

## Non-dioxin-like PCBs are undesirable in food and feed

BfR Communication No 037/2018 of 3 December 2018

Feed containing increased levels of non-dioxin-like polychlorinated biphenyls (ndl-PCB) was supplied to farms from North Rhine Westphalia. Humans can be exposed to ndl-PCBs via the food chain through animal feed. The German Federal Institute for Risk Assessment (BfR) received data from three federal states on ndl-PCBs in samples of eggs, turkey and chicken in concentrations higher than the regularized maximum levels. Foods exceeding the legally binding maximum level must not be placed on the market. Maximum levels are not primarily based on toxicological assessments. With regard to ndl-PCBs, maximum levels are oriented on occurrence data in food and the sensitivity of the analytical methods. The currently reported ndl-PCB mean levels are significantly higher than the levels usually measured as background concentrations in food in Germany. Ndl-PCBs are undesirable substances that are considered so-called environmental contaminants. They accumulate predominantly in fat-containing foods.

Consumers ingest low levels of ndl-PCBs via food every day (background concentration). The BfR has calculated that a theoretical increase in the intake of ndl-PCBs from 13% to 44% would result from the current ndl-PCB situation. This calculation is based on the theoretical worst case assumption that consumers consume eggs, turkey and chicken exclusively from farms involved in the current situation. Initial preliminary results of the BfR MEAL study do not show an increase in the background concentration.

A short-term exceedance of maximum levels in foods does not necessarily mean that the consumption of these foods represents a health risk. According to BfR, the occurrence of acute adverse health effects for consumers is unlikely in the current situation because PCB mixtures only have a low potential for acute toxicity. A health-based guidance value for toxicologically relevant long-term intake has not yet been derived for ndl-PCBs from the data available in international studies. Therefore, a risk assessment is not possible.

For reasons of consumer health protection, the ndl-PCB levels in foods should be kept as low as possible.

The German Federal Institute for Risk Assessment (BfR) received data from three federal states on non-dioxin-like polychlorinated biphenyls (ndl-PCBs) in samples of eggs, turkey and chicken in concentrations higher than the regularized maximum levels.

### Polychlorinated biphenyls

Polychlorinated biphenyls (PCBs) are a group of 209 congeners of chlorinated substances which are distinct from one another due to different numbers and positions of chlorine atoms on biphenyl. 130 of these congeners occur in produced mixtures. In contrast to dioxins, PCBs are manufactured on purpose and used for various applications, mainly as non-burning and viscid fluids with low conductivity in transformers and hydraulic oil. Like dioxins, PCBs are lipophilic, sometimes persistent, and therefore accumulate in the fatty tissue of humans and animals.

Some PCB congeners have a molecular structure similar to that of dioxins and comparable biological effects. They are therefore referred to as dioxin-like PCBs (dl-PCBs). Like dioxins, dl-PCBs are assigned toxic equivalency factors (TEF) which classify these PCB congeners according to their toxicity as compared to 2,3,7,8-TCDD. As with the PCDD/F, the dl-PCBs can be expressed as a toxic equivalent concentration (WHO-PCB-TEQ).

The remaining PCB congeners do not have dioxin-like properties. They have a different toxicological profile and are referred to as non-dioxin-like PCBs (ndl-PCBs). For the total of 6 congeners of ndl-PCBs (so-called indicator congeners: PCB28, PCB52, PCB101, PCB138, PCB153, PCB180, also  $\Sigma$ 6PCB), maximum levels for the different food categories apply according to Regulation (EC) No. 1881/2006. These congeners were not selected due to toxicological aspects, but due to their good analytical determination and the consideration of all relevant chlorination degrees.

According to BfR, the occurrence of acute adverse health effects for consumers is unlikely in the current situation because PCB mixtures only have a low potential for acute toxicity (JECFA 2016).

Thyroid effects, liver changes, neuronal effects, immunotoxicity, endocrine changes and reprotoxic effects, in particular, have been observed in animal experiments over long periods with individual ndl-PCB congeners. These findings have been partially confirmed in epidemiological studies. The liver and the thyroid have been identified as the most sensitive target organs for ndl-PCB intake (JECFA 2016). Data on chronic intake in animal experiments is only available for one congener (PCB153). A health-based guidance value for ndl-PCBs has not been derived to date by either EFSA (2005) or JECFA (2016) due to the insufficient toxicity data available. For this reason, a risk assessment is not possible.

