National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

WAGENINGEN UNIVERSITY & RESEARCH

FRONT OFFICE FOOD AND PRODUCT SAFETY

Estimate of the maximum tolerable level of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans and dioxin-like polychlorinated biphenyls in brown meat of the Chinese mitten crab
Revised version dated 21 December 2018

Risk assessment requested by:	BuRO
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Subject
In September 2017, the review committee of the Dutch Ministry of Health, Welfare and Sport recommended the Minister of this ministry to set maximum levels for dioxins and dioxin-like PCBs in brown meat of the Chinese mitten crab. Subsequently, the Ministry of Health, Welfare and Sport has asked the Office for Risk Assessment & Research (*Bureau Risicobeoordeling & Onderzoek* / BuRO) to estimate the public health risks of consuming brown meat of this crab by the Dutch consumer.

The maximum levels for these compounds in white meat of crab (including mitten crab) are 3.5 pg TEQ (= Toxic EQuivalent) per gram wet weight for the sum of dioxins and furans, 6.5 pg TEQ per gram wet weight for the sum of dioxins and furans and also dioxin-like PCBs, and 75 ng per gram wet weight for six non-dioxin-like PCBs (ICES-6[2]) according to Commission Regulation (EC) No 1881/2006. No maximum levels are specified for brown meat in this regulation.

Question
BuRO asks Front Office (FO) to derive the maximum tolerable level for dioxin in brown meat of the Chinese mitten crab before harmful health effects occur in adults and children who consume this crab, considering the following elements:
- Background exposure to dioxins for consumers of the mitten crab.
- Mitten crab weight of 100 - 150 grams (the mitten crab attains its highest weight in autumn) (Zaalmink & Rijk 2018; final report not yet available).
- 20% of the wet weight of the mitten crab consists of edible parts (see van Leeuwen et al., 2013). Take account of the ratio of brown to white meat in the mitten crab.

[1] This FO assessment includes the final version of the FO assessment of 6 September 2018 with a number of modifications for clarification.

[2] ICES-6; six indicator PCBs (PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180), as indicated by the International Council for the Exploration of the Sea.

- The majority (79%) of the mitten crab consumers interviewed consume all parts of the crab, i.e. both white and brown meat.
- During the mitten crab season (September to December), the median frequency of mitten crab consumption of the mitten crab consumers interviewed is "roughly once a fortnight" and the 95th percentile is "2-3 times a week".
- A small percentage (18%) of the mitten crab consumers interviewed consume the crab also outside the mitten crab season.
- The reported median number of mitten crabs consumed is "4-5 crabs per person per meal" and the 95th percentile is "8 or more crabs per person per meal". In a realistic worst case approach, the consumption of 10 crabs per person per meal may be assumed (see van Leeuwen et al., 2013).
- The following scenarios (for children and adults) in the mitten crab season:
  - Median consumption frequency & median consumption amount (= number per meal x mitten crab weight);
  - P95 consumption frequency & P95 consumption amount;
  - Median consumption frequency & P95 consumption amount;
  - P95 consumption frequency & median consumption amount.
- Potentially sensitive groups in the population that consume Chinese mitten crab.
- Can the calculations also be performed considering the reported differences in TEQ concentration in brown and white meat? (additional question from BuRO to FO in an e-mail of 29/08/2018)
- Can the calculations also be performed assuming that exposure to TEQ will average out over the year? (additional question from BuRO to FO in an e-mail of 29/08/2018)

Additional questions dated 11 October 2018
The above questions were answered in the FO assessment of 6 September 2018. Based on the tolerable weekly intake (TWI) applicable at that time (14 pg TEQ/kg body weight (bw) per week; SCF 2001), only a very limited consumption of mitten crab meat would be safe, and then only for consumers with a low background dioxin exposure (TEQ). Based on an annual average exposure to dioxins, consumers with a high background exposure may consume 20 to 30 mitten crabs per year containing the lowest measured levels of TEQ, 28 pg TEQ/g, in brown meat of mitten crabs caught at various locations in the Netherlands in 2016 and 2017. This lowest concentration was measured in crabs caught at the location Den Oever; the only location amongst the seven surveyed where mitten crab may be caught commercially.

The FO assessment of 6 September 2018 already indicated that the European Food Safety Authority (EFSA) is reviewing the TWI for dioxin (TEQ). Since then, EFSA has published an opinion on dioxin with a new TWI (EFSA, 2018).

In this supplement to the assessment of 6 September 2018, BuRO requests a revised calculation of the maximum tolerable level for dioxin in mitten crab based on this new TWI.

Conclusion 6 September 2018
Based on the current tolerable weekly exposure (TWI) of 14 pg TEQ/kg bw per week, there is almost no scope for a maximum tolerable level for the sum of polychlorinated dibenzo-p-dioxins + polychlorinated dibenzofurans + dioxin-like PCBs (expressed in TEQ) in brown meat of Chinese mitten crabs in any of the scenarios. Only when the consumption parameters and background exposure correspond to the 50th percentile (median) level, some scope for the presence of these substances in brown meat exists. However, maximum levels based on these median levels will provide insufficient protection for consumers who eat meat of mitten crabs at higher levels, such as 10 mitten crabs per meal at a frequency of 2 to 4 times a week. Assuming a fixed ratio of TEQ levels in brown to white meat of mitten crab and considering the seasonal nature of mitten crab consumption (only in September-November), a maximum tolerable level for brown meat of 1.5 pg TEQ/g (rounded) was calculated. This level also provides protection for children.

Based on the lowest measured TEQ level in brown meat of mitten crabs caught in Dutch waters, children can consume 20 and adults 35 mitten crabs per year. This lowest concentration, 28 pg TEQ/g brown meat, was the average concentration of all crabs caught at the location Den Oever; the only location amongst the seven, most recently surveyed locations in the Netherlands where mitten crab may be caught commercially.

The European Food Safety Authority (EFSA) recently established a new toxicological reference value for TEQ. The opinion concerned was not yet published on 6 September 2018. Given the current background exposure, there will only be scope for the presence of TEQ in mitten crabs if the new toxicological reference value is higher than 7 pg TEQ/kg bw per week (or a corresponding value).

This assessment considers consumers that are at high risk of elevated exposure to TEQ from Chinese mitten crabs due to their consumption behaviour, more specifically people (including children) of Chinese descent.

