Wild Scallops Q&A

Q1 When do the new regulations come into effect?

A1 The new Regulations came into effect on 1 January 2006.

Q2 Will the land testing be more stringent than the current testing regime?

A2 No. The toxin limits remain the same. The differences are mainly the location of official control testing which will be on land establishments as opposed to at sea direct from the shellfish bed and a new requirement which states that scallops are not be sold for human consumption unless via a processor or dispatch centre (unless exemption is used).

Q3 Are there any differences between Scotland and England as a result of the new regulations?

A3 No. The regulations are directly applicable in all member states therefore there should be no differences in requirements placed on the scallop industry between Scotland and England.

Q4 Is the 20μg/g limit for ASP on the whole scallop or just the meat?

A4 The limit for ASP applies to the product being placed on the market therefore a processor wishing to sell whole scallops would test them whole. Likewise any official control sampling would be carried out on the whole scallop. If a processor wished to sell a shucked product the test would be carried out on a shucked product.

Q5 How quick is the official control test?

A5 The turnaround time for official control test results is about 48 hours from receipt of sample (sometimes less) for ASP but up to 5 days for DSP and PSP due to the method of testing that FSA is currently required to carry out for these toxin groups.

Q6 How frequently will official control tests be carried out?

A6 The frequency of testing will be determined on a case by case basis by Local Food Authorities (LFAs). However generally in cases where there is good evidence of shucking being carried out to a high standard by trained processors, the business has full traceability, formal written HACCP, training records and a full biotoxin risk assessment in place, official control sampling will be carried out at every scheduled visit (minimum of twice per year). This frequency will increase where LFAs determine any shortcomings.

Q7 Is there a European wide sampling methodology?

A7 Yes. All competent authorities are required to use Official Control Reference methods which include the HPLC method for ASP, and the bioassay for DSP and PSP although it is hoped that a chemical methods will be approved for use on these two toxin groups in the near future.

Q8 What quantity of scallops are required for the test?

A8 The sample size should be sufficient to provide 100g of flesh for each test (ASP, DSP and PSP) therefore LFAs have been advised to collect 30 shells for whole scallop testing or 30 pieces for shucked or white meat only.

Q9 What would happen if you take a sample and it comes back positive, as the scallops will have already been sold within that time frame and probably eaten by the time the results come back?

A9 The rapid testing kits should allow processors to wait for test results prior to placing scallops on the market. However, we understand that some processors may chose to send their samples away to Aberdeen or Oban to be tested. In these cases the product may have been sold and even consumed by the time the results come back. If the results come back positive then the processor has an obligation to instigate withdrawal of the remaining product and inform the Local Food Authority and the Food Standards Agency.

In cases where for example end product testing results are negative and subsequent official control testing results are positive the remaining product would still have to be withdrawn since the Official Control test is the definitive check.

Q10 Should the processor determine how often they test? Will they receive guidance on how often tests should be carried out?

A10 Processors will have to determine how often they should carry out end product testing. This should be based on a number of factors associated with risk such as the time of year, the area where the product has been gathered from and the nature of the product being offered for sale (i.e. whole, shucked, white meat only). For example, more frequent testing (for ASP) would be expected for whole scallops caught in high risk boxes at the end of the summer than for white meat only product caught in a low risk box in Spring.

Q11 Are there new commercial tests being developed?

A11 There are commercially available detection methods for biotoxins which are suitable for rapid on-site and end product testing (See attached Annex)

Q12 Can these tests be carried out anywhere?

A12 The antibody based test strips (such as the Jellet) would be suitable to use in most situations. At the very least, sample preparation would require blending the shellfish. Therefore it could be done on a boat provided there was the means to do this.
The ELISAs are more technical and would require basic laboratory facilities but require a minimum of expertise and do not rely on sophisticated instrumentation.

Q13 What is the price of the testing?

A13 Kits tend to be sold in bulk. Approximate prices are included in the attached Annex but the ELISA kit for ASP costs around £185 for a 96 well assay (around £8 per sample) and the Jellet costs around £1520 for 125 strips (around £12.50 per test)

Q14 How rapid are the tests and what type of turnaround can be expected.

