Evaluation of heat treatment of live bivalve molluscs

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Summer School

"In Silico Methods for Food Safety"

efsa
European Food Safety Authority

THE MANDATE

- Full title: Evaluation of heat treatments, different from those currently established in the EU legislation that could be applied to live bivalve molluscs from B and C production areas, that have not been submitted to purification or relaying, in order to eliminate pathogenic micro-organisms
- Request for a Scientific opinion (Art. 29)
- Requestor: European Commission

Ref. Ares(2015)1041549 - 09/03/2015

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Deputy Director General for the Food Chain

INCOMING N° D7425
10 MAR 2015
EFSA

Brussels,
SANCO/G4/PCA/is(2015)

Dear Mr Url,

Subject: **Request for a scientific opinion on the evaluation of heat treatments, different from those currently established in the EU legislation that could be applied to live bivalve molluscs from B and C production areas, that have not been submitted to purification or relaying, in order to eliminate pathogenic micro-organisms.**

The current EU rules (Chapter II of Section VII of Annex III to Regulation 853/2004) state that live bivalve molluscs from B and C production areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms.

It seems that, at least for certain species (clams, scallops) the imposed treatments, if correctly applied, alter the organoleptic qualities of the final products, with the consequence that it is very difficult to place those products on the market.

Please find enclosed a request including the background and terms of reference for an EFSA scientific opinion.

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002[1], EFSA is requested to evaluate, in the light of the current EU and international rules, different temperature-time conditions from those currently established in the EU legislation, that could be applied to live bivalve molluscs from B and C production areas that have not been submitted for purification or relaying in order to eliminate pathogenic micro-organisms.

We would request EFSA to finalise its scientific assessment by 31 December 2015.

BACKGROUND

- live bivalve molluscs from B and C production areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms [Current EU rules: Chapter II of Section VII of Annex III to Regulation 853/2004]
- the treatments have been imposed to ensure the elimination of pathogenic micro-organisms, in particular Norovirus (NoV)

BACKGROUND

- The permitted treatment methods are:
  - sterilisation in hermetically sealed containers
  - heat treatments involving:
    - immersion in boiling water for the period required to raise the internal temp of the mollusc flesh to ≥90°C and maintenance of this temp for ≥ 90 s;
    - cooking for 3-5 min in an enclosed space where the temp is 120-160°C and the pressure is 2-5 kg/cm2, followed by shelling and freezing of the flesh to a core temp of –20°C
    - steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temp of the mollusc flesh mentioned under (i).

BACKGROUND

- At least for certain species (clams, scallops) the imposed treatments alter the organoleptic qualities of the final products, with the consequence that it is very difficult to place those products on the market

TERMS OF REFERENCE (TORS)

To evaluate, in the light of the current EU and international rules, different temperature-time conditions from those currently established in the EU legislation, that could be applied to live bivalve molluscs from B and C production areas that have not been submitted for purification or relaying in order to eliminate pathogenic micro-organisms

Heat treatment of relevance

- ≥ 90°C for ≥ 90 s in the mollusc flesh

Bivalve molluscs

- all molluscs consumed in the EU
- all types of molluscs/production areas together

Pathogenic micro-organisms

- focus on thermal inactivation of viruses
- heat treatments not aimed at eliminating bacterial spores
- phycotoxin outside the remit

HAZARD IDENTIFICATION

- to list the key viral hazards associated with consumption of live and processed bivalve molluscs

  → the most important viral hazards associated with the consumption of bivalve molluscs are **NoV and HAV** acquired from human faecal pollution of production areas

