EUROPEAN COMMISSION

Directorate-General for Health & Consumers

Scientific Committee on Health and Environmental Risks

SCHER

Derogation on the Drinking Water Directive 98/83/EC

Scientific Committees
on consumer safety
on emerging and newly identified health risks
on health and environmental risks

SCHER adopted this opinion by written procedure on 16 April 2010

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

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SCHER

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It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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1. BACKGROUND

Groundwater is the largest - more than 80% - freshwater resource of water for human consumption in Italy.

The introduction of the Drinking Water Directive 98/83/EC (DWD) had a tremendous impact on drinking water supply in Italy. Firstly, the application of parametric values significantly reduced with respect to previous water quality standards (*e.g.* As 50 µg/l in Directive 80/778/EC reduced to 10 µg/l by Directive 98/83/EC) caused non compliance for a number of parameters, such as As, F, B, which are frequent naturally occurring contaminants of Italian groundwater. Secondly, the water utility systems in Italy were extremely fragmented at the time of DWD transposition (D. Lgs. 31/2001), on account of historical, geographical and hydrological reasons. This situation evolved in the last decade due to the formation of ATO (*Ambito Territoriale Ottimale*), *i.e.* one managing company responsible for all the water services as resulting by the merging of previous existing operators. Currently 92 ATO are in place in Italy (territory of the ATO usually approximately corresponding to that of Provincia) and the number of water suppliers has being consistently reduced from 7826 (2003) to 3351(2009). The presence of a centralized water management system also brought a substantial benefit in approaching and solving the complex problems related to the establishing of compliance for naturally occurring parameters systematically exceeding the parametric values in wide areas (e.g. Toscana, Lombardia, Lazio, Campania) since a whole re-organization of the catchments and distribution systems and related large investments are usually required.

Thus, following the transposition of Directive 98/83/EC Italy has issued the highest number of derogations among Member States, mainly concerning parameters originating by natural geological sources: the original situation (first derogation) concerned 10 parameters with 56 derogation acts and involved 13 regions.

The system for the authorization of first and second derogations in Italy involved the initial application by the Health and Environmental Regional authorities followed by an analytical evaluation of the request by the Ministry of Health, the National Institute for Health and the Superior Council of Health, according to the provisions of art 9 of dir 98/83/EC. The final decision on derogation included the following criteria: (a) Risk Assessment and Risk Management approach to avoid potential danger to human health (b) the need of derogation as the only mean to assure water supply and to re-establish compliance (c) water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means (d) evidence of corrective actions, timetable and financing (annual basis) (e) derogation is not applied to water used by food industries.

Derogations in Italy are issued by legal instruments (Italian National Decree by Ministry of Health with agreement with Ministry of Environment), establishing Maximum permissible values (MPVs), *e.g.* As 50 µg/L, F 2.5 mg/l, B: 3 mg/l, accompanied by improvement measures and time limits, forming part of the derogation. Transposition of the National Decrees is demanded to the Regional Authorities which should adopt derogation values for local specific circumstances as low as possible under the MPVs, and should accompany the provision with possible limitations of water uses, information to population, groups at risk *etc*.

Within this framework, the period 2003-2009 has been characterized by massive investments in the drinking water sector, with a wide replacement of distribution systems, new catchment areas integrated with treatment plants. This allowed a substantial attenuation of population concerned by derogation and a significant decreasing of occurrence of systematic non-compliance calling for derogation, which is currently limited to 3 parameters originating from geological sources within local circumstances belonging to 5 Regions and 2 Autonomous Provinces.

2. TERMS OF REFERENCE

Italy has recently requested third derogations for a large number of water supply zones. The derogations refer to parameter values for three substances of geogenic origin: arsenic (As), boron (B) and fluoride (F) exceeding the maxima laid down in the Directive. From the info available it is evident that the concerned population has most likely already been exposed to concentrations in drinking water of the three substances for at least six years before the start of the third derogation. The derogated values and the duration of the derogations are summarized in the following table.