A14 Analysis time is usually around 2.5 hours for the ELISAs and 30 minutes for the test strips.

Q15 Can the test be used for all shellfish, e.g. mussels, winkles?

A15 Yes, although it is a good idea to check this with the manufacturer prior to use.

Q16 Are the self-tests (dipstick) available now?

A16 Yes. Contact information for the companies distributing the most widely used/available kits is included in the Annex.

Q17 The kits will tell you if toxins are present but not the percentage level is that correct?

A17 The ELISAs are quantitative and should show the level of toxins in the sample. The test strips will only show positive or negative but a positive result will usually be above a certain level, for example the Jellet Rapid Test kit for PSP will give a positive result if the sample is above 400μg/Kg or 40μg/100g (which is half the regulatory limit)

Q18 How much space is required for the testing set up?

A18The ELISA kits will require a small basic laboratory.

Q19 Do FSA supply the test equipment?

A19 No. FSA will not supply test equipment for end product testing. This remains the responsibility of the processor/dispatch centre owner.

Q20 Is it possible to wash scallops and then re-test?

A20 Yes.

Q21 Apart from the rapid testing, where in Scotland offers commercial toxin testing?

A21 At the moment the FRS Marine Laboratory in Aberdeen, Integrin Advanced Biosystems in Oban will provide commercial toxin testing services

Q22 How much do they charge?

A22 The approximate cost of testing is £250 (total) for the three tests (ASP, DSP and PSP)

Q23 Does every batch have to be tested by the processors?

A23 No, testing every batch is not required by the regulations. Testing frequency should be determined by risk (See Q10 above).

Q24 What defines what quantity a batch is?

A24 Batch size will have to be determined by the processor/dispatch centre. Again it should be determined by risk. However it is anticipated that batches will be from one production area or box. For example, all scallops caught in J6 on one day or all scallops caught in H5 in one week. This way end product testing results can be attributed to a specific area and shared to direct fishing activity.

Q25 What happens when a box brings back high toxin results when there are no longer any closures?

A25 It is hoped that the sharing of end product testing results will alert others to areas experiencing high levels of toxins. If the result is from an official control sample the information will be included in the weekly report which will continue to be distributed as normal. The product from that batch will of course need to be withdrawn from sale.

FSA has suggested that the industry should have some type of information database onto which they can input end product testing results. This would allow processors/dispatch centres to share information thereby alerting others to areas giving high results and helping to direct fishing activity. FSA has approached SEAFISH and the Scottish Executive who are interested taking this forward on behalf of Industry.

Q26 What are the fishermen of other EU Member States saying about the new regulations?

A26 We do not have any information on how the new regulations have been received by the industries in other countries. Other Member States are subject to exactly the same requirements since these Regulations are directly applicable and cannot be interpreted by individual member states. There may however be some differences in practical implementation and National measures due to the differences in the size and distribution of the industries.

Q27 Are the ASP levels elsewhere in the EU set to a different (lower) level?

A27 The ASP, DSP and PSP limits are set at the same level for all European Member States.

Q28 Is the Commission considering lowering the statutory levels of PSP levels in Mussels (or any other shellfish)?

A28 FSA is aware that the issue was under discussion for all shellfish species but there has been no move to change the limit as yet. The regulations, which came into force on 1 Jan 2006, still retain the limit of 80μg/100g or 800μg/Kg. Any change in toxin limits would have to be recommended by the European Food Safety Authority (EFSA) who would have called a committee of relevant experts to consider at all the available scientific information.

Q29 Do the new regulations apply to farmed scallops?

A29 The new regulations do apply to farmed scallops via the inshore classified production area biotoxin monitoring programme. There has been no change with

regards biotoxin testing other than a review of the frequency of testing being undertaken to comply with 854/2004 requirements. FSA is still required to monitor harvesting areas and producers are still required to carry out end product testing.

Q30 Is there any way to depurate biotoxins from scallops?

A30 Depurating toxins from scallops can be done but with normal facilities it tends to take a long time (anything up to 6 months). With a rapid interchange of water this process can be speeded up. FRS undertook a study of this and it was determined that it was not likely to be commercially viable to implement such a depuration process for elimination of biotoxins.

