



Discussion on the FDA questions related to "Fresh"

The answers to the questions asked by the FDA are given in regards to high-pressure technology, where Flow International Corporation (Flow) has experience. Specific comments are also given for orange juice.

FDA Questions identified in Docket Number 00N-1352

1. Do consumers associate the term "fresh" with organoleptic characteristics, nutritional characteristics, or some other characteristics?

Flow thinks that most consumers associate "fresh" with organoleptic (sensory) characteristics, and nutritional characteristics. Some consumers, especially the "health-conscious" customers tend to associate "fresh" with active enzymes in products such as "fresh" orange juice.

2. Do consumers want a way to identify foods that taste and look fresh but have been processed to control pathogens?

Flow does not think so. Consumers assume that the food they eat is already safe. Safety is assumed to be the role of the food retailer, producer, and the government regulators.

3. What does industry think the term "fresh" means?

The Food Industry generally identifies "fresh" with taste, quality, vitamins, color, and no added preservatives¹. (See attached summary of interviews with retailers and wholesalers for refrigerated perishable foods.)

Flow feels that from a regulatory viewpoint, "fresh" should be consistent with consumer expectations, fundamental science, and current regulatory precedence.

4. Is the term "fresh" when applied to foods processed with the new technologies misleading to consumers?

Most consumers expect that "fresh" is a marker of purity and highest quality. The use of the term "fresh" is not misleading provided that the consumer is informed about how the product was produced. This is consistent with the irradiation label approach.

5. Do the new technologies preserve the foods?

Yes. High-pressure is an active intervention technology. As such, foods can be made to retain their desired characteristics longer. Other non-thermal, active intervention technologies that do the same include irradiation, UV, and ozone.

¹ Flow International Corporation Internal Study, Food Industry Study, performed by TRD Frameworks (market study firm), Seattle, Washington, July 2000 (see attached report summary)

6. Are all the new technologies truly nonthermal?

Unless the same outcome is achieved at absolute zero (0°K) as at higher temperature, nothing is truly nonthermal. For high-pressure, the amount of temperature change as a result of compression (and de-compression) is minimal and is not responsible for the microbial reduction effect achieved. The extent of temperature change can be calculated using thermodynamics calculations ² and verified by experimental testing. The adiabatic temperature as a function of pressure change can be calculated for any starting temperature. Figure 1 shows the temperature for water under pressure starting at 3°C, for pressures up to 700 MPa. Upon pressure release, a temperature drop of the same magnitude is achieved. This figure has been validated for most water-based products such as juices, milk, salsa, etc. Since real processes are not perfectly adiabatic, the maximum temperature rise will be lower than the calculated value shown.

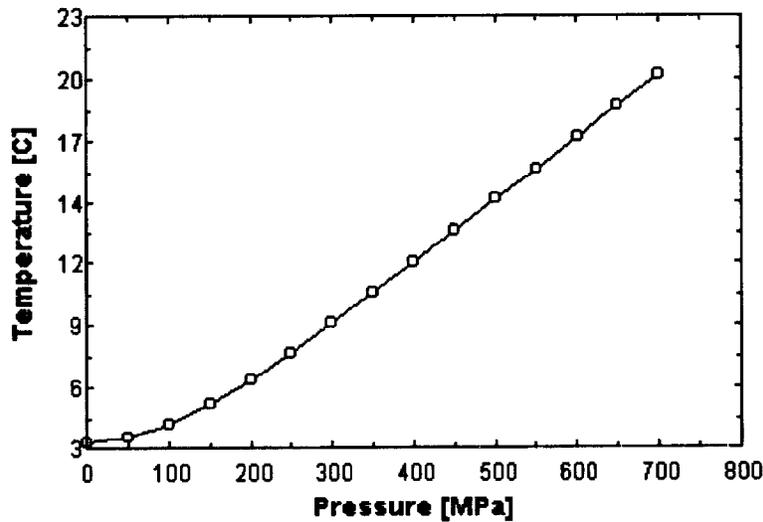


Figure 1: Water temperature under pressure due to adiabatic compression with a starting temperature of 3°C.