- to be used for the selection of the hazards in the analysis

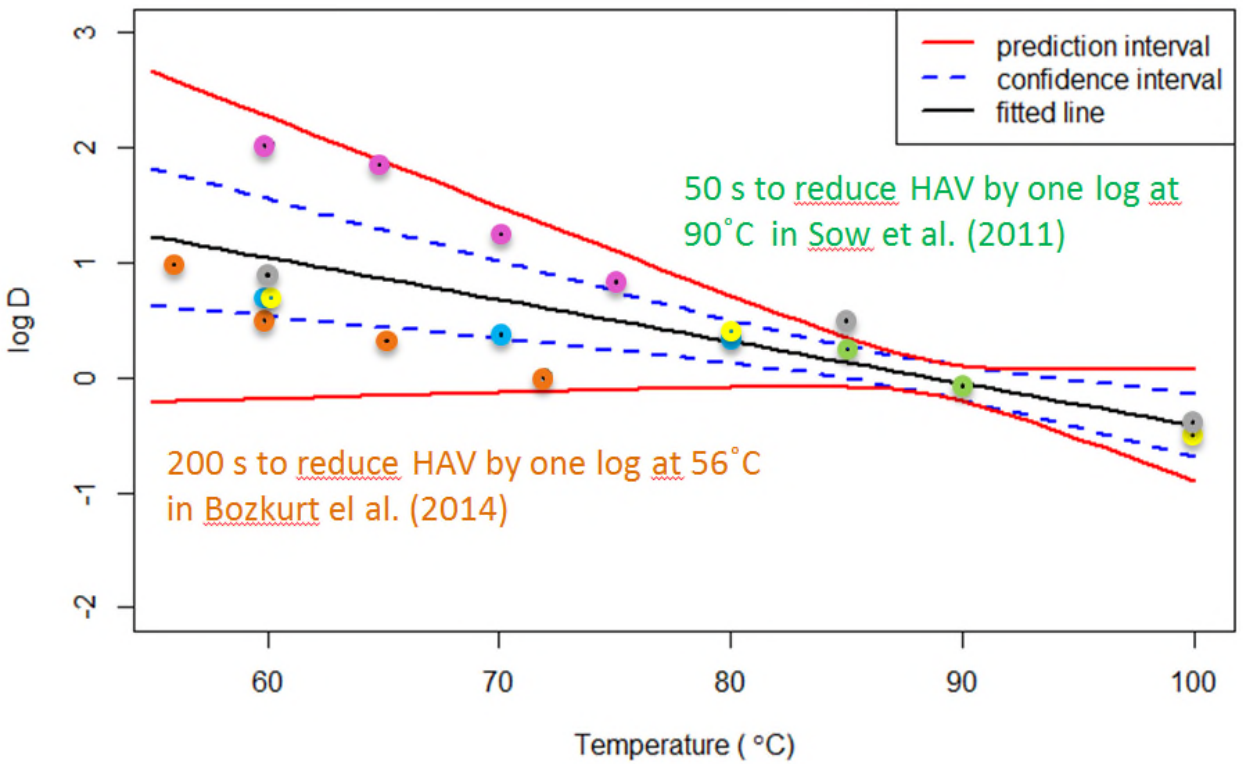
  → **HAV** was most appropriate for further evaluation because NoV is not effectively culturable and data on surrogates may not be representative in evaluating thermal resistance

Development of the HAV model

- Data:
  - HAV inactivation data in mollusc matrices during isothermal heat treatment
  - Set of criteria for relevance checking, e.g. mollusc matrix, isothermal conditions
- Two step-approach:
  - step 1: to calculate D_T-values
  - step 2: to estimate D_{90} and z-value of the secondary Bigelow model

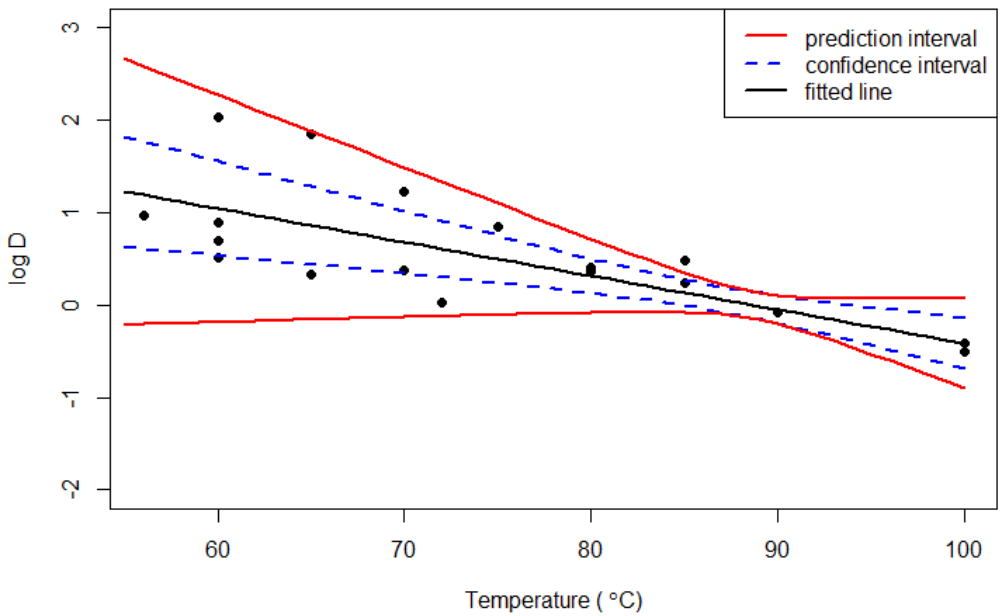
HEAT TREATMENT: HAV THERMAL INACTIVATION MODEL

- Step 1:
  - to calculate D_T-values
  - 15 D_T-values obtained from six studies