Summary of derogations on directive 98/83/EC requested by a Member State

Parameter	Directive's limit value	Requested Derogated Value	Unit	Persons concerned	Duration (years)
As	10	50	µg/l	634970	3
As	10	50	µg/l	301445	2
As	10	50	µg/l	1450	1
As	10	40	µg/l	27400	3
As	10	30	µg/l	34902	1
As	10	20	µg/l	9622	3
As	10	15	µg/l	4300	2
As	10	15	µg/l	7100	1
B	1	3	mg/l	109239	3
B	1	2	mg/l	100	1
	1				
F	1.5	2,5	mg/l	460539	3
F	1.5	2,5	mg/l	1000	2
F	1.5	2,5	mg/l	456944	1

As an important contribution to the forthcoming Commission's decision, DG ENV requests SCHER's opinion whether the specified derogation requests for the specified parameter values for As, B and F, and for the specific durations may constitute a potential danger to human health and whether there are possible risk groups which should not be exposed to values as requested in the derogation (specific advice, supply of bottled water, etc).

3. OPINION

Tolerable intakes and recent exposure assessments are available for borate and fluoride (COT-NRC, 2001; WHO, 2003b; WHO, 2003a; EPA-IRIS, 2004; EFSA, 2005; EU-Annex-XV, 2008). Regarding arsenic, EFSA has published an assessment of As-contamination of food and a number of recent large-scale epidemiology studies have been reported. The opinion is therefore based on these recent assessments.

3.1. General remarks

Health-based concentration limits for chemical contaminants in drinking water are usually defined by a general approach (WHO, 2008). Based on the available toxicity studies in animals, a tolerable daily intake (TDI) is derived using safety factors (usually 100) for extrapolation. This TDI is based on the No-observed-adverse-effect-level (NOAEL) in long-term oral toxicity studies and on the response in the most sensitive animal species. As default, consumption of the chemical contaminant with drinking water should only contribute to less then 20% of the TDI. In the process, average drinking water

consumption is assumed as 2 L/adult/day. An average body weight of 60 kg is used to translate the TDI into a contaminant limit in drinking water. The use of health-based limits is justified due to the possibility for risk comparisons, priority setting, and transparency of the approach.

However, the setting of tolerable limits of contaminants in drinking water is influenced by a variety of other considerations (Dieter, 2009). For example, the tolerable limit for plant protection products in drinking water in the EU is set at 0.1 µg/L, based on the "precautionary principle" despite the availability of high quality toxicology studies covering all endpoints to be considered in risk assessment. In contrast to the EU, some member states, the WHO and other regulatory bodies define toxicology-based limits for plant protection products. The tolerable concentrations of other anthropogenic contaminants in drinking water are often in good agreement with the health-based limits. In contrast, for geogenic contaminants such as arsenic or chromium^{VI}, or for contaminants introduced into drinking water by agriculture (nitrate), the tolerable concentrations may be above health-based limits (Melching-Kollmuss *et al.*, 2010). The main reason for such differences may be feasibility and cost-efficiency of reduction measures and inability to allocate such contaminants to a specific source (Dieter, 2009).

SCHER is aware that the request for derogation results in concentrations of As, B, and F that are higher than the EU drinking water standards and by that will result in human exposure, which may exceed the tolerable daily intake. To what extent the proposed derogation will increase human exposure and by that exceeds tolerable daily intake levels is exemplified for different scenarios for boron (Table 1) and for arsenic (Table 2 and 3) as given in the annex. It is evident that for all scenarios the PTWI value is exceeded when As drinking water concentrations are higher than 20 µg/L. However, considering the way that drinking water standards are set, concentrations that exceed these values are not automatically associated with adverse health effects. It is the aim of the SCHER's opinion to evaluate whether there is toxicological and/or epidemiological evidence that drinking water concentrations up to 50 µg/L As, 3 mg/ml B and 3 mg/L F for 3 years may lead to adverse health effects.

