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焦點個案 Incident in Focus

象拔蚌中的麻痺性貝類毒素 Paralytic Shellfish Poisoning (PSP) Toxins in Geoducks

食物安全中心

風險評估組

科學主任朱源強先生報告

Reported by Mr. Johnny CHU, Scientific Officer,
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二零一四年十二月，食物安全中心(中心)獲加拿大當局通知，指有大批產自卑詩省的活象拔蚌被檢出含百萬分之1.1麻痺性貝類毒素，超出加拿大標準及香港的行動水平(即不得超過百萬分之0.8)。中心除要求業界停售有問題食品及禁止卑詩省同一地點捕獲的象拔蚌進口外，還加強抽取加拿大其他地區進口的象拔蚌進行檢測。結果顯示，有16個象拔蚌樣本的麻痺性貝類毒素含量超過百萬分之0.8。為保障市民健康，中心即時通知加拿大當局檢測結果，並把暫停進口象拔蚌的範圍擴大至整個卑詩省。

食物中的麻痺性貝類毒素

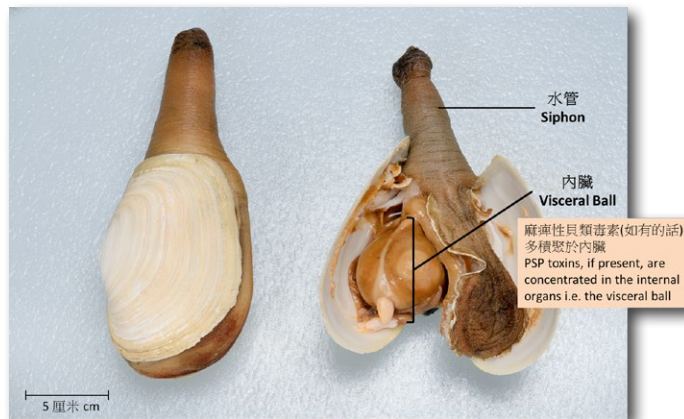
麻痺性貝類毒素由某些微藻類所產生，是一組相關的天然毒素。象拔蚌、青口、蜆、蠔和扇貝等貝類以濾過海水的方式進食水中的食物微粒(包括藻類)。貝類在吃下產毒藻類後，毒素會積聚在貝類組織內，特別是在內臟部分。而象拔蚌體中的毒素多集中在內臟。

在正常情況下，產毒藻類在海水中的數量是很低的，不足為患。但當這些藻類爆發性地大量繁殖，便會成為貝類的主要食糧。貝類吃下的毒藻愈多，體內所積聚的麻痺性貝類毒素便愈多。當海水中產毒藻類的細胞數目回復到正常水平後，貝類自然會逐漸釋出體內的毒素。但是，根據文獻記載，要等幾天至數月甚至更久，貝類才可再次安全食用。

In December 2014, the Centre for Food Safety (CFS) received notification from Canadian authorities that Paralytic Shellfish Poisoning (PSP) toxins at 1.1 ppm were detected in three consignments of live geoduck from British Columbia (BC). The level exceeded the Canadian standard which is also the action level in Hong Kong (i.e. a maximum level of 0.8 ppm). Besides stopping the sale of the products and banning the import from the same harvest area in BC, the CFS immediately stepped up the import surveillance of geoducks from other parts of Canada. Subsequently, 16 samples of geoduck harvested from other areas of BC were found containing PSP toxins at levels exceeding 0.8 ppm. To protect public health, the CFS immediately informed the Canadian authorities of the test results and extended the import ban on geoducks to the whole BC.

PSP Toxins and their Occurrence in Food

PSP toxins, produced by certain microscopic algae, are a group of related naturally occurring toxins. Shellfish (such as geoducks, mussels, clams, oysters and scallops) filter water through their gills and eat food particles including algae. When the shellfish eat toxins-producing algae, the toxins will be concentrated in tissues of the shellfish, in particular the internal organs. In geoducks, the toxins are mainly found in the visceral ball.



在食用象拔蚌前先把其內臟清除乾淨

Discard the visceral ball before consumption

It is normal and poses no problems when toxins-producing algae are present in marine water at very low concentrations. However, when the algae "bloom", they become a greater food source for shellfish. The more algae the shellfish eat, the more PSP toxins they accumulate. After the number of toxins-producing algal cells in the water returns to normal low levels, the shellfish gradually flush the toxins from their bodies. However, according to literature, it can be several days to several months or longer before the shellfish are safe for consumption again.

