

Title: Healthy lives, healthy people: consultation on the arrangements for consultations on the fluoridation of drinking water. IA No: 3075-RC Lead department or agency: Department of Health Other departments or agencies:	Impact Assessment (IA)		
	Date: 13/03/2012		
	Stage: Consultation		
	Source of intervention: Domestic		
Type of measure: Secondary legislation			
Summary: Intervention and Options			RPC: AMBER

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, One-Out?	Measure qualifies as
£0.12m	£0m	£0m	No	NA

What is the problem under consideration? Why is government intervention necessary?

The responsibility for running consultations and contracting for fluoridation currently sits with Strategic Health Authorities (SHAs). However, SHAs will be abolished under the Health and Social Care (HSC) Bill, transferring these responsibilities to Local Authorities (LAs). Water supplies generally span more than one LA however, resulting in coordination problems. Therefore, fluoridation consultations and decisions may lead to costly legal disputes between LAs and between an LA and its population. A sensitive, robust set of regulations on conducting open and transparent consultations can minimise the likelihood of such disputes, for example by ensuring that consultations take into account the full impact of fluoridation on the population.

What are the policy objectives and the intended effects?

(i) Increase democratic accountability of the decision making process of fluoridation, reducing the likelihood of a disputes between LAs and between an LA and its populations by the public, and therefore minimising administrative burden. (ii) Minimise the administrative burden on LAs of running a consultation. (iii) Increase the likelihood that the LAs will maximise the health benefit to the local population, through taking into account the full set of costs and benefits in deciding whether to fluoridate. These regulations are solely about how to consult. We expect no impact on the likelihood of fluoridation itself and no impacts on Water Companies or other private organisations.

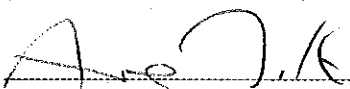
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing
 Option 2: Combination of different regulations (preferred option)

Not regulating (option 1) is not a possibility because SHAs will, subject to Parliament, be abolished from April 2013. The HSC Bill also prescribes that regulations must be laid with respect to some of the duties of LAs. The preferred option, therefore, is to use regulations to set out more details on how LAs should carry out their new responsibilities relating to fluoridation. There are several sub-options in this option, each detailing different levels of prescription over how LAs should act with respect to their new responsibilities. The full set is outlined in the Evidence Base.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Month/2012					
Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro No	< 20 No	Small No	Medium No	Large No
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent)			Traded: N/A		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 2/9/2012

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

These are defined to be zero.

Other key non-monetised costs by 'main affected groups'

These are defined to be zero.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0		0

Description and scale of key monetised benefits by 'main affected groups'

These are defined to be zero.

Other key non-monetised benefits by 'main affected groups'

These are defined to be zero.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
<p>The Government has committed to introducing regulations in some of these areas. Therefore, it is not possible to do nothing across the range of sub-options. In addition, if no regulations are laid then there will be a high chance of disputes in the process of consulting on fluoridation, with an associated administrative burden on local authorities.</p>		

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Summary: Analysis & Evidence

Policy Option 2

Description: Combination of different regulations (preferred option)

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0.12

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

No costs have been monetised.

Other key non-monetised costs by 'main affected groups'

The regulations will potentially increase the administrative burden on LAs to run a consultation, over and above what LAs would have done with no intervention. It is difficult to assess how LAs will choose to run a consultation in the absence of regulation, so such marginal costs cannot be monetised.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0.014	0.12

Description and scale of key monetised benefits by 'main affected groups'

The proposed set of regulations ensure democratic accountability in the decision-making process by prescribing the conduct of LAs in consulting on fluoridation. This decreases the likelihood of disputes including Judicial Reviews as a result of public legal challenge. The single consultation that has taken place since 1985 was disputed and cost the defendant approximately £350,000. The potential annual benefit of eliminating the possibility of a Judicial Review is therefore £14,000 p.a.

Other key non-monetised benefits by 'main affected groups'

The proposed regulations also ensure that disputes between different LAs in the same water region are minimised, with an associated reduction in legal costs. Further, they may have health benefits for the LA population by ensuring, through a prescribed conduct on consulting on fluoridation that any decision on fluoridation takes into account the fullest set of benefits and costs of such a scheme.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

It is assumed that giving the responsibility for proposing, consulting and deciding on fluoridation to LAs will not make fluoridation any more or less likely. However, subject to the final content of the regulations there is a risk that complexity of decision-making or lack of sufficient guidance will change the status quo. If appropriate/relevant, this will be assessed in the impact assessment of the final regulations.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OIOO?	Measure qualifies as
Costs: 0	No	NA
Benefits: 0		
Net: 0		

Evidence Base (for summary sheets)

Problem under consideration;

1. Water fluoridation is the controlled addition of fluoride to a public water supply to reduce tooth decay. Fluoridated water occurs naturally in all water supplies but generally needs to be supplemented to reach the one milligram per litre optimum level for reducing tooth decay. For the purposes of this IA, fluoridation is the process of adding fluoride to the local water supply.
2. Currently the responsibility for running consultations and contracting for fluoridation sits with Strategic Health Authorities (SHAs). The HSC Bill currently before Parliament abolishes SHAs and transfers the responsibility for proposing, and conducting consultations on fluoridation schemes from SHAs to local authorities. Therefore, the current regulations that govern processes in this area are no longer applicable.

