

Advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins

This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

Introduction

1. The Food Standards Agency (FSA) is considering the current advice and monitoring programme for marine biotoxins and whether there is a need to update or change existing legislative standards.
2. The main purpose of this work is to identify any emerging marine biotoxins in UK waters, including considerations on increasing occurrence with increasing temperatures due to climate change. The views of the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) were sought on whether any of these emerging marine biotoxins would pose a risk to human health.
3. A scoping paper on emerging biotoxins (TOX/2023/59) was presented to the COT at the December 2023 meeting. This paper provided an overview of potentially emerging biotoxins, brief summaries of any available toxicological information, occurrence data, with an emphasis on UK waters, and any additional relevant information, such as proposed or current limits/monitoring and considerations in other countries.

4. To assist the Committee in reaching a conclusion on which marine biotoxins potentially pose a risk to UK consumers, Members requested that the Secretariat produce a) a table providing the main toxicological information of the marine biotoxins discussed in the scoping paper for easier comparison and b) a table of the main toxicological information of currently regulated marine biotoxins. This would help the Committee compare non-regulated biotoxins to those already monitored, and to enable Members to put the potential risk of emerging biotoxins into perspective.

5. The Committee requested that the table should include a summary of the toxicological endpoint(s), the lethal doses, and information regarding the occurrence of each biotoxin. Due to difficulties in fitting all required information into one single table, each biotoxin has been placed into an individual table summarising the requested information on occurrence, lethal doses, adverse effects, health-based guidance values (HBGVs), human intoxications, and any comments deemed relevant. Annex A provides information regarding the identified emerging biotoxins, Annex B provides information regarding regulated biotoxins.

6. All information regarding emerging biotoxins has been extracted from the original scoping paper (TOX/2023/59) and its references. All information regarding regulated biotoxins has been extracted from the appropriate EFSA scientific opinion.

7. In addition, a table (Annex C) has been included providing estimated adult exposures (78.6 kg bodyweight) to unregulated marine biotoxins, based on EFSA's shellfish portion size of 400 g, and a fish portion of 140 g, as suggested by the Ministry of Agriculture Fisheries and Food portion size book. Due to the limited nature of the occurrence data, the exposure assessment was done as an approximate estimate to aid Members in prioritisation rather than aiming to provide a full exposure assessment. The occurrence data used in the exposure assessment has previously been discussed in the scoping paper and summarised in Annex A. The original sources of the occurrence data for the respective biotoxins were a combination of surveillance studies, submissions by member states in response to EFSA's calls for data, country specific monitoring data, and research projects including laboratory-based studies and field studies.

8. Please note, pinnatoxin ([TOX/2023/37](#)) and pectenotoxin (TOX/2023/58) have been discussed separately and have not been included in the tables.

Questions on which the views of the Committee are sought:

- i. Does the Committee consider there to be enough information to conclude on which marine biotoxins potentially pose a risk to UK consumers, based on the toxicology and occurrence data?
- ii. Based on the available information does the Committee consider it possible to comment on which marine biotoxins pose the highest risk to UK consumers (provide a risk ranking)?
- iii. Are there any data gaps, or any further information the Committee would like to highlight?
- iv. Does the Committee have any other comments.

Secretariat

July 2024

TOX/2024/25 - Annex A

The following table(s) summarise key occurrence data, and toxicological information, of the currently non-regulated marine biotoxins, as discussed in the scoping paper (TOX/2023/59).

Table 1: Brevetoxin (BTX), **Toxicological endpoint(s):** Neurotoxicity

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sy
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Neurological shellfish poisoning (NSP)

Humans

Nausea, vomiting, diarrhoea, paraesthesia, muscle cramps, bronchoconstriction, paralysis, seizures, coma.

Recreational Irritant effect on inhalation/dehydration exposure.

Animals

Depolarization of and muscle cell membranes resulting in impairment of and peripheral nervous system, including neurovegetative neuromuscular cardiorespiratory symptoms and signs such as seizure and decrease in body temperature.

