(1) ***What evidence does the Minister or Department have to prove that fluoride is safe for long-term daily consumption by humans? Note: since the Expert Body on Fluorides and Health is without expertise in toxicology, we do not regard safety assurances from this source as an answer to this question.***

Water fluoridation is the adjustment of the natural concentration of fluoride in drinking water to the optimal recommended level for the prevention of dental caries (tooth decay). The only known side effect of optimal levels of fluoride in water is enamel fluorosis, and this has been known since the 1930s. A number of other claims have been made in various media in relation to water fluoridation and potential health issues but none of these claims has been substantiated.

Safety is determined from the available scientific evidence. This evidence has been examined in detail by panels of experts from many diverse fields of science including medicine, dentistry, biochemistry, toxicology, environmental sciences and engineering.

Comprehensive and systematic reviews have been conducted in many countries including the United Kingdom (York Review 2000, Medical Research Council 2002), Australia (2007), Canada (2010) and most recently the European Union (2011). None of these reports has established any basis for considering that artificially fluoridated water poses any systemic health risks.

The Forum on Fluoridation, established by the Minister for Health in 2000, and which had senior representation from a broad range of relevant sciences, considered the issue of water fluoridation. They found there was no evidence at that time of any negative health effects, stating that

> "*The best available and most reliable scientific evidence indicates, that at the maximum permitted level of fluoride in drinking water at 1 part per million, human health is not adversely affected*" (Forum on Fluoridation, 2002).

The Irish Expert Body on Fluorides and Health was established in April 2004. The Expert Body and its sub-committees have broad representation from areas such as dentistry, biochemistry, environmental health and public health medicine. The sub-committees of the Expert Body may also co-opt members as the need arises, for example in toxicology, and seeks the advice of experts in other specific fields when required. The Minister of State and the Department believe that it is important that policy makers and the public have access to independent, evidence-based, expert advice on this issue and are satisfied that the Expert Body provides such advice.

(2) Has the Department carried out any research to ascertain the effects, other than in relation to tooth decay, of the fluoridation of the water supply in Ireland? If not, why not? And on what basis has the claim been made that the policy is having no adverse health impacts on Irish people's health?

The only known side effect of water fluoridation is enamel fluorosis, which is a cosmetic or aesthetic condition which refers to the way teeth look; it is not considered to be an adverse health effect.

The Department of Health, in addition to monitoring the impact of water fluoridation on dental decay, has also rigorously monitored enamel fluorosis and responded to evidence of change in fluorosis levels. In the National Survey of Children's Oral Health (1984) it was found that lifetime residents of fluoridated communities had substantially lower levels of dental decay than lifetime residents of non-fluoridated areas. The levels of fluorosis found were at levels predicted on the basis of the initial studies in the United States in the 1940s on communities served by naturally fluoridated water. Some 18 years later in the 2002 study on Children's Oral Health, again it was found that levels of dental decay were substantially lower in lifetime residents of fluoridated communities, but there had been an increase in the levels of enamel fluorosis. Since the levels of fluoride in water had not changed over this period, the most likely explanation for this change was the increased use of fluoridated toothpaste which had been introduced to Ireland in the early 1970s and became widely used in Ireland by the 1980s. The EU FLINT study, which involved seven European research groups, had reported that parents tended to commence toothbrushing of children at too young an age, that too much toothpaste was being placed on the toothbrush, and that young children had a tendency to swallow the toothpaste. As a result of these findings, The Forum on Fluoridation introduced two strategies to minimise fluorosis. The first of these was in relation to the appropriate use of fluoride toothpaste, and the second was to lower the level of fluoride in water from a range of 0.8 to 1.0 parts per million (mg/l), with a target of 0.9ppm, to a range of 0.6 to 0.8ppm with a target of 0.7ppm, in order to account for the extra availability of fluoride to the population. This second approach was consistent with evidence from Canada following research by Locker et al.

Regarding general health, the Department of Health considers evidence on all health effects in relation to all health issues from across the globe. For example, we accept the evidence that smoking is harmful even when none of the studies linking smoking to ill health effects were conducted in Ireland. We do not need to repeat these studies here in order to establish that smoking is harmful for people living in Ireland.

The same is true in the case of water fluoridation, which is one of the most widely studied public health policy initiatives in the world. The Department of Health uses information from across the globe in order to assess the health impact of water fluoridation. Public health workers in Ireland make use of official statistics published regularly by the World Health Organisation, the OECD, the European Union and others in order to monitor health trends.

