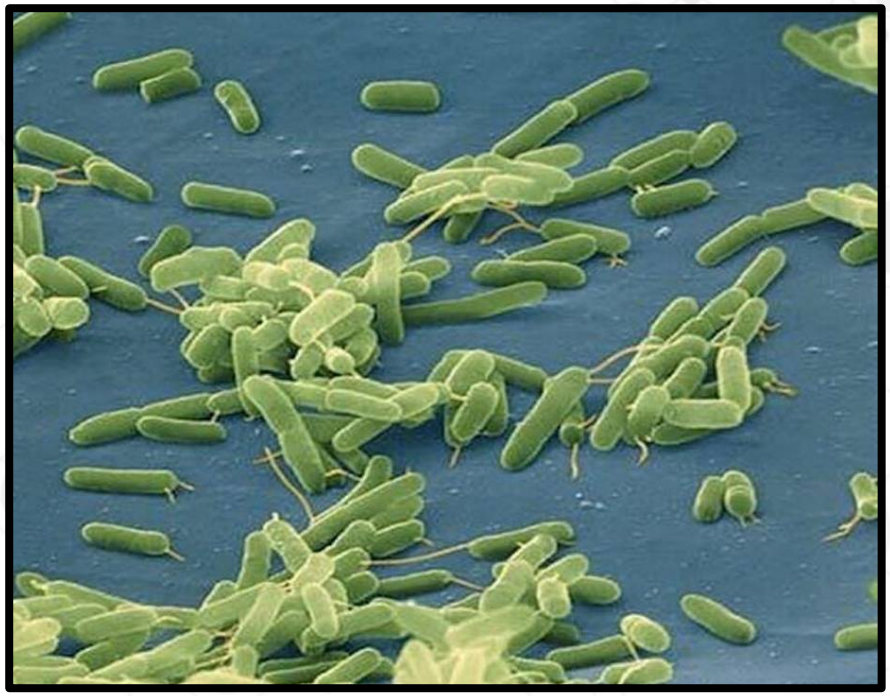
Ralph Imondi, Ph.D. | Coastal Marine Biolabs Integrative Biosciences Institute



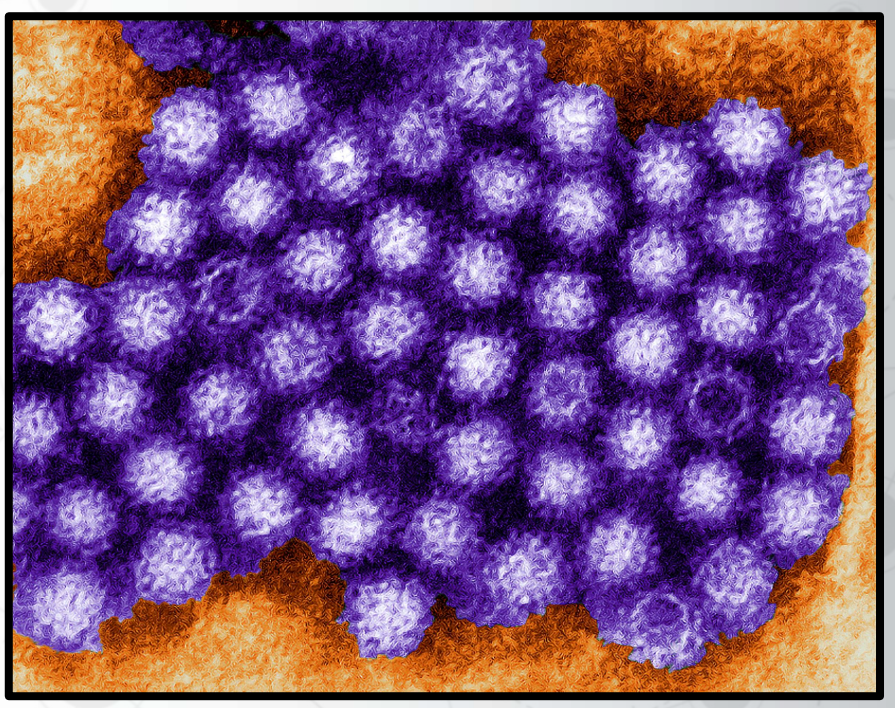


Pathogens

bacteria



viruses



Marine Microalgae

single-cell diatoms

Photo Credit: NOAA Climate.gov | Vera Trainer

Marine Microalgae

single-cell dinoflagellates

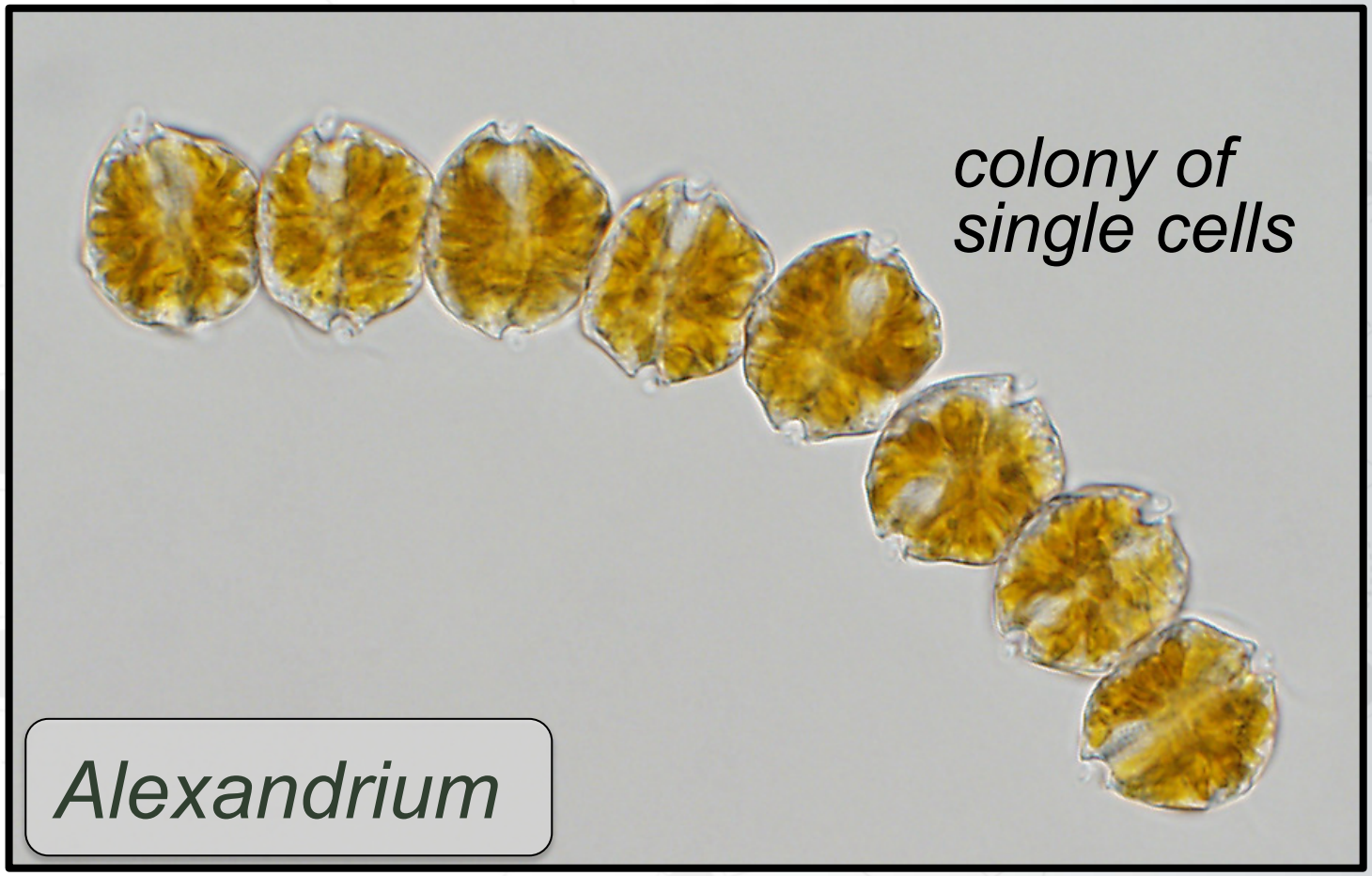
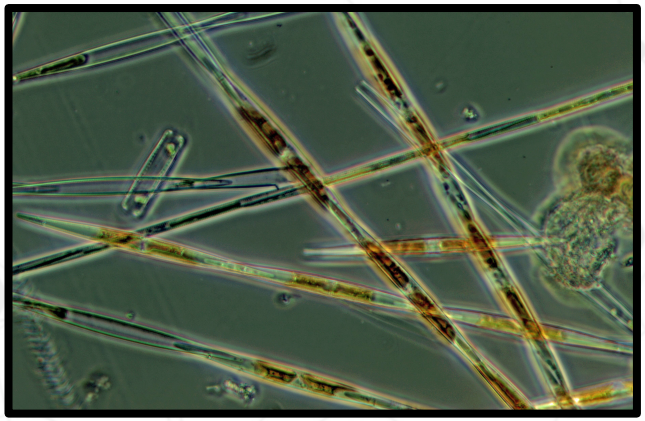


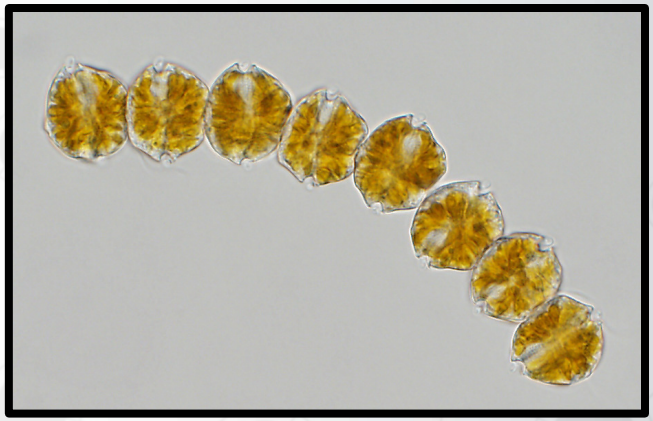
Photo Credit: SCCAP | © Gert Hansen

Marine Microalgae

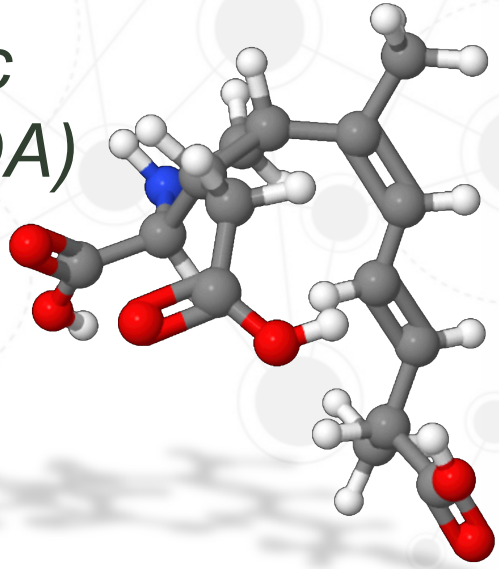
Pseudo-nitzschia



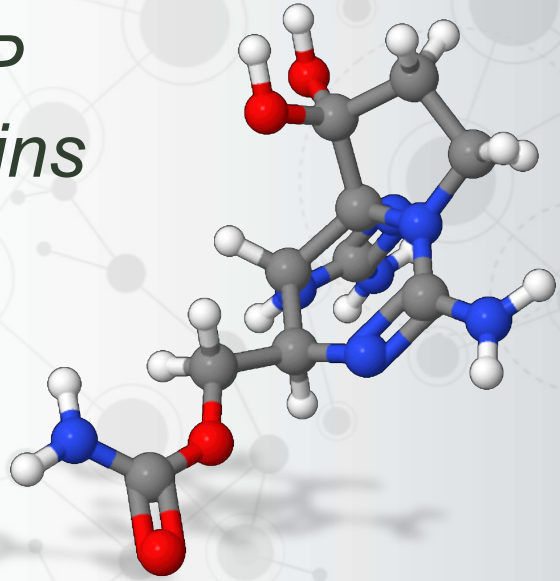
Alexandrium



Domoic Acid (DA)