HEAT TREATMENT: HAV THERMAL INACTIVATION MODEL

- Step 2:
  - to estimate D_{90} and z-value of the secondary Bigelow model
  - linear mixed effect model considering random effects of studies on both the intercept and the slope in equation



HEAT TREATMENT: HAV THERMAL INACTIVATION MODEL

- Results:
  - the model estimated that it takes 0.9 min to reduce the HAV population by one log unit at 90°C (D_{90} was −0.048; CI 0.6 to 1.3 min)
  - to obtain a one log change in this inactivation rate would require a temperature change of 27.5°C (z-value was 27.5°C; CI 13.6 to 41.3°C)

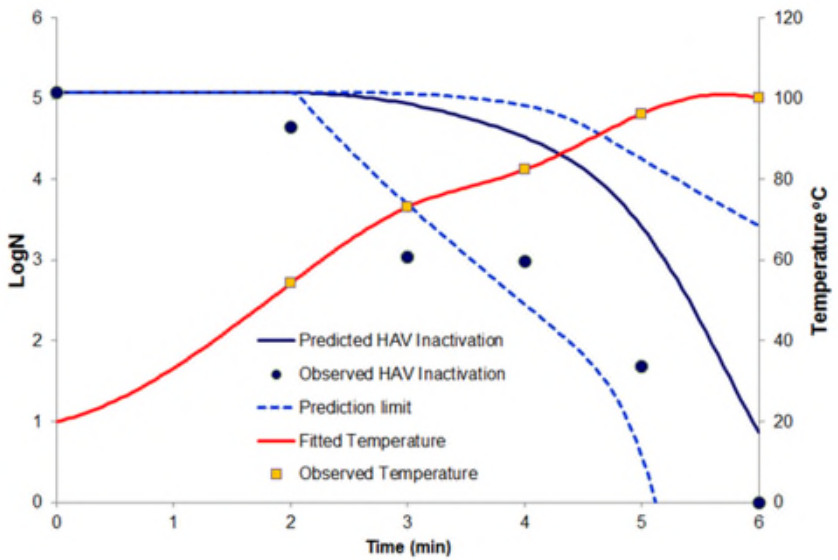
Evaluation (validation) of model

- at non-isothermal conditions

→ mean model predictions of the model generally under-predicted HAV inactivation

- for NoV thermal inactivation

→ under the conditions and matrices studied HAV is generally more heat tolerant than surrogate viruses