焦點個案
Incident in Focus

對健康的影響

麻痹性貝類毒素屬於神經毒素，毒性甚烈，現時並沒有已知的解毒劑。麻痹性貝類中毒的症狀通常在進食貝類後30至60分鐘內出現。初期症狀包括口舌刺痛，隨後可能會出現四肢失控，繼而呼吸困難，嚴重者甚至會致命。

規管情況

食品法典委員會採取的標準是雙殼貝類可食用部分中的麻痹性貝類毒素不得超過百萬分之0.8。香港亦以此為行動水平。

預防措施

在貝類捕撈區實施監察計劃是最有效的控制措施，很多已發展國家已在實行，由政府部門負責監測捕撈區的水質和毒素水平。舉例來說，除了檢測貝類商品外，亦可利用青口作為前哨物種，監察捕撈區是否存在毒素，因為比起其他貝類，青口較快積聚麻痹性貝類毒素。負責監測的政府部門一旦監測到捕撈區的細菌或毒素數量達到不安全水平，便禁止捕撈。

有毒貝類和無毒貝類在外觀上沒有分別，而且麻痹性貝類毒素不能通過烹調清除。故市民應向可靠的零售商購買貝類，烹煮前先去全部內臟，並避免進食過量。

注意要點：

- 在貝類捕撈區實施監察計劃是最有效的控制措施。
- 有毒貝類和無毒貝類在外觀上沒有分別，而且麻痹性貝類毒素不能通過烹調清除。
- 麻痹性貝類毒素(如有的話)多積聚於貝類的內臟。

給業界的建議

1. 向已建立麻痹性貝類毒素監察計劃的地區採購象拔蚌。
2. 切勿購買來源不明的象拔蚌。

給市民的建議

1. 向可靠來源購買象拔蚌。
2. 為免因進食含麻痹性貝類毒素的象拔蚌而中毒，在進食前應除去所有內臟。
3. 進食象拔蚌後若感到不適，應立即求醫。

Public Health Significance

PSP toxins are powerful nerve poisons with no known antidote. Early symptoms include tingling of the lips and tongue, which may appear from 30 to 60 minutes after eating the toxic shellfish. Symptoms may progress to loss of control of arms and legs followed by difficulty in breathing. Death can occur in severe cases.

Regulatory Control

The Codex Alimentarius Commission adopts a maximum level of 0.8 ppm for PSP toxins in bivalve shellfish (edible parts). Hong Kong adopts the same level for action.

Preventive Measures

The most effective control measure is the implementation of monitoring programmes in the harvest areas, as currently practised by many developed countries. Government agencies are responsible for monitoring water quality and toxin levels in shellfish in harvest areas. In addition to testing the commercial shellfish products, mussels may be used as sentinel species to monitor the presence of toxins in the harvest areas because mussels concentrate PSP toxins faster than other shellfish. Harvesting will be prohibited when bacteriological or toxin levels of the harvest areas are unsafe.

Toxic shellfish cannot be distinguished from non-toxic ones visually and cooking does not destroy PSP toxins. The public are hence advised to purchase shellfish from reliable retailers, discard all the internal organs of the shellfish before cooking and avoid over-indulgence in shellfish consumption.

Key Points to Note:

- The most effective control measure is the implementation of monitoring programmes in harvest areas.
- Toxic shellfish cannot be distinguished from non-toxic ones visually and cooking does not destroy PSP toxins.
- PSP toxins, if present, are more likely to accumulate in the internal organs of shellfish.

Advice to the Trade

1. Source geoducks from places where monitoring programmes for PSP toxins are established.
2. Do not accept geoducks from dubious sources.

Advice to the Public

1. Purchase geoducks from reliable sources.
2. To reduce the health risk of poisoning by PSP toxins due to consumption of geoducks, remove and discard all internal organs of geoducks before consumption.
3. Anyone who feels ill after eating geoducks should immediately seek medical attention.

風險傳達 工作一覽 Summary of Risk Communication Work

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歐盟對健康聲稱的科學佐證的評審

Scientific Substantiation of Health Claims in the European Union

食物安全中心
風險評估組
科學主任馮慧中女士報告

Reported by Ms. Jacqueline FUNG, Scientific Officer,
Risk Assessment Section,
Centre for Food Safety

健康聲稱應具科學佐證，即有公認的科學證據證明某食品／成分(例如某營養素)與聲稱所陳述的效果之間存在因果關係，以及能證明所聲稱的效果屬實。歐洲聯盟(歐盟)、美國、澳洲和新西蘭等已制定健康聲稱規例的地區均設有健康聲稱的評審機制。歐洲食物安全局負責評審歐盟地區內有關食物的健康聲稱。該局就健康聲稱的認可申請和評估事宜發出了數份指引文件。本文將參考這些文件，簡介歐盟在評審健康聲稱的科學佐證時的做法。

