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焦點個案 Incident in Focus

嬰幼兒配方奶粉中的肉毒桿菌

Clostridium botulinum in Powdered Formulae for Infants and Young Children

食物安全中心

食物安全中心風險評估組

科學主任馬嘉明女士報告

Reported by Ms. Janny MA, Scientific Officer,
Risk Assessment Section,
Centre for Food Safety

新西蘭初級產業部上月宣布，恆天然集團製造的濃縮乳清蛋白有部分批次懷疑受肉毒桿菌污染。問題產品已售出並與其他材料混合製成各種食品，包括嬰幼兒配方奶粉。為謹慎起見，本港一款較大嬰兒配方奶粉因而被回收。本文將探討配方奶粉含肉毒桿菌的風險。

肉毒桿菌與肉毒中毒

肉毒桿菌是一種會產生耐熱孢子的細菌，其孢子普遍存在於環境中，一旦環境變得有利，例如沒有氧氣，孢子便有可能萌發生長，並釋出極危險的神經毒素，引致一種罕見但可致命的疾病——肉毒中毒。

食源性肉毒中毒是因為吃下含有肉毒毒素的食物。容易受肉毒桿菌污染的食物包括輕微醃製的食物及未經妥善加工處理的罐頭或樽裝低酸食物，例如自製低酸蔬菜罐頭和真空包裝的肉類和魚類製品等。

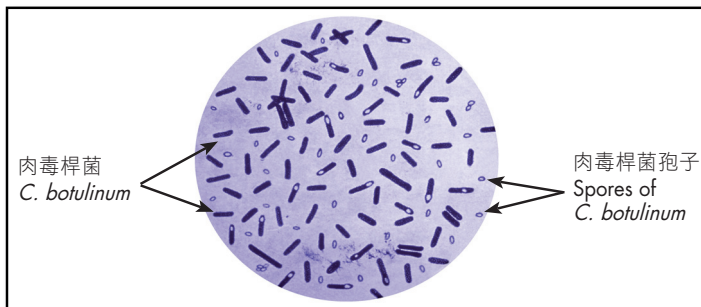
另一方面，腸道性肉毒中毒（舊稱嬰兒肉毒中毒）的成因是嬰兒吃下肉毒桿菌孢子後，孢子在其腸道內萌發和生長，繼而釋出毒素。此病極少發生在一歲以上的人身上，因為其腸道內的天然微生物菌羣已發展得較為成熟，不利這些孢子萌發。腸道性肉毒中毒有幾個可能的感染源，其中已知受肉毒桿菌孢子污染的蜜糖與若干嬰兒病例有關。因此，不應給一歲以下嬰兒餵食蜜糖。

在香港，自二零零八年七月十四日肉毒中毒被列為法定須呈報的疾病以來，尚未錄得感染個案。二零零七年曾有一宗懷疑肉毒中毒個案，但未能找出引致中毒的食品。

Last month, the New Zealand Ministry for Primary Industries (MPI) announced that some batches of whey protein concentrate produced by Fonterra were potentially contaminated with *Clostridium botulinum* (*C. botulinum*). The concerned products were sold and mixed with other ingredients to form various food products including powdered formulae for infants and young children. In Hong Kong, a brand of follow up formula was recalled as a precautionary measure. This article discusses the risk of *C. botulinum* in powdered formulae.

C. botulinum and Botulism

C. botulinum is a bacterium that produces heat-resistant spores which are widely distributed in the environment. When the conditions become favourable, for example in the absence of oxygen, the spores germinate, grow and excrete dangerous neurotoxins that can cause a rare but potentially fatal illness called botulism.



肉毒桿菌在惡劣的環境下以孢子的形式存活。一俟環境變得有利，孢子便萌發成細菌生長並釋出毒素。照片由美國疾病控制及預防中心提供。
C. botulinum survives in form of spores under adverse conditions. If the conditions become favourable, the spores germinate into bacteria, grow and produce toxin. Photo by courtesy of the US Centers for Disease Control and Prevention.

Foodborne botulism is caused by the ingestion of pre-formed toxin in contaminated food. Common implicated foods include lightly preserved foods and inadequately processed canned or bottled low-acid foods such as home-canned low-acid vegetables and vacuum packed meat and fish products.

On the other hand, intestinal botulism (formerly infant botulism) is caused by the ingestion of *C. botulinum* spores which germinate in the intestine and release toxin. Intestinal botulism rarely happens in persons over one-year-old as better developed natural microbiological flora in the intestine do not favour the germination and growth of the bacteria. There are several possible sources of intestinal botulism and spore-contaminated honey has been implicated in a number of cases in infants. Hence, it is recommended not to feed honey to infants less than one-year-old.