Q31 Can scallops be depurated if they have been dredged?

A31 Yes, although as with all dredging practices the shellfish may be subject to a greater degree of stress, damage and mortality all of which impact on the scallops ability to depurate.

Q32 How many processors are there in Scotland?

A32 There are approximately 67 premises handling scallops in Scotland. We suspect that between 20 and 40 of these are actually involved in processing.

Q33 Was the 5 tonne fisherman's allowance (permitted under the old Regulations) per diver or per boat?

A33 Per diver.

Q34 How will the new flexibility in relation to small, local and restricted, be Regulated for shellfish?

A34 Those using the flexibility are still required to make sure that their product meets the health standards laid down in the regulations e.g. comply with the biotoxin and microbiological limits. In addition, they are still subject to the requirements of the Food Safety Act 1990, which states that unsafe food may not be placed on the market for human consumption.

Q35 If you have a small amount of scallops e.g. 2 bags; can you sell them to a hotel?

A35 A 'small amount' of scallops may be sold directly to a hotel provided that the amount is within the flexibility provisions and meets the health standards required. Local Food Authority Guidance prescribed by the FSA suggests that this be set at the levels previously prescribed under the 'Fishermans allowance' (5 tonnes per annum for scallops).

Q36 Is the previous fishermen's allowance written in to the regulations?

A36 No. The regulations make it clear that the direct supply of small quantities of primary products (such as scallops) are exempted from its requirements and that Member States should establish their own rules for these activities, provided that these rules protect public health. For the time being therefore, the decision has been taken in the UK to keep the levels prescribed in the old allowance table as guidance. The FSA has undertaken to review the whole issue during 2006.

Q37 What is the definition of a "dispatch centre" in the regulations?

A37 "Dispatch centre" means any approved on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption.

Q38 What is classed by FSAS as in-shore and off-shore?

A38 Generally we use the term "in-shore" for classified shellfish production areas and "off-shore" for wild scallop grounds, however we are aware that there are a few wild scallop beds within classified production/in-shore areas.

Q39 Do the same sampling procedures apply to new scallop beds that are found?

A39 Yes. It applies generally to pectinidae harvested outside classified production areas.

Q40 Are the regulations for both Queen and King scallops?

A40 Yes. See above.

Q41 Are movement documents still required?

A41 Yes, although they are now referred to as registration documents. Copies of these must still be kept for at least twelve months.

Q42 What are you expecting regarding industry paperwork and own testing?

A42 We would expect that any business would have a record of the batch number, the area the product was fished from (box number) and the date it was fished, the species and product type (whole, shucked, white meat only), the date the sample was taken and the date of the result, the results, what type of testing was used and the final destination of the batch.

Q43 How long should people hold onto the paper work?

A43 A year at the very least although it may be beneficial for businesses to store EPT data on computer which would help when the data needed to be retrieved, in which case there would be no problem keeping records indefinitely.

Q44 If industry results showed increasing toxin levels would a FEPA be imposed?

A44 No. FSAS does not intend to continue with the open/closed box system exercised under FEPA Order.

Q45 Will the remaining closed boxes be opening sooner?

A45 The remaining closed boxes will open as soon as we receive two samples below the statutory maximum for that box. If levels of toxins start to drop they may open

sooner as they are receiving priority attention. This will not be the case if levels of toxins are rising.

Q46 Are there people in the UK that are using the whole scallop to make products?

A46 Yes, this is always a possibility. The industry led Portion Size Study surveyed consumers and restaurants in 4 countries including the UK. When asked what parts of the scallop were thrown away before serving, 7% of UK respondents said they discarded the roe/gonad, 71% discarded the black intestinal organ, 64% discarded the mantle/frill and 59% discarded the shell.

Q47 Did the portion size study get looked at?

A47 The Portion Size Study was sent to the Committee on Toxicity for comment. Their initial view was that it would not necessarily instigate a review of the limit for ASP due to the fact that no matter how few or how infrequently, the study showed that people still eat over 250g portions of scallops. This was found in all four countries surveyed.

Q48 Is there any way of taking the onus off the scallop processor by labelling scallops with a "this product must be shucked before consumption" sticker and therefore putting the safety issue back within the consumers hands?