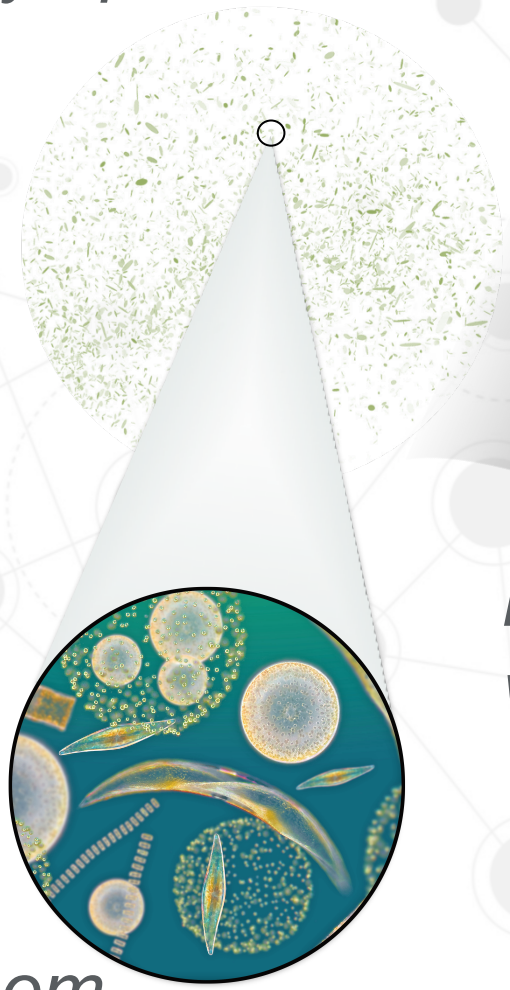


PSP Toxins



Mussel Uptake

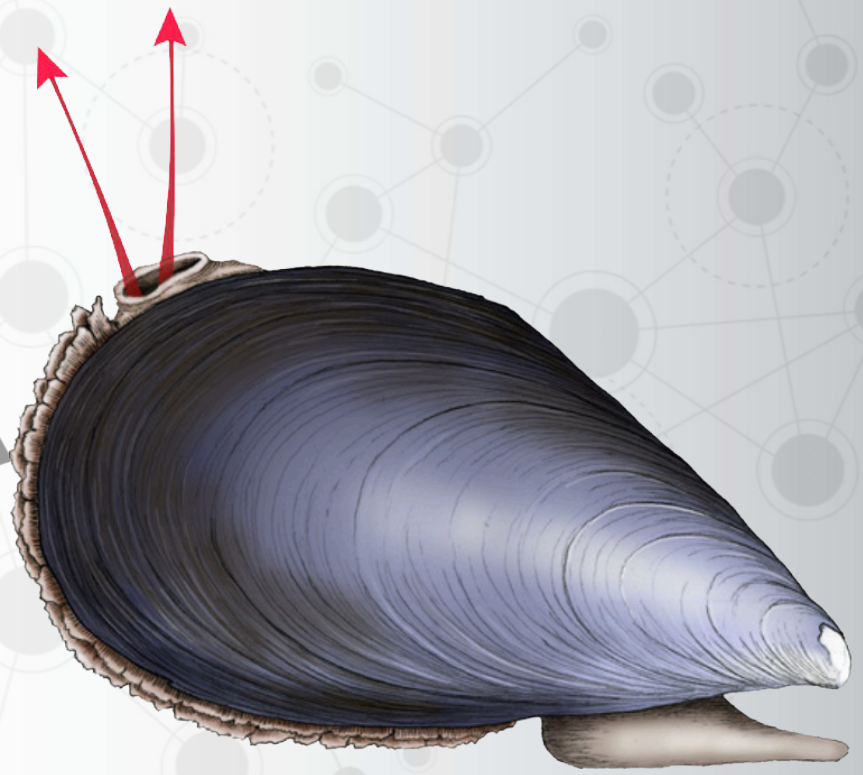
phytoplankton



zoom

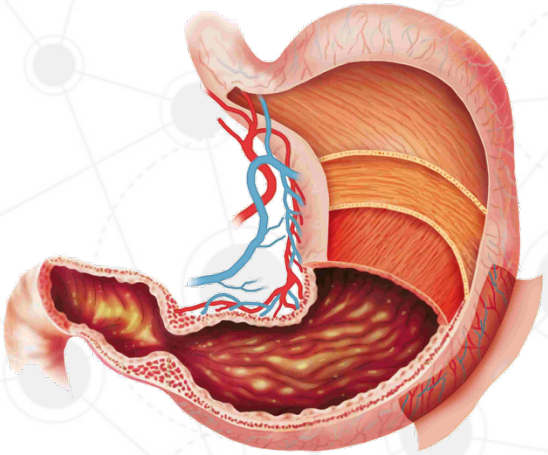
exhaled water

inhaled water

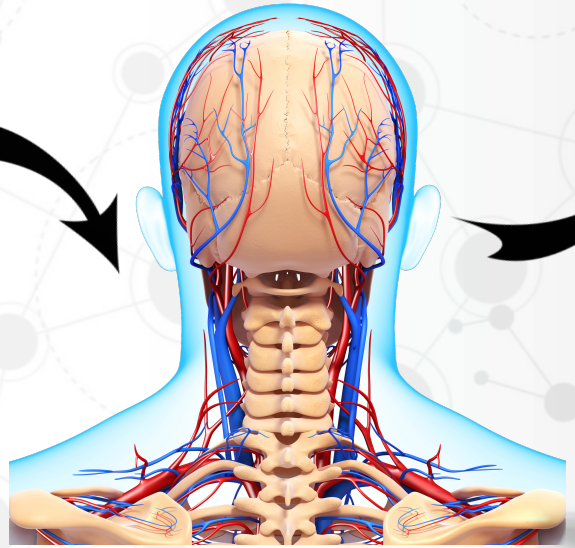


Human Uptake

digestive system

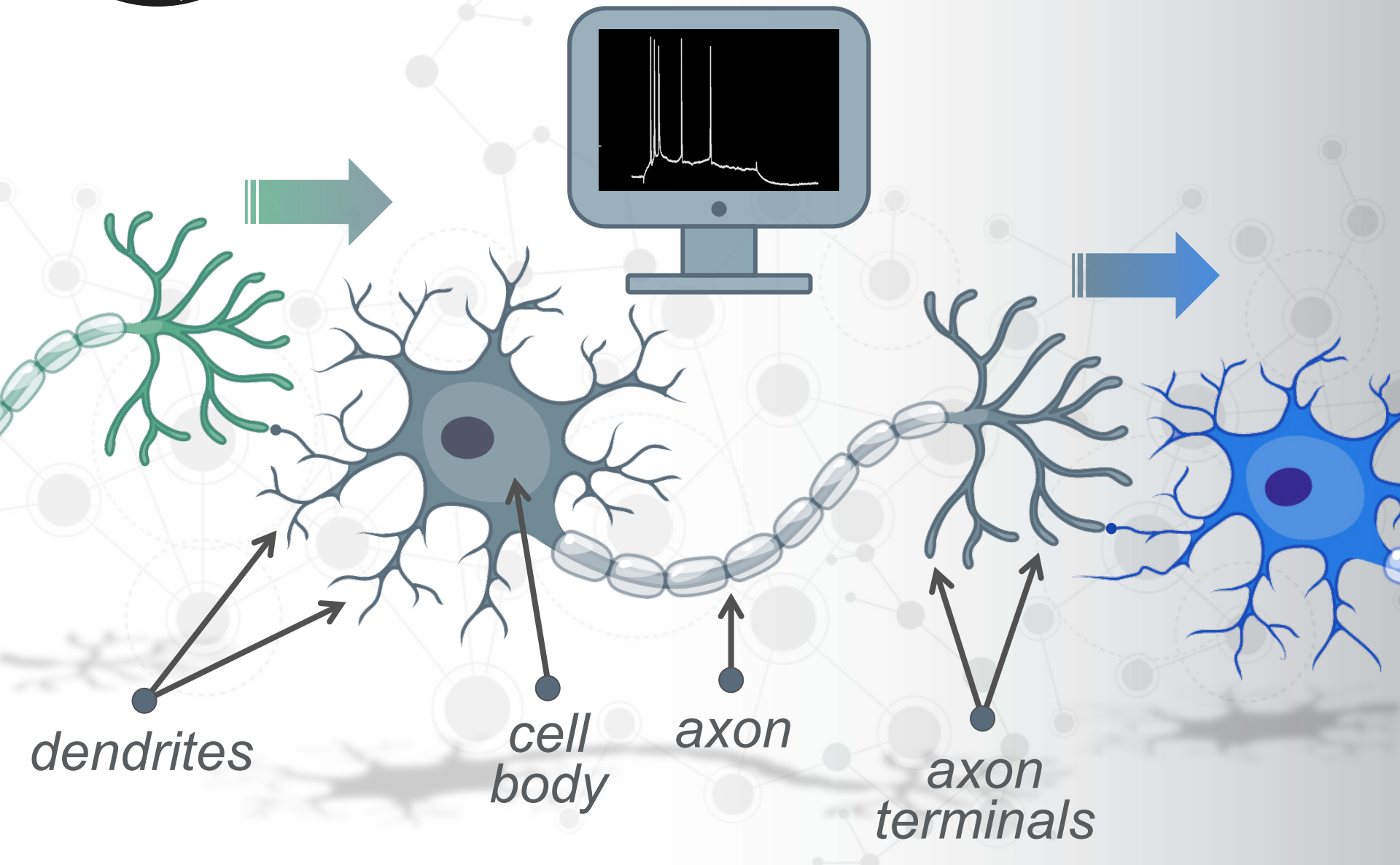


circulatory system



nervous system

Neurotransmission 101



Neurotransmission 101

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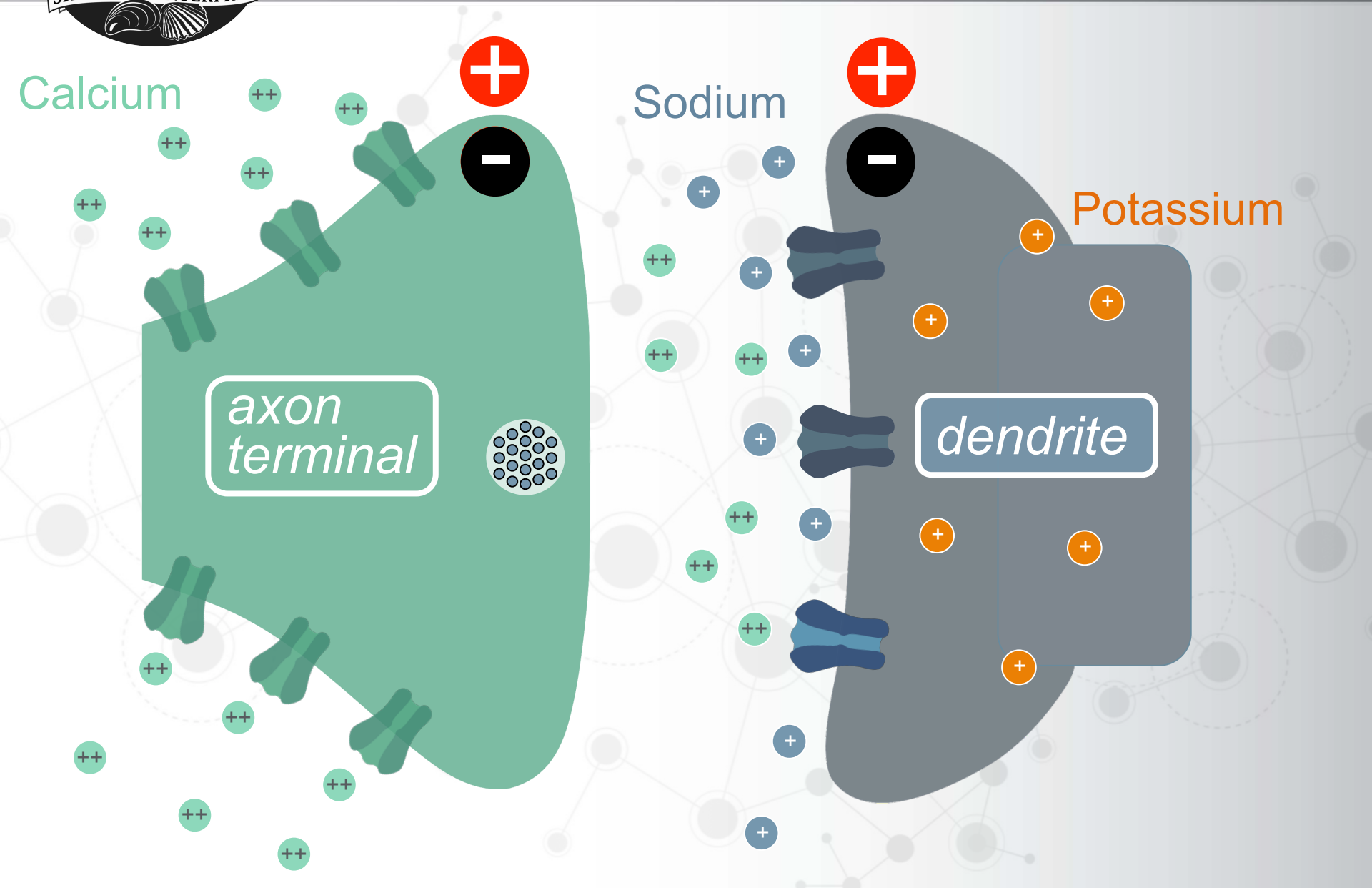