Rationale for intervention;

3. The Bill prescribes that the Department must produce some and may produce other regulations setting out further details on how these new responsibilities must be carried out by local authorities. Please see Annex 1 for more details.
4. The water supply in England does not correspond to the boundaries of local authorities. Often a local water supply system will entirely span some LAs and also include areas from within the boundaries of other LAs. The design of the water distribution system means that if a local authority wanted to consult on fluoridation and decide on whether to fluoridate the local water supply several other LAs would most likely have to be involved. This leads to complex decision-making structures and potential scope for disputes.
5. In addition, experience from one area (Southampton) shows that setting up a fluoridation scheme may also result in disputes including a Judicial Review, a time-consuming and costly process. A suitably specific set of regulations around how consultations are run and decisions on fluoridation made should reduce as far as possible the possibility of encountering such disputes, and in particular any successful challenge to a decision.

Policy Objective

6. The policy objective is to ensure that any decisions on water fluoridation by LAs take into account the full benefits and costs in that area in a democratically accountable way. This will minimise the likelihood of any disputes, while also minimising the administrative burden on LAs of any consultation process.
7. The options do not intend to affect the likelihood of LAs fluoridating their water supplies. It will be for LAs to decide whether to consult on fluoridation. Subject to the consultation feedback, it will also be for LAs to decide whether to fluoridate the

water in a local area. If the historical trend continues, the Department expects that many LAs, after assessing the needs of their local population, may seek to address those needs by other public health initiatives than through fluoridation. For these areas, fluoridation regulations will have no impact.

Description of options considered (including do nothing);

8. The options considered in this Impact Assessment are
 - Option 1: Do nothing across all areas of consultation.
 - Option 2: Combination of different regulations (preferred option)

9. **Option 1: Doing nothing** across all areas of LA consultation is not a possibility because the HSC Bill prescribes that some regulations must be laid (see annex 1 for more information on which areas require regulation following the HSC Bill).

10. **Option 2: Combination of different regulations:** The preferred option is to produce new regulations which are more detailed in areas where the scope for dispute is high relative to the administrative burden, and less detailed in areas where such a possibility is low. The possible combinations are set out below:

Area 1: Reaching a decision on whether to consult

<i>1A Arrangements for decision-making</i>	
(i)	require the proposing local authority to provide sufficient information to allow the affected local authorities to make a decision whether to proceed and requiring the local authority to respond to requests for further information.
(ii)	As option 1 but the proposer should request confirmation that each authority considers its joints strategic needs assessment and its joint Health and Wellbeing Strategy as well as requesting confirmation that each affected local authority has consulted its director of public health.

<i>1B Conditions on the decision to proceed</i>	
(i)	Require a simple majority of affected local authorities to agree
(ii)	Require a super-majority (two-thirds) of affected local authorities to agree to proceed.
(iii)	Require all affected local authorities to agree to proceed.

Area 2: Committee membership and procedures

<i>2A Membership of a decision-making committee</i>	
(i)	Impose no additional requirements on local authorities.

(ii)	<p>Require that the joint committee reflects the membership requirement for Health and Wellbeing Boards. Under this option the committee would have the following statutory members:</p> <ul style="list-style-type: none"> • at least one councillor from each LA • at least one director of public health from each LA • at least one representative from local Healthwatch Organisation for each local authority • a representative from a clinical commissioning group for each of the affected local authorities • a number of other persons as the statutory committee members consider appropriate.
(iii)	<p>Require that the joint committee reflects the membership requirements for Health and Wellbeing Boards, but also mandate the balance between health specialists and democratic representatives on any committee. For example, we could specify that 50% of membership should be comprised of councillors and/or representatives of Health Watch.</p>
(iv)	<p>Require a membership model, which is distinct from the Health and Wellbeing Board for example that 50% of the membership should be comprised of elected members or representative of the local HealthWatch.</p>
<i>2B Variation based on type of committee</i>	
(i)	<p>Only specify conditions of membership for new committees established by the local authority</p>
(ii)	<p>Use regulations to specify that membership of a new joint committee, an existing committee and a joint sub-committee of the Health and Wellbeing Board should have the same minimum membership as a set out under 2A</p>
<i>2C Minimum and Maximum Membership</i>	
(i)	<p>Impose no requirements on local authorities as to numbers</p>
(ii)	<p>Prescribe a minimum number of members to ensure that decisions are not made by a small group in isolation</p>
(iii)	<p>Prescribe both a minimum and maximum numbers of members</p>
(iv)	<p>Prescribe a maximum membership</p>
<i>2D Varying approach based on number of local authorities involved. (4 or more)</i>	
(i)	<p>Apply the approach from 2A in all cases</p>
(ii)	<p>Exempt cases involving a large number of LAs from the approach set out in 2A and allow LAs to decide members of the joint committee. (e.g. impose no requirements on local authorities)</p>
(iii)	<p>Prescribe an alternative approach for joint committees where there is a large number of local authorities. In particular, to have a simple requirement that the committee would consist of equal numbers of representatives from each local authority (with the number agreed by the authorities or prescribed in regulations). Option 3 might also be combined with a requirement about the joint committee consulting the authorities or their Health and Wellbeing boards</p>

Area 3: Fluoridation decision-making, consultation procedure and assessing public opinion