In Ireland, there was a study into cross-border rates of osteosarcoma (Comber et al, 2011) as a result of concerns raised in the United States regarding the plausibility of a link between this condition and fluoride exposure. This study did not show any difference in disease rates between fluoridated and non-fluoridated communities. Since the Comber et al study was

published, definitive results from two major studies in the United States has shown no association between fluoride exposure and osteosarcoma (Kim et al 2011, and Levy et al 2012).

(3) Does the Department know what the average level of fluoride is in the urine, blood, bone and hair of people in the State?

The determination of the fluoride concentration in body fluids such as urine and blood is useful as an indication of recent fluoride intake only (see Question 4 below). Renal fluoride excretion varies, moreover, with urinary flow and pH. Therefore, the term "average level of fluoride" has little real meaning, as these values vary widely during the course of a single day. There is no clear-cut relationship between fluoride content in bone and extracellular fluids.

One of the best biomarkers for fluoride absorption is the level of enamel fluorosis in the population. Irish researchers have rigorously monitored this condition for over 30 years.

(4) Have attempts been made to collect such values on a systematic or scientific basis? If not, why not?

No, because there is no reason to do this. The Department agrees with the views of the EU Scientific Committee on Health and Environmental Risk (SCHER) working group that:

> "*At present, there are no reliable biomarkers to assess fluoride exposure. The Working Group and SCHER expressed concern over the use of urinary biomarkers as indicators of fluoride exposure because they are considered to be unreliable due to fluctuations in urinary flow and pH which influence fluoride output. Therefore data from the UK National Diet and Nutrition Survey of 2000-2003 providing evidence of 24-hour urinary fluoride output and water fluoride concentration have not been presented in the opinion. A paragraph to this effect has been added to the SCHER opinion, and development and validation of appropriate biomarkers recommended as a research need.*" (SCHER Report explanatory note 2011).

As stated in question 3 above, the meticulous monitoring of enamel fluorosis is widely regarded as a reliable and non-invasive method for ongoing monitoring of fluoride exposure.

The measurement of the fluoride content of nail clippings is a promising technology which is currently in development (Whitford).

(5) Prestigious scientific associations, as well as thousands of individual scientists internationally, assert that fluoridated tap water poses unacceptable risks to human health. It is for this reason, as well as on ethical grounds, that other EU member states

do not fluoridate their water supplies. There are many quality peer-reviewed scientific studies associating serious health risks with fluoridated tap water. Why does the Irish Department of Health believe that it is safe to ignore the growing body of international scientific opinion which holds that fluoridated water presents an unacceptable danger to human health?

The Department does not accept that there is such a "growing body of scientific opinion". In fact European Council Directive 98/83 legislates and allows for a maximum permitted concentration of fluoride in drinking water up to 1.5mg/litre (or parts per million(ppm)), which is almost twice the maximum level permitted for water fluoridation in Ireland. This does not suggest that other EU Member states view that 'fluoridated tap water poses unacceptable risks to human health'.

The Expert Body advises that the balance of scientific evidence worldwide confirms that water fluoridation, at the optimal level, does not cause any ill effects and is the safest and most cost effective method of protecting the oral health of the population. The opinion of the Expert Body is supported by the World Health Organisation; the Centre for Disease Control and Prevention, the Public Health Service and the Surgeon General of the United States; the World Dental Federation; the International Association for Dental Research; the Royal College of Physicians of England and by major international scientifically validated reviews in many countries.

(6) Considering that Irish people are consuming fluoride from other sources as well as from tap water, how can the Department of Health guarantee that individual citizens in Ireland – including vulnerable sub-groups such as women with babies in utero, newborn infants, people with particular illnesses, and children with disabilities (for example, who are unable to spit out toothpaste) – are not ingesting a higher than recommended level of fluoride?

There are no reasons to consider any of the groups mentioned as being at risk of adverse health effects from fluoridated water.

According to the WHO "*In setting national standards or local guidelines for fluoride or in evaluating the possible health consequences of exposure to fluoride, it is essential to consider the intake of water by the population of interest and the intake of fluoride from other sources (e.g., from food and air). Where the intakes are likely to approach, or be greater than, 6 mg/day, it would be appropriate to consider setting a standard or local guideline at a concentration lower than 1.5 mg/litre*."