Locally, there has been no case of botulism recorded in Hong Kong since this disease was made statutory notifiable on 14 July 2008. Prior to that, one suspected case of botulism was recorded in 2007 but no implicated food could be identified.



配方奶粉含肉毒桿菌的風險

嬰幼兒配方奶粉並非無菌產品，有可能受病原體污染，引致嚴重疾病。

一般來說，用不低於攝氏70度的熱水沖調嬰兒配方奶粉，已可消滅阪崎克羅諾桿菌等有害細菌，但對肉毒桿菌產生的毒素和孢子卻起不到作用。原因是肉毒桿菌的毒素需要煮沸十分鐘或以上才能被破壞；要使其孢子喪失活性，則需要更高溫度。

話雖如此，聯合國糧食及農業組織及世界衛生組織均認為因進食嬰兒奶粉而染上肉毒桿菌引致的疾病的可能性不高，亦未有證據支持這種說法。雖然嬰兒配方奶粉中曾驗出肉毒桿菌，但沒有接到有嬰兒因食用這些奶粉而致病的報告。

事件新發展

根據新西蘭初級產業部的調查，這次濃縮乳清蛋白受污染，肇因是一根處理蛋白的臨時管道受到污染。

最初的檢測結果顯示，這批濃縮乳清蛋白含肉毒桿菌的孢子。然而，新西蘭初級產業部和美國疾病控制及預防中心經反覆驗證後證實，在這批濃縮乳清蛋白中發現的細菌，並非肉毒桿菌，而是一種無害的桿菌。基於最新的檢測結果，新西蘭初級產業部確認有關產品根本不存在食物安全風險，故撤銷之前針對該產品的預防措施。

食物安全中心(中心)採取的行動

中心得悉一款在本港有售的配方奶粉懷疑受肉毒桿菌污染後，隨即採取行動，包括發出食物警報及新聞公報，設立熱線電話，並與新西蘭當局和業界聯絡等。

為防萬一，中心還特地在市面上抽取了新西蘭製造供一歲以下嬰兒食用的乳製品樣本作肉毒桿菌檢測，檢測結果全部合格。

注意要點：

- 腸道性肉毒中毒的成因是嬰兒吃下肉毒桿菌孢子後，孢子在其腸道內萌發和生長，繼而釋出毒素。
- 使用不低於攝氏70度的熱水沖調嬰兒配方奶粉，可殺死部分病原體，但不能消滅肉毒桿菌毒素及孢子。
- 雖然在嬰兒配方奶粉中曾驗出肉毒桿菌，但沒有接到嬰兒因食用這些奶粉而致病的報告。

給市民的建議

- 依照衛生署編製的《奶瓶餵哺指引》沖調奶粉。雖然該指引的著眼點並非肉毒桿菌，但提供了正確沖調配方奶粉的方法。
- 使用不低於攝氏70度的熱水沖調嬰兒配方奶粉。這樣做即使不能消滅肉毒桿菌毒素及孢子，但至少可殺死某些與嬰兒配方奶粉有關的病原體。

給業界的建議

- 確保進口和出售的食物適宜供人食用。
- 向可靠的供應商購買食物及食材。
- 奶粉製造商應遵循食品法典委員會有關生產嬰幼兒配方奶粉的衛生指引和建議。

C. botulinum Risk in Powdered Formulae

Powdered formulae for infants and young children are not sterile products and may be contaminated with pathogens that can cause serious illness.

In general, using hot water no less than 70°C to make up powdered infant formula (PIF) can kill certain harmful bacteria like *Cronobacter sakazakii*. However, this practice can neither destroy toxin nor spores produced by *C. botulinum* since such toxin can only be destroyed by boiling for ten minutes or longer while inactivation of the spores requires much higher temperature.

Having said that, the Food and Agriculture Organization of the United Nations and the World Health Organization consider that the causality between the illness caused by *C. botulinum* and PIF consumption is less plausible or not yet demonstrated. Although *C. botulinum* has been identified in PIF, it has not been implicated as causing illness in infants.

The Evolvement of the Incident

According to MPI's investigation on the incident, the contamination of the concerned whey protein concentrate occurred when it was processed through a temporary connection pipe which had been contaminated.