Conclusion based on the additional questions of BuRO on 11 October 2018
EFSA established a TWI for TEQ of 2 pg TEQ/kg bw per week in 2018. The median and 95th percentile of the background exposure (excluding consumption of mitten crab) are 3.5 and 7 pg TEQ/kg bw per week, respectively, for 7- to 69-year olds living in the Netherlands. As the background exposure already exceeds the TWI, there is no scope for additional exposure to TEQ through the consumption of mitten crab meat. Consumption of this crab should therefore be avoided.

Introduction
In 2011, the Front Office (FO) performed a risk assessment for dioxins and dioxin-like PCBs (dl-PCBs) in Chinese mitten crabs, using concentration data of mitten crabs caught at various locations in the Netherlands in 2010 (RIVM-RIKILT, 2011). The concentrations in these crabs varied from 10 to 96 pg TEQ/g crab meat based on the then applicable toxic equivalency factors (TEFs) of 1998 (or from 8 to 70 pg TEQ/g crab meat based on the TEFs of 2005[3]) (Kotterman and van der Lee, 2011). These concentrations were higher than the then valid maximum level of 8 pg TEQ/g in meat from the claws and legs of crabs (appendages, usually referred to as "white meat") as set in Commission Regulation (EU) No 1881/2006.[4] The reported concentrations were determined in meat from the body, and not in that from legs and claws. Commission Regulation (EU) No 1881/2006 has no maximum level for meat from the body, based on the assumption that this meat is not commonly eaten. However, provisional data that were available for the 2011 FO assessment showed that this meat is also consumed. Based on a median background exposure (6.3 pg TEQ/kg bw per week), 28 to 248 grams of crab meat could be safely consumed per month depending on the TEQ level in crab meat (RIVM-RIKILT, 2011). In the event of a high background exposure (13.3 pg TEQ/kg bw per week), the amount of crab meat that could be safely consumed dropped to 3 to 23 grams per month.

In 2012, the 2011 FO assessment was updated (RIVM-RIKILT, 2012). This update was based on new TEQ concentrations in Chinese mitten crabs (averages per sample location ranged from 6.5 to 56 pg TEQ/g total crab meat; calculated using the TEFs of 2005) and consumption data for these crabs (van der Lee et al., 2012; Kotterman et al., 2012; Bakker and Zaalmink, 2012). The key finding of this 2012 assessment was that consumers with a high background exposure could exceed the provisional tolerable monthly intake of TEQ (PTMI; JECFA, 2002) when consuming a single portion of 50 grams of crab meat (with an average or maximum TEQ level). This single portion did not result in an exposure exceeding the tolerable weekly intake of TEQ (TWI; SCF, 2001) based on of a median background exposure. Higher background exposure or higher TEQ levels in crab meat resulted in exposures exceeding the TWI. Whether exposures higher than the TWI will result in health effects is not known; however, they cannot be excluded.

Since then, a new study on (background) exposure to dioxins for the Dutch population has been published (Boon et al., 2014) and BuRO has commissioned a study on the consumption of Chinese mitten crabs by the ethnic Chinese population in the Netherlands (research carried out by Motivaction, summary made available by BuRO; Motivaction, 2018).

The FO interprets the term "dioxin" in the question put by BuRO as the sum of polychlorinated dibenzo-p-dioxins (PCDDs) + polychlorinated dibenzofurans (PCDFs) + dioxin-like polychlorinated biphenyls (dl-PCB); abbreviated to "TEQ" in this assessment. This is in line with the FO assessments of 2011 and 2012. In view of the large number of scenarios to be included in the assessment, only the TWI of 14 pg TEQ/kg body weight (bw) per week (SCF, 2001) was used as a reference value. In the two earlier assessments, also the PTMI of JECFA (2002) was used.

Background dietary exposure TEQ
In 2014, the dietary exposure to TEQ was calculated for young children (aged 2-6 years) and children and adults (aged 7-69 years) (Boon et al., 2014). For this, consumption data from two Dutch National Food Consumption Surveys (Ocké et al., 2008; van Rossum et al., 2011) were combined with monitoring data on TEQ levels in a range of products available on the Dutch market. The calculated exposures related to the general Dutch population and were the most recent data available. See Table 1 for an overview of the calculated intakes.

[3] In 2011, Commission Regulation (EU) No 1881/2006 still used the TEF values of 1998 (van den Berg et al., 1998). The Regulation did not incorporate the new TEF values of 2005 (van den Berg et al., 2006) until 2012. The FO assessment of 2011 used both sets of TEF values in the risk assessment.
[4] In 2012, the legal maximum level was reduced to 3.5 pg TEQ/g for the sum of polychlorinated dibenzo-p-dioxins (PCDDs) + polychlorinated dibenzofurans (PCDFs) and to 6.5 pg TEQ/g for the sum of PCDDs, PCDFs + dioxin-like polychlorinated biphenyls (dl-PCB).

Table 1. Daily dietary intake of dioxins and dioxin-like PCBs in the Netherlands (Boon et al., 2014)

Age	Intake (pg TEQ/kg bw per day)[1]	
	P50[2]	P95[3]
2	1.0 (1.0-1.1)	1.6 (1.5-1.8)
3	1.0 (0.9-1.0)	1.5 (1.4-1.6)
4	0.9 (0.8-1.0)	1.4 (1.3-1.5)
5	0.9 (0.8-0.9)	1.3 (1.2-1.4)
6	0.8 (0.7-0.9)	1.2 (1.1-1.3)
7-69	0.5 (0.4-0.5)	1.0 (0.9-1.1)

bw: body weight; kg: kilogram; PCB: polychlorinated biphenyl; pg: picogram; TEQ: toxic equivalent
[1] Boon et al. (2014) also calculated the P90 and P99 intake
[2] = median or 50th percentile
[3] = 95th percentile

The intake of TEQ reported in Table 1 does not include the exposure through the consumption of Chinese mitten crab, since consumption of this crab was not reported in both food consumption surveys (Boon et al., 2014). The reported intakes should therefore be viewed as the best estimate currently available of the 'background exposure' to TEQ in the Netherlands. These new estimates for the background exposure were approximately a factor of 2 lower than those used in the earlier two FO assessments (RIVM-RIKILT, 2011; 2012). The extent to which this background exposure is relevant for the Chinese population in the Netherlands consuming mitten crabs is discussed at the end of this assessment.

