31 March 2017

Regulator Assessment: Qualifying Regulatory Provisions

Title of proposal	Reduction of purification times for shellfish purification cycles
Lead Regulator	**Food Standards Agency**
Contact for enquiries	Beverley Küster/Rebecca Watts

Date of assessment	31/03/2017
Commencement date	01/11/2016
Origin	Domestic
Does this include implementation of a Cutting Red Tape review?	No
Which areas of the UK will be affected?	England

Brief outline of proposed new or amended regulatory activity

Following a review of the UK regulatory requirements for live bivalve mollusc (LBM) - e.g. shellfish - purification, the FSA has revised its policy on the minimum purification time necessary to ensure consumer safety.

Until the policy change was introduced in November 2016, the standard time required for UK purification establishments to perform a purification cycle was a minimum period of 42 hours. The policy had been a long standing approach based on independent expert assessment of the minimum period considered to provide an effective means of safety for the final product and had not been updated to reflect the current requirements in EU Regulation. (**Annex I**).

In addition to going beyond the requirements of the EU Regulations the former policy approach did not allow for approved purification establishments own evidence based assessments to be taken into account and was inconsistent with the approach taken for other sectors producing products of animal origin (POAO)

As a result of the FSA policy change; approved purification establishments wishing to apply a reduced purification period may now do so in accordance with their own HACCP (Hazard Analysis Critical Control Points) based food safety management system.

As of November 2016 approved purification establishments wishing to take advantage of the change in policy need to notify their local authority providing evidence necessary to demonstrate that all relevant hazards (microbiological and viral) have been adequately addressed in their food safety management system. This is a requirement under EU legislation for all significant operational changes to approved establishments. New business requests for approval will be handled as with other businesses handling POAO, the approval of new purification establishments will be based on evidence provided by the food business operator (FBO) to the relevant competent authority. It is the responsibility of the FBO to demonstrate effective controls for all relevant risks and to meet end product standards through the implementation of effective HACCP-based food safety management systems.

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Which type of business will be affected? How many are estimated to be affected?

The policy change will be of interest to local authority approved purification establishments in England (An establishment that undertakes the purification of shellfish by placing them in specially designed tanks, fed by clean seawater, for the time necessary to reduce contamination to make them fit for human consumption).

There are currently 50 operating purification centres in England, whilst the size and scale of operation varies dramatically the vast majority are small or micro enterprises. The FSA anticipate that only those approved purification establishments that have established a significant commercial value to their product (i.e. those that supply large manufacturers, supermarkets or restaurant chains and/or those exporting their product) will have the necessary capability to demonstrate, in an economically viable way, their capacity to operate under reduced purification periods.

Despite the shellfish industry being consistently vocal in identifying the need for the policy change, and being heavily engaged in developing the policy change, they are particularly guarded and we have struggled to gather business evidence necessary to fully assess the impact of the policy change. The FSA has routinely requested business evidence – such as an indication as to those approved purification establishments that will want to operate reduced purification and an estimate of what the policy change will mean for their business in terms of reduced operating costs and increased number of batches that can be purified as a result of the change. Requests for information have been made through regular business engagement meetings as well as in our written consultation and emails to relevant regulating and industry bodies.

In lieu of evidence being provided following our open calls for information, the FSA has now received information from those identified by SAGB/Seafish as being likely to implement a reduced purification period. As a result of this approach we have now received 6 responses from establishments in England.

Out of the 50 approved establishments currently operating in England, 12% has indicated that they will be taking advantage of the policy change. (NB: 57 approved establishments in England, 7 ceased trading, 17 do not plan to apply a reduced purification time6 are planning to adopt reduced times and 27 have not responded. Out of the 27 establishments that have not responded it is not anticipated that any of these would be planning to take advantage of the change in policy at this stage. This rationale is shared by the Shellfish Association of Great Britain who is the industry body that represents approximately 60 % of purification establishments. This could be, at least in part, due to short-run capacity constraints limiting their ability to take advantage of the regulatory change. However, over the ten year period of assessment, it is possible that, in the medium or long-run, some of these small approved purification establishments might seek to expand and exploit the opportunities presented by this regulatory change for their commercial benefit. However, we are currently unable to quantify and monetise this potential impact due to a lack of information upon which to generate the analysis.