7. Are there quantifiable parameters, e.g., level of nutrients, vitamins, etc. that could be measured to determine if a food is "fresh"?

The answer depends on the definition of "fresh". From a sensory and nutritional viewpoint, high-pressure treated orange juice has been studied and has been found to be equal to that of the untreated condition.

² 1995 Formulation for the Thermodynamic Properties of Ordinary Water Substance for General and Scientific Use, issued by The International Association for the Properties of Water and Steam (IAPWS)

"Fresh" however should reflect consumer expectations. For example, even at 1KGy exposure, irradiated orange juice has a very strong off odor that can easily be detected by smell³. This is the result of induced chemical changes of the orange oils. It is highly unlikely that most consumers would consider irradiated orange juice "fresh" even if the regulation allows the use of the label "fresh". High-pressure technology comes far closer to meeting consumer expectation in both sensory and nutritional aspects.

The law and consumer expectations are separate considerations that need to be aligned for the definition of "fresh". Surveys and technical studies^{4 5 6 7 8} have shown that consumers rate high-pressure treated orange juice equal to or better than untreated orange juice. High-pressure also rates highly with consumers in terms of acceptance.

8. Is there a term other than "fresh" that could be used for foods processed with the new technologies?

There may be another term that could be used but this would involve substantial consumer education. The use of the term "fresh" is the most effective method to communicate quality to consumers. As the term "fresh" is already allowed for use with irradiation intervention technology, the use of the term "fresh" would be equally justified for other non-thermal, non-chemical active intervention methods. Based on our studies, consumers clearly indicate that they want to know more about how their foods are produced. However this is a different issue from "Fresh".

9. Would consumers understand a new term?

Consumers are different. Some consumers will understand a new term, but most will fail to understand a new term. The education cycle for the public is a long one. By allowing producers to use the term "fresh" where appropriate, consumers will be allowed to identify a high quality product with sensory and nutritional attributes that are equal to that of the untreated condition.

10. What is the economic impact of allowing the use of the term "fresh" on foods processed with new technologies?

The use of high-pressure technology will increase the availability of higher quality foods to the public. The food safety benefits of high-pressure food technology are well recognized. In addition, foods will taste better and have greater nutritional benefits

³ K.T. Pickett, F. Caporaso, D. Foley, A. Vasconcellos, A. Prakash; "Effect of low dose irradiation on the microbial counts, sensory attributes and ascorbic acid content of unpasteurized orange juice", presented at IFT Annual Meeting, Dallas, Tx, 2000

⁴ B.E. Brooker; "High-pressure Treatment of Liquid Foods and Derived Products (FAIR CT96-1113)", Presentation at IV Joint Meeting of Japanese and European Seminars on High-pressure Bioscience and Biotechnology, Heidelberg, Germany, 1998

⁵ Flow International Corporation Internal Study, Consumer Studies, performed by TRD Frameworks (market study firm), Seattle, Washington, July 2000 (see attached report summaries)

⁶ BBC TV, "Tomorrows World", 1999 (see video attachment)

⁷ Parish, M.E.; "Orange juice quality after treatment by thermal pasteurization or isostatic high-pressure". *Lebensmittel- Wissenschaft und-Technologie* 31:439-442, 1998

⁸ Parish, M. E.; "High-pressure effects on quality of chilled orange juice", *High-pressure Research in the BioSciences and BioTechnology*, K. Heremans (ed.). Lueven University Press, Lueven, Belgium. 1997

longer, and become more affordable as the effective food shelf life is increased and distribution cost reduced. The benefits of consuming foods that have not been heavily processed (cooked or chemical preservatives) are well recognized.

11. Would allowing the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage?

No. The fact is that the most successful users of high-pressure technology have been small companies (Avomex, Keller, Texas, and Motivatit, Houma, Louisiana).