Data on the consumption of Chinese mitten crabs
BuRO commissioned Motivaction to conduct a consumption survey on the consumption of Chinese mitten crab among people of Chinese descent living in the Netherlands (Motivaction, 2018). This population was identified as the largest Asian group consuming this crab in this country. Respondents were asked about the frequency and amount of Chinese mitten crab consumption.

A total of 990 persons of Chinese descent participated in the survey, of which 708 (72%) indicated that they consume Chinese mitten crab. The median (P50) and 95th percentile (P95) consumption frequencies and amounts (= number of crabs per meal) are listed in Table 2. These consumption parameters were based on persons aged 18 years and older. The survey also showed that children eat mitten crab as frequently as adults, and in the same amounts or less. The majority (79%) of respondents who consume mitten crab indicated that they consume all its edible parts.

Table 2. Results of the Chinese mitten crab consumption survey among persons of Chinese descent living in the Netherlands and aged 18 years and older
The values used in the calculations are shown in parentheses

Consumption parameter	P50[1]	P95[2]
Frequency	Once a fortnight (0.5 per week)	2-3 (2.5) times per week
Amount	4-5 (4.5) crabs per meal	≥ 8 (10) crabs per meal

[1] = median or 50th percentile
[2] = 95th percentile

The P50 and P95 values in Table 2 were used to establish the maximum tolerable level for TEQ in brown meat. As these values were not discrete, the indicated values between parentheses were used in the calculations. For the purpose of indicating "amount", the P95 number of crabs per meal of "8 or more" was arbitrarily set at 10 animals per meal.

Establishment of maximum tolerable level for TEQ in brown meat of the Chinese mitten crab
The maximum tolerable level for TEQ in brown meat of the mitten crab is the level at which the TWI is not exceeded, taking account of the background exposure. Based on the number of sub-questions asked by BuRO, three options could be distinguished:

Option 1) Calculations 1) using a TEQ concentration at the current legal maximum level of 6.5 pg TEQ/g for white meat, 2) considering that the resulting exposure should not exceed the TWI of 14 pg TEQ/kg bw per week, and 3) assuming that consumption (median and high) of Chinese mitten crab only occurs during the mitten crab season (September-November).

Option 2) As option 1, with the exception that the calculations considered a fixed ratio of the TEQ level in brown to white meat with substantially lower TEQ levels in white meat. According to Hoogenboom et al. (2015), the ratio varies between 15 and 120, with a median value of 49.

Option 3) As option 2, but considering that the total exposure over the year should not exceed 52 x TWI. This option reflects the situation that mitten crab is mainly eaten during the mitten crab season and not outside this period. Given the long half-lives in the body of the compounds covered by the term TEQ, a summation of the exposure over the entire year is not in itself incorrect for a risk assessment for TEQ. Due to time restrictions, a simple linear summation over time was applied. Ideally, a body-burden calculation using kinetic modelling should be performed. However, the FO does not expect that the results obtained with kinetic modelling would have differed substantially from the results of linear averaging.

The calculations assumed a high level of consumption (95^{th} percentile for both frequency and amount) during the mitten crab season (12 weeks). Motivaction (2018) reported that 79% of the mitten crab consumers consume the crab outside this season (40 weeks), but no data on the frequency or amount of consumption were provided. Therefore, FO assumed an arbitrary out of season frequency of once a month and that the number of crabs consumed per meal is not essentially different from the consumption during the mitten crab season. The scenarios were also calculated assuming that no mitten crabs are consumed out of season.

Children consume mitten crab in the same frequency and amounts as their parents (Motivaction, 2018). However, no information on the ages of children that consume mitten crab was provided. As considerable amounts of crabs may be involved, FO assumed that children consuming mitten crabs were 10 years of age. Additionally, it was assumed that their background exposure was identical to that of persons aged 7-69 years (in this assessment referred to as "adults"; Table 1).

Given the number of variables, 48 separate scenarios could be distinguished for option 1, arising from different combinations of the input variables:

- two for age (children aged 10 years and adults);
- two for background exposure (P50 and P95);
- two for consumption frequency (0.5 or 2.5 times a week; Table 2);
- two for number of crabs eaten (4.5 or 10 per meal; Table 2);
- three for crab weight (100, 125 or 150 grams).

Due to three different ratios of TEQ levels in brown to white meat for option 2, the number of scenarios would increase further by a factor of 3. Therefore, only the most favourable and most conservative scenario (i.e. those that produced the highest or lowest maximum tolerable TEQ levels) per age of option 1 were assessed for option 2, using a crab weight of 150 grams.

To estimate the maximum tolerable level according to the three options, also information is needed on the mass of brown and white meat in a Chinese mitten crab. These masses were estimated using data from a study of van der Lee et al. (2012). This study reported on the mass of white meat from the legs and of a mixture of white and brown meat from the body of 25 individual Chinese mitten crabs. As the meat from the body could not be specified further based on the available data, FO assumed that all body meat was brown meat. Van der Lee et al. (2012) indicated that a crab with a wet weight of 100-150 grams (shell + meat) consists on average for 21.7% of meat. Additionally, a crab has on average 2.8 times more meat in the body than in the legs. In other words: of the total meat mass, approximately 26.4% is

white meat and approximately 73.6% brown meat (body). These data were used in all three options.

To finally express the exposure to TEQ per kg bw, the body weights used for both children aged 10 and adults were 37.6 and 65 kg, respectively. These weights were based on the body weights measured amongst/reported by the respondents of the two food consumption surveys (Ocké et al., 2008; van Rossum et al., 2011).

Annex 1 describes the formulas that were used to calculate the maximum tolerable levels for TEQ in brown meat per option.

Results of the calculations

Results of option 1:
Annex 2 lists the results of the 48 scenarios. In all these scenarios, it was assumed that white meat had a TEQ level of 6.5 TEQ/g.

The highest calculated maximum tolerable level for TEQ in brown meat was 16.7 pg TEQ/g (scenario 25; see Annex 2). This level resulted in an exposure equal to the TWI for adults with a background exposure, consumption frequency and number of crabs per meal at the median value (0.5 pg TEQ/kg bw per day, 0.5 times a week (= once every fortnight), and 4.5 crabs per meal, respectively), and assuming an average crab weight of 100 grams. For a child, the corresponding calculated maximum tolerable level was 8.7 pg TEQ/g (scenario 1).