### Comparative exposure estimate

To be able to compare the current ndl-PCB findings (data current as of 28 November 2018, 12pm) with the existing occurrence data, three different data sources were used as the basis for comparison:

- Data from the LExUKon project (Blume et al., 2010) in which all relevant data sources for Germany up to 2010 were incorporated. This includes data from food monitoring (LM-M), the dioxin database of the federal government and the federal states, published studies of authorities and scientific literature.
- Data from the food monitoring of the federal states from the years 2010-2017 to carry on the data situation of LExUKon.
- Data from the national residue control plan for foods of animal origin (NRKP) from reporting year 2015 (BVL 2015<sup>1</sup>). The NRKP is based on an inspection rate of one sample per 200 tonnes annual production of poultry or per 1000 tonnes annual production of eggs in Germany. Sampling for the NRKP is target-oriented. This means that information of local or regional circumstances is taken into account and that reports on unauthorised or non-compliant treatment or feeding of animals are followed up. Hence, the NRKP is not aimed at attaining statistically representative data (BVL, 2018<sup>1</sup>).

Some of the concentration values currently reported are considerably higher than the values usually measured in Germany (background concentration) (Tab. 1). In addition, the maximum level of 40 nanograms (ng) ndl-PCBs per gram (g) fat or 0.8 ng ndl-PCBs per gram wet weight (in turkey containing less than 2% fat) is significantly exceeded in individual samples. In comparison, one of 109 egg samples tested for ndl-PCBs in 2015 exceeded the maximum level with a concentration of 55.4 ng per g fat (BVL, 2015).

---

1

[https://www.bvl.bund.de/EN/01\\_Food/01\\_tasks/02\\_OfficialFoodControl/05\\_NRCP/nrcp\\_node.html;jsessionid=7E8C38F3CB8FCFE10696AA96DC452ECD.2\\_cid322](https://www.bvl.bund.de/EN/01_Food/01_tasks/02_OfficialFoodControl/05_NRCP/nrcp_node.html;jsessionid=7E8C38F3CB8FCFE10696AA96DC452ECD.2_cid322)

**Table 1. Detected levels of ndl-PCBs [ng per g fat] in eggs, turkey and chicken in the current situation (November 2018) in Germany as compared to two data sources.**

Food	LExUKon <sup>a</sup>			Food monitoring <sup>b</sup>				Situation 2018 <sup>c</sup>				
	N	Mean	Max.	N	Mean	Median	Max.	N	Mean (all)	Median (all)	Mean. (over max. level)	Median (over max. level)
Eggs	74	39.4	-	71	15.7	9.7	17.0	63	47.9	43	86	62
Turkey	2	5.9	-	-	-	-	-	23	102.5	102.5	106.7	108
Chicken	50	5.2	40.8	185	56.1	4.7	8.5	39	68.7	60	88.5	73

<sup>a</sup>LExUKon project (Blume et al., 2010): Data up to 2010; mean values (mean) calculated with upper bound (UB). High value in eggs is also at upper bound. With lower bound, the mean value would be 14.4 ng/g fat.

<sup>b</sup>Food monitoring: Data 2010 to 2017: Mean value calculated with UB and can be traced back to the sum of limits of quantification, while the highest sum value at which at least one congener was above the limit of quantification is specified as maximum value (BVL 2011).

<sup>c</sup>Most recently detected values (data current as of 28 November 2018, 12pm). Mean and median values calculated on the basis of the values reported from official and non-official samples in the current situation. It is not known whether values below the limits of detection or quantification are included. The number of values refers to all samples, including the values below the regularized maximum level.

The results from the LExUKon project are used as the basis for a comparative consumer exposure estimate. They describe the usual background concentrations of ndl-PCBs valid in 2010. The findings of the second German National Nutrition Survey (NVS II) were used to determine the consumption levels. The NVS II is a food consumption study of adolescents and adults aged from 14-80 which is representative of the German-speaking population (MRI, 2008a; b). The "Dietary History" interviews – collected using the DISHES tool – from the NVS II were used for the evaluations in the LExUKon project and thus also for this assessment. Data from egg, turkey and chicken products was calculated back to the respective proportion of egg, turkey or chicken contained in the product (Blume et al. 2010).

Two different theoretical scenarios of how consumers could come into contact with affected foods are assumed in this exposure estimate (see Tab. 2). Both scenarios are based on the conservative assumption that eggs, turkey and chicken exclusively from the inspected farms were consumed. Because the concentrations in the individual affected foods differ, individual persons could obtain foods with higher and lower levels of contamination from the affected farms which accumulate over a long period of time.

