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Consultation on the proposed Transmissible Spongiform Encephalopathies Regulations 2008

April 2008



FOOD
STANDARDS
AGENCY



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<http://www.defra.gov.uk/corporate/consult/tseregs-2008/>

Published by the Department for Environment, Food and Rural Affairs

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Explanatory Note

Part I - Background

1.1 The proposed Transmissible Spongiform Encephalopathies (England) Regulations 2008 would update and replace the existing Transmissible Spongiform Encephalopathies (No.2) Regulations 2006, which would be revoked. The proposed new Regulations will include changes that have been made in response to several developments including reviews of procedure, changes to European legislation, and certain technical changes. Part II of this explanatory note includes all the changes being suggested by Defra whilst Part III lists proposed amendments from the Food Standards Agency, in relation to its responsibilities under the legislation.

1.2 The Transmissible Spongiform Encephalopathies (No.2) Regulations 2006 came into force on 3rd May 2006. They provide the necessary powers to administer and enforce the provisions of Regulation (EC) 999/2001 concerning the prevention, control and eradication of TSEs.

1.3 Over the past year or two there have been a number of amendments made to the EU TSE legislation. These have generally been technical amendments updating the detailed requirements of TSE monitoring arrangements and in the case of scrapie, implementing a more proportionate approach to controls in line with the EU's TSE Roadmap¹. There has also been a need to review the content of the main Regulations and the Schedules to the domestic legislation to ensure that any lessons learnt over the last year are incorporated into domestic legislation.

1.4 Please note that this consultation does not cover those provisions of EC Regulation 727/2007 which were suspended by an interim judgement of the European Court of Justice (ECJ) on 28 September 2007 (point 3 of the Annex to 727/2007 introducing points 2.3(b)(iii), 2.3(d) and 4 in Chapter A of Annex VII of Regulation 999/2001). EC Regulation 1428/2007 which implemented the ECJ judgment: (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:317:0061:0062:EN:PDF>) refers. The outcome of annulment proceedings is awaited but will not be due for some months yet.

1.5 Defra issued a consultation document on responsibility and cost sharing for animal health and welfare on 11 December 2007 (available at <http://www.defra.gov.uk/corporate/consult/ahw-nextsteps/index.htm>). This included, firstly, a proposal that abattoirs should pay for BSE tests where these are required by Regulation (EC) 999/2001 on cattle slaughtered for human consumption and, secondly, a proposal that laboratories that wish to carry out BSE tests should pay for the costs incurred by the Veterinary Laboratories Agency (VLA) in approving them and in arranging quarterly quality assurance exercises and an annual workshop. If these proposals were to be implemented, the former would not require any further amendments to

¹ http://ec.europa.eu/food/food/biosafety/bse/roadmap_en.pdf

the draft Regulations but the latter would require a power to enable VLA to charge. This additional power would be included in these amended Regulations as submitted to Parliament. The impact assessment for these two provisions, and for other BSE proposals in the responsibility and cost sharing document that would come into effect at a later date if agreed, is available at the link above.

1.6 A further technical amendment would also be made to incorporate into these Regulations the provisions of the Bovine Products (Restriction on Placing on the Market) (England) (No 2) Regulations 2005 as amended without changing the effect. This would mean all TSE-related provisions will be in one set of domestic Regulations and is thus de-regulatory.

1.7 The new Regulation would also incorporate amendments made to the 2006 Regulation by the Food Standards Agency in the Transmissible Spongiform Encephalopathies (No.2) Amendment Regulations 2008 which are expected to come into force sometime in May 2008. Details of these changes are set out in Part III of this document.

1.8 All references to the legislation in this document are based on the current format of the TSE (No.2) 2006 Regulations and are intended to demonstrate how the legislation will change. The structure of the legislation may change during the drafting process. This will not, however, affect the substance of the changes that have been outlined in this document.