In Ireland we have a concentration much less than 1.5mg/litre or parts per million(ppm) (as set out in Council Directive 98/83 EC), as the maximum limit permitted in fluoridation schemes in Ireland is 0.8mg/l (0.8ppm). The water is tested for existing water fluoride

content before any fluoride is added. The final product of 0.8ppm is a combination of the existing and the added fluoride. Water is known to be the major source of fluoride in the diet.

The quotation of an upper tolerable limit of 6mg/day requires some comment, as such limits have safety margins already built in. This is explained well by the European Food Safety Authority in its *Tolerable Upper Intake Levels for Vitamins and Minerals* (2006), which settled on a slightly different value of 7mg/day. They derived this figure from the potential health effect they could determine at the lowest level of fluoride exposure, which they determined to be an increased bone fracture risk associated with fluoridated water ranging from 4.32ppm to 7.97ppm in Chinese populations (Li et al 2001). The estimated intake for this population was 14.1mg/day, so the EFSA applied a safety margin of 2 to determine the Tolerable Upper Intake of 7mg/day.

All estimates of Tolerable Upper Intakes have an inbuilt safety factor, in this case the upper limit is defined as one half of the level at which it is thought any adverse effect may occur, and in this case the risk of bone fracture is determined to be the most sensitive condition.

An added complication is the evidence that too little fluoride might also raise fracture rates. The same study quoted by the European Food Safety Authority (Li et al 2001) reports that

> *"A U-shaped pattern was detected for the relationship between the prevalence of bone fracture and water fluoride level.* ***The prevalence of overall bone fracture was lowest in the population of 1.00-1.06 ppm fluoride in drinking water****, which was significantly lower ($p < 0.05$) than that of the groups exposed to water fluoride levels greater than or equal to 4.32ppm, and less than or equal to 0.34 ppm*".

Phipps et al (2001) also reported statistically significant reduced risk of hip and vertebral fracture in fluoridated populations compared to low fluoride populations in the UK. However, the York Review found neither damage nor protective effect from the available evidence and the Expert Body takes a similar view.

(7) Is the Department aware of the studies showing that the prevalence of dental fluorosis representing chronic overexposure of the population to fluoride is now endemic in Ireland?

The presence of enamel fluorosis at the levels found in the Republic of Ireland do not pose a public health problem. The optimal level of fluoride in water has always been associated with a low level of very mild enamel fluorosis in addition to its positive impact in reducing levels of dental decay.

As you are aware, the Expert Body on Fluorides and Health advises the Department on such matters. The author of one of the studies you cited in one of the articles in *Hot Press* is a member of the Expert Body. The level of fluorosis reported in this study of five-year-olds was very low and mostly confined to back teeth. The Expert Body and the Department are aware of the incidence of fluorosis, the only known side effect of fluoridation. Dental

fluorosis is a cosmetic or aesthetic condition which refers to the way teeth look; it is not considered to be an adverse health effect. At the levels at which fluoride is present in Ireland's water supplies (0.6 – 0.8 parts per million (ppm)) any occurrence of dental fluorosis is very mild or mild and in most cases only detectable by a dentist as faint white flecks on the surface of teeth. Not all enamel defects are caused by drinking fluoridated water. In the majority of cases dental fluorosis generally does not require any treatment but anyone who has any concerns in this regard should consult their dentist.

This must be contrasted with the treatment of tooth decay which may on occasion involve the use of general anaesthesia and hospitalisation. Furthermore, non-treatment of dental fluorosis has no health consequences, whereas non-treatment of tooth decay can lead to pain, trauma, disfigurement, loss of teeth and function, problems with nutrition and growth, work/school absenteeism and significant financial and social cost.

(8) Does the Department accept that the high dental fluorosis rates prevalent indicate that Irish children are currently getting too much fluoride?

No. It has been known since the 1940s that the presence of fluoride in water would be accompanied by a low level of mild dental fluorosis. This is not an indication of too much fluoride, since mild dental fluorosis is a surface level effect on dental enamel and is not in any way associated with any adverse health effect.

Symptoms of chronic excess consumption of fluoride, such as skeletal fluorosis, have not been reported in Ireland. According the WHO, European Union and OECD statistics, musculoskeletal symptoms that might be alleged to mimic signs of skeletal fluorosis are at quite low levels in Ireland. Such symptoms are endemic in parts of the world where there are high levels of naturally occurring fluoride in the groundwater, many times higher than the levels found in fluoridated water in Ireland. Dental fluorosis is a cosmetic or aesthetic condition which refers to the way teeth look; it is not considered to be an adverse health effect.