The lowest calculated maximum tolerable level for TEQ in brown meat was -1.9 pg TEQ/g (scenario 24). This level resulted in an exposure equal to the TWI for children with a background exposure, consumption frequency and number of crabs per meal at the 95th percentile (1 pg TEQ/kg bw per day, 2.5 times a week (= 2-3 times a week), 10 crabs per meal, respectively), and assuming an average crab weight of 150 grams. This maximum tolerable level was negative, because the background exposure together with the exposure to TEQ due to its presence in white meat already exceeded the TWI; no scope was available for the presence of TEQ in brown meat. The corresponding lowest maximum tolerable level for adults was -1.6 pg TEQ/g (scenario 48).

For children, the calculated maximum tolerable level for brown meat exceeded or equalled the current legal maximum level for white meat, if the background exposure, the consumption frequency and the number of crabs per meal were at the median value and it was assumed that a crab weighed 100 or 125 grams (scenarios 1 and 9). In adults, this was true if the background exposure corresponded to the median or 95th percentile value, the consumption frequency and number of crabs per meal corresponded to the median value and the crab weighed 100 or 125 grams (scenarios 25, 26, 33 and 34). When a crab of 150 grams was consumed, the maximum tolerable level for brown meat exceeded 6.5 pg TEQ/g only for adults with a background exposure, consumption frequency and number of crabs per meal at the median value (scenario 41).

Results of option 2:
Table 3 lists the maximum tolerable levels for brown meat ([Mbrown]) for both ages in the most favourable and in the most conservative scenarios of option 1 (scenarios 1 and 24 for children and scenarios 25 and 48 for adults, respectively; see Annex 2). Table 3 also lists the corresponding maximum level for white meat ([Mwhite]) based on ratios of TEQ levels of brown to white meat of 15 (lower limit), 49 (median limit) and 120 (upper limit) (Hoogenboom et al., 2015). The calculations showed that the maximum tolerable levels for brown meat were not influenced by the ratio (Table 3); the proportion of white meat in total crab meat was overall rather low (approximately 20%).

The lowest, most conservative, maximum tolerable level for TEQ in brown meat was calculated using a concentration ratio of 15 (Table 3). This ratio allowed a TEQ level in white meat that equalled roughly 7% of that for brown meat. If the actual ratio is higher, the maximum tolerable level for brown meat based on this low ratio remains safe. In that case, white meat will contribute less to the exposure than assumed in the calculations. On the other

Table 3: Maximum tolerable levels for TEQ in brown ([Mbrown]) and white meat ([Mwhite]) of mitten crabs as calculated for option 2.
The calculations assumed a fixed ratio of TEQ levels in brown to white meat and did not consider averaging out of the exposure to TEQ over the year

Scenario	Age group	Body weight (kg)	BG	CF	No.	Crab weight (g)	[Mbrown] (pg TEQ/g)	[Mwhite] (pg TEQ/g)
Assuming ratio [Mbrown]/[Mwhite] = 15 (lower limit of range)								
1	Children	37.6	P50	P50	P50	100	10.7	0.48
24	Children	37.6	P95	P95	P95	150	0.43	0.03
25	Adults	65	P50	P50	P50	100	18.6	0.82
48	Adults	65	P95	P95	P95	150	0.74	0.05
Assuming ratio [Mbrown]/[Mwhite] = 49 (median value)								
1	Children	37.6	P50	P50	P50	100	10.9	0.15
24	Children	37.6	P95	P95	P95	150	0.44	0.01
25	Adults	65	P50	P50	P50	100	18.9	0.25
48	Adults	65	P95	P95	P95	150	0.75	0.02
Assuming ratio [Mbrown]/[Mwhite] = 120 (upper limit of range)								
1	Children	37.6	P50	P50	P50	100	11.0	0.06
24	Children	37.6	P95	P95	P95	150	0.44	0.00
25	Adults	65	P50	P50	P50	100	18.9	0.10
48	Adults	65	P95	P95	P95	150	0.76	0.01

BG: background exposure (P50 = 0.5 pg TEQ/kg bw per day and P95 = 1 pg TEQ/kg bw per day; these were multiplied by 7 for the calculations); CF: consumption frequency (P50 = once a fortnight; P95 = 2-3 times per week); No.: number of crabs per meal (P50 = 4.5; P95 = 10); [Mbrown] and [Mwhite] = maximum tolerable levels of TEQ in brown and white meat, respectively; pg: picogram; TEQ: toxic equivalent

hand, if a maximum tolerable level for brown meat is set using a ratio of 120 while the actual ratio is lower, this TEQ level will result in an exposure above the TWI. In that situation, white meat accounts for a greater proportion of the total TEQ exposure. However, the TWI would then only be exceeded by 1%, which is insignificant from a toxicological viewpoint and negligible considering all uncertainties.

If the maximum tolerable level for brown meat was based on the results in Table 3, the safety of white meat (from legs and claws) would be guaranteed and the TEQ concentration in white meat would always be below 6.5 pg TEQ/g.

Results of option 3:
The calculations for option 3 were based on a maximum tolerable exposure over an entire year (52 x TWI) and performed for consumers with a high frequency of consumption of mitten crabs (P95) during the mitten crab season (12 weeks) and either no consumption or a consumption of once per month outside this season as well as having a high background exposure. The resulting maximum tolerable levels of TEQ for brown meat are listed in Table 4, including the corresponding maximum tolerable levels for white meat based on three fixed ratios of TEQ levels in brown to white meat (formula (2.d), Annex 1). For an out of season consumption of once a month, the maximum tolerable level for brown meat was approximately 1.4 pg TEQ/g for children (aged 10 years) and approximately 2.4 pg TEQ/g for adults. Assuming no out of season consumption, the maximum tolerable levels for brown meat increased to approximately 1.9 and 3.3 pg TEQ/g, respectively. These levels were independent of the ratio of TEQ levels in brown to white meat. The calculations were performed for a crab weight of 125 grams. Furthermore, it was assumed that the annual exposure could be calculated in a linear fashion and that the TEQ levels in brown and white were at the in season level throughout the entire year.