In vitro

Chromosomal damage (BTX-2)

LD50

Mice (i.p. administration; after 24 hours).

- 170 - >300 µg/kg bw (BTX-3),
- 200 - 400 µg/kg bw (BTX-(B)2)
- 211 µg/kg bw (S-deoxy-BTX-B2),

Mice (oral administration)

- 6600 mg/kg (BTX-2)
- 520 mg/kg bw (BTX-3).

Mice (i.v. administration)

- 94 µg/kg bw (BTX-3)
- 200 µg/kg bw (BTX-2).

MLD

Mice (i.p. administration)

- 100 µg/kg bw (BTX-4; 6-24 hours)

No regulatory limits in Europe.

USA

action level

≥ 0.8 mg BTX-2 equivalents/kg shellfish.

Australia/New Zealand

Maximum level 20 MUs*/100g, BTX analogue not specified.

ANSES

proposed guidance level

180 µg BTX-3 equivalent/kg shellfish meat.

82 to 345 µg/kg (BTX-2 + BTX-3; Mussels; France).

880 to 49,000 µg BTX-2 equivalents/kg (Shellfish; Mexico, New Zealand, USA).

580 to 6000 µg BTX-3 equivalents/kg (Fish; Mexico, New Zealand, USA).

Table 2: Cyclic imines (CIs) (Excluding PnTX and portimine), **Toxicological endpoint(s):** Neurotoxicity (SPX and GYM)

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
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LD50:

Mice (i.p.
administration)

- 40 µg/kg bw
(SPX mixture; crude
extract),
- 8 µg/kg bw
(SPX C; fed mice),
- 6.9 µg/kg bw
(13-desmethyl SPX
C; fed and fasted
mice),
- 27.9 µg/kg bw
(13-desmethyl SPX
C),
- 8 µg/kg bw (20-
methyl SPX G; fed
mice),
- 32.2 µg/kg bw
(13,19-didesmethyl
SPX C),
- 450 µg/kg bw
(GYM A; crude
extract),
- 96 µg/kg bw
(GYM A; >95%
pure),
- 80 µg/kg bw
(GYM A),
- 800 µg/kg bw
(GYM-B),
- Overall, 500-
1005 µg/kg bw
(SPX).

Table 3: Palytoxin (PITX), Toxicological endpoint(s):

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
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Humans

Myalgia and weakness, possibly accompanied by fever, nausea and vomiting, and rhabdomyolysis characterised by injury to skeletal muscle, muscle breakdown and leakage of myoglobin into plasma.

Renal failure and disseminated intravascular coagulation.

Death.

Skin, eye and respiratory irritation.

Animals

Reduced intracellular pH.

Rabbits

increased metabolism of arachidonic acid and the production of eicosanoids; arachidonic acid metabolised to prostaglandins releasing norepinephrine

Intoxications reported.

Some reports

LD50

Table 4: Saxitoxin (STX), Toxicological **endpoint(s):** Neurotoxicity

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
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Paralytic shellfish poisoning (PSP)

Humans

Mild symptoms include tingling sensation, numbness, mouth around the lips spreading to face, neck, headache, dizziness, nausea

Moderately severe symptoms: incoherent speech, progression of prickling sensation on arms and legs, stiffness, non-coordination of general weakness and feeling of lightness, slight respiratory difficulty and rapid pulse

Severe to extremely severe symptoms: muscular paralysis, pronounced respiratory difficulty to fetal respiratory paralysis.

Death from respiratory arrest

EU

800 µg STX equivalent/kg shellfish meat.