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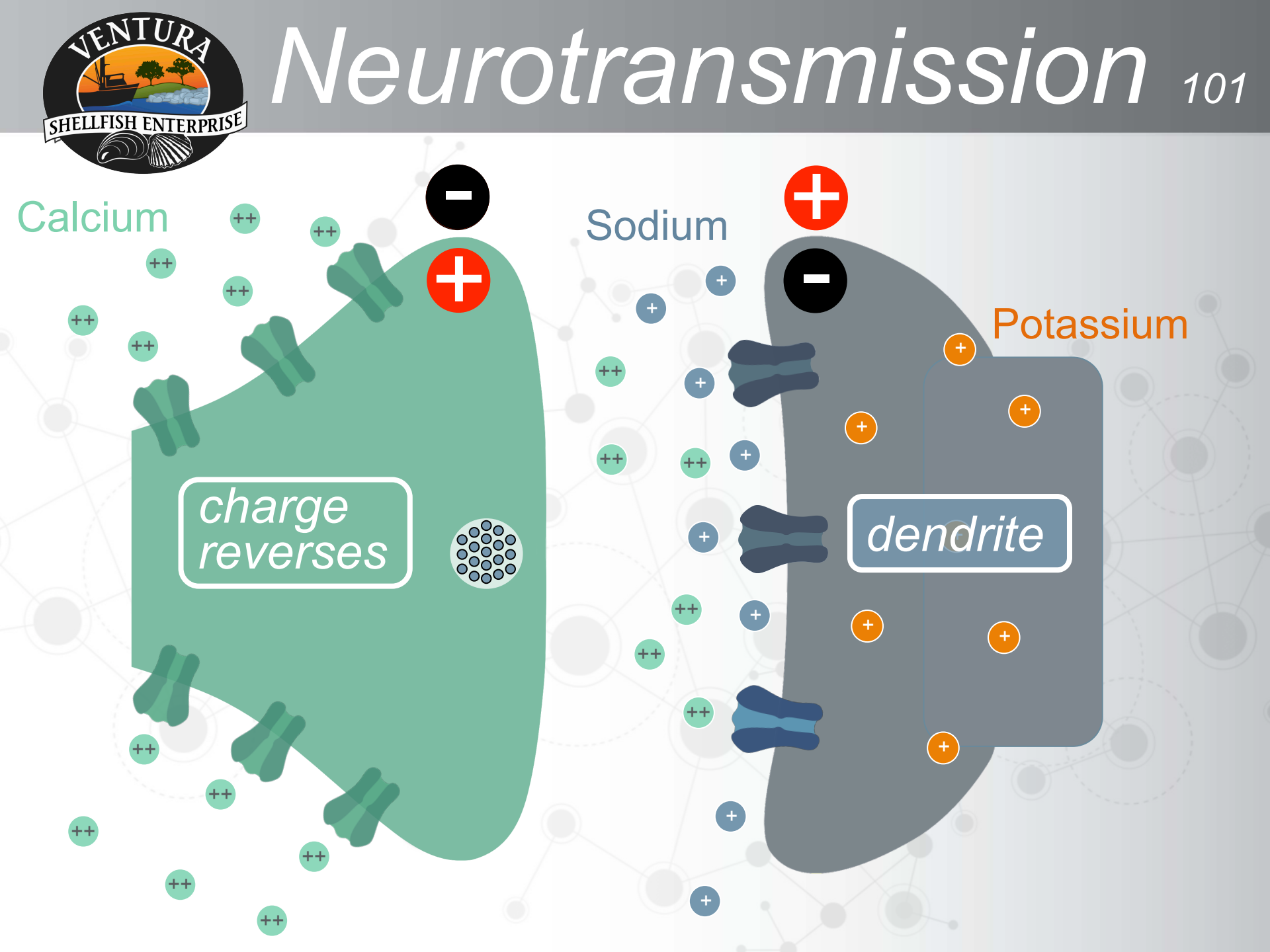

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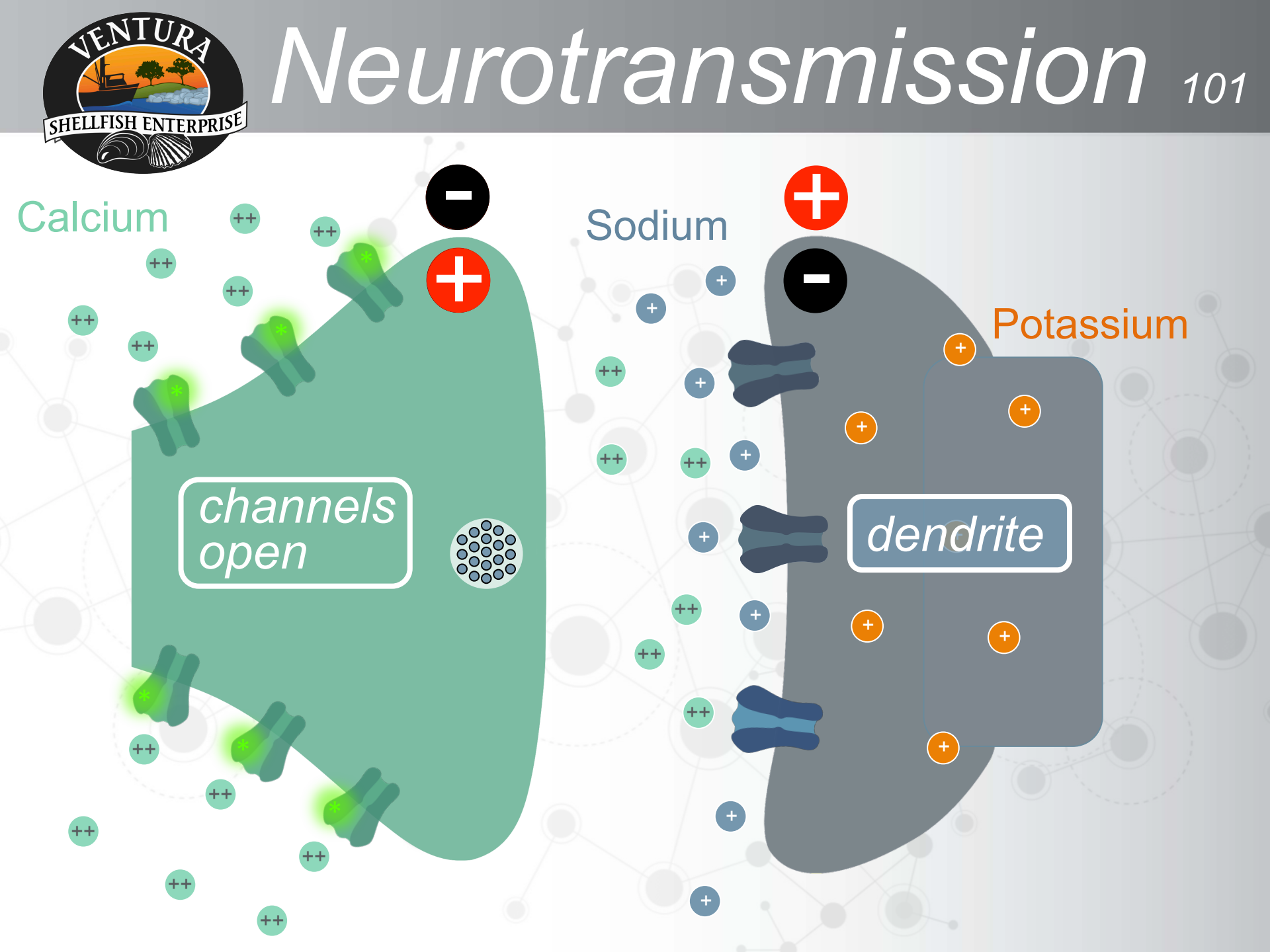

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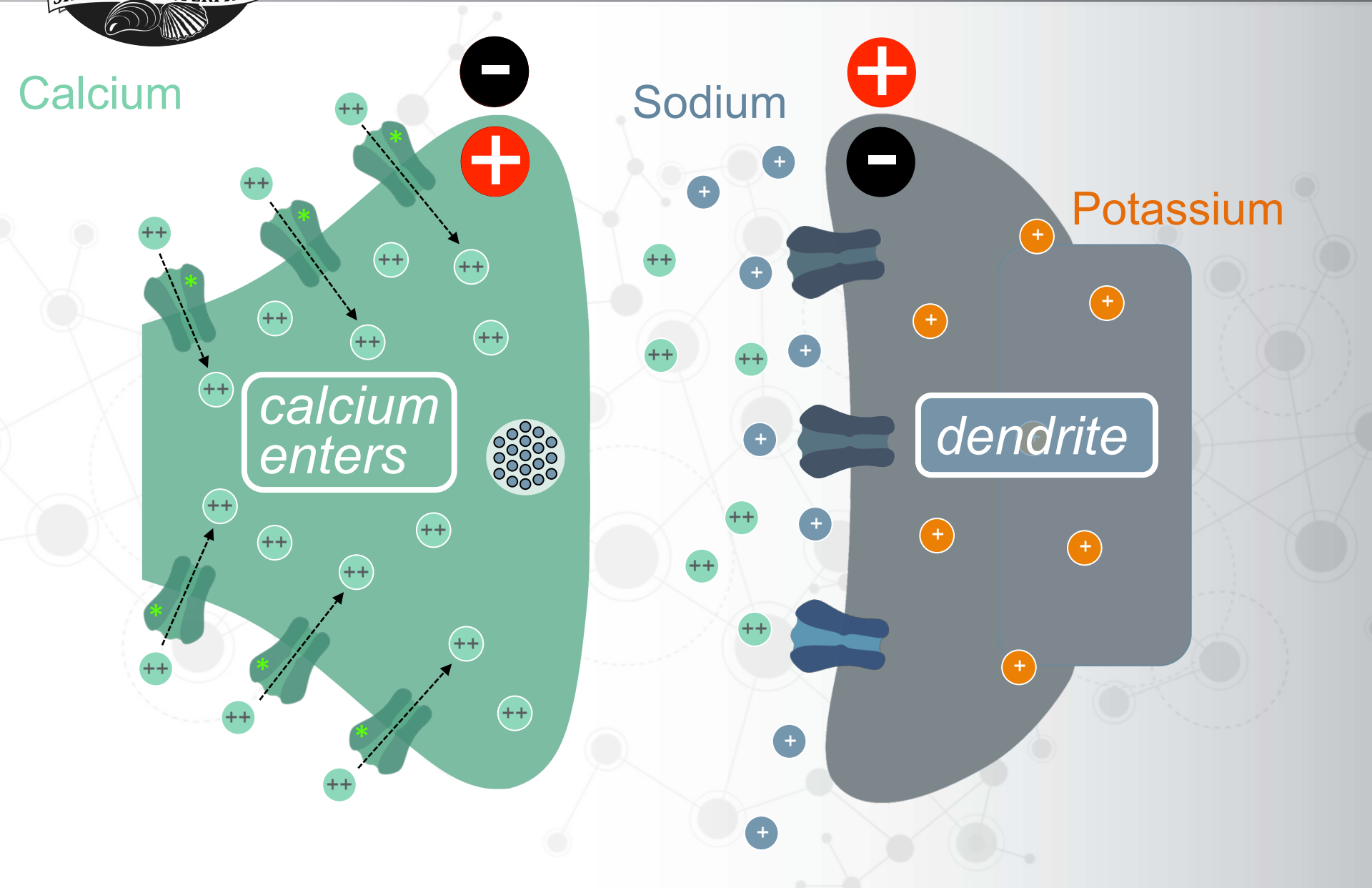