**Table 2. Estimate of PCB exposure (ng/kg BW per day) to ndl-PCBs with consumption of eggs, turkey and chicken with the levels detected in the current situation for two theoretical scenarios as compared to results of the LExUKon project.**

	Eggs Usual consumption	Eggs High consumption	Poultry Usual consumption	Poultry High consumption	Total exposure with usual consumption	Total exposure with high consumption
Background concentration: LExUKon 2010	0.5	1.3	0.1	0.4	10.9	22.6
Scenario 1: Mean of all reported values <sup>a</sup>	2.0	4.9	1.5	5.1	13.7	25.5
Scenario 2: Mean of values over maximum level <sup>b</sup>	3.6	8.8	1.9	6.5	15.7	27.5

<sup>a</sup> It is assumed that eggs, turkey and chicken from all inspected farms were consumed over a long period. Levels both above and below the maximum level are possible here and farms that were only inspected due to suspicion, without detection of violations of the maximum level in the farm, are also included.

\* It was assumed that eggs, turkey and chicken exclusively from the inspected farms that were above the maximum level were consumed. Even if values below the maximum statutory limit were also measured in one of the farms, these values were not included in the calculation of the mean value.

Current results of the **BfR MEAL study** were used for the first time to further categorise the latest findings. The BfR MEAL study is a total diet study representative of the whole of Germany in which an overall number of 60,000 individual samples of foods are studied. In total this makes up about 90% of overall consumption in Germany. The samples are prepared in a manner typical for households and examined in ready-to-eat pooled samples. The use of the ndl-PCB values for this assessment represents an event-driven and provisional observation based on the analysis data available up to 28 November 2018, 12 noon. The BfR MEAL analysis results on ndl-PCBs, which are not available, completely to date, have not yet been subjected to all intended quality assurance measures. The provisional inspection results for cooked chicken eggs, fried eggs and pre-cooked (poultry) sausages were lower than or roughly the same as the ndl-PCB concentrations from food monitoring and LExUKon. Therefore, on condition of the provisional evaluation, the results of the BfR MEAL study that are available to date (date of sample transmission 2017- 28 May 2018) confirm the generally much lower ndl-PCB concentrations in eggs, turkey and poultry as compared to the individual exceeded maximum levels in connection with the current situation. Under the specified condition, this suggests that the ndl-PCB situation is limited in terms of time and location.

### Assessment of uncertainties

#### Uncertainties relating to toxicity:

Data from long-term studies are not available for most ndl-PCB congeners. For this reason, the health risk of long-term exposure to ndl-PCBs cannot be reliably estimated.

There is only a two-year study on the carcinogenicity of ndl-PCBs for PCB153 (NTP 2006a and b). This congener is assessed by the IARC (2015) as "possibly carcinogenic" to humans.

The data on PCB101 and PCB138 is insufficient because there are no results from animal experiments. However, in the assessment of JECFA (2016), both congeners contribute to the

total exposure, in some cases significantly (PCB101: 8%; PCB138: 28%). The contribution of these congeners to the overall levels of ndl-PCBs in the current situation is not known.

In the current situation, the BfR does not have sufficient information on the congener pattern in the eggs, turkey and chicken.

#### Uncertainties relating to exposure estimate

The analysis results reported to the BfR (data current as of 28 November 2018, 12 noon) derived from samples that were taken directly in the affected farms and not in commercial businesses. We cannot conclude with certainty that the assumed scenarios accurately describe the actual situation.

For the exposure estimate by the BfR, it was not possible using the available data to create a reference scenario of consumption of products exceeding and not exceeding the regularized maximum level from the affected farms (i.e. with evidence of the regularized maximum level being exceeded in at least one case). The reason for this is incomplete assignment of the samples to individual production companies. In addition, only the results of a collective sample are available for many farms. Not every animal or egg is necessarily contaminated to the same degree, however. It is therefore not possible to describe the scenario whereby food is procured exclusively from an affected farm. The two scenarios outlined here underestimate (Scenario 1) or overestimate (Scenario 2) the theoretical reference scenario. The assumed scenarios only take the adult population into consideration.

The exposure estimate from LExUKon used for comparison derived from 2010. The consumption and the ndl-PCB contamination of foods may have changed since then. This also concerns foods not affected by the current situation which were included in the overall exposure. The concentration data used in LExUKon is not characterised by adequately large sample numbers and representativeness for all foods. An updated exposure estimate will be possible after the finalisation of the BfR MEAL study.

With respect to ndl-PCBs, there are fundamental uncertainties due to values below the limit of detection or quantification. In the LExUKon project, this was taken into consideration by representing the results with upper or lower bound. In this estimate, reference was made only to upper bound values, which tend to cause an overestimation of exposure. However, this approach is likely to underestimate the increase in exposure in relation to the background exposure.