It is possible to calculate how many crabs a consumer can consume per year before the exposure exceeds the maximum tolerable annual exposure. In Brust et al. (2018), TEQ levels are reported for mitten crabs that were caught in Dutch waters at various locations in 2016 and 2017. The range of TEQ levels (averages per catch location) varied from 28.4 to 82.1 pg TEQ/g brown meat. Based on the lowest TEQ level of 28.4 pg TEQ/g brown meat and a crab weight of 150 grams, children and adults can consume about 20 and 35 crabs per year,

Table 4. Maximum tolerable levels for TEQ in brown ([Mbrown]) and white meat ([Mwhite]) of mitten crabs as calculated for option 3.
The calculation assumed a fixed ratio of TEQ levels in brown to white meat and that the exposure to TEQ will average out over the year

Age group	Body weight (kg)	[Mbrown] (pg TEQ/g)	[Mwhite] (pg TEQ/g)
Out of season consumption: once a month			
Assuming ratio [Mbrown]/[Mwhite] = 15 (lower limit)			
Children	37.6	1.39	0.14
Adults	65	2.41	0.16
Assuming ratio [Mbrown]/[Mwhite] = 49 (median value)			
Children	37.6	1.42	0.03
Adults	65	2.45	0.05
Assuming ratio [Mbrown]/[Mwhite] = 120 (upper limit)			
Children	37.6	1.42	0.01
Adults	65	2.46	0.02
Out of season consumption: no out of season consumption			
Assuming ratio [Mbrown]/[Mwhite] = 15 (lower limit)			
Children	37.6	1.86	0.12
Adults	65	3.22	0.21
Assuming ratio [Mbrown]/[Mwhite] = 49 (median value)			
Children	37.6	1.89	0.04
Adults	65	3.27	0.07
Assuming ratio [brown]/[white] = 120 (upper limit)			
Children	37.6	1.90	0.02
Adults	65	3.28	0.03

[Mbrown] and [Mwhite] = maximum tolerable levels for TEQ in brown and white meat, respectively; pg: picogram; TEQ: toxic equivalent

respectively. The ratio of TEQ levels in brown to white meat had hardly an effect on the number of crabs that can be safely consumed per year. These numbers of crabs are considerably lower than those consumed according to the scenarios listed in Table 4: 390 per person per year with an out of season consumption of once a month and 300 per person per year with no consumption of mitten crabs outside the mitten crab season.

Conclusion
There is hardly any scope for a maximum tolerable level for the sum of polychlorinated dibenzo-p-dioxins + polychlorinated dibenzofurans + dioxin-like PCBs (total TEQ) in brown meat of mitten crabs for all scenarios. There is only some scope for the presence of TEQ in brown meat of Chinese mitten crabs in the most favourable scenarios where consumption parameters and background exposure are all at the median level (P50). In these scenarios, elaborated for option 1, the highest maximum tolerable level of TEQ for brown meat was 8.7 pg TEQ/g, which also provides protection for children. Note that these levels will provide insufficient protection for consumers that eat mitten crab meat at higher levels. In those scenarios, the consumption of white meat already resulted in an exposure to TEQ that almost equalled or exceeded the TWI of 14 pg TEQ/kg bw per week.

Only the most favourable and most conservative scenarios of option 1 were addressed in option 2, assuming a fixed ratio of TEQ levels in brown to white meat. Only the most favourable scenarios resulted in maximum tolerable levels for TEQ in brown meat that were higher than the current legal maximum level for TEQ in white meat: approximately 11 pg TEQ/g for children and approximately 19 pg TEQ/g for adults. For the conservative scenarios, the corresponding maximum tolerable levels were approximately 0.44 and 0.75 pg TEQ/g, respectively.

The calculations for option 3 were based on a maximum tolerable exposure over an entire year. Consequently, slightly higher maximum tolerable levels were calculated for the (conservative) scenarios compared to option 2 (3.3 to 4.3 times higher). However, the

calculated maximum tolerable levels for TEQ in brown meat were again below the legal maximum level for TEQ in white crab meat.

The average TEQ levels in crabs caught in Dutch waters in 2016 and 2017 (Burst et al., 2018) were higher than the calculated maximum tolerable levels for TEQ in brown meat for option 3 (Table 4), based on the assumed eating habits (2.5 crab meals per week during the mitten crab season; 1 meal per month outside the mitten crab season; 10 crabs per meal) and (high) background exposure. These crabs were therefore not suitable for human consumption. This conclusion corresponds with observations of Kotterman et al. (2012), who described that of the 107 crabs examined only approximately 9% had a TEQ level in brown (= body) meat below the then applicable legal maximum level for white meat of 8 pg TEQ/g. This percentage increased to 15%, when the TEQ levels of total meat (i.e. body plus legs and claws) were compared with this maximum level. For the 78 crabs with possible commercial value (e.g. because they are large enough to be sold), the percentage with a TEQ level in total meat below the maximum level of 8 pg TEQ/g meat was only about 8%.

The data on the individual crabs published by Kotterman et al. (2012) allow comparing the brown meat TEQ levels in 107 individual crabs measured at that time with the maximum tolerable levels calculated in this FO assessment. For option 3, this comparison showed that only one of these crabs had a TEQ level in brown meat (3 pg TEQ/g) that was below the maximum tolerable levels listed in Table 4, namely for adults that do not consume crabs out of season.

Discussion

- Background exposure was based on food consumption surveys that chiefly describe the consumption pattern of the Dutch-speaking part of the population. It is highly likely that the number of Chinese persons in the surveyed population is very limited, although ethnicity is not monitored. As a result, it is unclear how accurately the background exposure used for the different options reflects the background exposure of persons of Chinese descent living in the Netherlands. If Chinese people consume systemically more fish than the target population of the food consumption surveys, their background exposure is very likely underestimated, given the relatively high levels of TEQ in fish.
- The calculations assumed that the consumption data of Chinese mitten crabs for adults apply also to children aged 10 years. Studies by van Leeuwen et al. (2013) and Motivaction (2018) reported that many younger children eat mitten crab meat, but no data on the amounts consumed were reported.[5]
- The calculations of the maximum tolerable levels for TEQ in brown meat were based on the body weights of the age groups from the two food consumption surveys (Ocké et al., 2008; van Rossum et al., 2011). These body weights may not necessarily reflect the body weights of persons of Chinese descent living in the Netherlands. If they have a lower body weight than the target population of the food consumption surveys, the maximum tolerable levels for TEQ in brown meat will be too high. Data of the United States indicate that adult white Americans (men and women) are roughly 1.3 times heavier than Asiatic Americans (Fryar et al., 2016).
- The calculations assumed that all meat (white and brown) of the mitten crab is consumed. The study of Motivaction (2018) reported this for 79% of the consumers of mitten crab.
- EFSA is currently reviewing the toxicological reference value for exposure to TEQ. If the TWI is set at a level below 7 pg TEQ/kg bw per week and the background exposure equals 1 pg TEQ/kg bw per day (95th percentile), no safe maximum tolerable level for TEQ can be set for the consumption of mitten crab. In that case, the background exposure will either equal or exceed the TWI.
- Because all the meat (i.e. the entire mitten crab) is consumed by a large proportion of mitten crab consumers (79%), consideration should be given to derive a maximum tolerable level of TEQ for "mitten crab meat". In the case of children with a mitten crab consumption at the highest level (i.e. 2.5 meals per week and 10 mitten crabs per meal), with a high background exposure at 1 pg TEQ/kg bw per day and consuming crabs