Summary of costs and benefits

Price base year	Implementation date	Duration of policy (years)	Net Present Value	Business Net Present Value	Net cost to business (EANDCB)	BIT score
2014	2017	10	£24.4m	£24.4m	-£2.7m	-£13.5m

Please set out the impact to business clearly with a breakdown of costs and benefits

Whilst the standard purification time will remain at 42 hours for existing approved establishments, those approved purification establishments wishing to take advantage of a shorter period for purification will be impacted by this change.

Costs

i) One-off monetised familiarisation costs

Those FBOs wishing to take advantage of the policy change will be required to demonstrate to their local enforcement authority (LEA) that their HACCP-based food safety management system is robust and that their tanks are capable of purifying shellfish in a shorter time and to the required health standard. This is standard in the approval of all establishments.

Additional sampling is likely to be required at the outset to provide assurance that adequate controls are in place to produce a safe product; this is a standard requirement regardless of the purification time. Sampling requirements necessary to demonstrate regulatory compliance should therefore be no more than is necessary for a business to assure itself that the product it is placing on the market is safe for commercial assurance.

FBOs will need to ensure that risk factors, for example the time of year, species and following heavy rain are considered and factored into their process. Adequate sampling will need to be carried out in the first instance as well as routinely to verify HACCP procedures are sufficient to ensure their system remains effective.

As the operational procedure is the same, it is not anticipated that approved purification establishments will require additional time to familiarise themselves with the changes. The Shellfish Association of Great Britain (SAGB) supports the view that there should be no additional burden to those approved purification establishments that wish to apply the shorter purification time. They went on to say that FBOs know their tanks and have safeguards built in to negate risks; it is therefore considered that the familiarisation impact is negligible.

Approved purification establishments would need to amend their food safety management system in the usual manner to take account of the change to the process and would be validated at regular intervals to ensure effectiveness. This is standard commercial practice for any business that introduces changes to its food safety management system.

There is an estimated one-off cost to approved purification establishments of time spent by production managers/directors in becoming familiar with the approval process. This is assumed to take two hours. It is also assumed that is will take an additional 10 minutes to complete an application form. It is assumed that a production manager will undertake this task. The 2016 provisional ASHE hourly mean[1] wage rate for 'Production managers and directors' is used: £25.54[2] and a mark-up of 20% (according to the Standard Cost model)[3] is added resulting in a final wage rate of £30.23 (once adjusted to 2014 prices). The cost to the six approved purification establishments is £393 (PV).

[1] The median wage was not available.

[2] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

[3] Standard Cost Model - http://www.berr.gov.uk/files/file44503.pdf
http://www.statistics.gov.uk/downloads/theme_labour/ASHE-2009/2009_occ4.pdf

Benefits

i) On-going (annual) monetised benefit from a removal of the standard purification time of 42 hours.

It is expected that this regulatory change will permit shellfish food business operators (FBOs) to increase their output. It is estimated that the relevant purification centres are run seven days a week, for which potentially three cycles (three batches) could be completed in one week, therefore calculations of throughput have been calculated for two, three and a mid-point average of 2.5 cycles per week.

For the purposes of the assessment, we have assumed that these approved purification establishments will operate for 46 weeks per annum. This is considered to be a conservative estimate as the establishments the assessment is based on are unlikely to routinely cease operations for 6 weeks per annum. Purification establishments are understood to typically operate continuously on a 24 hour basis throughout the year, as the purification process itself is generally low maintenance; requiring very little activity beyond routine monitoring etc. It is therefore in the business interest to operate continuously to maximise efficiency.