#### Summary

- The German Federal Institute for Risk Assessment (BfR) received data from three federal states on non-dioxin-like polychlorinated biphenyls (ndl-PCBs) in samples of eggs, turkey and chicken in concentrations higher than the regularized maximum levels.
- Ndl-PCBs are undesirable substances that are considered so-called environmental contaminants. They accumulate predominantly in fat-containing foods. The currently reported ndl-PCB mean levels (data current as of 28 November 2018, 12 noon) are significantly higher than the levels usually measured in food in Germany.

- The BfR has calculated that a theoretical increase in the intake of ndl-PCBs from 13% to 44% would result from the current ndl-PCB situation. This calculation is based on the theoretical worst case assumption that eggs, turkey and chicken are consumed exclusively from farms involved in the current situation. A provisional evaluation of data from the BfR MEAL study indicates that the mean background concentrations of ndl-PCBs in comparable food groups (eggs, turkey and chicken) in 2017 and up to 28 May 2018 (date of sample transmission) correspond to or are even lower than the known background concentrations for these foods.
- Foods exceeding the legally prescribed maximum level must not be placed on the market. A short-term exceedance of maximum levels does not necessarily mean that the consumption of these foods does not represent a health risk. Maximum levels are not primarily based on toxicological assessments. With regard to ndl-PCBs, maximum levels are oriented on occurrence data in food and on the sensitivity of the analytical methods.
- According to BfR, the occurrence of acute adverse health effects for consumers is unlikely in the current situation because PCB mixtures only have a low potential for acute toxicity (JECFA 2016).
- Thyroid effects, liver changes, neuronal effects, immunotoxicity, endocrine changes and reprotoxic effects in particular have been observed in animal experiments over long periods with individual ndl-PCB congeners. These findings have been partially confirmed in epidemiological studies. In these studies, the liver and the thyroid have been identified as the most sensitive target organs for ndl-PCB intake (JECFA 2016). Data on chronic intake in animal experiments is only available for one congener (PCB153). A health-based guidance value for ndl-PCBs has not been derived to date by either EFSA (2005) or JECFA (2016) due to the insufficient toxicity data available. A risk assessment is not possible for this reason.
- For reasons of consumer health protection, the ndl-PCB contamination levels in food should be kept as low as possible. In this context, unnecessary additional contamination, particularly through non-compliance with the regularized maximum levels, must be avoided.

## References

- Blume K, Lindtner O, Heinemeyer G, Schneider K, Schwarz M. Aufnahme von Umweltkontaminanten über Lebensmittel (Cadmium, Blei, Quecksilber, Dioxine und PCB)-Ergebnisse des Forschungsprojektes LExUKon. Bundesinstitut für Risikobewertung; 2010.
- Commission Regulation (EC) No 1881/2006 of 19. December 2006 setting maximum levels for certain contaminants in foodstuffs  
as amended by Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs
- EFSA (2005) Opinion of the Scientific Panel on Contaminants in the Food chain on a Re-quest from the Commission related to the Presence of non dioxin-like Polychlorinated Bi-phenyls (PCB) in Feed and Food, 284, 1-137.

- IARC (2015). Polychlorinated biphenyls and polybrominated biphenyls. Lyon: International Agency for Research on Cancer (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 107).
- Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2016: Safety evaluation of certain food additives and contaminants Supplement 1: Non-dioxin-like polychlorinated biphenyls. WHO Food Additives Series: 71\_S1 World Health Organization, Geneva, 2016, 431pp
- Krems C, Bauch A, Götz A, Heuer T, Hild A, Möseneder J, Brombach C (2006): Methoden der Nationalen Verzehrsstudie II. Ernährungs-Umschau 53, Heft 2
- Max Rubner-Institut (MRI) 2008: Nationale Verzehrsstudie II (NVS II), Ergebnisbericht 1, 2  
<http://www.was-esse-ich.de/>
- NTP (2006a). Toxicology and carcinogenesis studies of 2,2',4,4',5,5'-hexachlorobiphenyl (PCB 153) (CAS No. 35065-27-1) in female Harlan Sprague-Dawley rats (gavage studies). Research Triangle Park (NC): United States Department of Health and Human Services, Public Health Service, National Institutes of Health, National Toxicology Program (Technical Report Series No. 529; NIH Publication No. 06-4465).
- NTP (2006b). Toxicology and carcinogenesis studies of a binary mixture of 3,3',4,4',5-pentachlorobiphenyl (PCB 126) (CAS No. 57465-28-8) and 2,2',4,4',5,5'-hexachlorobiphenyl (PCB 153) (CAS No. 35065-27-1) in female Harlan Sprague-Dawley rats (gavage studies). Research Triangle Park (NC): United States Department of Health and Human Services, Public Health Service, National Institutes of Health, National Toxicology Program (Technical Report Series No. 530; NIH Publication No. 06-4466).