如何審核健康聲稱是否屬實？

為確定一個健康聲稱是否屬實，歐洲食物安全局主要會從兩方面作出評審。首先，該健康聲稱必須有清晰的定義，這包括對有關食品／成分的特徵及聲稱所陳述的效果作出清晰的界定。其次，該健康聲稱必須有科學證據支持，當中要包括以人類為對象的相關研究。歐洲食物安全局認為，有關該聲稱的關鍵問題只要有一題的答案為否定，便代表其因果關係未能確立(見圖)。

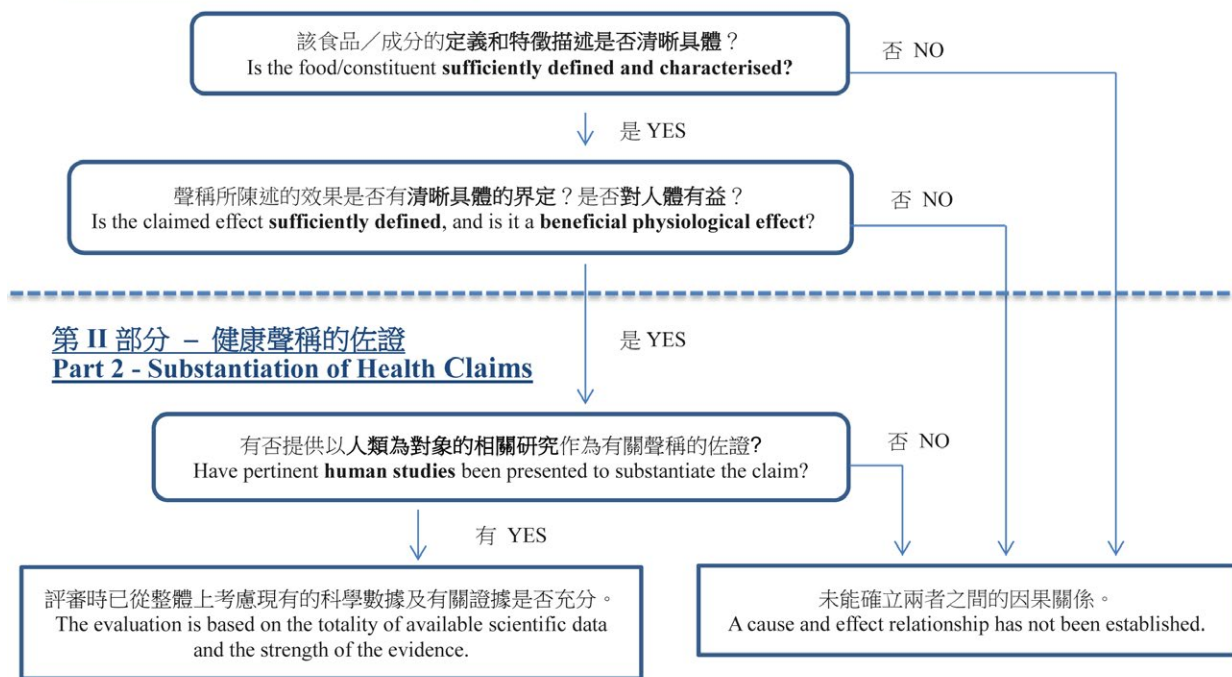
Health claims should be scientifically substantiated, i.e. a cause and effect relationship between a food/constituent (e.g. a nutrient) and a claimed effect has to be established according to generally accepted scientific evidence. Places with health claim regulations, such as the European Union (EU), the USA and Australia/New Zealand, have put in place a scheme for health claims evaluation. The European Food Safety Authority (EFSA) has been mandated to evaluate the validity of health claims made on foods in the EU. EFSA has issued several guidance documents to facilitate claims submission and evaluation. This article introduces the EU's approach to scientific substantiation of health claims by making reference to these documents.

How to Decide Whether a Health Claim is Substantiated?

In order to determine the validity of health claims, two key issues of a health claim are being examined by EFSA. Firstly, a health claim shall be clearly defined, which includes the definition and characterisation of the food/constituent and the definition of the claimed effect. Secondly, a health claim shall be substantiated by scientific evidence, which must include pertinent human studies. EFSA considers that a cause and effect relationship has not been established, if an unfavourable outcome is obtained from any one of the key questions addressing the claim (see Figure).