<i>3A Consultation Process</i>	
(i)	Impose no requirements on local authorities and joint committees.
(ii)	Retain existing provision with minor revisions (e.g. without the requirement to notify local authorities)
(iii)	Retain existing provision and specify additional steps such as: <ul style="list-style-type: none"> • a requirement to circulate an information pack containing copies of the formal consultation document to Members of Parliament with constituencies that would be affected by implementation of the proposal, • a requirement to hold a press conference to announce the proposals, • a requirement to hold a public meeting, • a requirement to display posters on local authority premises.
(iv)	<ul style="list-style-type: none"> • Replace with an entirely new set of requirements such as the additional requirements in option 3Aiii.
<i>3B Information provided to the public</i>	
(i)	Impose no additional requirements on local authorities (beyond what is proposed in 3A)
(ii)	Prescribe in regulations that a local authority or the joint committee must in preparing the consultation material take advice from the relevant director (or directors) of public health.
(iii)	Prescribe in regulations particular requirements for a local authority or the joint committee in relation to informing the public during the course of consultation. For example, we could prescribe that a local authority or the joint committee must ensure participation of hard to reach groups, and/or that the local authority or the joint committees should take advice from the relevant director (or directors) of public health on the preparation of consultation material for the public. It would also be possible to prescribe that the consultation documents should be based on scientific evidence or that the consultation material must acknowledge that some people have ethical concerns.
<i>3C Evidence Base – Role of Public Health England</i>	
(i)	We invite responses to the consultation on the role that should Public Health England should play in supporting local authorities with their fluoridation responsibilities.
<i>3D Assessment of balance of public opinion</i>	
(i)	Impose no specific procedural requirements in relation to the local authority process for evaluating public opinion.
(ii)	Prescribe additional requirements. For example that a local authority or joint committee must conduct an alternative polling mechanism such as a referendum, a focus groups or a survey.

<i>3E Reaching a decision on whether to proceed with a fluoridation proposal</i>	
(i)	Impose no requirements on local authorities
(ii)	Replicate the current requirements. (e.g. a Strategic Health Authority shall not proceed with any step regarding fluoridation arrangements...unless, having regard to the extent of support for the proposal and the cogency of the arguments advanced, the Authority are satisfied that the health arguments in favour of proceeding with the proposal outweigh all arguments against proceeding).
(iii)	Prescribe different requirements: For example that a local authority or joint committee must in determining whether to proceed with a fluoridation proposal: <ul style="list-style-type: none"> • have regard to the views of the local population, and the extent of support for the proposal • have regard to the validity of the arguments advanced, having particular regard to the scientific basis of the representations for and against, and views on the ethical arguments about fluoridation. • have regard to the Joint Strategic Needs Assessment and Health and Wellbeing Strategy for the affected areas, • have regard to the financial implications of a fluoridation proposal • consider whether the health arguments in favour of proceeding with the proposal outweigh all arguments against proceeding
<i>3F Seeking agreement to fluoridate (two or three LAs)</i>	
(i)	Impose no requirements on local authorities or the joint committee.
(ii)	Prescribe that the joint committee must make a decision through majority voting but that the committee is free to determine whether a majority is sufficient, or whether a larger majority would be more appropriate through their own rules of procedure.
(iii)	Prescribe that the joint committee must make a decision by a super-majority (two-thirds) where equal numbers of members from each local authority have a vote.
(iv)	Prescribe that the joint committee must make a decision by a super-majority (two-thirds) but that local authorities would be free to determine their own rules of procedure including which members of the committee would be eligible to vote.
<i>3G Seeking agreement to fluoridate (four or more local authorities)</i>	
(i)	Impose no requirements on local authorities.
(ii)	Prescribe that the joint committee must make a decision through majority voting (with one vote per local authority) but that the detailed rules of procedure on what form that majority could take would be determined through their own terms of reference.
(iii)	Prescribe a requirement for a super majority threshold for proceeding where only one representative from each local authority has a vote.

(iv)	Prescribe a requirement for population-weighted voting in the joint committee with a super majority threshold for proceeding again where equal numbers of members from each local authority have a vote.
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Area 4: Variation of terms and maintenance of arrangements

<i>4A Circumstances where the Secretary of State may vary or terminate arrangements without a request from a local authority</i>	
(i)	Do not give the Secretary of State any powers to vary or terminate a fluoridation scheme without receiving a proposal from a local authority.
(ii)	Give the Secretary of State powers to terminate a fluoridation scheme without a local authority proposal where a general risk to health is identified from fluoridation or a specific risk emerges due to the actions of a particular water company.
(iii)	Give the Secretary of State powers to vary and terminate a fluoridation scheme without a local authority proposal where a general risk to health is identified from fluoridation or a specific risk emerges due to the actions of a particular water company.
<i>4B Variation of terms</i>	
(i)	No prescription (local authorities would have to consult on all variation proposals)
(ii)	Replicate the current provisions by prescribing that consultation and joint committee process for a variation proposal is not required if: <ul style="list-style-type: none"> (a) it does not concern the boundary of an area to which arrangements relate; or (b) it does concern the boundary of an area, but the number of houses that would be affected by the variation, either by being brought within the area or by being excluded from it, does not exceed 20% of the number of houses within the area at the time the request is made and this variation occurs within the proposing local authority. In circumstances where more than one local authorities are affected by the variation, we intend to issue guidance to the effect that the proposing local authority should notify and seek agreement from the other affected local authorities to precede with the variation. This process would not be statutory.
(iii)	Prescribe a more limited set of circumstances where a variation does not require consultation
<i>4C Maintenance of existing arrangements</i>	
(i)	Impose no requirements on local authorities. (There would be no cases in which local authorities would be required to consult on maintaining a fluoridation scheme. Consultation would only be required if a local authority proposed variation or termination of the scheme)
(ii)	Replicate the existing provision. The current regulations state that consultation is required for maintaining fluoridation arrangements if it involves the upgrading or replacement of fluoridation plant other than for the purpose of meeting operational and health and safety standards.