A48 No. The responsibility for the safety of the product lies with the processor/dispatch centre. There is nothing in the regulations which would allow an unsafe product to be placed on the market which is what could potentially happen if the whole scallops were over the statutory limit for a certain toxin.

Q49 How easy is cross contamination in scallops?

A49 Very easy. When shucking it is vital that the shucked product be washed thoroughly and kept separate from fluid juices produced during shucking and from the waste, both of which contain 90% of the toxins. Batch separation must be maintained at all times and tables and knives must be washed down between batches. A high standard of shucking can make the difference between a positive and negative result on the end product test.

FSAS has produced a leaflet and poster for scallop processors on good shucking practice. These have been made available to all scallop processors and Local Authorities and further copies can be provided by FSAS if required.

Q50 If a fisherman lands scallops and they are over the specified toxin limits who loses out financially? Fisherman or processor?

A50 If a batch of scallops does not meet end product standards then the processor may not pay the fisherman. However this is an issue for Industry to deal with.

Q51 When will the shucking DVD for industry become available?

A51 The whole package of shucking training will be carried out this year. The DVD and training materials should be sent out to all processors by mid February.

Q52 When can the historic data on the boxes become available?

A52 This data is has always been available. FSAS would be happy to provide it at any time.

Q53 Has there been a PSP finding recently?

A53 Yes. Scallops with levels of PSP over the statutory limit were discovered recently and the box concerned closed by FEPA Order. It is therefore important that end product testing does not concentrate solely on ASP as PSP and DSP also affect scallops and PSP, in particular, is extremely hazardous to human health.

ANNEX

COMMERCIALLY AVAILABLE DETECTION KITS FOR SHELLFISH BIOTOXINS.

1. The annex summarises the commercially available detection methods for shellfish biotoxins that are suitable for rapid on-site and end product testing.

2. A range of relatively straightforward and rapid antibody based testing kits and functional assays have been employed for all three groups of toxins. The methods described are suitable for use basic laboratories, require a minimum of expertise, and do not rely on sophisticated instrumentation.

3. Please note that the information provided relates to methods that are most widely publicised, and does not represent endorsement from the Agency for any particular supplier.

Background

4. The simplest and most widely available detection kits for ASP, DSP and PSP are based on the binding of toxin to a specific antibody.

5. Antibody ELISAs (Enzyme-Linked ImmunoSorbent Assays) can **quantify** the toxicity of a sample by measuring the amount of toxin that binds to an antibody which is specific for that particular toxin.

6. In these assays, binding of the toxin to the antibody is detected according to a colour change. Interpretation of results therefore requires the use of a microplate reader to measure the degree of colour change and convert it into a number that can be related to toxin concentration.

7. Alternatively, antibody based test strips (which operate in a similar manner to a pregnancy test kit) are available from a Canadian company called Jellett Rapid Testing. Unlike the ELISA or functional assay formats, these kits are **not** quantitative, and provide only a positive or negative result for shellfish extracts, based on a particular level of toxin. Jellett Rapid Tests (JRTs) are simple to use and provide results that can be interpreted visually within approximately 30 minutes. They require no specialised equipment, making them useful for on-site or field-testing.

8. A list of the equipment required establishing a testing facility suitable for carrying out quantitative ELISA is provided in the Annex.

9. It should be noted that accurate use of ELISA kits and antibody based test strips require purified toxin standards to enable accurate toxin concentrations to be determined in shellfish samples. Standards are not available for all toxin variants within the DSP and PSP group, but representative compounds can be obtained from a number of suppliers.

10. Please note that all costs provided are approximate.

The toxin detection kits for each toxin group that are already available and those which are currently under development but likely to be available on the 1st January 2006 are listed below:

a. Domoic Acid (ASP)

Biosense Laboratories ASP Direct cELISA kit

Cost - £185 for a 96 well assay (sufficient for either 24 samples at approximately £8 per sample or 36 samples at around £6 per sample)

This kit has recently been reformatted from a solid plate kit into a strip based format (8 x 12-well strips). This format provides two options:

- The kit may be split into two rounds of analysis using 4 strips for each round. This allows 12 individual samples and a calibration to be analysed in each round (total 24 samples) or;
- All 8 strips can be run at once with the capacity to quantify 36 samples. This option requires only a single calibration for all 36 samples.