Initially, the whey protein concentrate had produced test results suggesting the presence of spores of *C. botulinum*. However, subsequent validation conducted by MPI and the US Centers for Disease Control and Prevention confirmed that the bacterium was not *C. botulinum* but another *Clostridium* species which is not pathogenic. In view of the latest finding, MPI confirmed that there was never a food safety risk associated with the concerned products and the precautionary advisory of these products has been revoked.

Actions Taken by the Centre for Food Safety (CFS)

Upon receipt of the information that certain powdered formulae potentially contaminated with *C. botulinum* were available in Hong Kong, the CFS took prompt actions including issuing food alert and press release, setting up designated hotline, liaising with the New Zealand authority and the local trade etc.

As a precautionary measure, the CFS also took *ad hoc* dairy product samples for children aged under one-year-old manufactured in New Zealand to test for *C. botulinum*. Results were all satisfactory.

Key Points to Note:

- Intestinal botulism is caused by the ingestion of *C. botulinum* spores that germinate and grow in the intestine of infants and release toxin.
- Use hot water no less than 70°C to make up PIF to kill certain pathogens, but this cannot destroy *C. botulinum* toxin or spores.
- Although *C. botulinum* has been identified in PIF, it has not been implicated as causing illness in infants.

Advice to the Public

- Caretakers should follow the "Infant Feeding Guide to Bottle-feeding" published by the Department of Health when reconstituting PIF. Although the guide is not targeted to address *C. botulinum*, it provides general safety advice on preparing powdered formulae for infants.
- Use hot water no less than 70°C to make up PIF. Even it cannot destroy *C. botulinum* toxin or spores, it kills certain pathogens of concern.

Advice to the Trade

- Ensure foods imported and for sale are fit for human consumption.
- Obtain food and food ingredients from reliable sources.
- Manufacturers of powdered formulae should refer to relevant Codex guidance and recommendations on hygienic manufacture of powdered formulae for infants and young children.

基因改造食物的安全關卡

Gateway for Safe Genetically Modified Foods

食物安全中心
風險評估組
科學主任莊梓傑博士報告
Reported by Dr. Ken CHONG, Scientific Officer,
Risk Assessment Section,
Centre for Food Safety

我們在上一期提到基因改造食物通常已通過海外規管當局的安全評估，可安全食用。為確保只有通過安全評估的基因改造食物才能在本港出售，我們建議在本港推銷銷售前安全評估計劃。這期我們會談談基因改造食物的安全評估問題。

食物的安全評估

銷售前安全評估計劃的目的是在基因改造食物在本港上市前評估其安全性，但評估方法有別於特定化學物(例如食物中的除害劑)的做法。食物並非化學上確定的物質，而是複雜的混合物，其成分和營養價值各異。人們進食基因改造食物的分量也遠遠高於大部分食用化學物。因此，食物中的化學物所採用的傳統毒性試驗和風險評估程序並不適用於基因改造食物，取而代之的是採用比較原則構成有系統的基因改造食物安全評估。

比較原則

比較原則是要確定基因改造產品相對於其原來或未經基因改造的品種的安全程度，做法是通過比較兩者，確立基因改造食物是否有新的危害或危害有所變化。原有品種有悠久的食用歷史，普遍被認為是安全的。舉例來說，評估人員會把含高油酸的基因改造大豆與其未經基因改造的原種和商業栽培種比較，評估兩者在成分方面的不同。此外，如食用原來品種素有某些不良反應，評估人員會詳加分析引起不良反應的成分，並在比較時特別留意基因改造對這些成分帶來的改變。

與原來品種作比較

基因改造食物的新特性是原來品種所欠缺的，評估人員在比較兩者時會評估這些新特性的安全性。舉例來說，抵抗害蟲的能力是藉由表達Bt蛋白而擁有的，故在進行安全評估時會研究Bt蛋白的毒性。

除了評估新特性是否安全外，改造基因帶來的非預期效應亦在評估之列。基因改造通常涉及植入新的基因，新植入的基因可能會改變其他基因的表達，繼而影響經過改造生物的正常代謝和內源毒素或致敏原的水平。此外，改造基因亦可能產生對個別易受影響人士有毒性或致敏性的新蛋白質。為處理這些非預期效應，評估人員會把基因改造生物與其原來品種在毒性、致敏性、營養價值和成分等方面作出比較。

食品法典委員會就基因改造生物的安全評估方法制定了多套安全評估指引，各食物安全規管當局多據此為評估原則。一般而言，接受評估的是生物科技公司開發的基因改造生物，而非這些生物製造的食品。換句話說，接受評估的是基因改造粟米，而非用該基

In the last issue, we mentioned that genetically modified (GM) foods generally had undergone safety assessment by overseas' authorities and are safe. To ensure that only GM foods that have passed safety assessment are sold in Hong Kong, it has been proposed to introduce a pre-market safety assessment scheme (PMSAS) locally. We will talk about safety assessment in this issue.