(iii)	Impose a requirement to consult on the continued operation of fluoridation schemes at specific intervals, for example, every twenty years and/or to impose a requirement for a maintenance consultation if oral health had substantially improved.
(iv)	Impose conditions relating to the cost of replacing /upgrading the plant i.e. a consultation must take place where these costs exceed a certain cost threshold based on an options appraisal.
<i>4D Termination of fluoridation schemes (timescales)</i>	
(i)	Impose no requirements on local authorities.
(ii)	Prescribe in regulation that there should be a minimum term between consultation proposals on termination schemes

Criteria for assessing the options

11. The Department has assessed the above sub-options against the policy objectives and intended effects.
12. **Does this sub-option increase democratic accountability of the decision making process, reducing the likelihood of a disputes brought by the public (including Judicial Review), and minimising administrative burden?** The Department recognises the risk of a judicial review by a local resident questioning the legality of council decisions on fluoridation. The regulations seek to support local democratic decision-making and limit the potential for judicial review by setting out the appropriate amount of detail on procedures that LAs must follow when carrying out their new responsibilities.
13. The last fluoridation scheme in the UK was set up in 1985. Since then only one fluoridation scheme has been planned and this scheme will be implemented in the next few years (in Southampton, covering the area outlined in Annex 4). This implies the national likelihood of implementing water fluoridation is approximately 4% per year. Therefore, the maximum likelihood of encountering a Judicial Review in any one year is around 4% (in the event that all fluoridation schemes are subject to a review). The cost of such Judicial Reviews varies. The Judicial Review following a water fluoridation proposal in Southampton cost £350,000. Therefore, the maximum potential annual benefit from reducing judicial reviews is £14,000. Discounted at 3.5% over a period of ten years gives the present value of this benefit as £120,000.
14. **Does this sub-option minimise the likelihood of disputes between LAs minimising administrative burden?** The Health and Social Care Bill 2011 specifies that the Department must make regulations setting out details on:
 - a. how the proposing local authority should enable affected authorities to decide whether further steps should be taken in relation to the proposal and
 - b. any conditions which must be satisfied before any further steps may be taken in relation to the proposal.

These regulations must be made in relation to a new proposal on consultation on fluoridation, setting up a new fluoridation scheme, as well as deciding on the variation or termination of an existing scheme. In addition to the legal requirement over some areas, legal disputes over any area are associated with an administrative burden. The Department is committed to setting out enough detail in regulations to seek to mitigate risks of disputes between local authorities and with members of their populations.

15. **Does this sub-option minimise the administrative burden on LAs of running a consultation?** The Department intends to use the regulations to minimise the administrative burden to reasonable levels wherever justified. At the very least, the intention is not to make the process any more burdensome in terms of statutory requirements for local authorities than it is for a Strategic Health Authority under the current system. However, as most LAs considering fluoridating their local water supply will need to consult with other LAs, (while an SHA may have been able to 'go-it-alone' in the past), there will be additional costs to LAs. The Department recognises that in many areas local authorities should be given the freedom to adopt the approach that is most suitable to a local area.
16. **Does this sub-option increase the likelihood that the LAs will maximise the health benefit to the local population, through taking into account the full set of costs and benefits in deciding whether to fluoridate?** The Department expects that setting out requirements for consultation and democratic decision-making will support a process in which all the relevant evidence is gathered and considered by all the relevant local authority staff and elected members when deciding on consultation for a new fluoridation scheme or varying the terms of an existing fluoridation scheme or terminating it. This should lead to a situation where the potential health gain from fluoridation is carefully considered against the cost of consulting on and setting up a new scheme (including the opportunity cost of the next best project in which the LA could have invested).

Benefits and Costs of sub-options

Area 1: Reaching a decision on whether to consult

1A Arrangements for decision-making

Preferred sub option: (i) The Department proposes to require a proposing local authority to provide sufficient information to information to allow the affected local authorities to make a decision whether to proceed and requiring the local authority to respond to requests for further information. The Department prefers this options as this might reduce the likelihood of dispute between local authorities over the content of the proposal.

1B Conditions on the decision to proceed

Preferred sub option: (i) The Department proposes to require a super-majority (two-thirds) of affected local authorities to agree to proceed before a consultation on fluoridation can be carried out.

Without this requirement for a majority, the committee is unlikely to make its decision in a way that best reflects the overall costs and benefits of fluoridating water in that area. However, requiring unanimity across all local authorities may be excessive, as the outcome of the decision is simply whether or not to pursue a consultation.

Area 2: Committee membership and procedures

2A: Membership of a decision-making committee

Preferred sub-option: (ii). Requiring the joint committee to reflect the Health and Wellbeing Boards will support local democratic processes and accountability and increase the likelihood that the LAs will take into account the full set of costs and benefits in their decision-making. It will not impose significant new administrative burden on the LA as a Health and Wellbeing Board will already be in existence. Please see annex 3 for more information.

2B Variation based on type of joint committee

Preferred sub-option: (ii) The Department proposed to use regulations to specify that membership of a new joint committee, an existing committee and a joint sub-committee of the Health and Wellbeing Board should have the same minimum membership. As this statutory membership mirrors the Health and Well-being committee, the points raised under 2A above remain valid.