第 I 部分 – 健康聲稱的定義

Part 1 - Definition of Health Claims



如何審定某健康聲稱是否屬實？(資料來源：歐洲食物安全局就第13.1、13.5及第14條健康聲稱的評審所發的通用準則)

How to Decide Whether a Health Claim is Substantiated? (Source: EFSA General Guidance for Article 13.1, 13.5 and 14 Health Claims Evaluation)

食品／成分的特徵

歐洲食物安全局在評估一種食品／成分的定義和特徵描述是否充分時，除了審核其成分組合(即配料和含量)、物理／化學特性和微生物特徵等規格細項外，還會考慮生產過程(例如批次間的差異檢測)、穩定性資料(例如貯存條件、保質期和分析程序等)及生物利用率的數據(例如吸收研究)等。

健康聲稱所陳述的效果

食品／成分的健康聲稱所陳述的效果必須是對人體有益，並且界定得非常清晰具體才會獲得批准。換言之，聲稱所陳述的效果必須經過公認可靠的方法證明是有益和可衡量的。這些方法包括分析化驗及使用經驗證問卷的調查(例如低密度脂蛋白膽固醇水平下降和排便次數)。而那些陳述空泛和不具體的健康聲稱

Food/Constituent Characteristics

In addition to specifications, such as composition (i.e. ingredients and amounts), physical/chemical properties and microbiological characteristics of the food/constituent, EFSA will take into consideration of the manufacturing process (e.g. batch to batch variability test), stability information (e.g. information with respect to storage conditions, shelf-life, and analytical procedures) and bioavailability data (e.g. absorption studies) when determining whether a food/constituent is sufficiently defined and characterised.

Effect of Health Claims

Only health claims made on food/constituent showing beneficial physiological effects that have been sufficiently defined are permitted. In other words, these claimed effects must be beneficial and measurable by generally accepted methods, such as analytical tests and validated questionnaires (e.g. reduction of LDL-cholesterol concentration, frequency of bowel movement). General and non-specific health claims (e.g. good for heart health, improve gut

(例如對心臟有益,改善腸臟健康等)是不會獲歐洲食物安全局考慮的。

健康聲稱的佐證

科學佐證是健康聲稱的重要評審項目。評審人員會從整體上考慮現有的科學數據(包括支持和否定該食品/健康關係的相關研究),並從以下幾方面分析有關證據是否充分:

- 數據的精確度:就聲稱所陳述的正面健康效果的統計學顯著性,判斷其是否屬實。
- 一致性:所有水平達標的研究在效果的趨勢方面是否有一致的結論。
- 劑量反應:食品/成分的進食分量與聲稱所陳述的健康效果之間的關係。
- 生物合理性:聲稱所陳述的健康效果具有生物相關性,並且有證據顯示該食品/成分與聲稱所陳述的健康效果之間有一致的關聯(例如機理)。

歐洲食物安全局在評審健康聲稱時主要考慮以人類為對象的研究。非以人類為對象的研究(即動物/試管研究)只能作為輔助證據,證明有關聲稱的機理/過程/生物合理性。

歐洲食物安全局在評審健康聲稱時,除了證據的質素外,還會考慮有關證據是否具類推性(即研究證據是否適用於聲稱所針對的目標人群),以及按均衡飲食的原則,食物/成分的建議進食分量能否達到所聲稱的效果。雖然評審工作並不包括安全評估,但如可能存在負面作用,歐洲食物安全局亦會在意見書上提出。

歐盟對健康聲稱的批核

根據歐盟的健康聲稱評審機制,歐洲食物安全局負責進行科學評估,但歐洲委員會才是歐盟批核健康聲稱的官方機構。歐盟委員會在作出決定時主要參考歐洲食物安全局的意見,但也會考慮安全和政策(例如有關聲稱是否符合營養政策)等其他問題。根據歐盟有關健康聲稱的記錄,截至二零一五年三月,核准清單上有250多個獲准使用的健康聲稱。

health) will not be considered by EFSA.

Substantiation of Health Claims

Scientific substantiation is the major aspect of evaluation of health claims. The evidence is weighed taking into account the totality of available scientific data (i.e. including pertinent studies that are in favour and not in favour of the food/health relationship) and the strength of the evidence, which is assessed by considering several dimensions, including:

- Statistical precision: The statistical significance of a positive claimed health effect to determine whether the effect is real.
- Consistency: Consistency of the findings across all research of acceptable quality, i.e. direction of effect.
- Dose-response: The relationship between the amount of food/constituent consumed and the claimed health effect.
- Biological plausibility: The claimed health effect is biological relevant and supported by evidence showing a consistent association between the food/constituent and the claimed health effect (e.g. mechanism).