Consultation with the industry indicates that 6 operational approved purification establishments in England (of the 22 operators that responded) will take advantage of the de-regulatory change. These FBOs have indicated the extent of the increase, which range, in general, from an increase of 2 to 3 times the weekly number of cycles.

Estimates of increased total weekly revenue range between £50k (for two extra batches) and £74k (for three extra batches); with a best estimate of approximately £62k per week. This is calculated by multiplying the estimated increase in the volume (in kilograms) of throughput per week by the wholesale price per kilogram for each species, net of business costs associated with the purchase of shellfish for purification.

Estimated wholesale prices were obtained from CEFAS FHI data for 2014 (consistent with the price base year); while data on the cost of purchasing shellfish (farm gate prices) for purification was not available. In order to account for this cost we assume that 35% of the wholesale price can be attributed to the purchase cost of shellfish for purification (equivalent to farm gate prices)[4]. Net of business costs, these estimates are taken as the unit values of output.

See table 1 below.

Table 1: Weekly increase in revenue

Species	Baseline of 2 cycles per week	Baseline of 3 cycles per week	Baseline of 2.5 cycles (mid-point) per week	Wholesale price per kg (£)	Farm gate price per kg (£)	Net Wholesale price per kg (£)
	A	B	C	D	E	F = (D - E)
Mussels	39,730	59,190	49,460	£1.90	£0.67	£1.24
Clams	168	168	168	£3.50	£1.23	£2.28
Cockles	180	180	180	£2.50	£0.88	£1.63
Total increase income (£)	**£49,741**	**£73,774**	**£61,758**			

[4] Based on the best available evidence from Scotland's Rural College (SRUC), taking account of operating costs and returns it can be assumed that shellfish farms receive 35% of the wholesale price: https://www.sruc.ac.uk/info/120184/fish_farming/300/shellfish/4

As approved purification establishments operate for 46 weeks of the year, we obtain annualised figures by multiplying weekly figures by 46.

The summary annualised figures are presented in table 2 below:

Table 2: Summary figures

Annual total:	
Best Estimate	£2.8m
Upper Estimate	£3.4m
Lower Estimate	£2.3m
Ten year Total	
Best Estimate (NPV)	£24.45m
EANDCB	-2.7
BIT Score	-13.5

Extensive efforts were made through Local Authorities, the SAGB and Seafish to obtain relevant information from approved purification establishments to ascertain the proportion of FBO wishing to apply the reduced timings and to establish the level of increased volume they anticipated it would bring. Due to the information available at this stage we consider the monetary benefit calculations conservative.

Impact on different sized businesses

There are varying sizes and types of purification systems ranging from an individual tank in a shed to sophisticated multi stacking systems. (**Details in Annex II**).

Approved purification establishments of all sizes would be required to demonstrate that their HACCP-based food safety management system is robust and that their system is capable of reducing the level of contamination to the required health standard.

The level of sampling required to demonstrate this would not be increased by the introduction of a reduced purification time as the Food Business Operator is required to sample to prove end product standards are being met when any changes are made to the system and periodically to ensure the systems in place are effective. This is therefore seen as a Business as usual cost for commercial assurance not an impact of the policy change. .

Please provide any additional information (if required) that may assist the RPC to validate the BIT Score

N/A

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Annex I

Purification background

Bivalve molluscs are filter feeding shellfish, extracting food from the water around them. Purification involves the transfer of the live molluscs from the harvesting area into purpose built shore based tanks containing clean seawater. Here they continue filtration and normal digestive activity where they purge themselves of any bacterial contamination present.

Purification alone is not suitable for cleansing the shellfish harvested from highly contaminated areas or areas subject to chemical contamination or by marine toxins.

Only shellfish that are harvested from class B production areas are required to undergo the process of Purification to ensure that end product standards are achieved. (Class A shellfish can also be purified if required)

The standard purification cycle time across the UK is 42 hours. This was established under the previous Shellfish Regulations and has been continued as it was considered to be best practice. This policy position has been reviewed and the FSA considers it is for FBOs to demonstrate, in accordance with their HACCP plans, that all relevant risks (from bacteriological and viral contamination) have been considered and the Local Authority is satisfied the system (and any reduced purification time) is effective and protective of public health.