(9) Why do the Minister and Department believe that it is safe to ignore the findings of international peer-reviewed studies that have found fluoride to be a neurotoxin and that modest exposure lowers IQ in children in geographic areas with endemic fluorosis?

The Minister and the Department do not have such a belief and have not ignored that study you cite. The Harvard study referred to was a review of studies mainly from China. These studies were assessed by the Expert Body in 2011 and were found to be of no relevance to Ireland given our regulated fluoridation levels. Their view is that the overall design of the studies is poor and they do not provide evidence of any effect on children's IQ from either high or low fluoride levels. The EU Scientific Committee on Health and Environmental Risks (SCHER) in its 2011 Report shared this view of the studies.

The Deans of Harvard Medical School and the Harvard School of Dental Medicine have recently (22/3/13) confirmed their support of water fluoridation as a safe public health measure for people of all ages and have stated:

> *"Numerous reputable studies over the years have consistently demonstrated that community water fluoridation is safe, effective, and practical. Fluoridation has made an enormous impact on improving the oral health of the American people. Our country is fortunate to have over 204 million Americans living in fluoridated communities and having access to the health and economic benefits of this vital public health measure."*

(10) Considering that most dental researchers now concede, as did the European Commission Scientific Assessment on Fluoride in 2010, that the major benefit of fluoride in relation to dental health is TOPICAL not SYSTEMIC, is the Department still justified in exposing the population systemically through drinking water?

It is simplistic to say that the major benefit of fluoride is "topical" rather than "systemic". The fluoride ion in saliva may act topically on the erupted tooth, but the availability of that fluoride ion is from systemic sources. In addition, there is a substantial pre-eruptive protective effect from fluoride (Grunewald et al 1990).

The situation is complicated by the site of the caries lesion on the tooth. Post-eruptive fluoride may have its greatest effect on the smooth enamel surfaces. Commenting on the effects on the biting tooth surfaces, on which the majority of early caries develops in young people, Singh et al (2007) stated the following:

> "*In conclusion a high exposure at crown completion was important for caries prevention irrespective of the effect of exposure at maturation and post-eruption. The strongest caries-preventive effect was produced by a high exposure at crown completion supplemented by a high exposure at maturation and/or post-eruption, but the latter two phases could not produce a significant caries-preventive effect on their own. Since most of the caries occurred on pit and fissure surfaces, the findings relate to this class of lesion*".

(11) What is the logic in exposing every tissue in the body – including the bones, the brain and the endocrine system- to a toxic substance or a potentially toxic substance, when its benefit can be achieved topically via fluoridated toothpaste?

Fluoride at the concentrations found in optimally fluoridated drinking water is not toxic. As stated above, this benefit cannot be achieved simply through use of fluoridated toothpaste. Fluoridated populations have lower levels of dental decay, irrespective of fluoride toothpaste usage. For example, in the All-Island survey of Children's Oral Health (2002), the decay levels were considerably lower in the lifetime residents of fluoridated areas in the Republic of

Ireland that residents of Northern Ireland, which does not have fluoridated water. Residents of both jurisdictions use fluoridated toothpaste but recent evidence shows that toothpaste usage is higher in Northern Ireland. From the same study, the percentage of 8-year olds who brush their teeth twice a day or more was 68% in Northern Ireland compared to 58% in the Republic. The corresponding figure for 15 year olds was 64% in the North and 57% in the Republic. Therefore, in spite of higher toothpaste usage in the North, decay rates are much lower in fluoridated areas of the Republic (Whelton et al 2002).

The logic derives from observing and then emulating a natural process. Lower tooth decay rates are found in areas in which people ingest naturally-present fluoride at levels close to 1 part per million (ppm). In such cases, human saliva contains a consistent level of fluoride to produce the beneficial topical effect. The origin of this fluoride is from ingestion.

One advantage is regarding population coverage, in that it is difficult to access children for examination and treatment prior to primary school age, and that very small children are sometimes unhappy to permit dentists to apply treatments to their mouths, at the very age when they need protection for their primary teeth, which begin eruption from 6 months onwards.

Water fluoridation is also cost-effective. The total cost per annum is in the order of €4 million – roughly one Euro for each inhabitant – and the entire population in fluoridated areas receives the benefit, adults and children alike. The cost of delivering a topical preventive service similar to that used in some of the Nordic countries would imply a very much greater cost simply to provide the preventive service to primary school children alone. In Finland, for example, the topical preventive programme involves every schoolchild being seen for examination and topical fluoride application by a dentist or dental hygienist twice a year. This would mean, in primary school alone, that a child would have 16 examinations and treatment programmes. In Ireland at present, the target is for each child to be seen three times for an examination in primary school, in 1st, 4th and 6th classes.