3.2. Derogation request for boron

Boron is an essential element for plants, essentiality for humans has not been convincingly demonstrated. The toxicology of boron (in the form of borate) is intensively studied and a tolerable upper intake level (UL) in humans of 0.16 mg/kg bw/day (10 mg/adult) was derived by EFSA from the results of a comprehensive reproductive toxicity study (reduced foetal weights at 13.3 mg/kg bw/day and skeletal malformations at in offspring at 25.3 mg/kg bw/day in the absence of maternal toxicity) in rats with a NOAEL of 9.6 mg/kg bw/day using a safety factor of 60 (EFSA, 2004). This UL also applies to pregnant and lactating women. UL values for children were derived by extrapolating from the UL for adults on a body surface area basis, giving values (mg/day) of 3, 4, 5, 7 and 9 for children aged 1-3, 4-6, 7-10, 11-14 and 15-17 years of age, respectively. In the US, the Institute of Medicine of the National Academy derived an UL for adults of 20 mg boron/day (0.28 mg boron/kg/day for a 70 kg person), of 17 mg boron/day for pregnant women 14-18 years of age, and 20 mg boron/day for pregnant women 19-50 years of age (IOM, 2001). The US EPA defined a reference dose (RfD) for boron (RfD represents the human dose that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime) of 0.2 mg boron/kg bw/day (14 mg/adult/day) (EPA-IRIS, 2004).
Consumption of drinking water with boron concentrations at the EU-legal limit of 1 mg boron/L will already cover 20% of the UL for boron. In a recent Austrian-risk assessment report (Austrian-RAR, Transitional dossier), the typical intake of boron from food was estimated at approximately 1.5 mg per adult. For worst-case estimations, the RAR suggests values of 1.94 and 2.7 mg boron/adult. A contribution of 2 mg from drinking water based on the EU drinking water limit of 1 mg/l was considered. Regarding the

request for derogation, using the boron food intake from the Austrian-RAR, the total intake of boron in a region with a drinking water concentration of 3 mg/L will remain below the EFSA-UL for boron for adults. In children, using the intakes of drinking water from the exposure assessment to fluoride in a recent SCHER opinion (0.46 L/day for children aged 1 – 12 years, and 0.56 L/day for adolescents aged 12 – 15 years), the boron intake will also remain below the EFSA-UL. However, the consumption data of drinking water used by EFSA (2005) is low. The data on water intake in children from 1 to 12 years of age show some variability (from 0.5 to 1.3 L/d). Considering that water consumption in Italy, as a warm country, may be higher than the EU average, a conservative scenario of 1 L/day is assumed. In this case, the EFSA-UL for boron will be exceeded for children due to additional intake of boron with food. When the drinking water is used for the preparation of infant formula and a conservative scenario for formula consumption is applied, the EFSA-UL is also exceeded. However, in both scenarios, the boron intake will remain below the UL derived by the US National Academy.
A higher boron exposure is expected for some subpopulations. Vegetarians receive more boron from food due to the high boron content in some vegetables. It should be noted that using the 95th percentile of boron food intake for vegetarian women of 4.18 mg/day (Rainey *et al.*, 1999) as realistic worst-case estimate, the EFSA-UL would be slightly exceeded at a drinking water concentration of 3 mg boron/L also in adults.
Occupational exposures should be also considered in certain cases. The Austrian-RAR already indicates potential concerns for several work-place scenarios; if relevant, the increased contribution to the systemic exposure from drinking water should be considered when setting risk management measures at the work place. Finally, the Austrian-RAR suggests low exposure levels from consumer products; however the Austrian assessment does not cover some sources that may become relevant for specific groups of consumers, such as the use of boron in cosmetics, biocides, and photographic applications.