FAO/IOC/WHO

provisional ARfD of 0.7 µg STX

Recreational

Table 5: Tetrodotoxin (TTX), **Toxicological endpoint(s):** Neurotoxicity

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
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Humans

Perioral numbness and paraesthesia with or without symptoms to lip numbness, ear motor paralysis incoordination, slurred speech normal reflexes generalised flaccid paralysis, aphasia and fixed/dilated pupils to hypoxia hypotension, bradycardia, cardiac dysrhythmias and unconsciousness

Death, caused by respiratory failure and cardiac collapse

Animals

Skeletal muscle fasciculation, ataxia, lethargy, ataxia ascending progressive paralysis and death.

Mice: urine production significantly decreased (at 100 µg/kg and 125 µg/kg daily). Exposure to the highest concentration resulted in ch

No maximum levels in the EU.

EFSA

ARfD

0.25 µg/kg bw.

LD50

Mice (i.p. administration and s.c. administration)

· 8-13 µg/kg bw

Some human case reports.

Kasteel et al. (2017)

ARfD

1.33 µg/kg bw.

Mice (oral administration and intragastric administration)

· 232 µg/kg bw and 532 µg/kg bw

Onset of symptoms within 10-45 minutes of ingestion, although delayed responses of 3-6 hours have also been reported.

Finch et al. (2018)

ARfD

10.1 nmol/kg (3.2 µg/kg).

LD100

Mice (oral administration)

· 1000 µg/kg bw

(EFSA, 2017;

TTX and analogues:

0.0003 to 0.541 mg/kg (gastropods and bivalves; France; Spain; Italy; Greece; The Netherlands; Ireland; UK).

TTX most common analogue in all regions.

Unknown

Table 6: Novel azaspiracids (AZAs), **Toxicological endpoint(s):**

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
Japan	No information available.	No information available.	None reported	No information available.

Table 7: Novel PSP analogues domoic acid analogues, **Toxicological endpoint(s):**

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
No information available.	No information available.	No information available.	None reported.	No information available.

Table 8: Cyanobacteria toxin(s), **Toxicological endpoint(s):** Depending on cyanotoxin, ranging from neurotoxicity, hepatotoxicity, cytotoxicity to dermal toxicity and irritation.

Occurrence Data (Concentration/ Species/Country)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Sym
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Humans

MCs

Most common
gastroenteritis

Intrahepatic
haemorrhage

Fatalities (after
mistreated water
used in dialysis)

BMAA

Implicated in
neurodegenerative
diseases: Amyotrophic
lateral sclerosis,
Parkinsonism-
dementia complex,
and Alzheimer's

Animals

MCs

Lung effects
(thickening of
alveolar septa,
disruption of cell
junctions, alveolar
collapse, and
apoptosis).

Serum profile
changes (increased

TOX/2024/25 - Annex B

The following table(s) summarise key occurrence data, and toxicological information, of current regulated marine biotoxins extracted from the appropriate EFSA scientific opinion.

Table 9: Saxitoxin, **Toxicological endpoint(s):** Neurotoxicity

See Annex A: Emerging Biotoxins, Table 4, for further details.

Table 10: Domoic Acid, **Toxicological endpoint(s):** Neurotoxicity

Occurrence Data (Country/Species/Concentration)	HBGVs /Maximum levels permitted	Lethal dose (LD50/LD100/ Human MLD) in animals	Adverse Intoxications effect(s)/Symptoms	Con
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Humans

Amnesic Shellfish
Poisoning (ASP)
including
gastrointestinal
symptoms (vomiting,
diarrhoea, or
abdominal cramps)
and/or neurological
symptoms (confusion,
loss of memory,
potential seizure, or
coma).

Animals

Mice (oral
administration)

Scratching (35 mg/kg
bw) *, clinical signs
(not detailed; 71 mg
DA/kg bw; acidified
extract), death (71 to
83mg DA/kg bw;
acidified extract).

Rats (oral
administration)

Flaccidity, head on
floor, inactivity,
mastication, seizures,
mild to moderate CNS
damage, death (n=1-
4; given 60-80 mg/kg
bw DA *per os*).