2C: Minimum and Maximum Membership

Preferred sub-option: (i). The Department does not propose to impose minimum or maximum membership requirements because this might unnecessarily increase the administrative burden on LAs. While there is a risk that the group will be too small, the requirement in 2A (for the committee to broadly reflect the Health and Wellbeing Board) should mitigate against any biased decisions. Maximum membership requirements might preclude relevant stakeholders from engaging with the decision-making process, reducing its robustness. While a larger committee will be associated with increased administrative costs, the LA is best placed to decide whether there is sufficient additional benefit from larger committee membership.

2D: Varying approach based on number of local authorities involved.

Preferred sub-option: (iii). In cases of four or more local authorities, the likelihood of disputes between LAs is higher. This may outweigh the increased administrative burden of running a larger consultation. As a result, the Department prefers to set out a different statutory approach that prescribes how individual local authority areas form sub-committees and how these committees would in turn contribute to the democratic decision-making process.

Area 3: Fluoridation decision-making, consultation procedure and assessing public opinion

3A Consultation Process

Preferred sub-option: (ii). The Department prefers to retain the existing provisions with minor revisions around consultation processes to minimise any potential administrative burden on LAs. The Department does not propose

removing them entirely as this might increase the likelihood of disputes between LAs as well as the local population lacking information and feeling unable to make representations. The cost incurred by LAs if they choose to consult on fluoridation should not differ from the cost SHAs would have incurred under the current system. Regulations that are more prescriptive (such as sub-option iii) are not required as local authorities are covered by the public sector equality duty, which ensures that the consultation is accessible to people with protected characteristics. Therefore, the net impact on the consultation process will be minimal (although the final cost will necessarily differ depending on the consultation approach followed in a local area).

3B Informing provided for the public

Preferred sub-option: (ii). Local Authorities are subject to the Equalities Act 2010, which means that they have several obligations toward people with protected characteristics when running a public consultation. Alongside this duty the Department wants the local authority or the joint committee to take advice from the relevant director (or directors) of public health when preparing the consultation material.

3C Evidence Base – Role of Public Health England

No preferred sub-option. The Department is seeking views on the role Public Health England should play in supporting local authorities with their fluoridation responsibilities.

3D Assessment of balance of public opinion

Preferred sub-option: (i). The Department prefers not to prescribe any specific procedural requirements in relation to the local authority process for evaluating public opinion. This approach gives LAs the flexibility of finding the most suitable way to take account of local public opinion. This could include anything from a count of responses or number of respondents up to holding a referendum to take a count of public opinion. However, the department prefers to leave local authorities the autonomy to make this decision to reflect local circumstances. The cost of a referendum varies but estimates suggest that the recent referendum on the alternative vote cost local authorities in England £200,000 each.

3E Reaching a decision on whether to proceed with a fluoridation proposal

Preferred sub-option: (iii). The Department expects that the decision-making on fluoridation should take account of the views of the local population that would be affected and their health needs. Therefore, the Department prefers to add some specific requirements around the decision-making process, over and above those regulations that applied to SHAs. This is because clarity around the decision criteria might limit potential for dispute between LAs as well as the risk of objections from the local population, which could lead to a judicial review.

3F Seeking agreement to fluoridate (two or three LAs)

Preferred sub-option: (ii or iii or iv). In order to increase democratic accountability and possibly reducing the risk of disputes the Department proposes either:

(ii) to prescribe that the joint committee must make a decision through majority voting but that they are free to determine whether a majority is sufficient, or a larger majority through their means their own rules of procedure. r,

(iii) to prescribe a requirement for population-weighted voting in the joint committee with a super majority threshold for proceeding again where equal numbers of members from each local authority have a vote.

or,

(iv) to prescribe that the joint committee must make a decision by a super-majority (two-thirds) but that local authorities would be free to determine their own rules of procedures

This is because setting up a fluoridation scheme is costly and will be binding on the participating LAs for a number of years. Therefore, there must be sufficient support for the decision to fluoridate in the first place.

3G Seeking agreement to fluoridate (four or more local authorities)

Preferred sub-option: (ii or iv). When a group of four or more LAs have to decide on whether to fluoridate a local area, the Department proposes that the regulations should prescribe either:

(ii) that the joint committee must make a decision through majority voting (with one vote per local authority) but that the detailed rules of procedure on what form that majority could take would be determined through their own terms of reference.

or,

(iv) a requirement for population-weighted voting in the joint committee with a super majority threshold for proceeding again where only one representative from each local authority has a vote.

The broad representation of the decision-making committee should be subject to local determination. As the likelihood of a dispute is higher when more LAs are involved, the additional administrative burden of this regulation is outweighed by the reduced likelihood of a dispute. This requirement will increase the democratic accountability of the decision making process.

Area 4: Variation of terms and maintenance of arrangements

4A Circumstances where the Secretary of State may vary or terminate arrangements without a request from a local authority

Preferred sub-option: (iii) Give the Secretary of State powers to vary or terminate a fluoridation scheme without a local authority proposal where the current concentration of fluoride poses a risk to the health of the population. This is to ensure that if (against all evidence to date), risks to general health were identified from fluoridation and there was a need to 'switch off' the supply without delay then Secretary of State for Health would continue to be able to do so.