[5] Quote from van Leeuwen et al. 2013, page 15": "In principle, mitten crab is eaten at all ages. For example, all family members share the meat during a family meal. Small children sometimes have difficulty extracting the edible parts from the crab. They may be handed the meat on a spoon by their mother." And Motivaction (2018) page 2: "The consumption survey shows further that children and adults eat mitten crab with the same frequency, with children eating similar or smaller portions compared to adults".

weighing 150 grams (= scenario 24, Annex 2), crab meat could contain 0.32 pg TEQ/g (= (14-7) × 37.6/(2.5 x 10 × 150 x 0.217; formula 1.1 (Annex 1)). For option 3, the maximum tolerable level for TEQ in crab meat for children with an out of season consumption frequency of once a month, would be 1.05 pg TEQ/g. The corresponding levels for adults would be 0.56 and 1.82 pg TEQ/g crab meat.

Response to additional question of 15 October 2018

The EFSA derivation of the TWI for TEQ in 2018
Based on epidemiological findings (the association between the presence of dioxins measured in blood of young boys and the quality of their sperm in young adulthood), EFSA recently proposed a TWI of 2 pg WHO_{2005} PCDD/F TEQ/kg bw per week. The proposed TWI aims at a dioxin concentration in blood of the (average) young boy that will not exceed a critical level (NOAEL) of 7.0 pg WHO_{2005} PCDD/F TEQ/g serum fat, as measured in blood of boys aged 9. This does not mean that the effect will occur at this age. The precise moment of that is not clear. The TEQ concentration in blood at age 9 must be considered as an indicator value for the effective concentration at the "site-of-action" at the critical moment or period in the development. The TWI is viewed as protective for the general population, because it is based on the most sensitive toxic effect.

Interpretation of the TWI
To derive the TWI, EFSA assumed that the dioxin level in blood of young boys is determined by exposure through the regular diet and by dioxins still present in blood after exposure via breast milk. Physiological-kinetic modelling was used to estimate the contribution from breast milk to the dioxin level in blood, assuming a breast-feeding period of 1 year, a daily intake of 800 ml breast milk, a level of 5.9 pg WHO_{2005} TEQ/g in milk fat and a fat percentage of 3.5% for breast milk. Exposure via the diet in young boys was assumed to be twice the level of exposure experienced by adults, due to a higher food consumption of children per kilogram body weight.

The TWI aims to prevent that dioxins in the body of the mother and her sons will accumulate to such levels that they may pose a reprotoxic risk for young boys (due to combined intrauterine exposure, exposure via breast milk, and exposure via food).

Revised calculation of maximum tolerable levels of TEQ for crab meat
Mitten crab meat can only be safely consumed if the background exposure to TEQ is below the TWI for TEQ. The background exposure to TEQ was determined for the Dutch population in 2014 (Boon et al., 2014). Depending on age, the median background exposure was approximately 1.0 pg TEQ/kg bw per day for children aged 2 years and 0.5 pg TEQ/kg bw per day for persons aged 7-69 years (see Table 1). The corresponding P95 values were roughly 1.6 and 1.0 pg TEQ/kg bw per day, respectively. In the FO assessment of 6 September 2018, children younger than 10 years were assumed not to consume mitten crab. The median and P95 background values for TEQ exposure considered were therefore 0.5 and 1.0 pg TEQ/kg bw per day for both children and adults, which correspond to 3.5 or 7 pg TEQ/kg bw per week. These daily exposure estimates are above the TWI of 2 pg TEQ/kg bw per week[6] and therefore the possibility of health risks cannot be excluded; in this case, potential effects on sperm quality in young adult males that have been exposed via breast milk and/or diet. The maximum tolerable level for TEQ in crab meat or maximum numbers of crabs that can be safely consumed are zero.

Conclusion for additional question of 15 October 2018:
In 2018, EFSA established a TWI for TEQ of 2 pg TEQ/kg bw per week. The median and P95 background exposure levels (excluding exposure through consumption of mitten crab) were 3.5 and 7 pg TEQ/kg bw per week, respectively, for 7-69 year olds living in the Netherlands. Consequently, the background exposure exceeds the TWI and there is no scope for exposure to TEQ through the consumption of mitten crab meat.

[6] EFSA also concluded that the toxic equivalence factor (TEF) for PCB-126, which is an important contributor to the dietary exposure to TEQ, is possibly too high. This could mean that the current exposure to TEQ is overestimated by at least a factor of 2. Reassessment of the TEF values is primarily the responsibility of the WHO. A median background exposure without PCB-126 might be just below the TWI of EFSA. However, the P95 percentile value is expected to remain higher than the new TWI.

It is irrelevant for this conclusion whether TEQ in mitten crab meat is present in brown meat, white meat or both. Any consumption of mitten crab meat results in an exposure that will further exceed the TWI. Beacuse almost all foodstuffs of animal origin, and in particular fish, have TEQ levels that are lower than those in mitten crabs (EFSA, 2018), the consumption of mitten crab meat as a "replacement" for other animal foodstuffs will not reduce the exposure to TEQ. The consumption of mitten crabs must therefore be considered as unsafe.

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Annex 1

Mathematical formulas for the calculation of the maximum tolerable levels for TEQ in brown meat of the Chinese mitten crab.