EU Regulations do not prescribe any minimum purification time. In the UK a minimum recommended period of 42 hours has been in place as it was considered an appropriate means of ensuring that food placed on the market is safe but it is seen to be in excess of the regulations and restricts the level of shellfish that can be processed. This policy position has now been reviewed and the FSA recognises that a minimum time is not specified in the Hygiene Regulations.

Businesses wishing to apply a reduced period must develop their own HACCP-based food safety management system which has considered all relevant hazards (microbiological and viral) and provide evidence to satisfy their relevant local authority that the reduced time requested is protective of human health and produces shellfish that are compliant with end product standards.

Businesses will need to consider a range of issues which might affect the period of time whichshellfish are purified, including (but not necessarily limited to):

- The species
- The time of year and the associated risks from contamination
- Recent weather
- Most recent official control monitoring results
- Other information relating to the harvesting area e.g. pollution event etc.

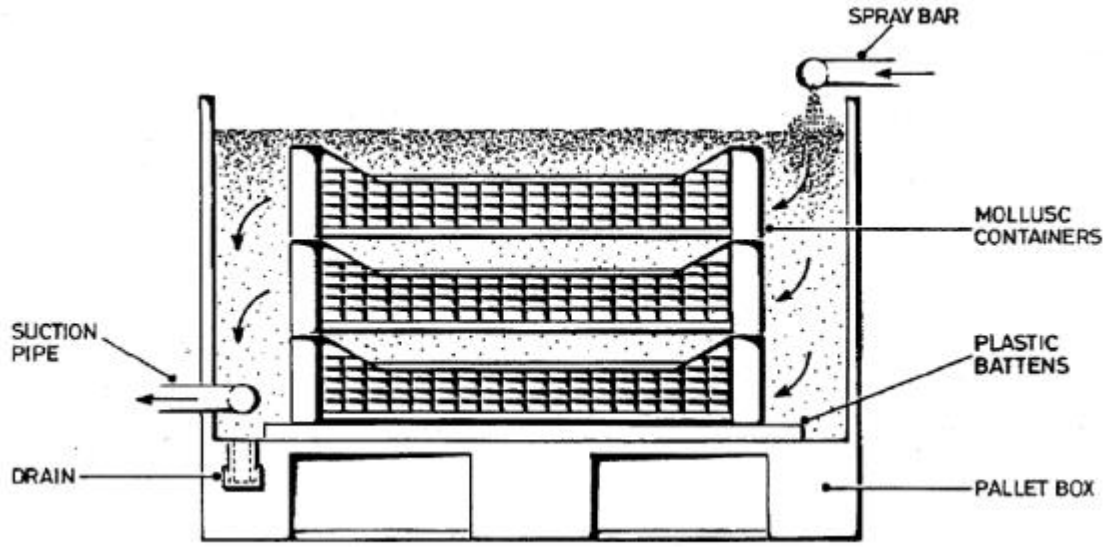
The recommended minimum period for shellfish purification will remain at 42 hours; reduced purification times will only be permitted for FBOs who can demonstrate and satisfy their authorities that food safety will continue to be maintained.

Annex II

Types of purification systems

There are five types of standard design systems ranging in capacity from **650 litre capacity to 9200** litres that are capable of purifying batches of between **90kg (approx. 750 oysters) to 1500kg** of shellfish.