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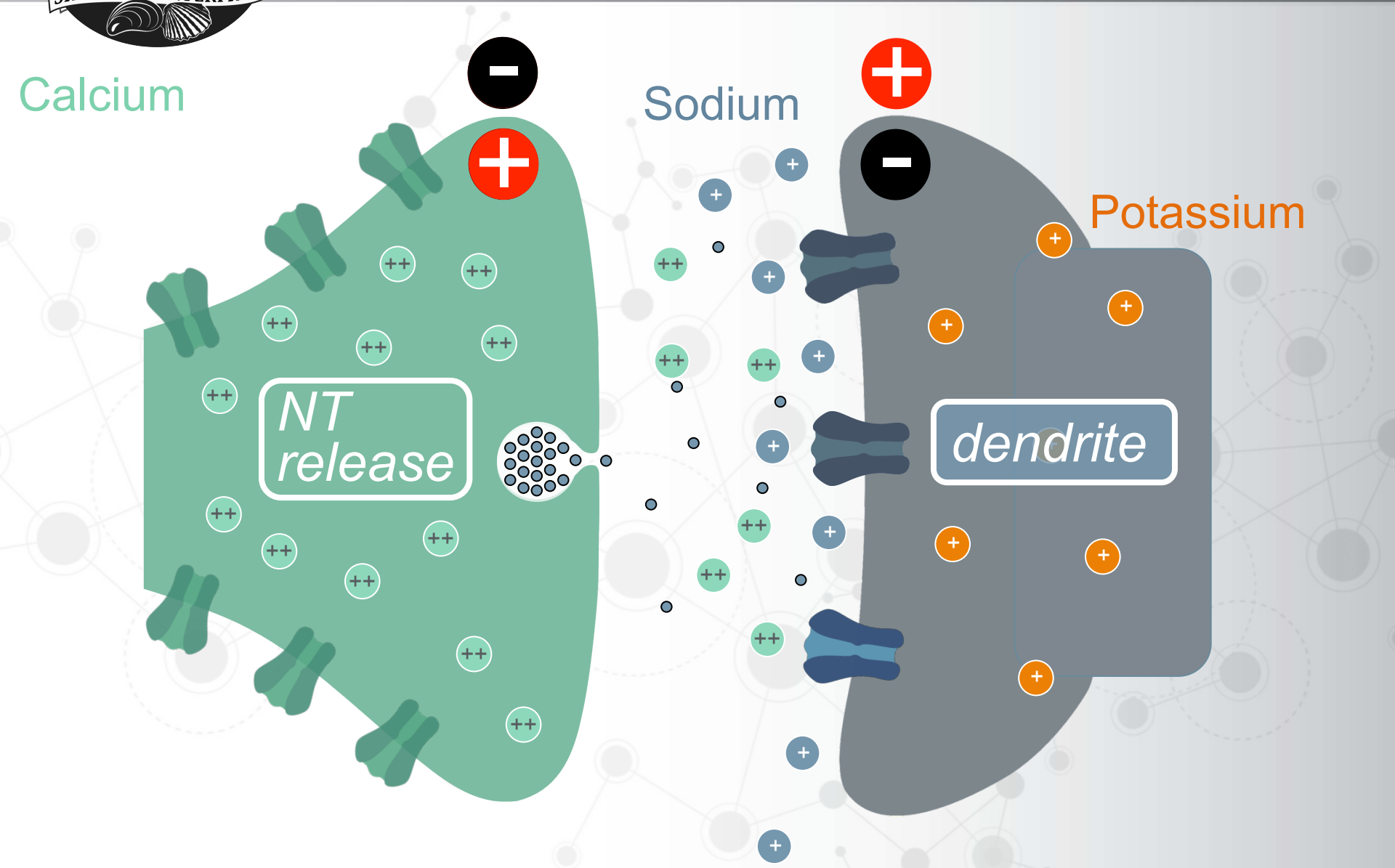

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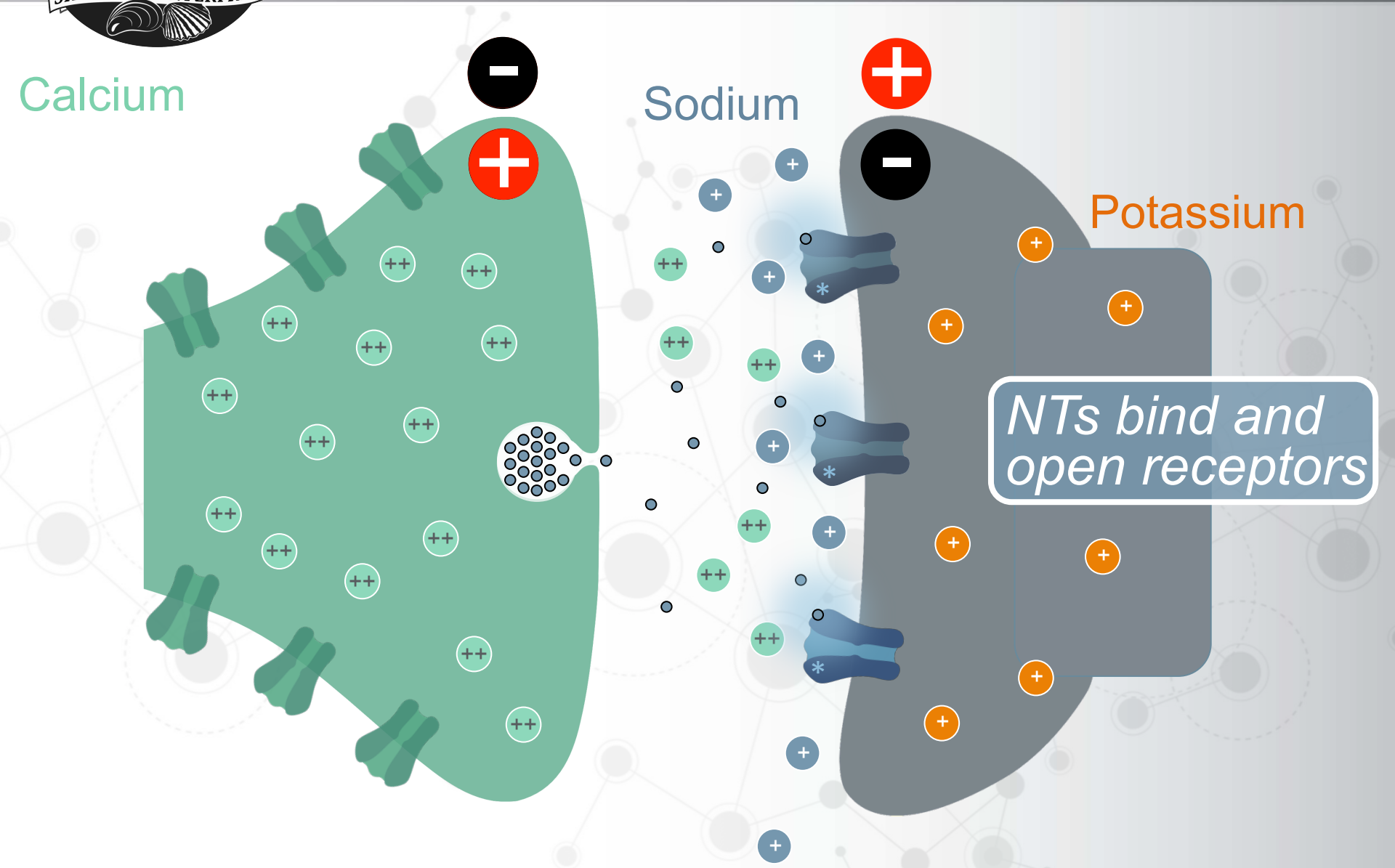

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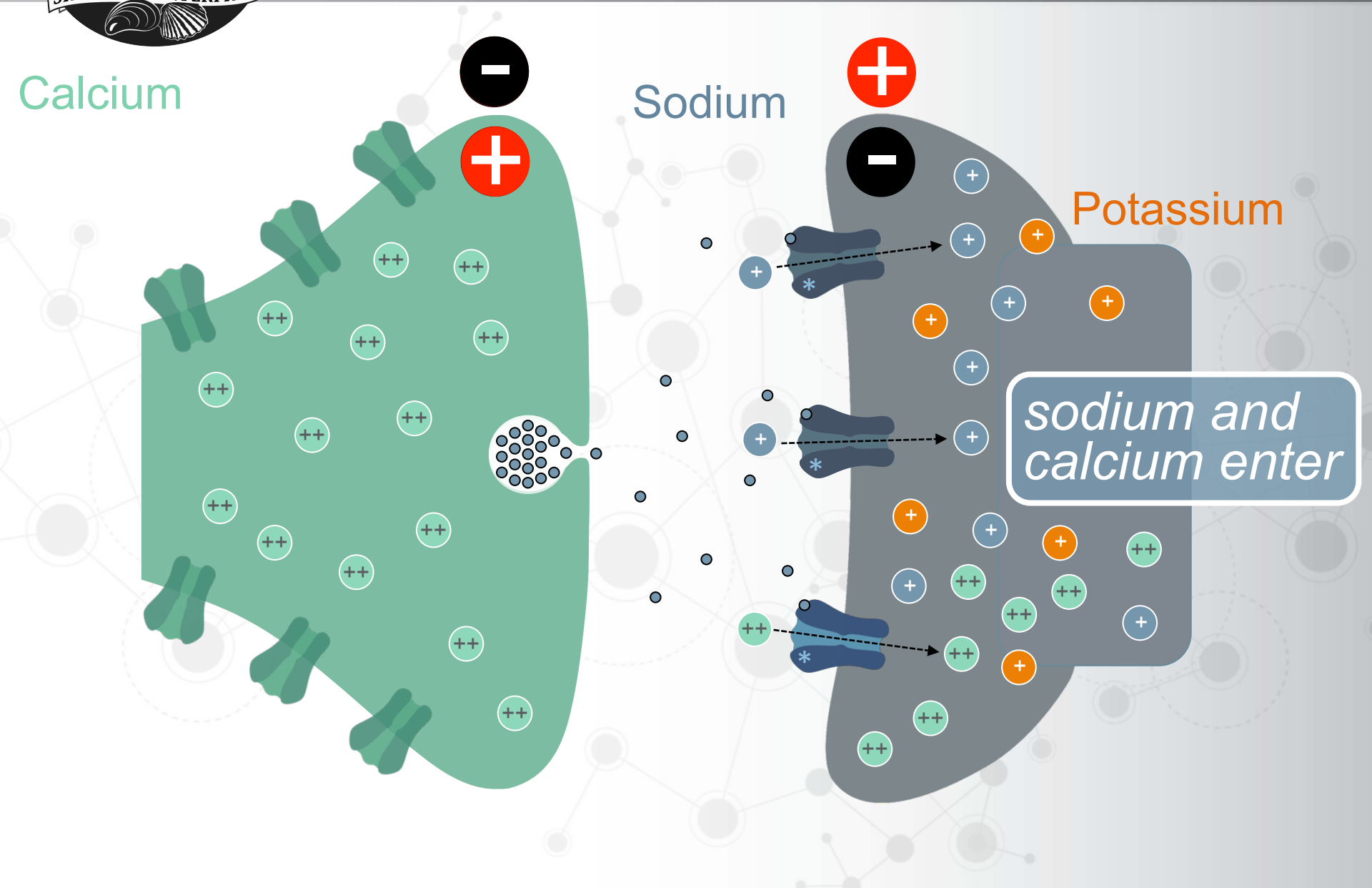

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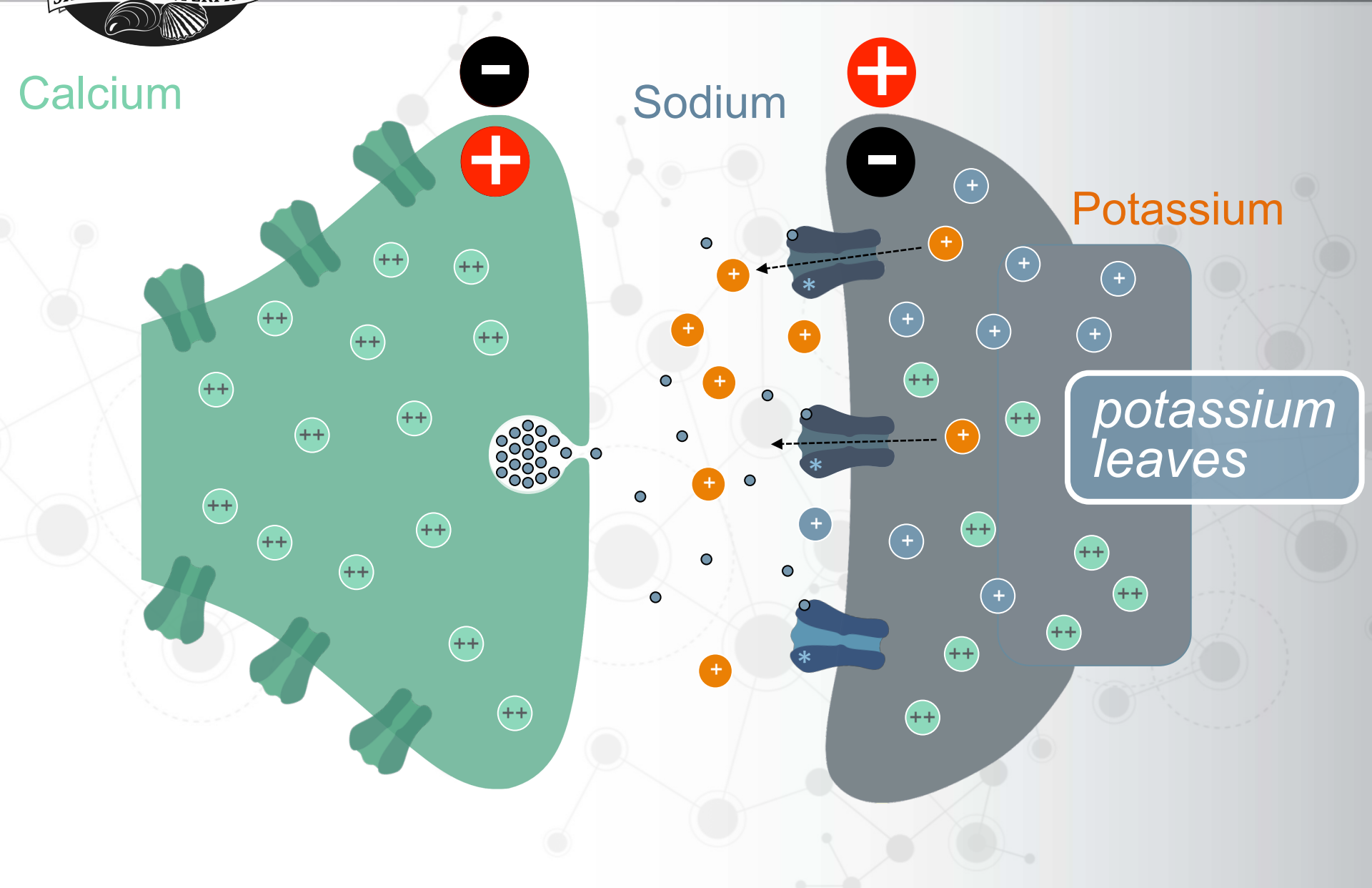