Safety Assessment of Whole Foods

The PMSAS aims to assess GM foods before they can be sold in the local market. The assessment approach is different from that for specific chemicals such as pesticides in food. Whole foods are complex mixtures of compounds that vary in composition and nutritional value, but not chemically defined substances. Furthermore, the intake amount of GM foods by human is much higher than that of most chemicals for food use. As such, the traditional toxicological testing and risk assessment procedures for chemicals in food are not quite suitable for GM foods. Instead, a comparative approach has been developed to address or structure the safety assessment of GM foods.

Comparative Approach

The comparative approach is aimed to establish the relative safety of a GM product with its comparator, i.e. the conventional or non-modified counterpart, by determining if a GM product has new or altered hazards. The comparator is usually considered safe on the basis of its long history of consumption. For example, GM soya bean containing higher level of oleic acid is compared with its non-GM parental line and commercial cultivars for assessing differences in compositional constituents. In cases if a comparator is known to associate with certain adverse effects, the components causing the effects should be well characterised. The comparison will take into account the change of the components as a result of the genetic modification.

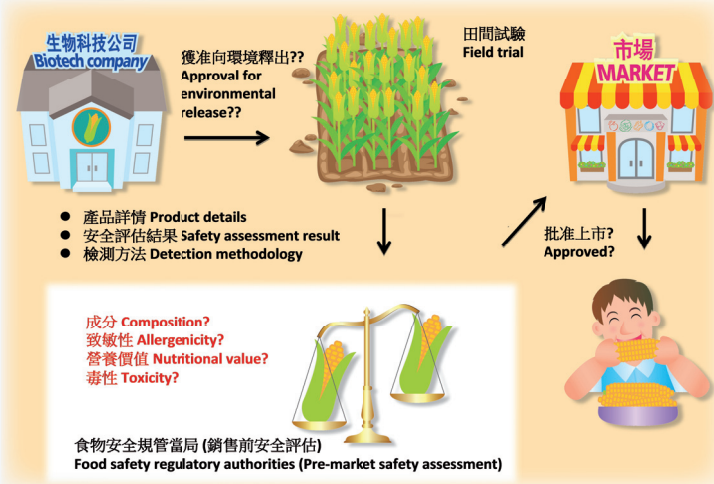
Comparison with Conventional Counterparts

The introduced desirable characteristics which are absent from the non-modified counterparts will be assessed under the comparative approach. For example, the insect resistance characteristic is conferred by the Bt proteins, and toxicological study of the Bt proteins will be included in the safety assessment.

Besides assessing the safety of the introduced desirable characteristics, the assessment will also address unintended effects as a result of the genetic modification. The modification in GM organism usually involves the insertion of a new gene and this might change the expression of other genes

in the modified organism, which in turn affects the normal metabolism and level of endogenous toxins or allergens in the GM organism. In addition, the modification has the potential to create additional new proteins that might be toxic or allergic to susceptible individuals. To address these unintended effects, the GM organism will be compared with its comparator, in terms of toxicity, allergenicity, nutritional value, composition, etc.

The approach for conducting safety assessment of GM organism has been included in different sets of guidance formulated by the Codex Alimentarius Commission. The principle of the assessment conducted by food safety regulatory authorities is usually in line with the guidance. In general, only the GM organism, but not its products, generated by a developer would be assessed, i.e. GM corn, instead of the corn chip made from GM corn, would



基因改造食物批准上市流程圖 Brief GM food approval process

因改造粟米生產的粟米片。

設立基因改造食物的安全關卡

基因改造食物發展蓬勃，湧現出各種為吸引農民、食物製造商和消費者而植入不同特性的基因改造食物，預料將來會有更多來自四方八面，林林總總的基因改造食物打進國際市場。我們建議採納世界衛生組織的建議，在香港推行強制性銷售前安全評估計劃，以加強對基因改造食物的食物安全管制。該計劃既可確立為防止未經評估的基因改造食物進入本地市場的法律基礎，亦可建立一個掌握轉基因資料及標準物質的機制，以便檢測基因改造食物開發商的基因改造產品。

be assessed.