(12) Has the Department conducted or can it cite any randomised clinical trial that has conclusively demonstrated the effectiveness of water fluoridation in reducing tooth decay?

In common with cigarette smoking, obesity and a raft of other topics for health investigation, it is not possible to conduct a randomised clinical trial for water fluoridation. This same argument was used for many years as a defence by the tobacco industry to try to deny the findings of public health researchers.

We know that smoking is harmful. We know that obesity results in greater health risks. We know that driving after alcohol consumption increases the likelihood of a traffic accident. None of these could ever be tested using randomised control trials, but they are still known to be true.

The key distinguishing feature of the randomised clinical trial is that study subjects, after assessment of eligibility and recruitment, but before the intervention to be studied begins, are randomly allocated to receive one or other of the alternative treatments under study. For cigarette smoking, this means that from a recruited population of non-smokers, half would be selected at random and forced to take up smoking for a number of years while the rest are forbidden from smoking over the same time period. Similarly, for obesity, half of the randomly selected group would be forced to over-ingest for a long period while the other half would be forced to maintain a healthy diet. For fluoridation, half of the randomly selected group would be forced to live in, and not leave, a fluoridated area for 5 to 10 years while the other half could never enter a fluoridated area for this time period.

It can be quickly seen the idea of using the randomised clinical trial design is impracticable for many health studies. However, other randomised observational study designs have been used in longitudinal and cross-sectional epidemiological studies. It is these that provide the evidence in water fluoridation, in the same manner as they do for smoking and obesity.

The reliance on randomised clinical trials is inappropriate in many situations. For example, a prominent epidemiologist has stated that "The view is widely held that experimental methods (randomised control trials) are the gold standard for evaluation and that observational methods (cohort and case control studies) have little of no value. This ignores the limitations of randomised trials which may prove unnecessary, inappropriate, impossible, or inadequate (Black 1996)". Following these observations the STROBE initiative was promulgated (Downer 2007, von Elm et al 2008) to deal with these limitations and to emphasis the essential role of observational studies in developing the evidence base of many public health initiatives.

(13) What primary published peer-reviewed studies (as opposed to reviews) have convinced the Department that swallowing fluoride actually reduces tooth decay by a significant amount?

There have been many hundreds of peer-reviewed studies showing the benefits of water fluoridation. Examples of Irish studies include the 1984 Survey of Childrens Dental Health, the 2002 All-Island Survey of Childrens Dental Health, the CAWT study of 16 year olds in a border region in 2005, and the survey on the dental health of Adults in 2002, all of which have been published in peer-reviewed journals. Other recent studies include Slade et al (2013) on the impact of fluoridation on adults in Australia. The list is far too numerous to mention all. That is why reviews are useful – there is a superabundance of studies which can benefit from meta-analysis.

(14) Does the Minister agree that tooth decay is concentrated in families of low income? Why then is everyone else being subjected to the mandatory consumption of fluoride when there is no evidence that they need any dental treatment?

Fluoridation benefits people across all incomes, but may favour those in low income to a greater extent. In many public health programmes, particularly those delivered through individualised treatments, persons of lower income tend to miss out disproportionately. The reasons include issues such as literacy problems and lacking the resources to travel to appointments. An advantage of fluoridation is that all ages and all socio-economic groups receive the benefit at no cost or no effort to themselves.

However, the benefits of water fluoridation are not confined to those on lower incomes.

(15) Would the Department consider that it would make more sense to target children from low income families with education for better dental hygiene and better diet, rather than forcing an entire population to drink a toxic, or potentially toxic, substance.

Fluoridated water is not toxic and water fluoridation does not prevent other health promotion programmes.

It should be noted that for over the past 40 years, numerous dental health education campaigns have been undertaken in the Republic of Ireland. The Dental Health Foundation, which was established in the mid 1970s, regularly conducted national dental health weeks with a view to promoting oral health. The core messages have been (a) reduce the frequency of intake of foods containing sugar, (b) brush the teeth thoroughly at least once a day with a fluoride toothpaste, and (c) visit the dentist regularly, in order to control the progression of early signs of decay and gum disease. The Irish Dental Association and the oral healthcare industry generally have been to the forefront in these campaigns.