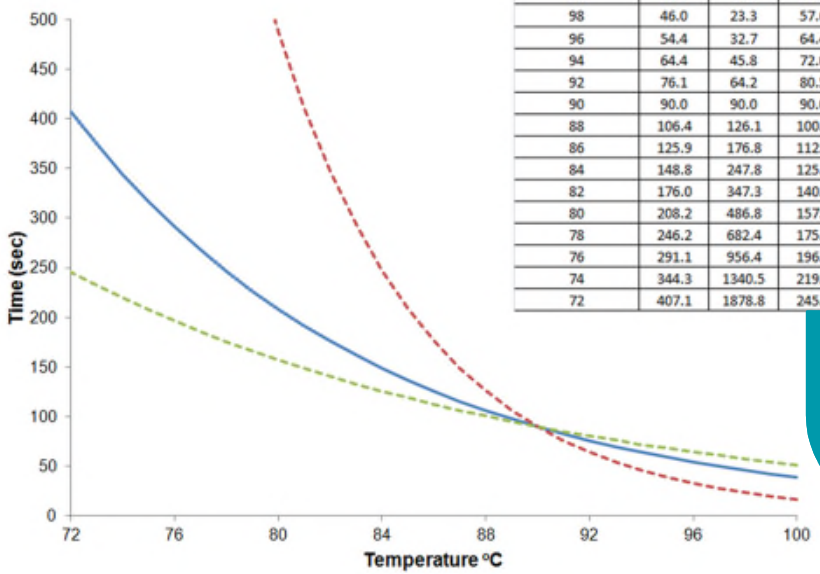
HEAT TREATMENT: EQUIVALENT THERMAL PROCESSES

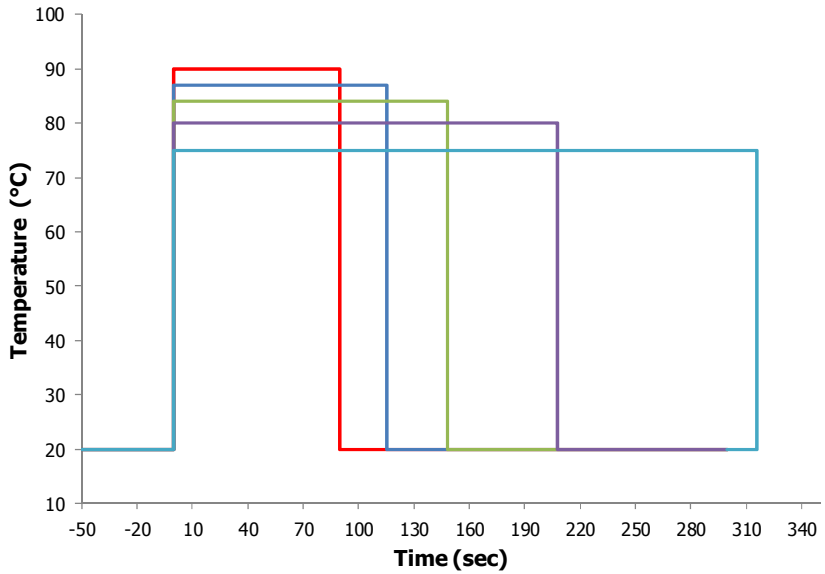
without heat-up and cool-down times

- Aim: to identify **equivalent** time–temperature combinations to the 'notional' heat treatment of 90°C for 90 s without considering the effect of heat-up and cool-down times on virus inactivation
  - two thermal processes are considered equivalent only if they result in the same lethal effect
- 90°C for 90 s resulted in a predicted mean reduction of HAV of 1.67 log PFU/g

HEAT TREATMENT: EQUIVALENT THERMAL PROCESSES

Temperature (°C)	Time (sec) Best Fit	LCI(z)	UCI(z)
100	38.9	16.6	51.5
98	46.0	23.3	57.6
96	54.4	32.7	64.4
94	64.4	45.8	72.0
92	76.1	64.2	80.5
90	90.0	90.0	90.0
88	106.4	126.1	100.6
86	125.9	176.8	112.5
84	148.8	247.8	125.8
82	176.0	347.3	140.6
80	208.2	486.8	157.2
78	246.2	682.4	175.8
76	291.1	956.4	196.5
74	344.3	1340.5	219.8
72	407.1	1878.8	245.7





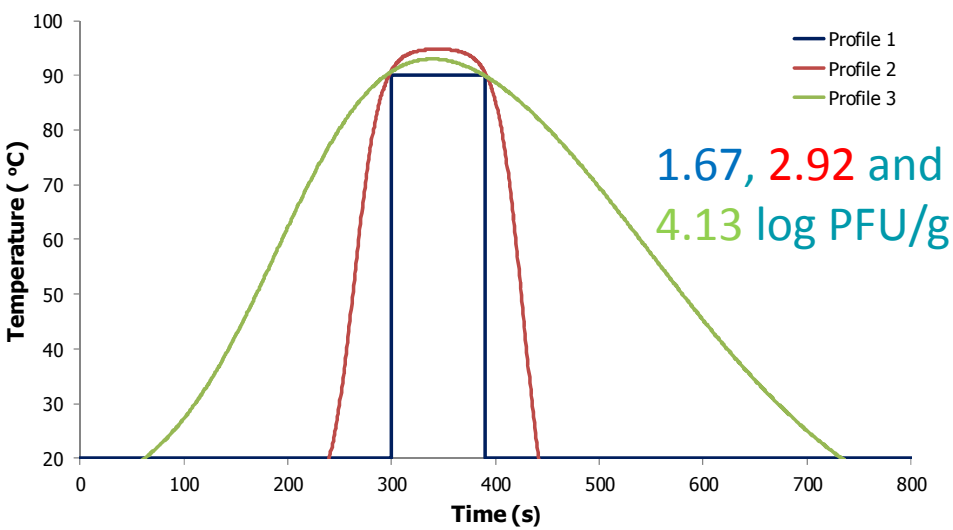
- Conclusions: Numerous time–temperature profiles are equivalent to the 'notional' profile of 90°C for 90 s (without considering the effect of heat-up and cool-down times on virus inactivation)