Building a Gateway for Safe GM Foods

With active development of GM foods and availability of GM foods with introduced characteristics that may be attractive to farmers, food manufacturers or consumers, more varieties of GM foods from different places of origin are expected to enter the international market in the future. Echoing the recommendation of the World Health Organization and enhancing the local control of GM foods, it has been proposed to introduce the PMSAS locally. The PMSAS would provide the legal basis for preventing unauthorised GM products from entering the local market and establish a mechanism for obtaining transgenic information and reference materials for testing of GM products from GM food developers.

日本乾菇含微量輻射

食物安全中心(中心)上月驗出一個乾菇樣本含微量輻射，但水平遠低於食品法典委員會的指引限值，消息受到本地傳媒報道。

Low Level of Radioactivity in Japanese Dried Mushroom

Last month, the Centre for Food Safety (CFS) found a dried mushroom sample to have low levels of radioactive substances. The result was reported in the local media. The levels were well below the guideline levels established by the Codex Alimentarius Commission (Codex).

食物事故點滴 Food Incident Highlight

中心進行的風險評估結果顯示，以該乾菇的輻射量，即使是攝取量偏高人士，進食一年後所受到的輻射量也只相等於乘坐飛機來回香港和美國西岸旅程中所攝取輻射劑量的6%。因此，進食有關乾菇影響健康的可能性很低。

Risk assessment conducted by the CFS showed that the exposure to radioactive substances from consuming the dried mushroom with the same level of radioactive substances for one year even for high consumers was only about 6% of the radiation dose received from a return trip from Hong Kong to the West Coast of the United States. Hence, consuming the dried mushroom concerned is unlikely to pose adverse effects to human health.

對於本港食物中的輻射水平，中心設有嚴謹的監察計劃。二零一一年日本發生核事故後，中心已在進口和零售層面加強監察來自日本的食物。政府亦頒布了命令，禁止進口和供應來自日本五個縣的多種食物。從這五個縣出口到香港的其他食品種類必須附有證明書，證明其輻射水平低於食品法典委員會的指引限值。中心會繼續密切留意事態發展。

In Hong Kong, the CFS has a surveillance programme to monitor radioactivity in food. After the nuclear incident in Japan in 2011, the CFS has stepped up surveillance at both the import and retail levels for food imported from Japan. A prohibition order has been issued to ban import of a variety of produce from the five concerned prefectures into Hong Kong. Specific food categories are allowed to be imported from these areas only when accompanied by certificate indicating radiation is below Codex guideline level. The CFS would continue to closely monitor the situation.

美國爆發圓孢子蟲病

美國自六月底爆發圓孢子蟲病以來，已有逾600人受到感染。美國食物及藥物管理局的調查發現，預先包裝的什錦沙律或為此次疫情的“元兇”。

Outbreak of Cyclosporiasis in the United States

Since late June, there have been reports of outbreaks of cyclosporiasis in the United States (US) affecting more than 600 people. Investigations by the US Food and Drug Administration showed that prepackaged salad mix may be a possible vehicle for the infection.

圓孢子蟲病是一種由寄生蟲圓孢子蟲菌引致的腸胃病。食用了受圓孢子蟲菌污染的食物或食水有可能患病。潛伏期平均約為一星期，常見的病徵包括水狀腹瀉、胃痛、腹脹、噁心、食慾不振、體重下降及疲倦。圓孢子蟲病是很多熱帶和亞熱帶地區(包括非洲、南美洲和中美洲、亞洲和中東)的風土病，前往這些地區的外遊人士感染這種病的風險較高。

Cyclosporiasis is an intestinal illness caused by the parasite *Cyclospora cayetanensis*. People can become infected with *Cyclospora* by consuming food or water contaminated with the parasite. The average incubation period of cyclosporiasis is about one week and common symptoms include watery diarrhoea, abdominal cramps, bloating, nausea, loss of appetite, weight loss and fatigue. Cyclosporiasis is endemic in many tropical and subtropical regions, including Africa, South and Central Americas, Asia, and the Middle East. Individual travelling in these areas may be at increased risk for infection.

全球多個地區的圓孢子蟲病爆發均與新鮮農產品有關。外遊人士應加倍注意，並採取預防措施，避免染上經食物或食水傳播的疾病，例如進食新鮮食品前先徹底清洗。返港人士如有染上圓孢子蟲病的病徵，應即時求醫。

Fresh produce has been associated with a number of cyclosporiasis outbreaks worldwide. Travellers should remain vigilant and take precautionary measures, for example, ensuring fresh produce is thoroughly washed before consumption, to prevent food-borne or water-borne illnesses when abroad. Returning travellers with symptoms of cyclosporiasis should seek immediate medical attention.

風險傳達 工作一覽 Summary of Risk Communication Work

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