3.3. Derogation request for arsenic

Arsenic in drinking water mostly results from the erosion of soil and solution of ores in ground water. While arsenic may be an essential element in some animal species, there is no evidence of essentiality or deficiencies in humans. With drinking water, humans are usually exposed to inorganic arsenic (arsenite and arsenate); at the present legal limit, humans are exposed to approximately 20 µg As (0.33 µg As/kg bw/day for a 60 kg adult) with drinking water. In contrast, food contains inorganic As-species and a number of organoarsenicals. Most of the organoarsenicals in food have a lower potential for toxicity as compared to inorganic As. Human exposures to inorganic arsenic from food range from 0.13 to 0.56 µg As/kg body weight/day for average consumers, and from 0.37 to 1.22 µg As/kg bw/day for 95th percentile consumers. Dietary exposure to inorganic arsenic for children under three years old is in general estimated to be about 2 to 3-fold that of adults (EFSA, 2009).
Exposures to high concentrations of arsenic in drinking water (> 200 – 2 000 µg/L) are associated with increased incidences of lung, skin and internal organ cancers, cardiovascular diseases, peripheral vascular disorders ("Blackfoot disease"), and skin effects (EFSA, 2009). As-induced cancer is the health-endpoint with highest concern due to the clear association of high As-exposures with drinking water and cancer incidence (COT-NRC, 2001). However, information on a potential increase in cancer incidence in humans exposed to drinking water with As concentrations < 100 µg/L is inconsistent due to difficulties in estimating past exposures and possible confounders (Cantor and Lubin, 2007; Kitchin and Conolly, 2010). Animal toxicity studies with arsenic do not provide a solid basis for extrapolation and definition of a cancer risk at low daily As intakes with drinking water.
The US National Research Council (COT-NRC, 2001) performed a risk assessment for As in drinking water using a linear extrapolation of observed tumor incidences at high As-concentrations to derive risk estimates at lower As-intakes from epidemiological data

(Taiwan and Chile). This extrapolation already predicts a significant cancer risk at the present EU-legal limit. Based on the current US-EPA cancer slope-factor for arsenic, calculated excess cancer incidences (lifetime drinking water intake of 2 L/day, a concentration of 10 µg As/L) are between 24 (females) and 46/10,000 (males) for bladder cancer and 36 (females) and 28/10,000 (males) for lung cancer. Integration of dietary exposure to As at the 90th percentile and drinking water consumption data (for the US) was estimated to provide an excess cancer risk of 1/1,000 based on the assumption of compliance with the US drinking water standard of 10 µg As/L (Tsuji *et al.*, 2007). Application of the NRC risk estimates to the derogation request (50 µg As/L for an additional three years) translates into an additional cancer risk for both cancer sites in the range of 1.5 - 3/10,000.

However, the results from the linear extrapolation of cancer incidences at high As-intakes are inconsistent with a number of recent observations. A meta-analysis (Chu and Crawford-Brown, 2006; Chu and Crawford-Brown, 2007) combining seven epidemiological studies on As-induced cancers from different regions and applying dose-response modeling predicts a much lower excess lifetime risk for bladder cancer (between 0.8 to 6.3/10^{-5} at lifetime exposure to 50 µg As/L). No increase in excess bladder cancer risk at lifetime exposures to 50 µg As/L was indicated in a second meta-analysis only considering studies with lower As-exposures (Mink *et al.*, 2008). These analyses are consistent with or integrated the results of recent comprehensive epidemiology studies in the US (Meliker *et al.*, 2010) and in Denmark (Baastrup *et al.*, 2008), which did not observe increased cancer risks in individuals exposed to arsenic concentrations below 10 µg/L (US) or between 0.05 – 25.3 µg/L (Denmark). The study in Denmark reported a decreased incidence of non-melanoma skin cancer at As-higher exposures. A study in Taiwan (Chen *et al.*, 2010) also did not observe a statistically significant increased risk for urinary tract cancer in individuals exposed to < 100 µg As/L. Based on the predicted excess tumor incidence by the linear extrapolation, a significant increase in excess cancer incidence should be observable in these populations. In addition, a number of studies on the mode-of-action for tumor induction by As also support a non-monotonous dose-response in the low dose region since inorganic As and its metabolites are not DNA-reactive and likely induce tumor formation by indirect mechanisms such as "oxidative stress" (Kitchin and Wallace, 2008; Kitchin and Conolly, 2010; Hughes *et al.*, 2007). In summary, the available information indicates that the requested derogation may only induce a very low additional tumor risk, probably less then 1/1 000,000 and thus much less then that predicted by the NRC-extrapolations.

