Clarification

Worst case scenario for PCDD/PCDF (Final Report, p. 349f.)

In order to assess the potential impact of elevated levels of PCDD/PCDF in soil one approach could be to establish a correlation with human intake levels. This has been done by means of a worst case approach using limits and recommendations from European food legislation as indicators for contamination levels and safety margins. The project team does not intend to establish a causal chain between food legislation and other sectors or a direct correlation between food limits and tolerable daily intake (TDI). Current knowledge does not allow such a linkage.

To assess the impact of elevated levels on human exposure, following aspects are taken into account:

- The EU scientific body (formerly Scientific Committee on Food (SCF), currently European Food Safety Authority (EFSA)) established a tolerable weekly intake ("TWI") of 14 pg WHO-TEQ/kg body weight for dioxins, furans and dioxin-like PCBs (which corresponds to a Tolerable Daily Intake (TDI) of 2 pg WHO-TEQ/kg body weight on the basis of a risk assessment applying an overall uncertainty factor of about 10 (9.6) in relation to the LOAEL derived EHDI.

- Average dietary intake in EU is in the range of 1.2-3.0 pg WHO-TEQ/kg body weight and day (bwd). The average contamination (background contamination) of eggs with PCDD/PCDF is 1 pg PCDD/PCDF-TEQ/g fat with a wide range of contamination.

- Maximum levels for PCDD/PCDF in eggs have been set at 3 pg PCDD/PCDF-TEQ/g fat in European food legislation[1]. These levels are taking into account current background contamination with the purpose of constituting a strict but feasible control instrument in the light of the overall objective to lower European intake levels.

For the calculation of a worst-case scenario a two step approach have been used by the project team.

In a first rough approach it has been assumed that a 10-fold contamination in relation to the maximum level for PCDD/PCDF in eggs will cause a very significant effect on the overall dietary intake. This approach is presented in the report.

In a second more detailed approach the relative contribution of eggs to the overall estimated daily intake (EDI) as well as the contribution of the PCB-TEQ is taken into account.

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[1] Council Regulation (EC) No 2375/2001 amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs; OJ L 321, 6.12.2001, p.1

For the second step the following additional assumptions have been made in terms of a worst case approach:

- The estimated dietary intake (EDI) of PCDD/PCDF and dioxin-like-PCB in the EU is 3 pg/kg body weight and day.

- Dioxinlike PCB contribute 50% to the overall dietary intake

- Thus the estimated dietary intake of PCDD/PCDF-TEQ is 1.5 pg/kg body weight and day

- The contribution of eggs to the total dietary intake is 20%

- The average contamination of eggs with PCDD/PCDF is 1 pg PCDD/PCDF-TEQ/g fat

- The "critical" level for dietary intake is the lowest observed adverse effect level (LOAEL) associated estimated human daily intake (EHDI) of 20 pg/kg bw.

- Thus the "critical" level for dietary intake of PCDD/PCDF is 10 pg/kg bw

Based on these assumptions the following calculation can be made:

Eggs 1 pg PCDD/PCDF-TEQ/g fat  =  dietary intake  0.3 pg/kg b.w.

Eggs 10 PCDD/PCDF-TEQ/g fat  =  dietary intake 3 pg/kg b.w.

Eggs 20 PCDD/PCDF-TEQ/g fat  =  dietary intake 6 pg/kg b.w.

Eggs 30 PCDD/PCDF-TEQ/g fat  =   dietary intake 9 pg/kg b.w.

Eggs of 40 PCDD/PCDF-TEQ/g fat  =  dietary intake 12 pg/kg b.w.

Taking into account the "critical" level of 10 pg/kg b.w. as regards the dietary intake of PCDD/PCDF (see above), a PCDD/PCDF concentration of 30 pg PCDD/PCDF-TEQ/kg fat in eggs must be assumed as critical contamination level. Beyond that risks to human health cannot be excluded.

As two studies providing information on hot spot levels and average levels both in soil/contaminated material and eggs [Pless-Mulloli et al 2001a, Nouwen et al 2004] correlate a 7-10 pg/g fat concentration in eggs to a soil/material concentration of 0.04 - 0.9 ppb the critical value of 30 pg/g fat could be expected to be exceeded at soil/material levels of >1 ppb.

The project team is aware that the calculation is loaded with considerable uncertainty. However the assessment shows that risks might exist that require specific provisions on management for all wastes exceeding levels of 1 ppb.(see Figure 1).

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critical level where safety factor might be exceeded: **30 pg/g fat**

assumption:

contamination soil/material → contamination eggs

0.04 - 0.9 ppb → elevation by 7 -10 pg/g fat

1 – 4 ppb → elevation > 30 pg/g fat in eggs

➡ *health risk might not be excluded by >1 ppb low POP content limit*

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Figure -1:    Assessment of critical pathways from wastes into the food chain

In the framework of a plausibility check this result fits quite well to the dimension of the proposed limit in sewage sludge and action/target values for soil set up in a number of Member States based on TDI recommendations. It has to be taken into account that these limits include safety margins following the precautionary principle which have been excluded for the above worst case estimation.