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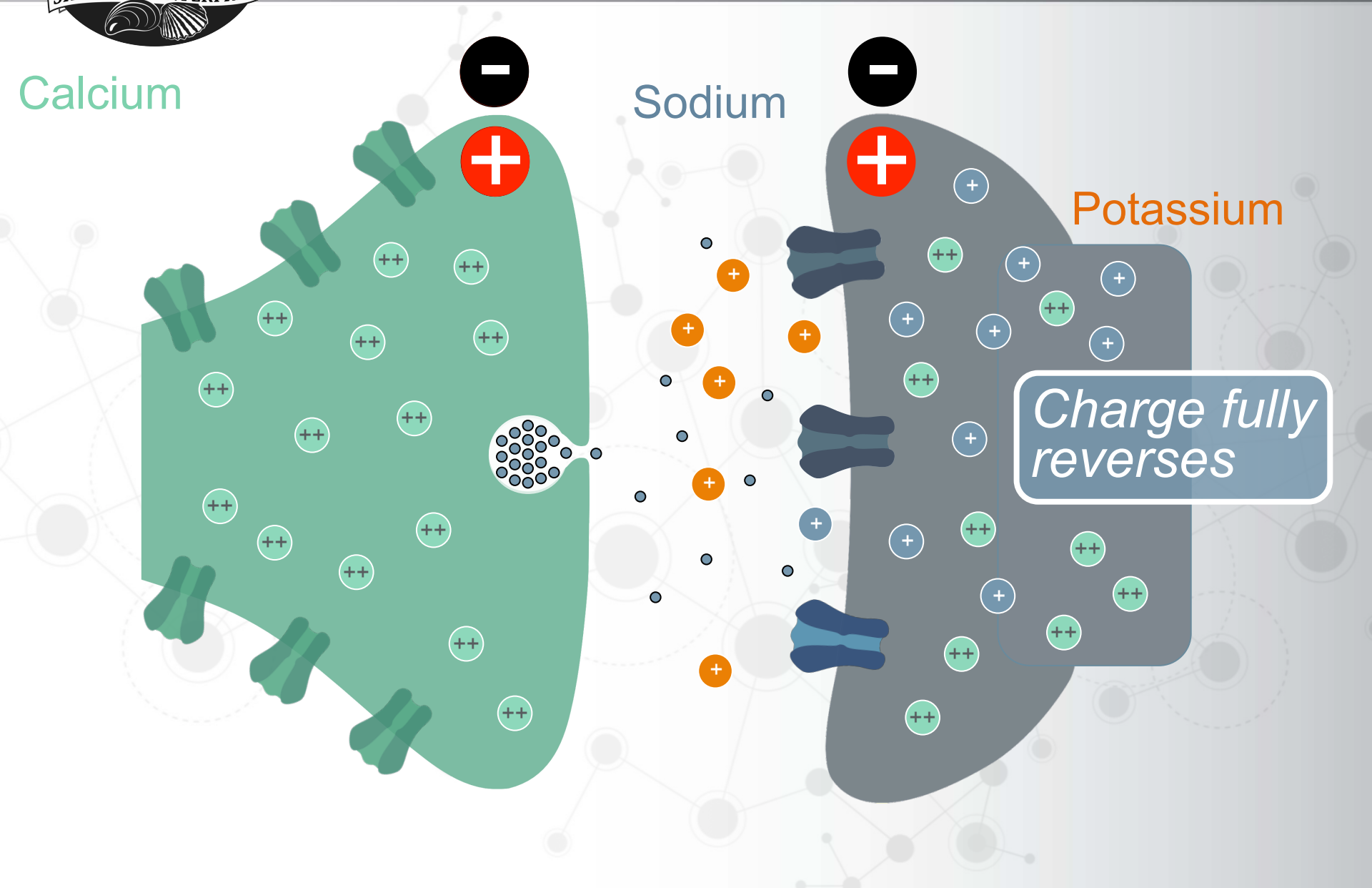

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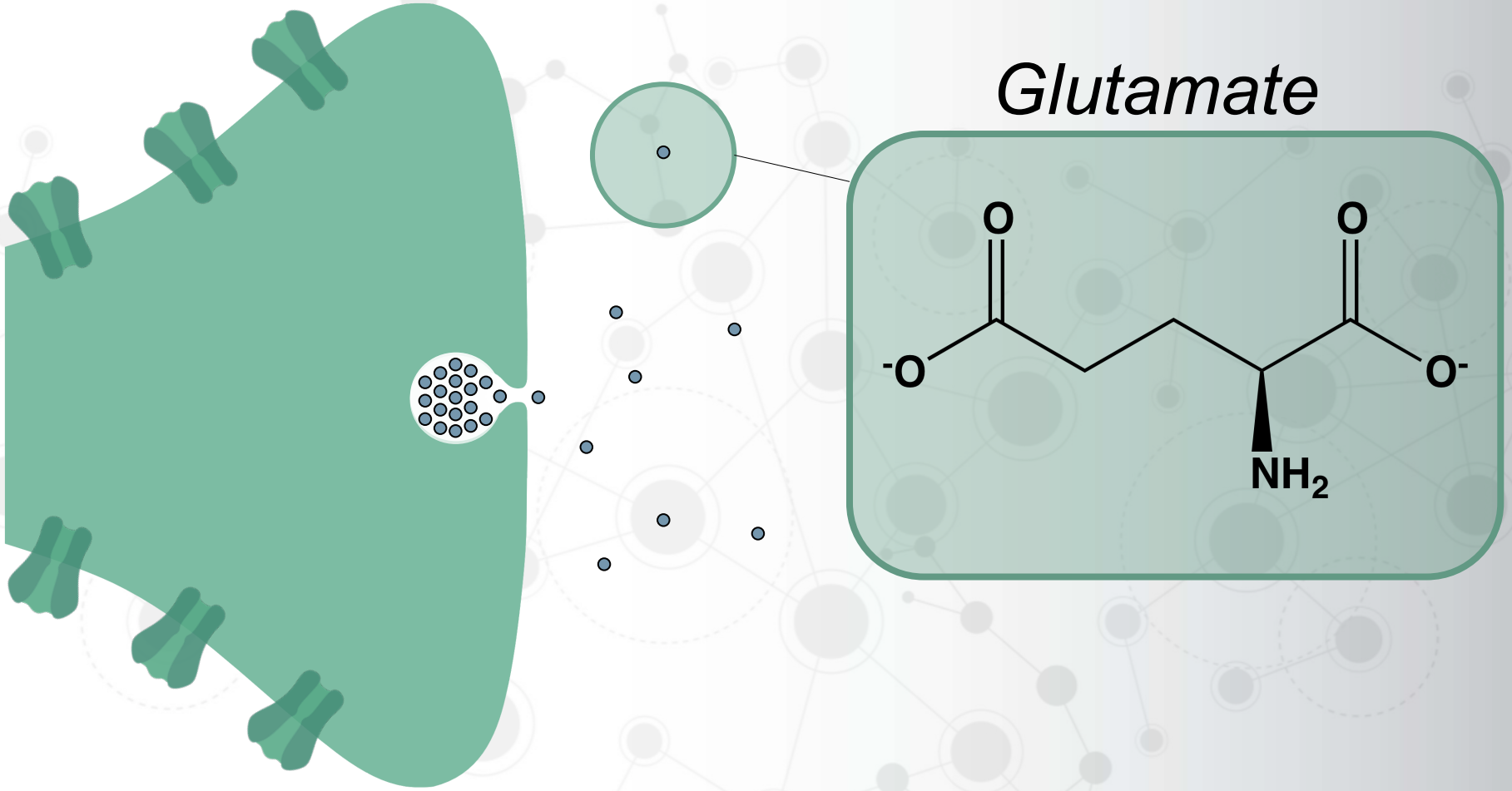
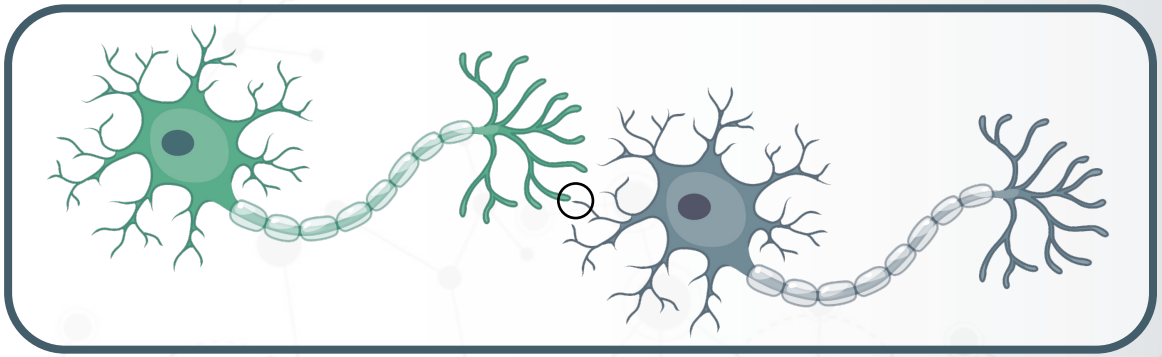
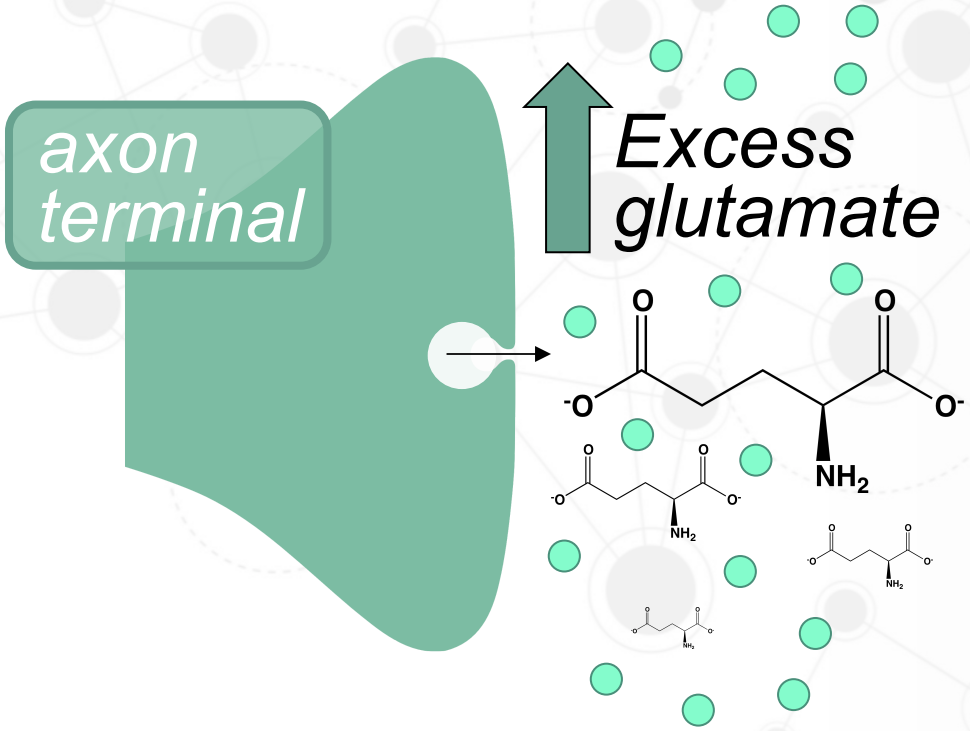
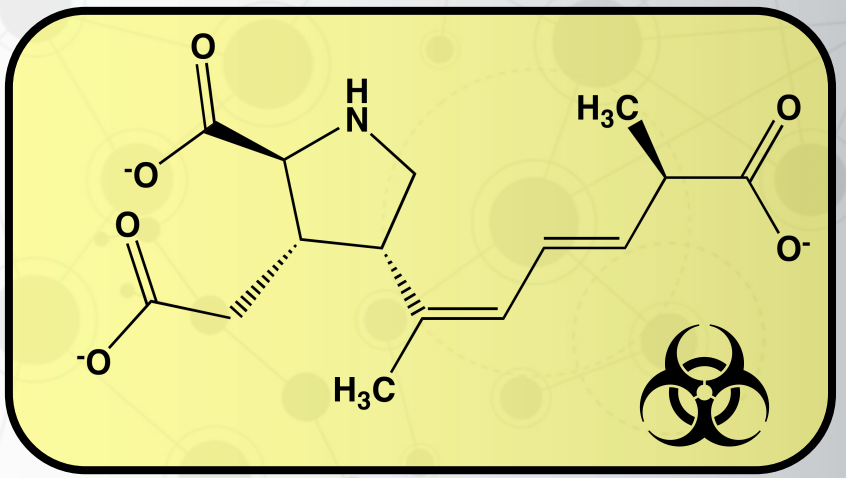