The evidence to date is that, while there may be an increase in knowledge regarding desirable oral health behaviour, changing to desirable oral health habits continues to be challenging. Similar findings have been reported in a systematic review of the effectiveness of health promotion campaigns aimed at improving oral health (Kay & Locker 1998). This is true of health education generally.

(16) Why does the Department believe that force-feeding fluoride to an entire population represents a better option than initiating a campaign to get children to consume less sugar and take personal responsibility for their teeth?

The effectiveness of fluoridation has been demonstrated in, for example the “North South Survey of Children’s Oral Health (2002)” which demonstrates the substantial benefits of

fluoridation in the Republic when compared to Northern Ireland. This is despite the fact that there are ongoing oral health promotion and healthy eating campaigns in both jurisdictions.

(17) Is the Department aware that, according to the European Commission, the toxicological characteristics of the chemicals are inappropriately known? (EU Scientific Committee on Health and Environmental Risks SCHER; Committee on Fluoride in Drinking Water, NRC, National Academy of Sciences, 'Fate of Fluorosillicate Drinking Water Additives', Edward Todd Urbansky, US EPA, 2002)

The SCHER report was unequivocal in stating that the only species of interest is the fluoride ion, since the fluoridating chemicals completely dissociate in water, and are therefore not present at the consumer's tap.

Urbansky's original estimate regarding HFSA dissociation was based on a theoretical model which, if anything, may have strayed on the side of being too cautious regarding the completeness of the dissociation. This theoretical framework was tested experimentally by Finney (2006), who reported that

> "*No fluorosilicate intermediates were observed, even under conditions of excess fluoride ion added. In addition, silica polymerization at moderate pH removed silicon from this equilibrium process,* ***resulting in a greater proportion of dissociated fluoride at moderate pH than expected from previously reported values of the dissociation constant****. The results of this study do not contradict previous findings that at pH7 and at typical drinking water formal fluoride concentration,* ***hexafluorosilicate dissociation to produce free fluoride ions will be essentially complete***".

No contradictory evidence is available. Finney's work was referenced by SCHER in its report.

(18) Based on numerous MSDS (material safety data sheets) it has been shown that one of the contaminants of these fluoridating chemicals is arsenic. Is the Department aware that the US EPA considers that there is no safe level of exposure to arsenic because it is a known human carcinogen? (Forum on Fluoridation Review 2002; "Arsenic in Drinking Water" WHO 2011, "Basic Information about Arsenic in in Drinking Water" US EPA) (19) What evidence has the Minister or the Department that the use of these arsenic-contaminated industrial grade chemicals in the water will NOT increase cancer rates in this country?

"Arsenic-contaminated industrial grade chemicals" are not used in fluoridation in this country. Only high quality chemicals are used in fluoridating water supplies in Ireland. The fluoride currently used is sourced as a primary product; it is mined directly from a raw material source, the mineral fluorospar as calcium fluoride (CaF2). It then goes through a

purification process to conform to tightly controlled specifications under the requirements of CEN Standard I.S.EN 12175:2001 to produce Hydrofluosilicic Acid (HFSA), specifically used as the mineral additive, fluoride, to water.

Furthermore, all public drinking water supplies in Ireland are monitored for a comprehensive range of drinking water parameters including Arsenic at a frequency prescribed by the European Communities (Drinking Water) (No.2) Regulations 2007 which gives effect to Council Directive 98/83/EC. These monitoring results show no evidence to support any assertion that the addition of HFSA is increasing undesirable chemical concentrations in drinking water supplied to the consumer.

(20) Does the Department consider it justifiable to risk increasing cancer rates in order to possibly reduce tooth decay by a very small amount via ingestion, when topical treatment with fluoridated toothpaste is just as effective?

The Department is not risking increasing cancer rates. The issue of topical treatment with fluoridated toothpaste was dealt with in Question 10.

There is no evidence that water fluoridation is associated with any increased cancer rates. The Irish Cancer Registry has stated that

> "*There is no good evidence to link fluoride levels in water, whether natural or added, to cancer risk. The International Agency for Research on Cancer has concluded "The relationship between cancer mortality or incidence and both natural and artificial fluoride in drinking-water has been investigated in a large number of descriptive epidemiological studies of population aggregates, carried out in Australia, Canada, New Zealand, Norway, the United Kingdom and the United States. None of the studies provided any evidence that an increased level of fluoride in water was associated with an increase in cancer mortality*" (http://www.ncri.ie/pubs/water%20fluoridation-6.shtml).