Although the calculations were based on the same principles (see Formula 1.1), the different assumptions per option required adjustments of the calculation rules. Where possible, the same symbols were used for all three options.[7]

Option 1

Option 1 includes the legal maximum level of 6.5 pg TEQ/g in white crab meat as set in Commission Regulation (EU) No 1881/2006.

The maximum tolerable level for TEQ in brown meat [Mbrown] was calculated as follows:

$$[Mbrown] = BM \times bw / (CF \times Nm \times bwc \times fm \times fb) \quad (1.1)$$

Where:

- [Mbrown] = calculated maximum tolerable level for TEQ in brown meat, taking into account background exposure and exposure from white meat to TEQ (pg TEQ/g meat).
- BM = weekly maximum tolerable exposure to TEQ due to the consumption of brown meat (pg TEQ/kg bw per week)
- bw = consumer's body weight (in kilograms)
- CF = consumption frequency (number per week)
- Nm = number of crabs per meal
- bwc = weight of crab (grams)
- fm = fraction of total crab meat (brown + white) in the entire crab body (21.7%)
- fb = fraction of brown meat in total crab meat (73.6%)

Here, BM was calculated as:

$$BM = RfD - BG - WM \quad (1.2)$$

Where:

- RfD = reference dose expressed in TEQ (= TWI of 14 pg TEQ/kg bw per week)
- BG = weekly background exposure (= 7 × daily background exposure (Table 1))
- WM = weekly exposure to TEQ due to the consumption of white meat containing TEQ at the legal maximum level (pg TEQ/kg bw per week)

And, WM was calculated as:

$$WM = ([Mwhite] \times CF \times Nm \times bwc \times fm \times fw) / bw \quad (1.3)$$

Where:

- [Mwhite] = legal maximum level for TEQ in white meat (6.5 pg TEQ/g)
- CF = consumption frequency (number per week)
- Nm = number of crabs per meal
- bwc = weight of crab (grams)
- fm = fraction of total crab meat (brown + white) in the entire crab body (21.7%)
- fw = fraction of white meat in total crab meat (26.4%).
- bw = consumer's body weight (in kilograms)

Option 2

Option 2 did not include the legal maximum level for TEQ in white meat, as in option 1, but a fixed ratio (indicated by the term "ratio" in the formulas below) of TEQ levels in brown to

[7] These symbols are also used in the EXCEL sheet that was used to compile this overview.

white meat. This means that if the concentration in brown meat is set at a certain maximum level [Mbrown], the corresponding maximum tolerable level in white meat [Mwhite] is also determined.

The maximum level [Mbrown] was calculated as follows:

$$[Mbrown] = Ecrab \times bw / (bwc \times fm \times (fb + fw / ratio) \times CF \times Nm) \quad (2.1)$$

Where:

- Ecrab = exposure to TEQ via the consumption of crab meat (brown + white) (pg TEQ/kg bw per day)
- bw = body weight
- bwc = weight of crab (grams)
- fm = fraction of total crab meat (brown + white) in the entire crab body (21.7%)
- fb = fraction of brown meat in total crab meat (73.6%)
- fw = fraction of white meat in total crab meat (26.4%)
- ratio = ratio of TEQ levels in brown to white meat
- CF = consumption frequency (number per week)
- Nm = number of crabs per meal

$$Ecrab = RfD - BG \quad (2.2)$$

Where:

RfD = reference dose expressed in TEQ (= TWI of 14 pg TEQ/kg bw per week)
BG = weekly background exposure (= 7 × daily background exposure (Table 1))

Formula (2.1) was derived as follows:

The exposure to TEQ through the consumption of a single crab with the maximum level in both brown and white meat (Exp1 in pg TEQ per crab) was:

$$Exp1 = Qmb \times [Mbrown] + Qmw \times [Mwhite] \quad (2.a)$$

Where:

Qmb = quantity of brown meat (gram) = $bwc \times fm \times fb$ (2.b)
Qmw = quantity of white meat (gram) = $bwc \times fm \times fw$ (2.c)
bwc = weight of crab (grams)
fm = fraction of total crab meat (brown + white) in the crab body (21.7%)
fb = fraction of brown meat in total crab meat (73.6%)
fw = fraction of white meat in total crab meat (26.4%).

$$[Mwhite] = [Mbrown] / ratio \quad (2.d)$$

Entering 2.b, 2.c and 2.d in (2.a) leads to, after simplification:

$$Exp1 = [Mbrown] \times bwc \times fm \times (fb + fw / ratio) \quad (2.e)$$

For an exposure during one week in pg (Expw) where CF times crab is eaten with Nm crabs per meal, the exposure in that week equals:

$$Expw = Exp1 \times CF \times Nm = [Mbrown] \times bwc \times fm \times (fb + fw / ratio) \times CF \times Nm$$

And per kg body weight, therefore

$$Expw\_bw = [Mbrown] \times bwc \times (fb + fw / ratio) \times CF \times Nm / bw \quad (2.f)$$

As this exposure should not exceed Ecrab, it follows from (2.f) that

$$Ecrab = [Mbrown] \times bwc \times fm \times (fb + fw / ratio) \times CF \times Nm / bw$$

from which follows [Mbrown] as indicated in formula (2.1) and [Mwhite] as indicated in formula (2.d)

Option 3

The maximum tolerable level for TEQ in brown meat ([Mbrown]) was calculated in such a way that the exposure during one year would not exceed 52 x TWI, and taking into account a fixed ratio of TEQ levels in brown to white meat.

[Mbrown] was calculated as follows:

$$[Mbrown] = Ecraby \times bw / (Wkin \times Cfin \times Nm \times (bwc \times fm \times (fb + fw / ratio)) + Wkout \times Cfout \times Nm \times (bwc \times fm \times (fb + fw / ratio))) \quad (3.1)$$

And:

$$Ecraby = 52 \times (TWI-BG) \quad (3.2)$$

Where:

- Ecraby = total tolerable exposure to TEQ from mitten crab meat per year
- bw = body weight of children and adults (37.6 and 65 kg, respectively)
- TWI = tolerable weekly intake (14 pg TEQ/kg bw)
- BG = weekly background exposure (= 7 × P95 daily background exposure (Table 1))
- Wkin = length of the mitten crab season (12 weeks)[8]
- Wkout = length of period outside the mitten crab season period (40 weeks)
- Cfin = consumption frequency in the mitten crab season: (2.5 x per week = 95th percentile; Table 2)
- Cfout = consumption frequency during the out of season period (two options considered: (arbitrarily) once a month or no consumption)
- bwc = weight of crab (125 grams)
- fm = fraction of total meat (brown + white) in crab body (21.7%)
- fb = fraction of brown meat in total crab meat (73.6%)
- fw = fraction of white meat in total crab meat (26.4%)
- Nm = number of crabs per meal (10; "if you're going to eat them, do it properly")
- ratio = ratio of TEQ levels in brown to white meat (15 (low), 49 (P50 value; median) or 120 (high))

Formula (3.1) is similar to formula (2.1), except that in formula (3.1) the denominator is divided into two terms indicating the in-season and out of season crab consumption, respectively.