3.4. Derogation request for fluoride

The concentrations of fluoride in ground water in the EU are variable and large variations exist between and within countries, e.g., Ireland <0.01- 5.8 mg F/L, Finland 0.1-3.0 and Germany 0.1-1.1 (EC-SCHER, 2010). Fluoride intake from food is generally low; therefore, intake of drinking water and use of fluoride-containing dietary supplements are major sources of fluoride exposures. An UL for fluoride has been derived by the EFSA NDA panel in 2005, based on the induction of mild dental fluorosis as the critical endpoint (prevalence of more than 5%). ULs are 1.5 mg/day for children 1-3 years of age, 2.5 mg /day for children 4-8 years, 5 mg /day for children 9-14 years of age, and 7 mg/day for populations 15 years and older. ULs for fluoride have not been established for infants. For infants up to 6 months old, the UK DoH (1994) concluded that 0.22 mg F/kg bw/day is safe and the US IOM (1999) derived an UL for fluoride of 0.1 mg/kg bw/day.
In an opinion on drinking water fluoridation (in preparation), SCHER concluded that for adults and children over the age of 8 years, the total intake of fluoride from all major sources is below the UL, when drinking water concentrations of fluoride are below 3 mg/L, even when drinking water intake is > 3 L/day. For children from age 1 to 6, provided tooth brushing behaviour is appropriate and water consumption is less than 1.0 L/day, only fluoride levels in drinking water below 0.8 mg/L have a low risk of developing mild dental fluorosis (presence in less than 5% of the exposed population). Therefore, a

higher risk for mild dental fluorosis in children is already present at the legal drinking water limit of 1.5 mg fluoride/L and is obviously higher at the proposed values of derogation. Intake of fluoride by formula fed infants, when applying a conservative estimate of drinking water use for formula preparation and a drinking water concentration of 1.5 mg F/L (present legal limit), the UL is marginally exceeded. The risk of mild dental fluorosis in formula-fed children is also increased due to the higher exposures to fluoride in the area of derogation.

3.5. Final conclusion

Notwithstanding the fact that drinking water concentrations exceed the EU standards and therefore potentially give cause for concern, SCHER is of the opinion that taking into account the toxicological and epidemiological evidence the risks for all age categories are tolerable in general. Based on its evaluation of the potential risks of human exposure of inorganic arsenic, boron and fluoride in drinking water, SCHER concludes as follows:

i) the prolongation of the derogation for drinking water containing up to 50 microg/L As, 3 mg/L B and 2.5 mg/L F for up to 3 years does not result in or, at most, very low additional health risks in the adult population.
ii) The UL for boron may be reached or can be slightly exceeded in children below 3 years age at a high consumption of drinking water.
iii) For boron and fluoride, the ULs are also marginally exceeded in non-breast fed infants when drinking water is used for the preparation of infant formula and a conservative scenario for formula feeding is applied.

4. Minority opinion

The minority opinion has been agreed upon by Prof U. Ackermann and Dr. S. Canna-Michaleidou and affects section 3.3 of the opinion (derogation request for arsenic).

Beyond the discussion provided in the opinion, we consider essential for an integrated evaluation of potential risks, to estimate the exposure at the proposed derogation values at least for sensitive groups like infants and children and to evaluate the daily intake with available benchmark values. We disagree with the final assessment of the opinion because even though these calculations on exposure are presented in the annex there were not taken into consideration for the final assessment and conclusions.

The provisional tolerable weekly intake (PTWI) established for arsenic (15 µg/ kg, by JEFCA) was used, as the only one available as benchmark value, for indicative evaluation at different exposure scenarios. We are aware that the CONTAM Panel of EFSA in its opinion of 2009 noted that "new data had established that inorganic arsenic causes cancer of the lung and urinary tract in addition to skin and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA". The CONTAM Panel concluded "that the overall range of BMDL01 values of 0.3 to 8 µg/kg b.w. per day should be used instead of a single reference point in the risk characterisation for inorganic arsenic".

It should be also noted that As intake through food and air (in particular in smoking environment) was not taken into account in this evaluation because of the lack of data. The situation for lactating and pregnant women was also not evaluated because of lack of data and time constraints.

Based on the above arguments and calculations our conclusions are as follows:

The potential risks of human exposure to arsenic, boron and fluoride in drinking water, containing up to 50 µg/L (of As), 3 mg/L (of B), and 2.5 mg/L (of F) for up to and maximum of 3 years may result in low additional health risks in the adult population. However, in the case of children up to 18 years and non-breast-fed infants, considering at least their comparatively higher intake (see tables 1-3), the risks are higher. The major concern is for arsenic, in particular for levels greater than 20 µg/L. The overall

risk will also depend on the total exposure from food and air (especially in homes with smokers).

5. LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
ATO	Ambito Territoriale Ottimale
D. Lgs.	Decreto legislativo
DWD	Drinking Water Directive
EU-RAR	EU-risk assessment report
MPVs	Maximum permissible values
NOAEL	No-observed-adverse-effect-level
PTWI	Provisional Tolerable Weekly Intake
TDI	Tolerable Daily Intake
UL	Tolerable Upper (intake level)

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Annex

Table 1. Boron exposure for Infants

Age months	Kg	UL mg/d	ml water as 90% of Formula	ml formul	1ppm	2ppm	
3	6.1	0.976	954	1060	0.954	1.908	
6	7.9	1.264	1272.6	1414	1.2726	2.5452	
12	9.6	1.536	1546.2	1718	1.5462	3.0924	SCM

Table 2: Arsenic exposure for infants at ages 3, 6, and 12 months

Arsenic PTWI 0.015 mg/kg (of water) corresponds to approximately 0.0021 mg/kg/bw/day

	Age months	Kg	ug/d	ml formul	net ml of water 90%	50 ug/l	40ug/l	30ug/l	20 ug/l	15ug/l	10 ug/l
WHO*		5	10,5		750	37,5	30	22,5	15	11,25	7,5
	3	6,1	**12,81**	1060	954	**47,7**	**38,16**	**28,62**	**19,08**	**14,31**	**9,54**
	6	7,9	**16,59**	1414	1272,6	**63,63**	**50,904**	**38,178**	**25,452**	**19,089**	**12,726**
	12	9,6	**20,16**	1718	1546,2	**77,31**	**61,848**	**46,386**	**30,924**	**23,193**	**15,462**
WHO*		10	21		1000	50	40	30	20	15	10
	*WHO 2006 default values for water consumtion										

Table 3: Arsenic exposure for children 1 to 18 years of age

Arsenic PTWI 0.015 mg/kg (of water) corresponds to approximately 0.0021 mg/kg/bw/day

					Assume that there is no other exposure 100% allocation to water							
		Range Kg*		Water from drinks**	accepted total intake		50 ug/l	40ug/l	30ug/l	20 ug/	15ug/l	10 ug/l
Children	1-3 years	10,9	13,4	0,9	22,89	28,14	45	36	27	18	13,5	9
Children	4-8 years	16,7	25,3	1,2	35,07	53,13	60	48	36	24	18	12
Boys	9-13 years	28,13	44,95	1,8	59,073	94,395	90	72	54	36	27	18
Girls	9-13 years	28,5	46,1	1,6	59,85	96,81	80	64	48	32	24	16
Boys	14-18 years	50,77		2,6	106,617	0	130	104	78	52	39	26
Girls	14-18 years	50,28	56,6	1,8	105,588	118,86	90	72	54	36	27	18

The calculations of daily intakes of As are based on the ULs for fluoride and boron and the JECFA PTWI (15 µg/kg bw/week) for As established in 1981. The tables describe specific exposure scenarios for different age groups and compare them to the PTWI.

Table 2 shows that the As-exposures calculated for the different scenarios exceed the PTWI values for infants.

Table 3 shows that the PTWI is exceeded in children from 1-18 y even without considering additional exposure from food and air in particular due to ETS. Indicative calculations were made for ages 1-18 years based on all available data. Water consumption data are taken from Canadian Guideline Technical Documents, Arsenic, Health Canada 2006 whilst children weight data were taken from USA National Centre of Health Statistics by using the 50th% values.

However, SCHER notes that EFSA recommends that the PTWI should not be further used:

„The CONTAM Panel concluded that the provisional tolerable weekly intake (PTWI) of 15 µg/kg b.w. established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is no longer appropriate as data had shown that inorganic arsenic causes cancer of the lung and urinary bladder in addition to skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA".

Therefore, SCHER is basing its conclusions on the most recent human epidemiology data as evaluated in the text.