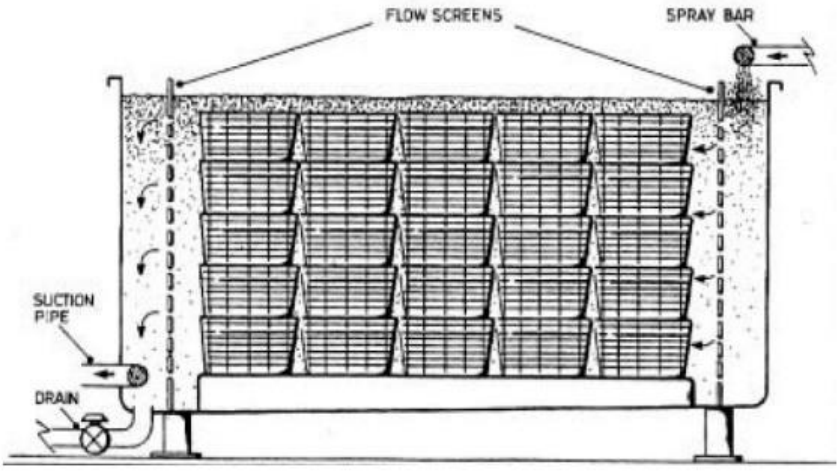
The Standard Design Shallow Tank System (Small Scale) This uses a 650 litre plastic pallet box or similar as the tank into which six mesh type plastic trays may be stacked in two tiers, each three trays high. When fully loaded the system has a maximum **capacity of 90 kg** of mussels and requires a minimum operational seawater volume of **550 litres.**



The Standard Design Multi Layer Systems (Medium and Large Scale)

Medium Scale

Mesh type plastic trays may be stacked in ten tiers, when fully loaded the system has a maximum **capacity of 750 kg** of mussels and requires a minimum operational seawater volume of **2500 litres**.



Large Scale

Mesh type plastic trays may be stacked in twenty tiers, when fully loaded the system has a maximum **capacity of 1500 kg** of mussels and requires a minimum operational seawater volume of **9200 litres.**

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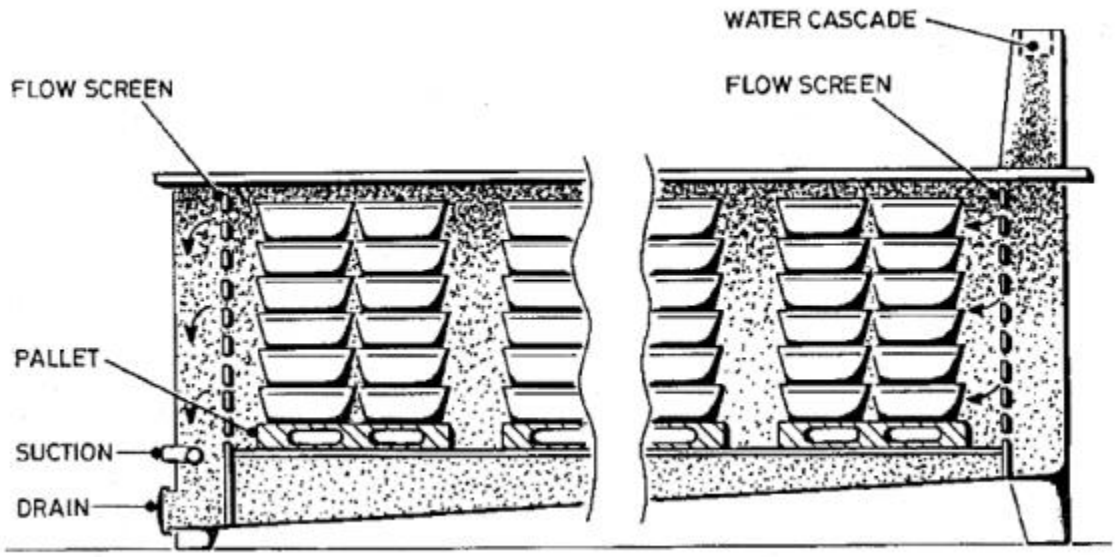
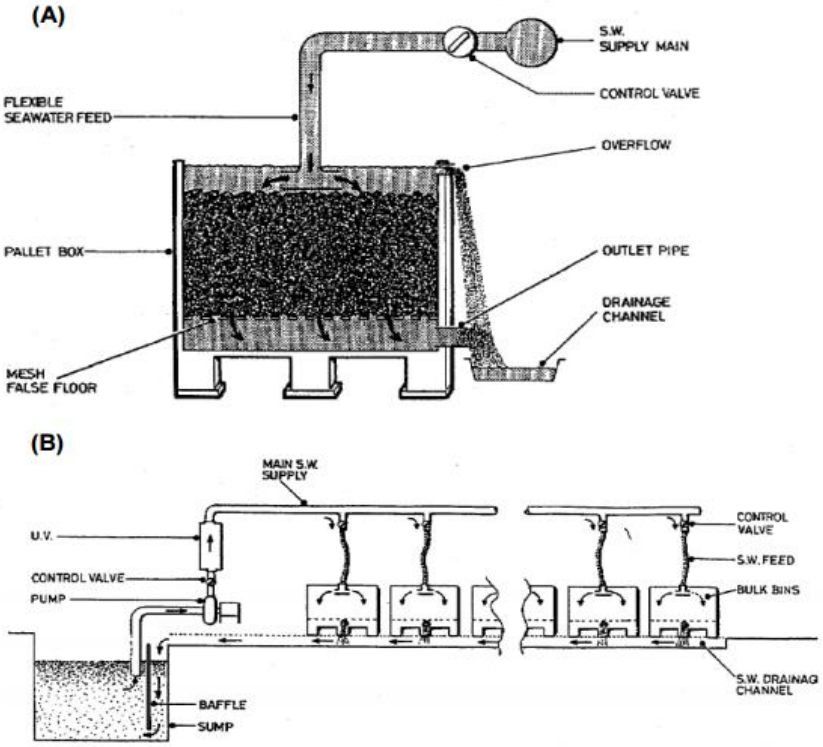