Table 11: Okadaic Acid (and OA group toxins), **Toxicological endpoint(s):**
Gastrointestinal (DSP)

Occurrence

Data

HBGVs

Lethal dose

(LD50/LD100/

Human

Adverse

(Country/

/Maximum

MLD) in

Intoxications

effect(s)/Symptom

Species/

levels

animals

permitted

Concentration)

DSP reported in Japan, the Netherlands, Norway, Sweden, Belgium, Portugal, UK, Canada, Chile and New Zealand.

Humans

Japan

164 people suffering with diarrhoea, nausea, vomiting and abdominal pain from eating mussels or scallops containing mostly DTX1. Intakes estimated 48 µg OA

Diarrhoeic Shellfish Poisoning (DSP): diarrhoea, nausea, vomiting and abdominal pain. Fever, chill, and headache.

Animals

Mice

LD50

Mice (i.p. administration):

- 204 µg/kg bw,

- 200 µg/kg bw ,

- 225 µg/kg.

Lethal dose

Mice (i.p. administration):

- 200 µg/ kg bw.

equivalents/person for mild symptoms or 80-280 µg OA equivalents/person for severe symptoms.

Portugal

6 cases from consuming: razor clams: 500 µg OA equivalents /kg flesh.

Hypersection in the small intestine (75, 150 and 250 µg/kg bw), severe mucosal injury, extravasation of serum into lamina propria of villi, degeneration of absorptive epithelium of iliac villi, and desquamation of the

Denmark,
France,
Germany,
Ireland,
The Netherlands,
Norway,
Portugal,
Spain,
Sweden,
UK.

EU

160 µg OA equivalents/kg shellfish meat.

FAO/IOC/WHO

ARfD
0.33µg OA equivalents/kg

Table 12: Dinophysis toxins, **Toxicological endpoint(s):** Gastrointestinal (DSP; as part of OA group)

Occurrence

Data	HBGVs	Lethal dose	Human	Adverse	Comm
(Country/ Species/ Concentration)	/Maximum levels permitted	(LD50/LD100/ MLD) in animals	Intoxications	effect(s)/Symptoms	

Denmark,
 France,
 Germany,
 Ireland,
 The Netherlands,
 Norway,
 Portugal,
 Spain,
 Sweden,
 UK.

Shellfish.

Of 6072 samples:

DTX 1.

416 samples \geq LOD up to 160 μg toxin/kg shellfish meat.

89 samples $>160 \mu\text{g}$ toxin/kg shellfish meat.

DTX2

None specific for DTX.

See Table 3 for HBGVs for OA equivalents.

LD50

Mice (i.p. administration):

- 350 $\mu\text{g}/\text{kg}$ bw (DTX2).

Lethal dose

Mice (i.p. administration):

- 160 $\mu\text{g}/\text{kg}$ bw for (DTX 1), See Table 3.
- 200 to 500 $\mu\text{g}/\text{kg}$ bw. (DTX 3).

Mice (oral

Humans

As part of OA group toxins, See Table 3.

Animals

Mice (i.p. administration).

Intestinal injury (50-500 $\mu\text{g}/\text{kg}$ bw for DTX1 and at 375 $\mu\text{g}/\text{kg}$ bw for DTX3)

Bleeding in the abdomen (DTX3).

Mice (oral administration).

Light diarrhoea and slight reduced bodyweight. Light erosions to the stomach, intestinal damage (600 and 700 $\mu\text{g}/\text{kg}$).

Mice and rats (i.p.

Table 13: Yessotoxins (and analogues), **Toxicological endpoint(s):**

Occurrence Data (Country/Species/Concentration)	HBGVs /Maximum levels permitted	Lethal dose (LD50/LD100/ Human MLD) in animals	Adverse Intoxications effect(s)/Symptoms	Com
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Humans

No reports on adverse effects in humans.

Animals

Mice (i.p. administration).

Dyspnoea and death ($\geq 300 \mu\text{g}/\text{kg}$).