1.9 Your views are sought on the amendments proposed by Defra, as described here and as set out in Part II, and on the amendments proposed by the Food Standards Agency, as described in Part III.

Part II – Summary of proposed Defra Amendments

Changes to the General Regulations - Details

2.1 It is proposed to add a new sub-paragraph to **Regulation 8 (at 8(2))** which would allow the Secretary of State to amend a Required Method of Operation (RMOP – see Schedule 2, Part 1, paragraph 4 of the existing SI) to reflect technical or scientific developments. Previously, the legal basis for any change to the RMOP was directly linked to non-compliance with the existing requirements reflected in the RMOP, or to non-compliance with the provisions of EU or domestic TSE legislation. This direct linkage provided no legal coverage for changes which needed to be made to the RMOP to account for changes of a technical or scientific nature (such as the introduction of new techniques in brain stem sampling, or in relation to the form of packaging of brain stem samples prior to despatch to the testing laboratory).

2.2 The appeals procedure will be clarified at **Regulation 10** with some textual changes to make the procedure more transparent.

2.3 Powers of entry will be clarified at **Regulation 13** to highlight the circumstances where a Justice of the Peace needs to sign a warrant authorising an inspector to enter premises, if need be by reasonable force.

2.4 Currently **Regulation 15 (1) (c)** only enables an inspector to serve notices on persons in possession of animal protein, and feedingstuffs which may contain animal protein. But in relation to the recall powers in Regulation 15 (3) (g), the persons on whom such notices can be served need to include the suppliers. The proposed amendment will make this change to improve the enforcement powers for such recalls.

2.5 **Regulation 21** will revoke the Transmissible Spongiform Encephalopathies (No. 2) Regulations 2006.

Changes to the Schedules

Schedule 1 (Ambulatory References)

3.1 This will set out the EC instruments quoted in the Regulations, with an explanation that they are construed as being amended from time to time. The use of ambulatory reference means that the Regulations should be able to remain in force, whatever amendments are subsequently made to the corresponding EU legislation.

Schedule 2 (TSE Monitoring)

4.1 Schedule 2, Part 1 - new Paragraph 3(1) (b). This new requirement will make it an offence to submit a brain stem sample for testing if the bovine animal from which it was taken cannot be identified. This follows an incident where DNA testing used at an OTM approved abattoir demonstrated that a brain stem sample could not be correlated to any OTM cattle slaughtered on that day.

4.2 Schedule 2, Part 1- amendment to Paragraph 3(4) (c) – the requirement for the testing laboratory to notify the consigning abattoir of test results is to be amended so it is clearer that that these results must also be available to the Secretary of State.

4.3 Schedule 2, Part 1- amendment to Paragraph 5(3) (b). Poor quality brainstem samples, where the obex cannot be adequately identified are classified as “no-tests”. Until recently (see below) the UK authorities had applied a worst case scenario to these “no-test” samples (i.e. treating them as though they were samples from cattle which would have tested positive for BSE) . This resulted in the destruction of up to 4 animals on each occurrence of a “no-test” result (because of the requirement to apply the ‘one before and two after rule’ – (1b2a) to positively tested cattle). We estimate that this rule when applied to “no-test” samples has cost the UK meat industry about £1.2 million since the OTM rule was changed in November 2005.

4.4 Given the continued rapid decline in the number of cattle testing positive for BSE (and hence the increased odds against any “no test” animal testing positive for BSE), the Veterinary Laboratories Agency (VLA) was asked by Defra to conduct a comprehensive risk assessment on BSE including the application of the 1b2a rule in the event of a “no-test” result. The outcome from this research led to Defra writing to the EU Commission seeking a more proportionate and risk based approach to “no-test” samples. On the basis of advice from the VLA, we proposed that “no-test” samples should be subject to multiple testing and that the 1b2a rule would only be applied if a positive or inconclusive result was found, or if there was insufficient brain stem material for testing. However, the carcass and body parts from the original “no-test” animal or batch would still need to be destroyed. This move was supported by the Food Standards Agency.