4B Variation of terms

Preferred sub-option: (ii) Replicate the current provisions by prescribing that consultation and joint committee process for a variation proposal is not required if:

- (a) it does not concern the boundary of an area to which arrangements relate; or
- (b) it does concern the boundary of an area, but the number of houses that would be affected by the variation, either by being brought within the area or by being excluded from it, does not exceed 20% of the number of

houses within the area at the time the request is made and this variation occurs within the proposing local authority.

The Department prefers to replicate the provision in the current regulations to minimise the cost on the local authority of running consultations.

4C Maintenance of arrangements

Preferred sub-option:(ii). In terms of maintenance of arrangements, the Department proposes to replicate the current provision because it minimises the administrative cost of running a fluoridation scheme, while ensuring democratic accountability,

It is important to note that if there is a significant change to the fluoridation scheme (above meeting operational health and safety standards), a consultation will be required in any case.

4D Termination of fluoridation schemes (timescales)

Preferred sub-option: (ii). When considering the termination of an existing fluoridation scheme the Department proposes that there should be a minimum waiting period between consultations on the termination of a scheme. This is to ensure that where a local consultation has resulted in the democratic decision to keep an existing fluoridation scheme, then input of the local population and the local decision-makers should be respected by not immediately launching a new termination consultation. Moreover, this provides some stability for the water companies, who are running the fluoridation schemes. Possible timescales could be the electoral cycle to allow LAs to reflect changing political priorities or a sufficient time period to evaluate the effect of fluoridation in a local area.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

17. When consultations are carried out, the most recent consultation cost £380,000 (in Southampton over 2007-9, as outlined in Annex 5). Prior to this, the second most recent was in 1985, implying an annual frequency of 4%. This frequency is not expected to increase with LAs being responsible for fluoridation, nor with the implementation of any of the options for regulation. Therefore, the likely annual cost of consultations is in the region of £15,000.
18. The regulations set out in the preferred options will only alter a portion of these costs, so the overall annual cost will be significantly less than £15,000. Therefore, it would be disproportionate to monetise the overall impact and that of each sub-option.

Risks and assumptions;

19. It is assumed that giving responsibility for proposing, consulting and deciding on fluoridation to local authorities will not make fluoridation any more or less likely. However, subject to the final content of the regulations there is a risk that complexity of decision-making or lack of sufficient guidance will change the status

quo. If appropriate or relevant, this will be assessed in the impact assessment of the final regulations.

20. There is a risk that disputes might arise between local authorities over the process for deciding on whether to consult and fluoridate the local water supply. There is also a risk of judicial review against a local authority for the decisions on whether to fluoridate a local area. However, by laying regulations, the Government seeks to make the process more democratically accountable, which aims to reduce this risk.

Direct costs and benefits to business calculations (following OIOO methodology);

21. These regulations are solely about how to consult. We expect no impact on the likelihood of fluoridation itself and no impacts on Water Companies or other private organisations.
22. These regulations concern local authorities and how they interact with each other and the public in relation to fluoridation. Therefore, the private sector is not directly affected by these regulations. The only time the private sector is involved in the consultation process is when a local authority wanting to fluoridate the water of a local area must obtain a quote from the local water company as well as an assessment that fluoridation would be technically possible in an area. This is similar to how any other business bids for work. If a local area decides to go ahead with fluoridating the water supply it is expected that the water company will provide the fluoridation according to the initial quote supplied. The water company will be reimbursed for the full costs of fluoridation. Therefore, there will be no net cost to business.
23. Current legislation on fluoridation states that water business must fluoridate the water of a local area (if it is feasible) upon request of the relevant authority. This will impose costs on the water business but these costs are reimbursed. However, as these regulations do not make water fluoridation more or less likely, the net cost to business will also be zero.

Wider impacts

Economic / Financial

24. The Department does not expect that these regulations will impact on the market, consumers or businesses. This includes micro businesses. Under the new regulations, water undertakers will continue to have to fluoridate the local water supply if requested to do so by a relevant authority. This is a continuation of the current system. Evidence suggests that there are no water undertakers that could be classed as micro businesses. These regulations do not limit competition or in any other way change the working conditions for water undertakers.
25. The decision to transfer responsibility for proposing, consulting and deciding on fluoridation of a local area from SHAs to LAs might lead to a decrease of disputes

including Judicial Reviews and therefore have a positive impact on the Justice System.

Social

26. The Department expects that the proposals will have a neutral impact on social, wellbeing or health inequalities as the frequency of fluoridation is not expected to be impacted by these regulations. However, fluoridation has the potential to reduce inequalities in oral health. By seeking to increase the likelihood that the LAs will maximise the health benefit to the local population, through taking into account the full set of costs and benefits in deciding whether to fluoridate and by increasing democratic accountability these regulations may positively impact on health inequalities. Additionally, local authorities will also have responsibility for a range of other public health areas. It is expected any decision-making in this area will reflect the wider needs of the local community, maximising the health of the local population.

Environmental

27. The Department does not expect this policy to have any impact on the emission of Greenhouse Gases

Summary and preferred option with description of implementation plan.

28. The preferred option is outlined below:

Area 1: Reaching a decision on whether to consult

1A Arrangements for decision-making

(i) require the proposing local authority to provide sufficient information to allow the affected local authorities to make a decision whether to proceed and requiring the local authority to respond to requests for further information.

1B Conditions on the decision to proceed

(ii) Require a super-majority (two-thirds) of affected local authorities to agree to proceed.