Restlessness and jumping before death at lethal doses.

Shivering (at 750 and 1000 $\mu\text{g}/\text{kg}$) and cramps.

Vacuolation in the cardiac muscle, and intracellular oedema, cardiac damage (500 $\mu\text{g}/\text{kg}$), swelling of myocardial cells (5-10mg/kg) and

alterations of myocardiocytes (1-2 mg/kg YTX).

Cytoplasmic protrusions of myocardiocytes, rounding of mitochondria and fibre modifications (1mg/kg 1a-homoYTX

LD50*

Mice (i.p. administration; male).

· 80-462 $\mu\text{g}/\text{kg}$ bw (YTX),

· 301 $\mu\text{g}/\text{kg}$ bw (Di-desulfoYTX),

Mice (i.p. administration; female),

· 112-750 $\mu\text{g}/\text{kg}$ bw (YTX),

· 444 $\mu\text{g}/\text{kg}$ bw (1a-HomoYTX).

Lethal dose **

Mice (i.p. administration; sex not reported)

· 100 $\mu\text{g}/\text{kg}$ bw (1a-HomoYTX),

EU

1 mg YTX eq./kg shellfish meat.

EFSA

ARfD

25 μg YTX equivalents/kg bw

3.75 mg YTX eq./kg shellfish meat.

Germany,

Italy,

Norway,

Portugal,

Spain,

United Kingdom.

Shellfish.

“not detected” to 9620 μg YTX eq./kg shellfish meat.

No reports of human illness.

No reports of

Anal

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Table 14: Azaspiracids, **Toxicological endpoint(s):** Gastrointestinal (similar to DSP)

Occurrence Data (Country/Species/Concentration)	HBGVs/Maximum levels permitted	Lethal dose (LD50/LD100/MLD) in animals	Human Intoxications	Adverse effect(s)/Symptoms	Com
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Humans

AZA poisoning (AZP):
nausea, vomiting,
diarrhoea and
stomach cramps.

Animals

Mice (oral
administration),

AZA poisoning
reported
across the
Netherlands,
Ireland, Italy,
France, and
the UK.

Shortened villi, injury
to small intestine
(600 or 700 µg/kg
bw; slow recovery
after 24h). 38%
increase in liver
weight after 24h, fine
fat droplets
distributed in liver
(500 µg/kg bw).

Netherlands

8 cases,
unwell after
consuming 8-
10 mussels
harvested
from the west
coast of
Ireland.
Intakes
estimated
initially
between 6.7
µg (5th
percentile)

Dose-dependent
necrotic lymphocytes
in the thymus,
spleen, and Peyer's
patches of the small
intestine (500 to 700
µg/kg bw),

Lethal dose

Mice (i.p.
administration;
male)
200µg/kg
with a median

Changes to the small
intestine: congestion,
watery substance in
the lumen, small
changes to surface
epithelial cells,
atrophic lamina
propria spatially

Som
long
repe
dose
toxic

TOX/2024/25 - Annex C

Table 15: Estimated adult exposures (78.6 kg bodyweight) to unregulated marine biotoxins, based on EFSA’s shellfish portion size of 400 g, and a fish portion size of 140 g, as suggested by the Ministry of Agriculture Fisheries and Food portion size book.

Toxin	Occurrence	HBGVs	Exposure Assessment in Adults
Brevetoxin.	82 to 345 µg/kg (BTX-2 + BTX-3; Mussels; France).	No regulatory limits set.	0.42 to 1.8 µg/kg bw.
	880 to 49,000 µg BTX-2 equivalents/kg (Shellfish; Mexico, New Zealand, USA).	<p>EFSA</p> <p>ARfD for sum of PITX and ostreocin-D: 0.2 µg/kg bw.</p>	4.5 to 250 µg/kg bw.
	580 to 6000 µg BTX-3 equivalents/kg (Fish; Mexico, New Zealand, USA).	<p>NRL for Marine Biotoxins provisional limit</p> <p>250 µg/kg shellfish.</p> <p>ANSES</p> <p>Short term toxicity reference value for PITX 0.08 µg/kg bw per day.</p>	1.03 to 11 µg/kg bw.