Molecular Targets of DA





Domoic Acid



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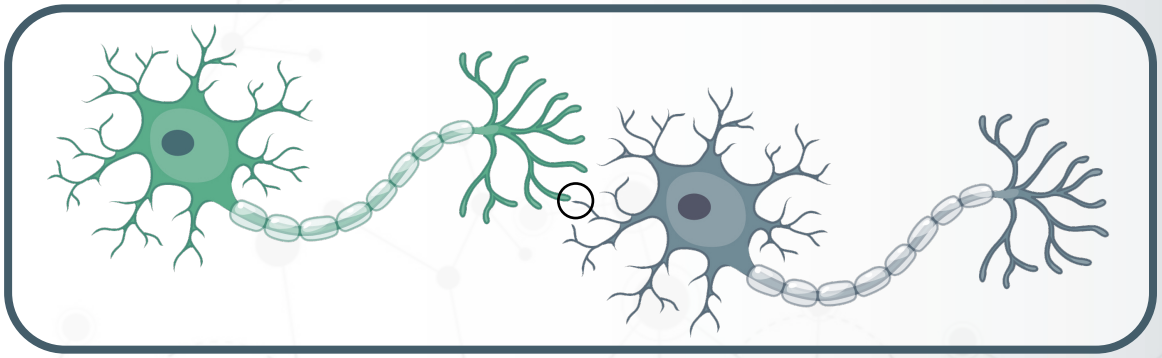
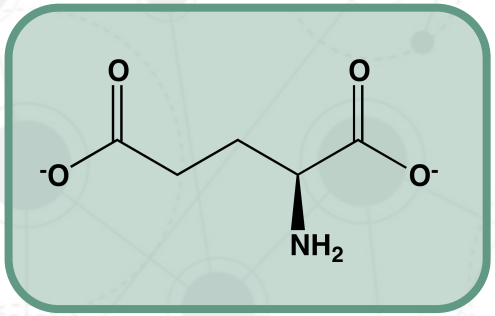
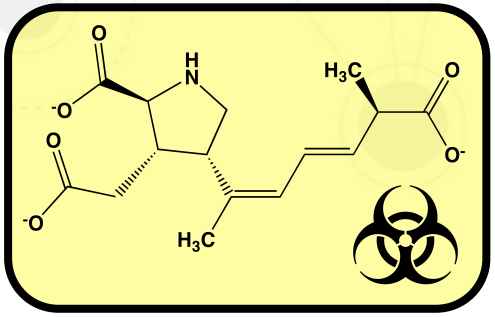
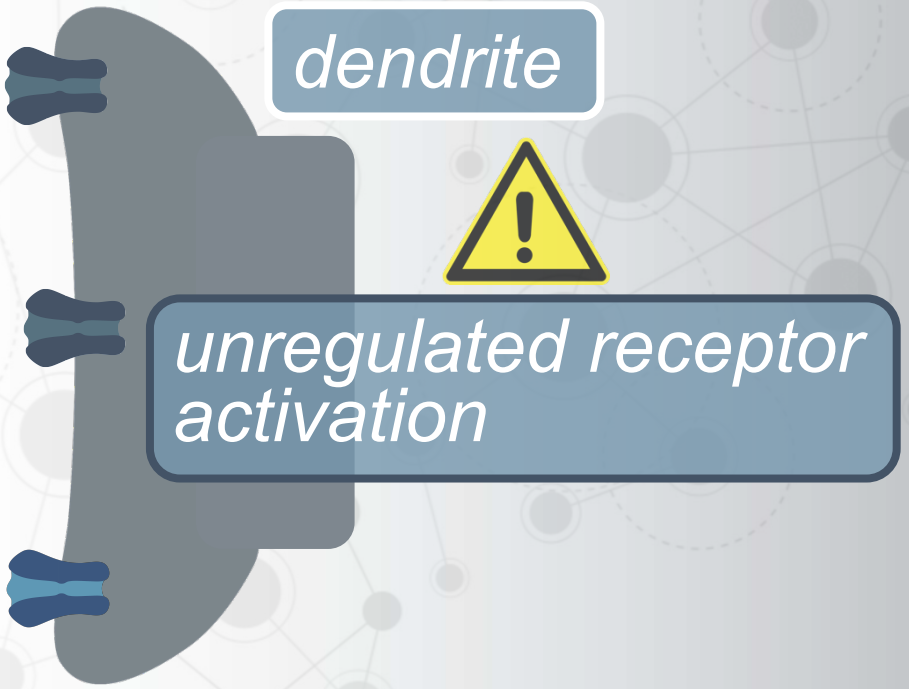