Area 2: Committee membership and procedures

2A Membership of a decision-making committee

(ii) Require that the joint committee reflects Health and Wellbeing Boards. Under this option, the committee would have the following statutory members:

- at least one councillor from each LA
- at least one director of public health from each LA

- at least one representative from local Healthwatch Organisation for each local authority
- a representative from a clinical commissioning group for each of the affected local authorities
- a number of other persons as the statutory committee members consider appropriate.

2B Variation based on type of committee

(ii) Use regulations to specify that membership of a new joint committee, an existing committee and a joint sub-committee of the Health and Wellbeing Board should have the same minimum membership (as set out in 2A)

2C Minimum and Maximum Membership

(i) Impose no requirements on local authorities as to numbers

2D Varying approach based on number of local authorities involved.

(iii) Prescribe an alternative approach for joint committees where there is a large number of local authorities. In particular, to have a simple requirement that the committee would consist of equal numbers of representatives from each local authority (with the number agreed by the authorities or prescribed in regulations). Option 3 might also be combined with a requirement about the joint committee consulting the authorities or their Health and Wellbeing boards

Area 3: Fluoridation decision-making, consultation procedure and assessing public opinion

3A Consultation Process

(ii) Retain existing provision with minor revisions

3B Information provided to the public

(ii) Prescribe in regulations that a local authority or the joint committee must in preparing the consultation material take advice from the relevant director (or directors) of public health.

3C Evidence Base – Role of Public Health England

We invite responses to the consultation on the role that Public Health England should play in supporting local authorities with their fluoridation responsibilities

3D Assessment of balance of public opinion

(i) Impose no specific procedural requirements in relation to the local authority process for evaluating public opinion.

3E Reaching a decision on whether to proceed with a fluoridation proposal

(iii) Prescribe different requirements: For example, that a local authority or joint committee must in determining whether to proceed with a fluoridation proposal:

- have regard to the views of the local population, and the extent of support for the proposal
- have regard to the validity of the arguments advanced, having particular regard to the scientific basis of the representations for and against, and views on the ethical arguments about fluoridation.

- have regard to the Joint Strategic Needs Assessment and Health and Wellbeing Strategy for the affected areas,
- have regard to the financial implications of a fluoridation proposal
- consider whether the demonstrable health arguments in favour of proceeding with the proposal outweigh all arguments against proceeding

3F Seeking agreement to fluoridate (two or three LAs)

(ii) Prescribe that the joint committee must make a decision through majority voting but that they are free to determine whether a majority is sufficient or whether a larger majority would be more appropriate through their own rules of procedure.

or

(iii) To prescribe a requirement for population-weighted voting in the joint committee with a super majority threshold for proceeding again where equal numbers of members from each local authority have a vote.

or,

(iv) To prescribe that the joint committee must make a decision by a super-majority (two-thirds) but that local authorities would be free to determine their own rules of procedure (including which members of the committee would be eligible to vote).

3G Seeking agreement to fluoridate (four or more local authorities)

(ii) Prescribe that the joint committee must make a decision through majority voting (with one vote per local authority) but that the detailed rules of procedure on what forms that majority could take would be determined through their own terms of reference.

or

(iv) Prescribe a requirement for population-weighted voting in the joint committee with a super majority threshold for proceeding again where only one representative each local authority has a vote.

Area 4: Variation of terms and maintenance of arrangements

4A Circumstances where the Secretary of State may vary or terminate arrangements without a request from a local authority

(iii) Give the Secretary of State powers to vary or terminate a fluoridation scheme without a local authority proposal where there is a general risk to health identified from fluoridation or a specific risk emerges due to the action of a particular water company.

4B Variation of terms

(ii) Replicate the current provisions by prescribing that consultation and joint committee process for a variation proposal is not required if-

(a) it does not concern the boundary of an area to which arrangements relate;

or

(b) it does concern the boundary of an area, but the number of houses that would be affected by the variation, either by being brought within the area or by being excluded from it, does not exceed 20% of the number of houses within the area at the time the request is made and this variation occurs

within the proposing local authority. In circumstances where more than one local authorities are affected by the variation, we intend to issue guidance to the effect that the proposing local authority should notify and seek agreement to proceed with the variation. This process would not be statutory.

4C Maintenance of arrangements

Preferred sub-option:(ii). In terms of maintenance of arrangements, the Department proposes to replicate the current provision because it minimises the administrative cost of running a fluoridation scheme, while ensuring democratic accountability.

4D Termination of fluoridation schemes (timescales)

(ii) Prescribe in regulation that there should be a minimum term between consultation proposals on termination schemes

29. Overall, this package of regulations best satisfies the policy objectives and intended effects as laid out in the summary sheet (and argued in the Benefits and Costs section). These are to:

- Increase democratic accountability of the decision making process, reducing the likelihood of a disputes brought by the public, and minimising administrative burden
- Minimise the likelihood of disputes between LAs, minimising administrative burden
- Minimise the administrative burden on LAs of running a consultation
- Increase the likelihood that the LAs will maximise the health benefit to the local population, through taking into account the full set of costs and benefits in deciding whether to fluoridate