The Standard Design Bulk Bin This is for mussels only and is not suitable for other species. The mussels are held in deep layer bins up **300kg capacity and 650 litres of**
water



The Standard Stacking System The bivalve molluscs are held in trays over a plastic pallet box (**650 litres**) used as a sump tank with a total of sixteen containers in two vertical columns.

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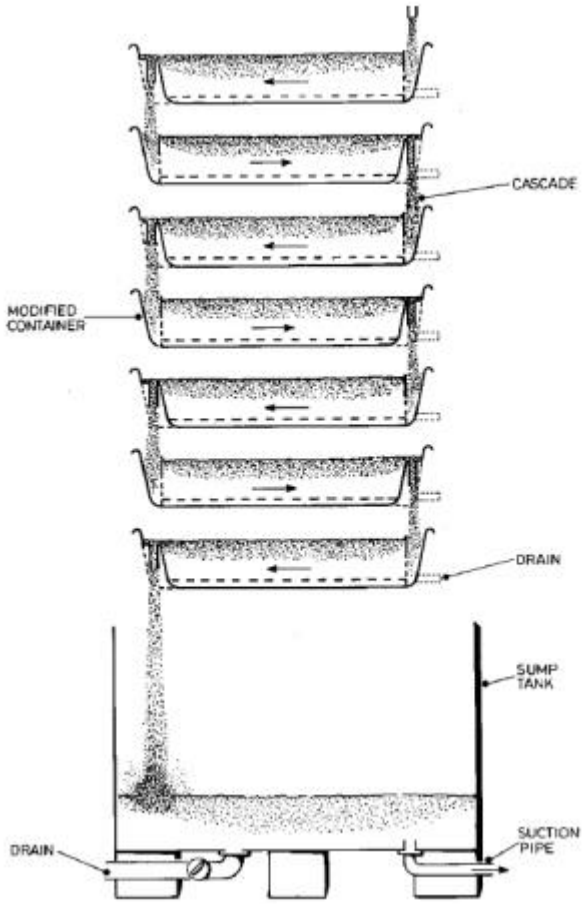

Non-Standard design

There is no obligation on a purification centre operator to install standard design systems. The operator may wish instead to install a system to his own specification. Such a purification system must still meet the technical requirements of Government Departments