Excess glutamate

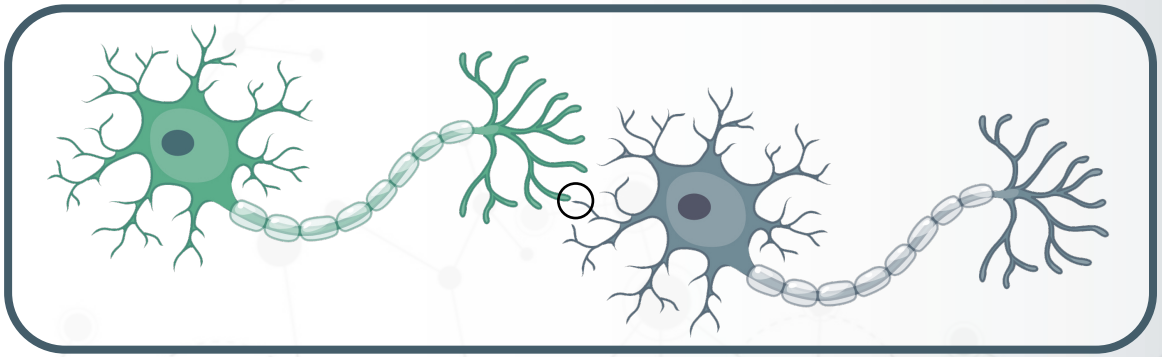


Domoic Acid

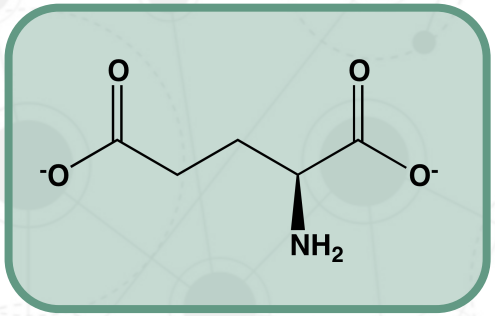




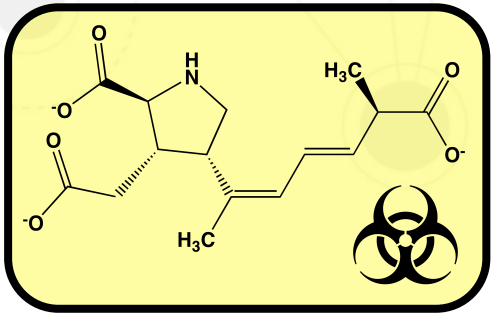
Molecular Targets of DA

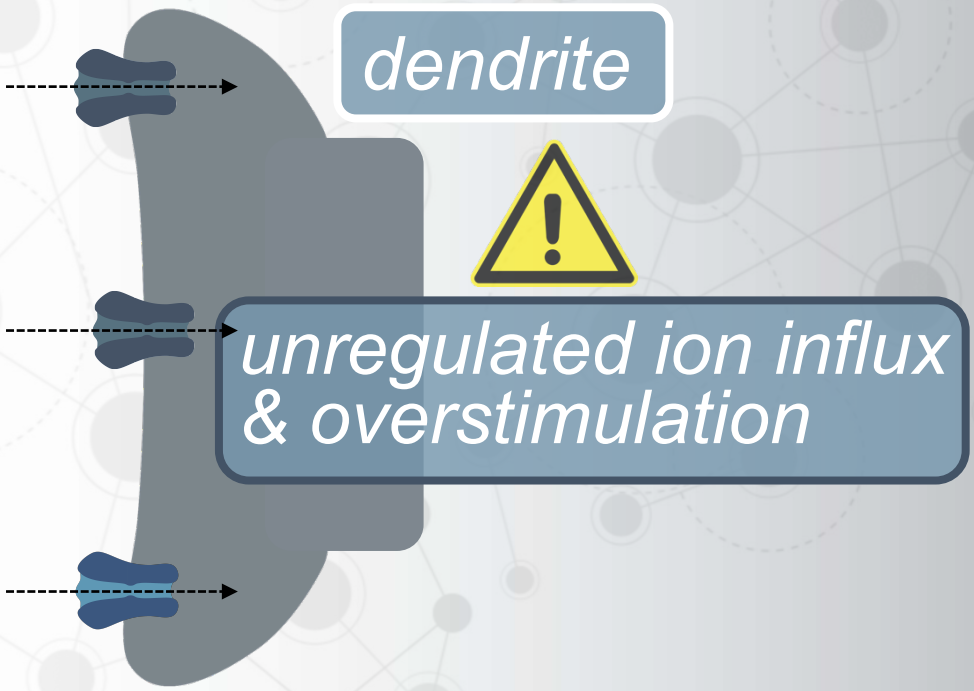


Excess glutamate

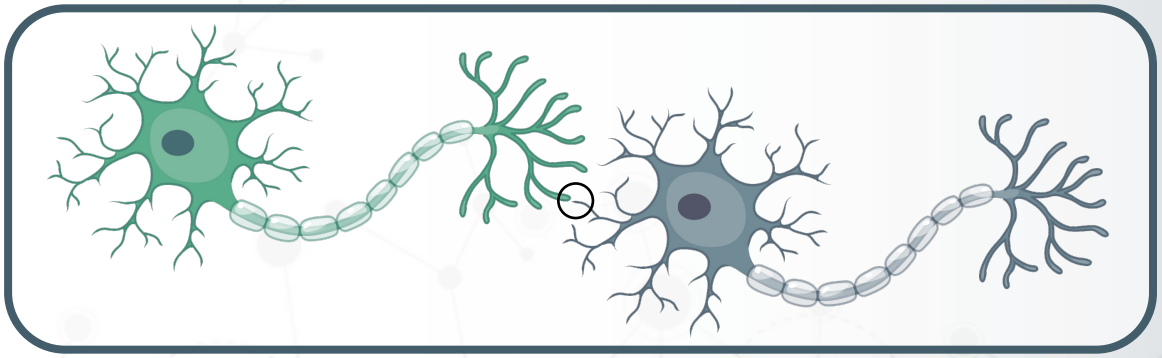


Domoic Acid

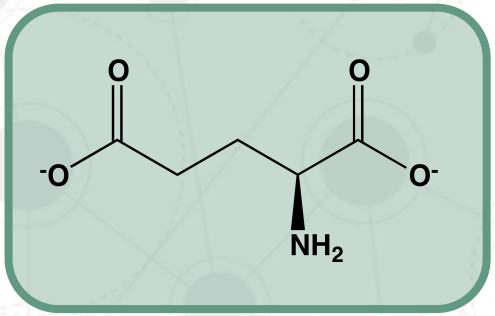




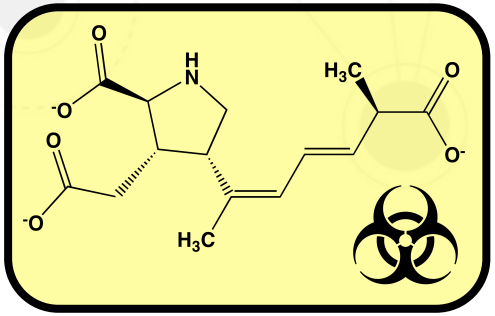
Molecular Targets of DA

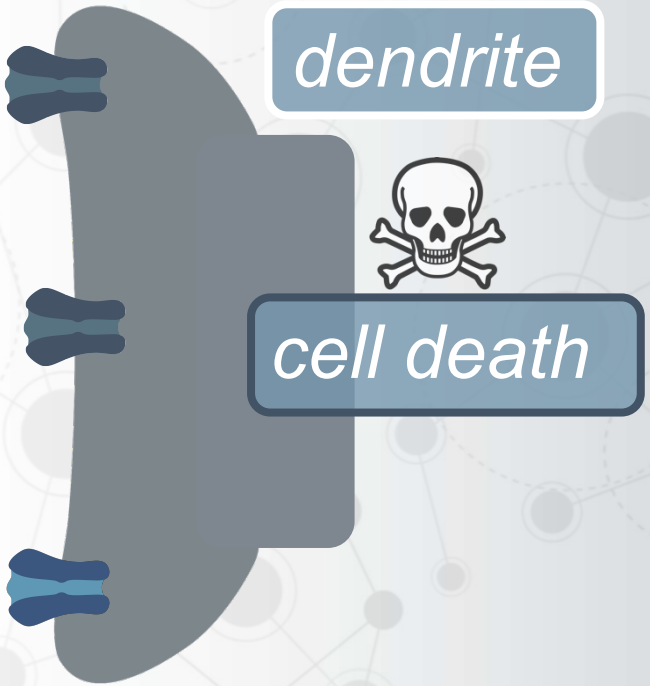


Excess glutamate



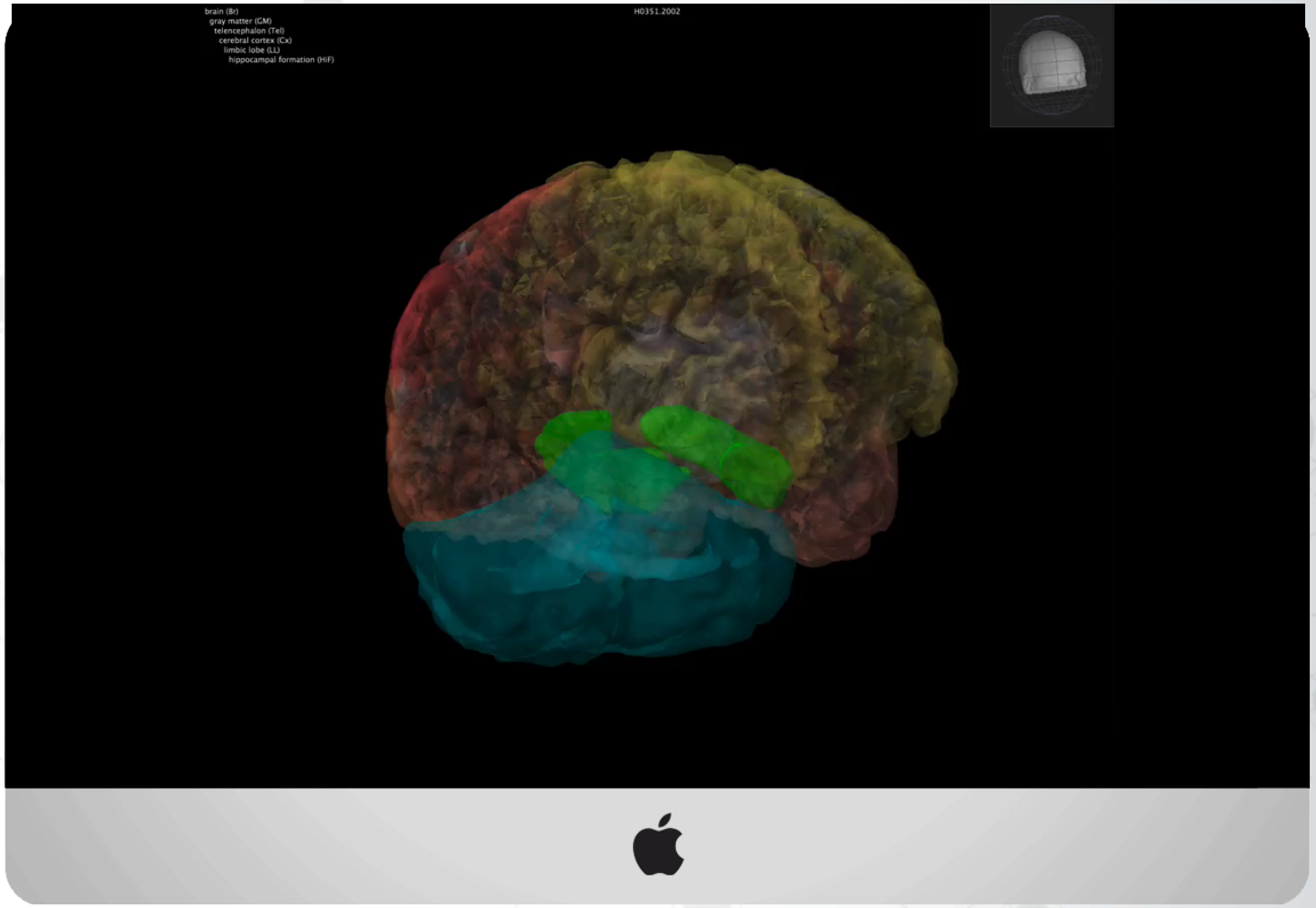
Domoic Acid





Brain Sensitivity

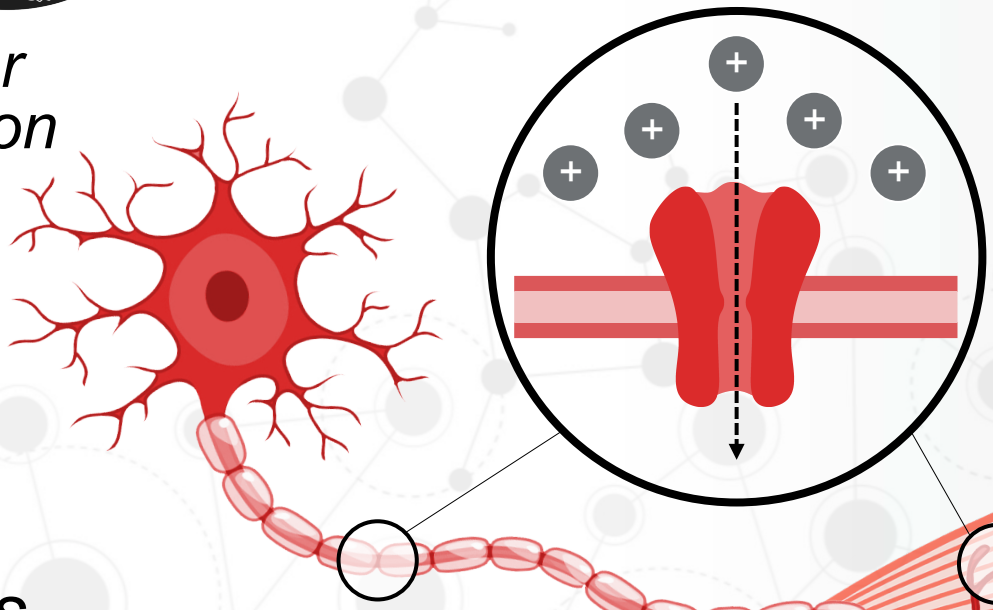
The hippocampus is a high-sensitivity target of DA



Generated from Brain Explorer 2 | Allen Institute for Brain Science

Molecular Targets of PSPs

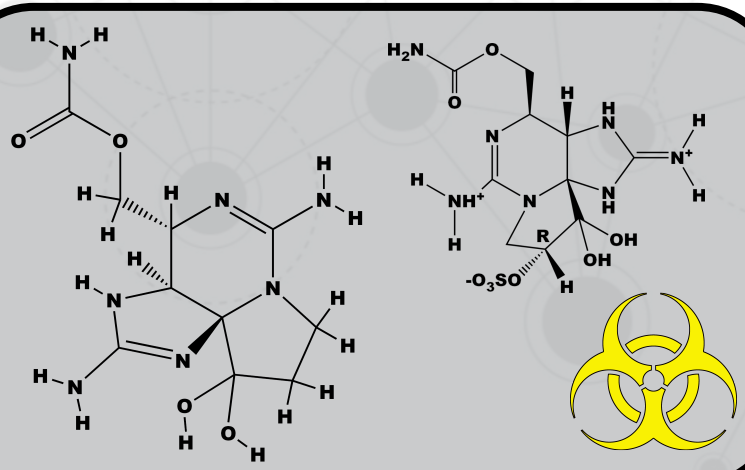
Motor neuron



Sodium influx required for neuron and muscle activation

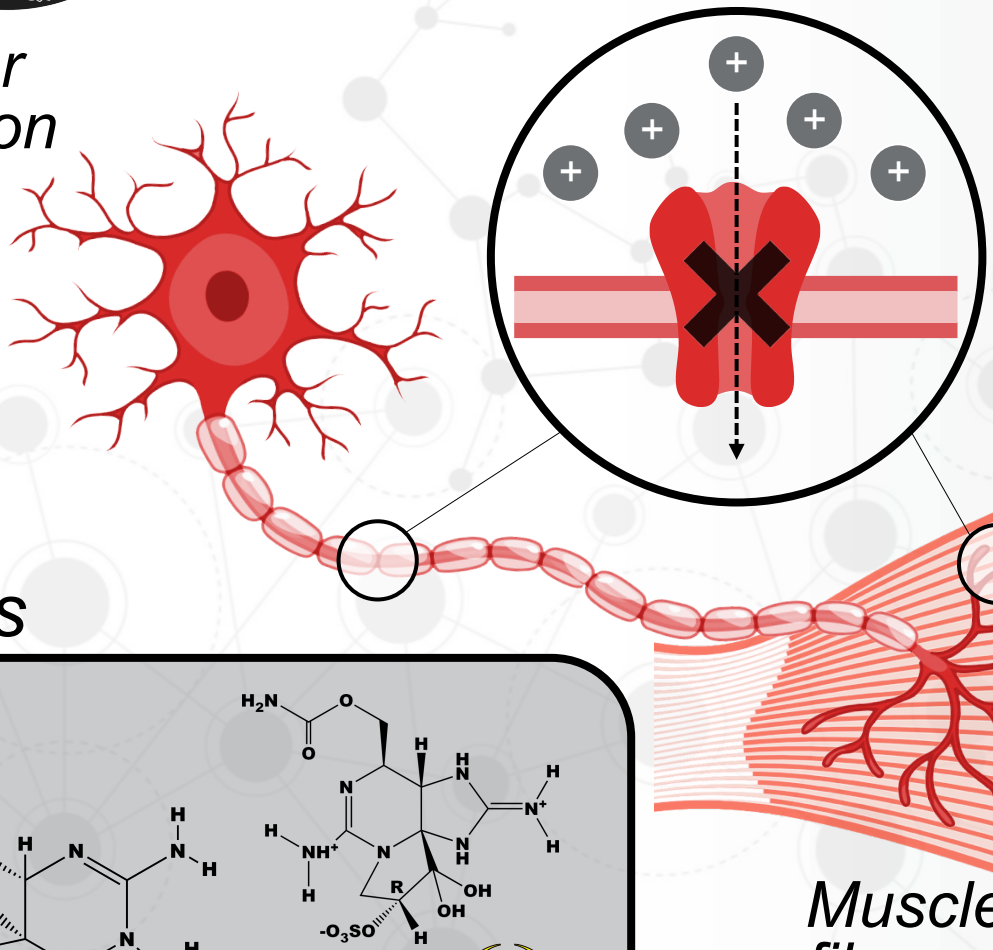
Muscle fiber

PSPs



Molecular Targets of PSPs

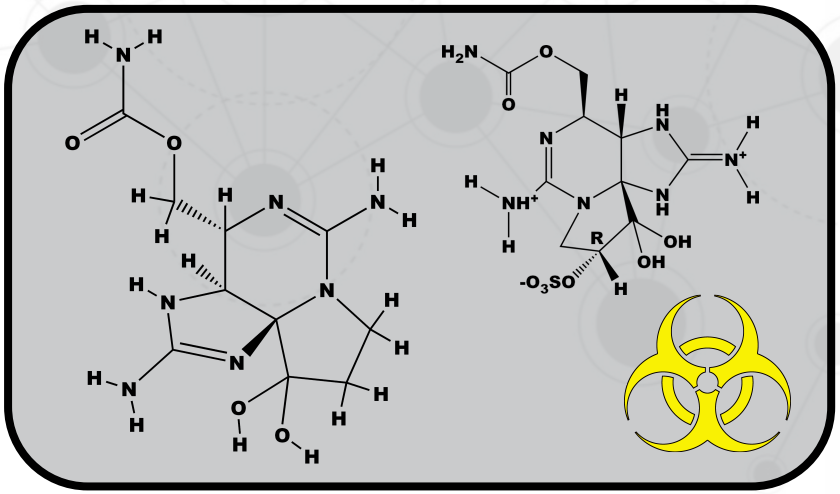
Motor neuron



PSPs block ion flow and prevent neuron and muscle activation

Muscle fiber

PSPs



Cases of DAP in CA

Cases by month of estimated illness onset | 2011-2015

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2011	0	0	0	0	0	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0	0
2013	0	0	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	0	0	0	0	0	0	0	0
2015	0	0	0	0	0	0	0	0	0	0	0	0

From Yearly Summaries of Selected Communicable Diseases in California, 2011-2015. Surveillance and Statistics Section | Infectious Diseases Branch | Division of Communicable Disease Control | Center for Infectious Diseases | California Department of Public Health