Annex 1: List of regulation we may and must lay

Policy themes	Policy detail → with cross reference to the relevant section of the Water Industry Act 1991 (as amended by the Bill)	Status of Regulations
Theme A: Participation in decision-making by affected local authorities	New consultation / fluoridation proposal - Section 88D <ul style="list-style-type: none"> • Detail how the proposing local authority should enable affected authorities to decide whether further steps should be taken in relation to the proposal • Prescribe conditions which must be satisfied before any further steps may be taken in relation to the proposal Variation / termination proposal (Section 88K) <ul style="list-style-type: none"> • Prescribe conditions which must be satisfied before any further steps may be taken in relation to the proposal • Detail how the proposing local authority should enable affected authorities to decide whether further steps should be taken in relation to the proposal 	Regulations must be laid
Theme B: Committee Membership and procedure	Sections 88 F and 88M <ul style="list-style-type: none"> • Detail the membership of joint committees and the procedures that must be followed by any joint committee in exercising fluoridation functions 	Regulations may be laid
Theme C: Fluoridation decision-making, consultation procedure and assessing public information.	Sections 88E and 88L <ul style="list-style-type: none"> • Specify the steps taken for the purpose of consulting in relation to fluoridation proposal • Detail in regulations circumstances where modification of a proposal is acceptable • Specify circumstances where a proposal could be modified to extend the boundary of a proposal/add another area • Specifying factors that the proposer/committee must or may take into account in making the decision whether to ask the SofS to proceed with a proposal • Specifying the procedure to be followed in exercising functions related to the points above. 	Regulations may be laid
Theme D: Variation of terms and	Sections 88 I, 88 K, 88 L and 88M <ul style="list-style-type: none"> • The circumstances when the Secretary of 	Regulations may be laid

<p>maintenance of arrangements</p>	<p>State can request a water undertaker to vary/terminate a scheme without a request from the affected local authorities.</p> <ul style="list-style-type: none"> • Detail relating to length of time between proposals to terminate a fluoridation scheme (i.e. should there be a minimum period) • The Secretary of State may specify circumstances where the proposer does not need to make arrangements to inform other local authorities and/or form joint committees (in relation to termination/variation only) • The Secretary of State may specify circumstances where the proposer does not need to consult on the fluoridation proposal • The Secretary of State may specify the circumstances for consulting and ascertaining opinion on whether fluoridation schemes should be maintained and for establishing arrangements to allow LAs to propose that schemes be maintained. • Regulations may make provision requiring the Secretary of State to terminate a scheme if the affected LAs do not want it to continue. • Regulations may make provision similar to sections 88K-88M 	
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Annex 2: Extent of Fluoridation in England.

30. Currently 5.5 million people in England drink fluoridated water. The following areas have artificially fluoridated water: Workington, Newcastle upon Tyne, Crewe, Mansfield, Lincoln, Birmingham and Bedford
31. There are many areas in England, which have significant natural fluoride content in drinking water. These include Norwich, Ipswich, Cambridge, Hartlepool, Slough, Bath, Swindon, Colchester and parts of the counties of Essex, Norfolk, Suffolk, Durham, Shropshire, Wiltshire and North East London.
32. The newest example of a fluoridation scheme is Southampton, which won a Judicial Review on a proposed fluoridation scheme in February 2011. Apart from this scheme, the most recent fluoridation scheme was set up more than 25 years ago.

Annex 3 – Health and Wellbeing Boards

33. The Health and Social Care Bill establishes health and wellbeing boards on a statutory basis in every upper-tier local authority in England.
34. The key benefits of establishing these boards will be to increase the influence of local people in shaping services through democratically elected councillors and local HealthWatch, so that services can better meet local need, be more joined up for the people using them and improve integrated working
35. Key features of health and wellbeing boards are:
 - Clear duties on clinical commissioning groups and local authorities to prepare the Joint Strategic Needs Assessment (JSNA) through the health and wellbeing board
 - A new joint health and wellbeing strategy prepared by the health and wellbeing board and based on the needs identified in the JSNA
 - This will include a requirement to consider the use of health act flexibilities (such as pooled budgets) in developing the strategy
 - Commissioners required to have regard to the Joint Strategic Needs Assessment and the joint health and wellbeing strategy
 - Health and wellbeing boards will have a duty to promote integrated working
 - Beyond minimum membership set out in legislation, local authorities and the board can decide to invite and include other members as they see fit
 - Local authorities will have the flexibility to decide how best to discharge their scrutiny powers
36. The health and wellbeing board may also take on any other function the local authority wishes to delegate to it, with the exception of scrutiny functions.
37. To increase local democratic legitimacy and to represent the interests of the public, the Bill prescribes there must be a minimum of at least one local elected representative on the health and wellbeing board. It will be for local authorities to determine the precise number of elected members on a health and wellbeing board, and they will be free to insist upon having a majority of elected councillors.
38. Other members of the board specified in the Bill will include a representative of each local clinical commissioning group, the Director of Adult Social Services, the Director of Children's Services, the Director of Public Health and a representative from the local HealthWatch organisation.
39. Beyond this minimum membership, local authorities and the board can decide to invite and include other members, for example other groups or stakeholders who can bring in particular skills or perspectives. For example, the board could invite a

representative of the allied health professions, providers or local voluntary sector groups.

Annex 4 – Southampton Fluoridation Scheme

40. The number of people covered by the Southampton fluoridation scheme within individual local authority boundaries is as follows. Please note all figures are based on population estimates and therefore are approximate:

- Southampton City – 160,000
- Eastleigh Borough Council – 25,065
- New Forest District Council – 8,264
- Test Valley Borough Council – 1,431

Map outlining the areas in Southampton and south west Hampshire where fluoridation would occur

