

Summary of responses to consultation on:

Draft Commission Regulation concerning the composition and labelling of foods suitable for people intolerant to gluten

Consultation issued: 23/07/2008

Consultation ended: 30/09/2008

Response from	Comment	Initial View
Tepnel Research Products and Services	<p>Point (4) of the Draft Commission Regulation concerning the composition and labelling of foods suitable for people intolerant to gluten states: 'A revised Codex standard for foods for special dietary use for persons intolerant to gluten was adopted in [July 2008], with a view to enable those persons to find on the market a variety of food suitable for their needs and to their level of sensitivity to gluten. These rules should be taken appropriately into consideration for the purposes of this regulation.' With this statement the draft commission regulation is clearly harmonising itself alongside the revised 'Codex standard for foods for special dietary use for persons intolerant to gluten' (July 2008). While not specifically stating a required method of analysis by association with the Codex standard the Draft regulation is indirectly stipulating the use of the 'Enzyme Linked immunoassay (ELISA) R5 Mendez method' for the determination of Gluten. This gives us cause for concern on both an analytical and a commercial level for the following reasons:</p> <p>1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (29th Session, Nov 2007) agreed that the method of analysis should be validated against a certified reference material (Section 5, 61, page 7). With no certified reference material being available, what are the alternative</p>	<p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p>

options for validating methods, whether it be the R5 ELISA Mendez method or other methods? What criteria need to be attained for such a material for it to be used for calibration of methods? Does the material used for calibrating the R5 ELISAs attain such criteria?

2. In the absence of an internationally available certified reference material how can methods of analysis assist the application of the standard with the 20ppm and 100ppm gluten thresholds?

3. With the endorsement of the R5 ELISA Mendez method by Codex as an internationally accepted method of analysis; how may the method be made readily available to all when the R5 antibody appears to be licensed to only four companies

(http://www.cnb.uam.es/~gluten/english/ukits_eng.htm) ?

4. When the Codex Standard refers to the R5 ELISA Mendez method, which commercial kit is being specified? R-Biopharm offer three R5 based ELISAs: R7001 Ridascreen Gliadin, R7002 Ridascreen FAST Gliadin and R7011 Ridascreen Gliadin competitive (<http://www.r-biopharm.de/>).

The latter kit expresses the results in peptide equivalents. How are these results related to the gluten thresholds for application of the standard? Are the results of the other two kits considered to be equivalent? and on what basis ?

5. Biocontrol (previously called Raisio and Diffchamb) offer PR0320 Transia Plate Prolamin

([http://www.biocontrolsys.com/pdf/SL_Plate%20Prolamins\(1\).pdf](http://www.biocontrolsys.com/pdf/SL_Plate%20Prolamins(1).pdf)). Is this kit deemed to be equivalent to other R5 based ELISAs even though the design of the kit, quality of reagents and manufacturing standards of the kit may be different?

6. Which commercial kit's data has Codex accepted as the basis for the Type 1 endorsement?

7. Without the ready availability of the R5 antibody, if an antibody is used in a method with equivalent specificity to the R5 antibody will it to be deemed to be equivalent? Which

performance criteria will be needed (if any) to demonstrate equivalence? and who would grant this acceptance ?

8. The revised 'Codex standard for foods for special dietary use for persons intolerant to gluten' (July 2008) states: 'The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA Methods)'. There is no mention on the validity of qualitative lateral flow based tests which are finding a unique place within the field of gluten analysis and provide the means for manufacturing companies to perform 'on-site' testing and avoid the loss of time associated with sending samples for analysis to a lab based service. For screening lab based results are not a substitute for onsite control where immediate decision making is required. These types of test also provide an affordable option for the smaller company with a limited testing budget enabling them to operate on-site control of potential Gluten Cross contamination and to demonstrate due diligence. By strong association with the Codex standard the Draft regulation is indirectly stipulating the use of the R5 Mendez method for analysis for Gluten. This would lead to companies with procedures already in place utilising the immediate and cost effective control of Gluten by lateral flow testing being forced to seek a lab based R5 service. This would certainly have an economic impact and possibly an effect on compliance with reduced testing. The R5 ELISA cannot satisfy the demands for screening and confirmation as well as official control.

9. The revised 'Codex standard for foods for special dietary use for persons intolerant to gluten' (July 2008) also states: 'The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients'. The stipulation for the use of R5 Mendez ELISA method for analysis for Gluten goes against this statement as the R5 antibody is specific to

	the 'QQPFP' amino acid sequence only found in the Gliadin like proteins and not the other toxic protein fraction of gluten namely the Glutenins.	
Aberdeen City Council	No comment	