Cases of PSP in CA

Cases by month of estimated illness onset | 2011-2015

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2011	0	0	0	0	1	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0	0
2013	0	0	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	0	0	0	0	0	0	0	0
2015	0	0	0	0	0	0	0	0	0	0	0	0

From Yearly Summaries of Selected Communicable Diseases in California, 2011-2015. Surveillance and Statistics Section | Infectious Diseases Branch | Division of Communicable Disease Control | Center for Infectious Diseases | California Department of Public Health

Regulatory Safeguards

Pre-harvest Shellfish Program

Commercial Shellfish Regulation

Environmental Management Branch

CDPH California Department of PublicHealth

- ✓ *certify growing areas*
- ✓ *monitor water quality*
- ✓ *implement closures*
- ✓ *prevent illegal harvesting*

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast




By

Mas Hori, Retired CA Department of Public Health

Food and Drug Branch, Supervising FDB Investigator

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Shellfish Aquaculture
  - The requirements of the Authority (CA FDB)
    - Inspect commercial land-based and floating aquaculture systems at least annually
    - At minimum inspect operator records to verify that appropriate permits are up to date and operational plans required are being implemented
    - The Authority shall establish the submarket size for each species of shellfish
    - The Authority shall approve the written operational plan for any land-based or float aquaculture facility prior to its implementation

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Shellfish Aquaculture
  - Requirements for the Harvester/Dealer
    - Aquaculture encompasses both mono culture and polyculture
    - Any person who operates a aquaculture facility to raise shellfish for human consumption shall obtain (A permit from Authority; A harvester's license; Certification as a dealer, where necessary)
    - Water quality at any site must be met
    - Shellfish cultured from approved classification may be immediately marketed
    - Only drugs sanctioned by FDA shall be used for shellfish treatment
    - Harvesting, processing, storage, and shipping requirements have the same requirements as wild shellfish

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Shellfish Aquaculture
  - Complete and accurate records shall be maintained for at least 2 years by the aquaculturist and shall include:
    - Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification
    - Dates of transplanting and harvest
    - Water source, its treatment method, if necessary and its quality in the land based systems

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Shellfish harvested from controlled shellstock growing areas
    - Open, with approval from areas classified as restricted, conditionally restricted or prohibited or in closed status of the approved or conditionally approved classification
  - Patrol of growing areas
    - The Authority shall patrol harvest areas at sufficient intervals to deter illegal harvesting, which include for night, weekend and holiday periods
    - Minimum frequencies
      - Low Risk – 4 times per 30 harvestable days
      - Medium – 8 times per 30 harvestable days
      - High – 16 times per harvestable days

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - By licensed harvesters
    - The Authority shall issue a license to commercially harvest shellstock including those harvested from aquaculture
    - Valid for a year
  - Identification of certain growing areas
    - The Authority shall chart, describe and mark the boundaries of the growing areas as to their classification
      - Be marked by fixed objects or landmarks
      - Be described in a manner which allow easy recognition

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Enforceable legal penalties sufficient to encourage compliance
    - The CA Fish and Game will also be involved in the patrolling of shellfish growing areas in CA that may issue
      - Citations
      - Fines in dollars
      - Equipment or property confiscations and forfetitures
      - License suspensions or revocations
      - Jail sentences
      - Written warning

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Shellstock Time to Temperature Controls

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Exposure to Receipt at a Dealer's Facility
Level 1	< 50°F (10°C)	36 Hours
Level 2	50°F - 60°F (10°C - 15°C)	24 Hours
Level 3	> 60°F - 80°F (15°C - 27°C)	18 Hours
Level 4	> 80°F (≥ 27°C)	12 Hours

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Requirements for Harvesters
    - Each Harvester shall have a valid license
    - Each Harvester shall obtain Authority approved training at interval to be determined by the Authority not to exceed five years
    - Boat crew under the supervision of a licensed harvester need not have required training

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Shellstock Harvesting and Handling
    - Vessels
      - The operator shall assure that all vessel used to harvest and transport shellstock are properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock
      - Cats, dogs and other animals shall not be allowed on vessels

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Disposal of Human sewage from vessels
    - Human sewage shall not be discharged overboard from the vessel used in harvesting of shellstock
    - Must use approved marine sanitation devices (MSD)
  - Shellstock Washing
    - Shellstock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable
    - Water used for shellstock washing
      - Potable water source
      - Approved classification growing water
      - In open status of conditionally approved clasification

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Shellstock Identification
    - Each Harvester shall affix a tag to each container of shellstock
    - Harvester's tags shall
      - Be durable, waterproof and sanction by Authority prior to use
      - Be at least 13.8 square inches (89.03 cm^2) in size
      - Harvester's identification number as assigned by the Authority
      - Date of harvest
      - Precise location of harvest location

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Control of Shellfish Harvesting
  - Shellstock Identification
    - Harvester's Tag
      - The following statement in bold capitalized type on each tag

"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

- Bulk Tagging of a lot of shellstock

"All shellstock containers in this lot have the same harvest date and area of harvest"

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Transportation
  - Conveyances used to transport shellstock to the Original Dealer
    - Any conveyance properly constructed to prevent contamination, deterioration and decomposition
    - Storage bins used be cleaned and provide effective drainage
    - Temperature of the conveyance truck shall not exceed ambient temperature when the ambient air temperature is above 50^{o}F

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Transportation
  - Conveyances used to transport shellstock from Dealer to Dealer
    - All containers used to transport shall be easy to clean and operated and maintained to prevent product contamination
    - All containers shall be cleaned with potable water and detergents an sanitizers for food contact surfaces

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Transportation
  - Cargo protection from cross contamination
    - All containers used for storing shellfish shall be clean and fabricated from safe materials
    - Shellfish Cargo Only
      - Except for bulk shipments, shellstock shall be shipped on pallets
      - In-shell products shipments shall be shipped on pallets
      - If the conveyance does not have a channeled floor, pallets shall be used for all shellfish

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Transportation
  - Mixed Cargoes (Shellfish with seafood products)
    - Shellfish products are protected from contamination by the other cargo
    - All cargo is placed on pallets
    - No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers
  - Ice
    - Any ice used to cool shellfish shall meet the requirements
      - Ice made from potable water or from an approved source

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Transportation
  - Shipping Temperature
    - Shellfish dealers shall ship shellstock adequately iced or in conveyance pre-chilled at or below 45^{0}F ambient air temperature
  - Transportation Records
    - All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and all shipping conveyance comply with the adequately iced or 45^{0}F ambient air temperature

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- General Requirements for Dealers
  - General Hazard Analysis Critical Control Point (HACCP)
    - All live and fresh shellfish products require a HACCP plan by the dealers
    - All licensed shellfish will have the following Critical Control Points in their HACCP plan
      - Receiving
      - Storage
      - Distribution
      - There may be other if the firm processes the shellfish

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

Firm Name
Address
City, State Zip Code

HACCP Plan for Fresh Live Molluscan Shellfish and Shucked Molluscan Shellfish Products

Product Description: Molluscan Shellfish –Fresh Live Oysters, Clams, Mussels and Whole scallops and Shucked Molluscan Shellfish
Method of Storage and Distribution: Refrigerated storage and distributed in refrigerated trucks
Intended Use and Consumer: Consumed raw and the product can be cooked for the general public

Date:

(1) Critical Control Points (CCP)	(2) Hazard	(3) Critical limits of the Preventive Measures	Monitoring				(8) Correction Actions	(9) Records	(10) Verification
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving CCP #1	**Bacterial pathogen contamination**	Temperature of product not to exceed 45°F All lots received are accompanied by truck records/data loggers that show temperature was maintained at or below 45ºF on shipments over 4 hours to our locations All shipments under 4 hours of transportation will document the time of shipment to and from the vendor and temperature	Temperature of product Transportation Records of temperature during transport which include time and temperature of transit (data loggers or transportation	Thermometer Visual	Every Lot Every Shipment	Receiving Personnel Receiving Personnel	Hold, segregate and evaluate Inspect shellfish if temperature is above 45°F Take internal temperature of the shellfish and if above 50°F, the product will be rejected and the supplier is notified Discontinue use of the supplier or carrier until evidence is obtained that transportation-handling practices have been improved and approved	Shellfish receiving records Calibration records for thermometers Accuracy records of thermometers Corrective Action records	Weekly verification of Incoming receiving logs and corrective action records Check ISSCL for Certified dealers (Monthly basis) Calibration of the Thermometer (Yearly) Accuracy Thermometer Checks (Daily)
	Bacterial pathogen contamination	Shellfish must come from certified growing areas, not closed for contamination and Properly tagged/labeled on ISSCL	Shellfish tags/labels From certified harvest areas	Visual	Every container	Receiving Personnel	Hold and evaluate. Reject if untagged or improperly tagged form closed areas or from non-certified dealer.	Shellfish receiving records ISSCL Log Corrective Action records	
	Chemical contamination	Shellfish must come from certified growing areas, not closed for contamination and properly tagged/labeled on ISSCL	Shellfish tag/label From certified harvest areas	Visual	Every container	Receiving Personnel	Hold and evaluate Reject if untagged or improperly tagged form closed areas or from non-certified dealer.	Shellfish receiving records ISSCL Log Corrective Action records	
	Natural toxin	Shellfish must come from certified growing areas, not closed for contamination and properly tagged/labeled on ISSCL	Shellfish tag/label From certified harvest areas	Visual	Every container	Receiving Personnel	Hold and evaluate Reject if untagged or improperly tagged form closed areas or from non-certified dealer.	Shellfish receiving records ISSCL log Corrective Action records	

Reviewed By:_____ **Date:**_____

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- General Requirements for Dealers
  - General Sanitation Requirements
    - Sanitation Monitoring
      - Safety of Water
      - Condition and Cleanliness of Food Contact Surfaces
      - Prevention of Cross Contamination
      - Maintenance of Hand washing, Hand Sanitizing and Toilet Facilities
      - Protection of Food, Food Packaging Materials and Food Contact Surfaces fro Adulteration
      - Proper labeling, Storage and Use of Toxic Compounds
      - Control of Employee Health Conditions
      - Exclusion of Pests

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

Firm Name, Address, City, State, Zip Code

Sanitation Standard Operating Procedures (SSOP) Monitoring Record

Date:_____ **Time:**_____ **Prepared by**_____

Item Description	✓ or CA Pre-Op	✓ or CA Post-Op
Time of Day:		
1. **Safety of water:** a. Back Siphonage-hose_____ b. (Ice) ice machine, clean, protected from contamination_____ c. Ice bins, shovels clean and protected from contamination_____		
2. **Condition and cleanliness of food contact surfaces:** Equipment cleaned and sanitized: a. Plastic containers_____ b. Other equipment_____ c. Gloves and aprons clean and good repair_____		
2(a). **Condition and cleanliness of food contact surfaces:** Sanitizer Strength a. Sanitizer Type_____ b. Strength:_____		
3. **Prevention of Cross-Contamination:** a. Hands, gloves, equipment and utensils washed/sanitized after contact with unsanitary objects _____ b. Employees working on raw products, wash and sanitize hands/gloves/outerwear before working with cooked products_____ c. Unpackaged cooked products separated from raw products_____		
4. **Maintenance of Hand-washing, hand-sanitizing and toilet facilities:** a. All hand-washing stations clean and properly supplied_____ b. Toilets clean, properly functioning and adequately supplied_____		
5. **Protection from Adulterants:** a. Processing operations separated by partitions, space or time_____ b. Condensate not contaminating shellfish, food contact surfaces or packaging material____ c. Coolers, refrigerators and freezers in good repair and clean; items properly stored_____ d. Product protected from contamination_____ e. Floors cleaned_____ f. Walls Cleaned_____ g. Ceilings Cleaned_____ h. Lights Protected_____ i. Racks in Shellfish Cooler Clean_____		
6. **Labeling, storage and use of Toxic compounds**: a. Poisonous/toxic materials properly used, stored, separated and labeled_____ b. Only chemicals necessary for plant operations maintained on premises_____ c. Adequate equipment for cleaning, sanitizing (sinks, brushes, detergents, sanitizers, etc.)___		
7. **Employee Health Conditions:** Employees do not show signs of medical problems_____		
8. **Exclusion of Pests:** a. Insects, rodents controlled; proper doors, screens, barriers_____ b. Refuse containers emptied and cleaned as necessary_____ c. Pest excluded from processing areas_____		

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- Other Model Ordinance Requirements
  - Recalls
    - Written procedures for conducting recalls of adulterated misbranded shellfish products
    - Dealers shall follow their written recall procedures to include timely notification

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

- General Requirements for Dealers
  - Shipping Documents and Records
    - Each dealers must have traceability of all shellfish sold and where the product came from on file
    - The dealers shall have receiving/purchase records of shellfish they distribute
    - The dealers shall have distribution records for all the shellfish that they sold
    - These records include the following
      - Type of Shellfish and Amount Received
      - Shellfish Certification Number of the Original Shipper
      - Harvest Area and Harvest dates

Sea to Table: Requirements for Safe Molluscan Shellfish Harvesting from the California Sea Coast

Thank You for Your Attention!

Mas Hori

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