An Excel Macro spreadsheet is also provided with the kit for the calibration and calculation of results.

The analysis time for the kit is around 2.5 hours (although this could be cut down if required), and can detect down to 10 μg domoic acid/kg shellfish flesh (approximately 2000 times less than the regulatory limit).

Additional information (including ordering details) is available from the website (www.biosense.com).

Jellett Rapid Test for ASP

Cost – £1520 for 125 strips (approximately £12.50 per test)

This kit has been developed to test methanol shellfish extracts, and has a limit of detection or 2.5-5 μg/g shellfish flesh (approximately 5-8 times less than the regulatory limit). The strips provide a visual determination of the presence of ASP toxins in a sample within 35 minutes.

Additional information (including ordering details) is available from the website http://www.jellett.ca/asp.htm

b. Okadaic Acid and DTX (DSP)

R-Biopharm DSP-check

Cost £475 for 48 tests (approx. £10 per test)

The DSP-check is a 96-well ELISA kit that enables the quantitative detection of okadaic acid and DTX toxins, and has an analysis time of around 20 minutes.

Additional information (including ordering details) is available from the website www.r-biopharm.com/foodandfeed/dsp_check.php

Jellett Rapid Test for DSP

A JRT kit for DSP has been developed and is currently undergoing validation. This kit should be commercially available by the end of the year.

c. Yessotoxin (DSP)

Cost – not yet available (but expected to be around €8-10)
Biosense have recently developed an ELISA kit for the quantitative detection of yessotoxin. The detection limit for the kit is 0.16 mg/kg shellfish (approximately 6 times less than the regulatory limit). The kit has an analysis time of around 1.5 hours, and has a similar format to the ASP kit available from Biosense (see above). This ELISA kit is in the final stages of validation and not yet commercially available.

d. Paralytic Shellfish Toxins (PSP)

R-Biopharm Ridascreen®FAST Saxitoxin Test

Cost - £195 for 48 tests (approx. £4 per test)

The Ridascreen®FAST Saxitoxin Test has a detection limit of 50μg saxitoxin/kg shellfish (approximately 16 times less than the regulatory limit). However, it should be noted that the kit does not detect all PSP compounds with equal sensitivity. The kit has an analysis time of around 1-hour.

Additional information (including ordering details) is available from the website www.r-biopharm.com/foodandfeed/ridascreenfastsaxitoxinpsp.php

Jellett Rapid Test for PSP

Cost – £1520 for 125 strips (approximately £12.50 per test)

The JRT for PSP has been developed to test shellfish extracts prepared using both the reference extraction method and a much simpler method that employs white vinegar and rubbing alcohol. The detection limit of the kit is reported as approximately 400 μg/kg shellfish (approximately half of the regulatory limit). However, it is known to pick up lower concentrations, depending on the compounds present.

The JRT for PSP operates in a similar manner to the ASP kit described above.

List of lab equipment required for setting up an ELISA test facility and approximate costs (prices for reagents and toxin standards are not included in this list)

Equipment		**Approximate Cost**
Var.Volume Pipette	(40-200 microlitre)	£100
	(200-1000 microlitre)	£100
	(1000-5000 microlitre)	£100
Pipette tips,	0-200 microlitre(1000)	£ 15
	200-1000 microlitre (1000)	£ 13
	1000-8000 microlitre (1000)	£160
Pipettor (8 channel)	**30-300 microlitre**	**£520**
Pipettor tips	**20-300 microlitre (1000)**	**£ 23**
Washer (8 channel)		**£175**
Shaker, Vortex, 1 speed, 240V		£375
Tube, Micro 1.5ml (500)		£ 20
Tube, centrifuge, 50ml (500)		£180
Adapter, 1x50ml, 2/pack		£103
+ scale down to 0.1 g		
	Microplate reader, 400-750 nm	**£4000**
Or portable strip reader		£2000
Centrifuge, general, 240V		£1500
Eppendorf centrifuge		£ 200
	TOTAL COST = Approximately	**£10,000**