(21) Is the Minister aware that according to two scientific reports (Irish Study, published in Caries Research, Sept-Oct 2004 and EU Report from the Scientific Committee on Health and Environmental Risks, 2011), Irish children frequently exceed the upper limit set for fluoride consumption? Why does the Department of Health consider this overexposure risk to children and infants to be acceptable?

This finding relates to the risk of enamel fluorosis only and does not refer to any health risks. It confirms a fact that has been known since the 1930s, that water fluoridation will be accompanied by a low level of mild dental fluorosis.

22. In light of the many serious concerns over health risks raised by thousands of scientists and other experts, and a growing body of scientific evidence associating fluoride toxicity with harmful health effects, on what basis does the Department of Health believe that the Irish State's fluoridation policy conforms to the Precautionary Principle? (As an EU member state, Ireland is obliged to follow this principle.)

There is no "growing body of evidence" associating water fluoridation with any negative health effects. The Expert Body advises that the balance of scientific evidence worldwide confirms that water fluoridation, at the optimal level, does not cause any ill effects and is the safest and most cost effective method of protecting the oral health of the population.

Applying the Precautionary Principle in the extreme manner suggested to other areas of human endeavour would likely end in a non-functioning society. The European Union states that this Principle cannot be used to make simple arbitrary decisions in the manner suggested, but may only apply when three primary criteria are met, concerning the identification of potentially adverse effects, the evaluation of the scientific data available; and the extent of scientific uncertainty.

It is noteworthy that, following the SCHER report, neither SCHER nor the EU Commission has stated that the Precautionary Principle should be invoked in relation to water fluoridation.

23. Does the Department classify sodium fluoride as a medicine? If not, how is it classified? 24. Does the Department classify hydrofluorosilicic acid as a medicine? If not, how is it classified?

The Irish Medicines Board (IMB) is the competent authority for the licensing of human and veterinary medicines and medical devices in Ireland. Its role is to protect and enhance public and animal health through ensuring the quality, safety and efficacy of medicinal products available on the Irish market. Companies wishing to place medicinal products onto the Irish market must apply to do so to the Irish Medicines Board. Such applications are then assessed and only approved where the required standards of quality, safety and efficacy are met, in line with the requirements of European [Council Directive 2001/83/EC, as amended] and associated national legislation. This legislation addresses the need for licensing of medicinal products for human use but does not address the licensing of individual substances, such as fluoride. The IMB considers that neither drinking water itself nor the fluoride added to drinking water in the form of fluoride salts or silica fluoride, as defined in the Health (Fluoridation of Water Supplies) Act 1960, should be categorised as medicinal products requiring marketing authorisations. Drinking Water is regulated by Council Directive 98/83/EC which is given effect in Ireland by the European Communities (Drinking Water) (No.2) Regulations 2007. Drinking water also is regulated by the EC Regulation 178/2002

which specifies that water, when it comes out of the tap (point of compliance) is defined as a food or foodstuff unless it is otherwise defined as a medicinal product. The IMB considers that the fluoridation of drinking water should be seen as a measure consistent with general public health management.

The fluoride currently used is mined directly from a raw material source and goes through a purification process to conform to tightly controlled specifications under the requirements of CEN Standard I.S.EN 12175:2001 to produce Hydrofluosilicic Acid (HFSA), specifically used as the mineral additive, fluoride, to water.

As Minister, Alex White, told the Seanad on 30th January 2013 that hydrofluorosilicic acid added to Irish drinking water is supplied by Derivados del Fluor in Spain. It is our understanding that this product has not been clinically trialled and does not have a marketing authorisation in the EU. Since Irish fluoridation is based on the minister's medical claim in the Seanad of 'making teeth more resistant to decay in people of all ages', why has the Dept of Health not obtained legal authorisation for this use of hydrofluorosilicic acid in the EU, as is required to comply with the Clinical Trials Directive (2001/20/EC) and Medicinal Products Directive 2001/83/EC?
25. Based on what appears to us to be an ongoing infringement of EU law, has the Dept. of Health sought a derogation from the European Commission? And if not, why not?

As hydrofluorosilicic acid is not a medicinal product the issue of clinical trials or marketing authorization does not arise. Water fluoridation does not infringe of EU law.

It is helpful that the EU Commission has addressed such concerns in its replies to the petitions made by Irish and British antifluoridation campaigners (EU Petitions 0210/2007 and 0211/2007). The EU Commission clearly does not have any difficulty in law with the practice of water fluoridation. The Commission stated in 2007:

> "*Taking into account that there is no evidence of an infringement of EU law in this case, the Commission can take no legal action*".