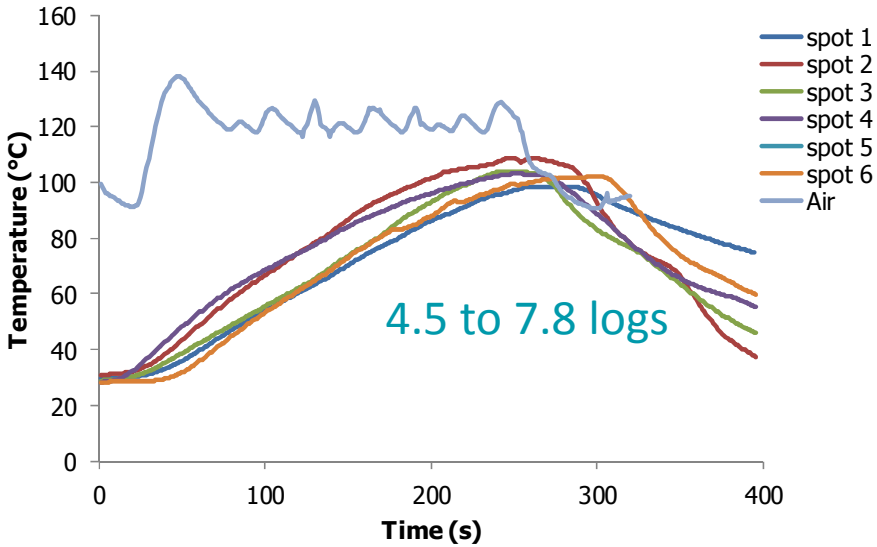
with heat-up and cool-down times

- Aim: to predict the total HAV inactivation resulting from "realistic" heat processing time–temperature profiles in compliance with the 90°C for 90 s process, but that differ in relation to the rates of temperature increase during heating and decrease during cooling
- Method: the HAV thermal inactivation model was used with considering the effect of heat-up and cool-down times on virus inactivation; heat processing time–temperature profiles
  - theoretical process including heat-up and cool-down times
  - industrial thermal (pressurized steam) processes of bivalve molluscs

HEAT TREATMENT: EQUIVALENT THERMAL PROCESSES

- heat processing time–temperature profiles
  - theoretical process including heat-up and cool-down times
  - industrial thermal (pressurized steam) processes of bivalve molluscs



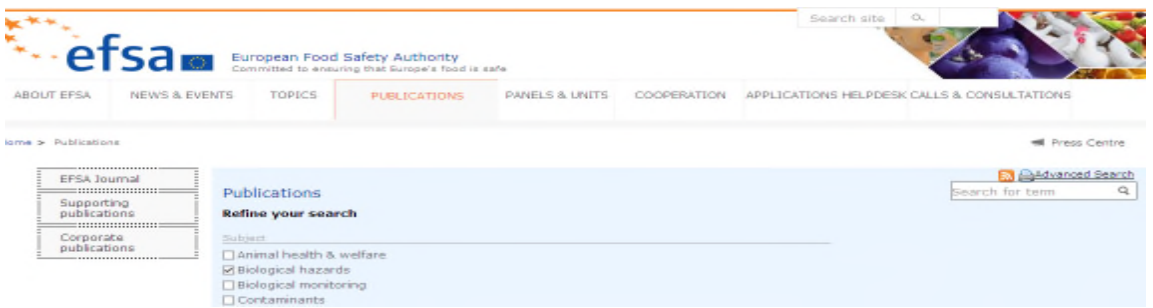


HEAT TREATMENT: EQUIVALENT THERMAL PROCESSES

- Conclusions:
  - Realistic 90°C for 90 s processes, can lead to significant variations in HAV log reduction depending on the process design
  - When considering equivalency of processes, these heat-up and cool-down times must be taken into account.
  - A **PrC such as an F-value** which takes into account the whole time–temperature profile during heat treatment is a more appropriate requirement than a single time–temperature combination. The use of an F-value allows the food business operators (FBOs) to best balance product safety and quality.

USEFUL INFORMATION!

EFSA website: www.efsa.europa.eu



Questions

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on EFSA activities: www.efsa.europa.eu/askefsa

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