SPX:

CRLBM/EURL

Norway,

proposed guidance

Spain,

level 400 µg sum of

Italy.

SPXs/kg shellfish meat.

Toxin producing
organism:

Cyclic imines (e
xcluding PnTX
and portimine).

Scotland,

Italy,

N/A

Denmark,

Ireland.

PtTX and GYM not
detected in Europe.

GYM found in imported
shellfish.

No regulatory limits set.

EFSA

ARfD for sum of PITX and ostreocin-D: 0.2 µg/kg bw.

Palytoxin (PITX).
300 to 625 µg/kg shellfish meat (PITXs; Mussels and sea urchins; France; Greece; Italy; Spain;).

NRL for Marine Biotoxins provisional limit

1.5 to 3.2 µg/kg bw.

250 µg/kg shellfish.

ANSES

Short term toxicity reference value for PITX 0.08 µg/kg bw per day.

EU

800 µg STX
equivalents/kg
shellfish meat.

FAO/IOC/WHO

provisional ARfD of 0.7
µg STX equivalents/kg
bw.

EFSA

ARfD

0.5 µg STX
equivalents/kg bw.

ANSES

TRV

~ 0.1 µg/kg bw.

OHA

TDI

N/A

0.05 µg/kg bw per day.

Interim drinking water guidance levels

1 µg/L (Australia, New
Zealand and OHA)

3 µg/L (Brazil,
Australia, and WHO).

Saxitoxin (STX).

Toxin producing algae:

Norway,

Portugal,

France,

Germany,

Italy,

Turkey,

Egypt.

No maximum levels in the EU.

EFSA

ARfD

0.25 µg/kg bw.

TTX and analogues:

Kasteel et al. (2017)

ARfD

0.0003 to 0.541 mg/kg (gastropods and bivalves; France; Spain; Italy; Greece; The Netherlands; Ireland; UK).

1.33 µg/kg bw.

0.0015 to 2.8µg/kg bw

Tetrodotoxin (TTX).

Finch et al. (2018)

ARfD

10.1 nmol/kg (3.2 µg/kg).

TTX most common analogue in all regions.

Unknown

110 µg TTX equivalent/kg shellfish meat.

(Reference not found, taken from a review by Katikou 2019 citing the study Kasteel et al. 2017).

Novel azaspiracids (AZAs).	Japan	No information available.	N/A
Novel PSP analogues domoic acid analogues.	No information available.	No information available.	N/A

	MCs:		
		EFSA	
		TDI of 0.04 µg/kg bw per day.	
Northern Ireland (Lough Neagh)			MCs:
			0.18µg/kg bw.
		ANSES	
	MCs:	Subchronic TRV 1 ng/kg bw per day.	
	100 µg/kg fresh weight (Fish muscle; Europe).		0.23 to 0.72 µg/kg bw.
		WHO	
	45 to 142 µg MC-LR/kg fresh weight (Saltwater mussels; Greece).	Provisional TDI of 0.04 µg/kg bw.	
		OHA	
	NOD:	TDI of 0.05 µg/kg (for MC-LR specifically).	NOD:
	80 to 817 µg/kg dw (Shellfish; Finland; Poland).		0.41 to 4.2 µg/kg bw.
		ATX:	
	BMMA:	WHO	BMMA:
Cyanobacteria toxin(s).	900 to 14,000µg/kg (Oysters; France; Sweden; Greece).	No formal TDI set.	4.6 to 71µg/kg bw.
		NOAEL 98 µg/kg bw per day.	
	2 DAB:	CYN:	2 DAB:
	1,100 to 9,700 µg/kg (Mussels; France).		5.6 to 49µg/kg bw.
		WHO	
	DAB:		

References:

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