More specifically, it ruled in 2008 that

> "*The Commission has scrutinised the practice of adding hexafluorosilicic acid to drinking water whilst adhering to the maximum permissible fluoride concentration values under the Drinking Water Directive. It confirms that it does not see any evidence of infringements of the Drinking Water Directive, the Dangerous Waste Directive and the Medicinal Products Directive.*"

The Commission also noted that there was no impediment to water fluoridation arising from international treaties:

> "*It must be noted that adding fluoride to drinking water is a national decision which does not flow from any obligation under Community law. "The Biomedicines Convention, focussing upon human rights and upon the involuntary application of*

medication has been opened for signature by the Council of Europe in Oviedo in 1997. However, the convention has not been ratified at this stage by the European Community, and for the time being it has no legal effects in the Community. Moreover, it is noted that according to the information available to the Commission, none of the EU members States which add fluoride to drinking water is a party to the Convention."

There have been no EU Commission statements or rulings from the European Court that have defined water fluoridation as being in any ways contrary to EU or international law.

26. Irish fluoridation policy is based on the report produced in 2002 by the government-appointed Forum on Fluoridation.
This report was criticised by an international team of eleven scientists, all experts on the effects of fluoridation. These scientists stated: "In our view, by failing to assess properly all the evidence available in the international scientific literature, the (Irish) Forum wasted a valuable opportunity to fully engage the scientific case opposing fluoridation… We can only conclude that the aim of the authors of this report (the Forum's) was not to study the evidence but to find ways to get around it. The report's primary conclusion that there are no adverse health effects is not defensible and in our view is blatantly false."
The scientists also concluded:
*** The Fluoridation Forum report failed to address a number of recently published important studies of fluoridation.**
*** It failed to establish a significant clinical difference in dental decay between children living in fluoridated and non-fluoridated communities in Ireland and throughout largely non-fluoridated Europe.**
*** It failed to 'deal convincingly with the issue of dental fluorosis', 'making several unsupportable assertions'.**
*** It failed to discuss the fact that certain individuals in a population are going to be 'more sensitive and more vulnerable to fluoride's toxic effects than others'.**
*** It failed to provide the necessary precautionary advice to mothers not to use infant formula made up with fluoridated tap water. Taking the above into account:**
26. Why does the Department of Health insist on following the advice of an 'Expert Body' whose foundation document recommending ongoing fluoridation has been so roundly condemned by prestigious international scientific experts?

The "foundation document" referred to is the report of the Forum on Fluoridation. The Forum consisted of people with expert knowledge spanning the areas of public health, biochemistry, dental health, bone health, food safety, environmental protection, ethics, water quality, health promotion and representatives from the consumer and environmental areas. This diversity of professional backgrounds and representation was reflected in the comprehensive way the Forum conducted its work and research. Ultimately, the Forum took an evidence based

approach to its examination of water fluoridation. An Expert Body was recommended by the Forum to oversee the implementation of the recommendations of the Forum and to advise on all aspects of fluoride. It is entirely appropriate that advice on scientific matters should come from those with the necessary expertise.

In contrast, the team of scientists to whom you refer state quite openly in their document that they are long standing and vocal lobbyists against water fluoridation rather than disinterested or objective commentators. Members of this group have also attacked the findings of the other scientific committees that have reviewed this question, for example the recent report of the European Union's Scientific Committee on Health and Environmental Risks (SCHER). The report of the Forum on Fluoridation has proved to be consistent with the other international reviews, and with the views of the World Health Organisation.

27. And finally, considering the criticism above, what is the reason for the Minister's and the Department's apparent resistance to establishing a fully independent inquiry into Ireland's policy of mandatory fluoridation of the water supply, taking on board all the new scientific evidence for the harmful effects of fluoride that have emerged since 2002, when the recommendation for ongoing fluoridation in Ireland was made?

Such an inquiry has already taken place. The Forum on Fluoridation reviewed the fluoridation of public piped water supplies in Ireland. The Forum's Report was published in 2002. Since then the Expert Body on Fluorides and Health has continued to review this policy and continues to monitor new research on fluoride-related issues. In the light of other international reviews, particularly that of the European Union (SCHER) to which the Department contributed, and which reported in 2011, there is no obvious need to conduct yet another such review at this time.

The Department continues to monitor the effectiveness and safety of water fluoridation in Ireland. The Department keeps the policy of water fluoridation under constant review and will undertake a comprehensive scientific review if the need for such an exercise becomes apparent in the future.