EFSA's evaluation of a health claim is mainly based on human studies. Non-human studies (i.e. studies in animals/*in vitro*) are supporting evidence for showing the mechanisms/pathways and the biological plausibility of the claim.

Besides the quality of evidence, EFSA will also consider the generalisability (i.e. the translation of research evidence into application on the target population) and the feasibility of consuming the suggested amount of food/constituent in a healthy balanced diet to obtain claimed health effect when deciding whether the assessment is a favourable one. Although safety assessment is not part of the health claim substantiation, EFSA will note the possible adverse effects, if any, in the opinion.

Authorisation of Health Claims in the EU

Under the EU health claims evaluation scheme, EFSA is responsible to carry out scientific assessments, whereas the European Commission (EC) is the official body authorising health claims in the EU. EFSA's advice forms the basis for authorisation decisions by the EC. In addition, the EC will take into consideration of other issues, such as safety and policy issues (e.g. whether the claim is in line with the nutrition policy) when authorising a health claim. According to the EU register on health claims, as of March 2015, there are over 250 permitted health claims on the approved list.



乾冬菇的鎘含量超標

食物安全中心(中心)上月透過恆常食物監察計劃,檢出兩個乾冬菇樣本的鎘含量超出法例標準,中心已指令涉事店舖停售受影響的產品,追查有關食物的來源和分銷情況,並向業界和市民公布事件。

鎘是天然存在於地殼表面的金屬元素。一般人主要從膳食和吸煙攝入鎘。鎘很容易被植物和真菌吸收,研究顯示多種菇類可積聚較高濃度的鎘。雖然從食物攝取鎘導致急性中毒的機會微乎其微,但長期攝取過量的鎘可能會損害腎臟和骨骼。

中心所作的風險評估顯示,一般食用受影響的乾冬菇,不會對健康造成不良影響。雖然如此,如市民曾購買並存有受影響批次的產品,亦應立即停止食用。

Excessive Cadmium in Dried Mushroom

Last month, the Centre for Food Safety (CFS) in its regular Food Surveillance Programme found two dried mushroom samples contained cadmium at levels exceeding the legal limit. The CFS has instructed the vendors concerned to stop the sale of the affected products, traced the source and distribution of the food items in question, and alerted the trade and the public of the incident.

Cadmium is a naturally occurring metallic element in the Earth's crust. Food and tobacco smoking are main sources of cadmium exposure to the general population. Cadmium is readily taken up by plants and fungi, and a number of mushroom species have been shown to accumulate cadmium at higher concentrations. Acute toxicity of cadmium due to dietary exposure is very unlikely but prolonged excessive intake of cadmium may have adverse effects on the kidneys and bones.

Although risk assessment conducted by the CFS revealed that usual consumption of the affected dried mushroom will not cause adverse effects to health, for the sake of prudence, consumers who have bought and still possess the affected batches of the products should stop eating them.

在食物中添加山梨酸

食物安全中心(中心)上月在調查時令食品時發現有兩款賀年預先包裝食物含山梨酸:一個是年糕樣本,而法例不准在年糕中使用山梨酸;另一個是肉鬆麻花糖樣本,該樣本沒有在標籤上標明含山梨酸。一般食用有關產品不會對健康造成不良影響。中心已把調查結果向外界公布,並要求業界停售有關產品。

山梨酸的毒性屬低,獲准用於多種食物中,例如果汁、蔬菜汁、即食湯及肉湯、煎炸魚丸、杏脯和葡萄乾等。業界須注意,山梨酸只能用於法例規定的食物,並且不能超逾最高准許含量;此外,食物添加了山梨酸須在標籤上妥為標明。市民購買食物時應光顧可靠的零售商,並保持均衡飲食。

Use of Sorbic Acid in Food

Last month, the Centre for Food Safety (CFS) detected sorbic acid in two prepacked Lunar New Year foods in its seasonal food surveillance. One sample of rice cake was detected with sorbic acid, a preservative not permitted in rice cake. And one sample of pork floss cracker was detected with sorbic acid which was not properly labelled. Usual consumption of the products concerned is unlikely to pose any adverse health effect. The CFS has informed the public of the incidents and instructed the trade stop selling the products.

Sorbic acid is of low-toxicity. It is allowed to be used in many foods, such as fruit/vegetable juices, ready-to-eat soups and broths, fried fish ball, dried apricots and raisins. The CFS reminds the trade to use sorbic acid only in food stipulated in the law and at a level not exceeding the maximum permitted level. Moreover, its use should be properly labelled. The public is advised to buy food from reliable retailers and maintain a balanced diet.