[8] Strictly speaking, a year has 52 weeks + 1 day + 0.25 leap day. The 365th day and the leap day were not included in the calculations. If they had been included and these 1.25 days had been assigned to the seasonal period (Wkin) or to the out of season period (Wkout), [Mbrown] would have decreased or increased by 1.0% in all scenarios, respectively.

Annex 2

Maximum tolerable levels for TEQ in brown and white meat of mitten crabs as calculated for option 1.

For the calculations, the following parameter values were used for children (aged 10 years) and adults:

Percentile	Background exposure (pg TEQ/kg bw per day)	Consumption frequency (meals per week)	Number of crabs per meal
P50	0.5	0.5	4.5
P95	1	2.5	10

For all scenarios described below, the level of TEQ for white mitten crab meat was equalled to the legal maximum level of 6.5 pg TEQ/g.

The abbreviated column headings in the table below correspond to the symbols used in the formulas (see Annex 1)

Results of option 1

Scenario	Age group	Body weight (kg)	BG[1]	CF	Nm	Crab weight (grams)	WM	BM	[Mbrown]
1	Children	37.6	P50	P50	P50	100	2.2	8.3	8.7
2	Children	37.6	P95	P50	P50	100	2.2	4.8	5.0
3	Children	37.6	P50	P95	P50	100	11.1	-0.6	-0.1
4	Children	37.6	P95	P95	P50	100	11.1	-4.1	-0.9
5	Children	37.6	P50	P50	P95	100	5.0	5.5	2.6
6	Children	37.6	P95	P50	P95	100	5.0	2.0	1.0
7	Children	37.6	P50	P95	P95	100	24.8	-14.3	-1.3
8	Children	37.6	P95	P95	P95	100	24.8	-17.8	-1.7
9	Children	37.6	P50	P50	P50	125	2.8	7.7	6.5
10	Children	37.6	P95	P50	P50	125	2.8	4.2	3.5
11	Children	37.6	P50	P95	P50	125	13.9	-3.4	-0.6
12	Children	37.6	P95	P95	P50	125	13.9	-6.9	-1.2
13	Children	37.6	P50	P50	P95	125	6.2	4.3	1.6
14	Children	37.6	P95	P50	P95	125	6.2	0.8	0.3
15	Children	37.6	P50	P95	P95	125	30.9	-20.4	-1.5
16	Children	37.6	P95	P95	P95	125	30.9	-23.9	-1.8
17	Children	37.6	P50	P50	P50	150	3.3	7.2	5.0
18	Children	37.6	P95	P50	P50	150	3.3	3.7	2.6
19	Children	37.6	P50	P95	P50	150	16.7	-6.2	-0.9
20	Children	37.6	P95	P95	P50	150	16.7	-9.7	-1.4
21	Children	37.6	P50	P50	P95	150	7.4	3.1	1.0
22	Children	37.6	P95	P50	P95	150	7.4	-0.4	-0.1
23	Children	37.6	P50	P95	P95	150	37.1	-26.6	-1.7
24	Children	37.6	P95	P95	P95	150	37.1	-30.1	-1.9
25	Adults	65	P50	P50	P50	100	1.3	9.2	16.7
26	Adults	65	P95	P50	P50	100	1.3	5.7	10.3
27	Adults	65	P50	P95	P50	100	6.4	4.1	1.5
28	Adults	65	P95	P95	P50	100	6.4	0.6	0.2
29	Adults	65	P50	P50	P95	100	2.9	7.6	6.2
30	Adults	65	P95	P50	P95	100	2.9	4.1	3.4
31	Adults	65	P50	P95	P95	100	14.3	-3.8	-0.6
32	Adults	65	P95	P95	P95	100	14.3	-7.3	-1.2

33	Adults	65	P50	P50	P50	125	1.6	8.9	12.9
34	Adults	65	P95	P50	P50	125	1.6	5.4	7.8
35	Adults	65	P50	P95	P50	125	8.1	2.4	0.7
36	Adults	65	P95	P95	P50	125	8.1	-1.1	-0.3
37	Adults	65	P50	P50	P95	125	3.6	6.9	4.5
38	Adults	65	P95	P50	P95	125	3.6	3.4	2.2
39	Adults	65	P50	P95	P95	125	17.9	-7.4	-1.0
40	Adults	65	P95	P95	P95	125	17.9	-10.9	-1.4
41	Adults	65	P50	P50	P50	150	1.9	8.6	10.3
42	Adults	65	P95	P50	P50	150	1.9	5.1	6.1
43	Adults	65	P50	P95	P50	150	9.7	0.8	0.2
44	Adults	65	P95	P95	P50	150	9.7	-2.7	-0.6
45	Adults	65	P50	P50	P95	150	4.3	6.2	3.4
46	Adults	65	P95	P50	P95	150	4.3	2.7	1.5
47	Adults	65	P50	P95	P95	150	21.5	-11.0	-1.2
48	Adults	65	P95	P95	P95	150	21.5	-14.5	-1.6

[1] BG: background exposure (pg TEQ/kg bw per week); CF: consumption frequency (meals per week); Nm: number of crabs per meal; WM: exposure to TEQ from white meat with a level of 6.5 pg TEQ/g meat (pg TEQ/kg bw per week); BM: maximum tolerable exposure to TEQ from brown meat (pg TEQ/kg bw per week); [Mbrown]: maximum tolerable level for TEQ in brown meat (pg TEQ/g) at which the tolerable weekly intake (TWI) of 14 pg TEQ/kg bw per week (SCF, 2001) was not exceeded: pg; picogram