4.5 Following agreement to this approach by the EU Commission in late 2007, the new system of multiple testing began on 7 January 2008. As a result of this change, Schedule 2, Part 1, paragraph 5, sub-paragraph (3) of the 2006 Regulations will need to be amended to clarify the application of the 1b2a rule to “no test” samples.’

4.6 Schedule 2, Part 1- amendment to Paragraph 5(5) – There will be a technical change to the existing requirement to retain and dispose of sheep or goat carcasses as specified. The addition of the words ‘**selected for sampling**’ will correct a potential gap in the Regulations between the selection for sampling (at a slaughterhouse, hide market or tannery) and the

actual sampling. We are already operating under these measures, so there will be no additional burdens or issues for the industry.

Schedule 3 (Control and eradication of TSE in bovine animals)

5.1 A number of amendments to the provisions governing movement restrictions, the appeals procedure, valuation and compensation issues are being proposed.

5.2 In order to bring this Schedule in line with Regulation (EC) No.999/2001 all references to BSE will be amended to TSE in bovines. This is a technical amendment which avoids any potential confusion between classical BSE and emerging “unusual” strains of BSE e.g. “H-Type” BSE.

5.3 Schedule 3, Paragraph 3(2) will be amended and a new clause 3(3) will be added to administer the requirements in Article 12 of Regulation (EC) No.999/2001 and Article 2(1)(a) of Commission Decision 2007/411/EC. These relate to the restriction of the movement of bovine animals which may be linked to (e.g. may be a cohort or an offspring of) a bovine animal suspected of being affected with a TSE.

5.4 An amendment at Schedule 3, Paragraph 5(2) will provide a right of appeal to any decision to cull a cohort animal following an inspector’s rejection of evidence alleging that the animal did not have access to the same feed as an animal affected by BSE. The appellant would have 21 days following the notification of the decision, to make representations to a person appointed by the Secretary of State. Other than the exemptions administered by Schedule 3, Paragraph 5(1)(b) and by Regulation 4 (research premises) the culling of cohorts as soon as possible is a legal obligation under Regulation (EC) No. 999/2001 and no other rights of appeal are considered compatible with this requirement.

5.5 Schedule 3, Paragraph 9(1) will be amended to clarify that the compensation payable under the published calendar month standard values is the average price paid in Great Britain for that age and category of animal in the six months (pedigree) or month (non-pedigree) **before the date of its valuation** (rather than the date of slaughter or death). The age and category will be determined at the point the notice of intention to slaughter is served. This amendment avoids any confusion if, for example, an animal’s value is determined in a calendar month before that in which it is slaughtered (Schedule 3, Paragraph 8(a)) or dies (Schedule 3, Paragraph 8(b)).

5.6 Schedule 3, Paragraph 10(3) will be amended to require the owner of animals killed under this schedule to pay for valuation fees, in line with the practice elsewhere in the TSE legislation.

Schedule 4 (Control and eradication of TSE in sheep and goats)

6.1 Revised EU controls have been agreed (EU Commission Regulation No. 727/2007) which allow Member States more discretion in the way they apply controls in cases of atypical scrapie where BSE is excluded and atypical scrapie is confirmed.

6.2 A new Paragraph 9 of Schedule 4 will enable the Secretary of State to choose from the options available where atypical scrapie is confirmed. These are the options of monitoring flocks/herds for two years, or requiring them to be killed and destroyed under a whole flock/herd cull. The paragraph will also set out provisions for administration of the new options and the responsibilities of occupiers of holdings. These include a prohibition on the export to other member States or third countries, of any live animals, or embryos or ova from animals that have been subjected to the monitoring option. The appeals procedure would apply to a decision to apply either of the options.

6.3 A number of other drafting and technical amendments will be made to reflect the revised EU controls and to update the Schedule.

Schedule 5 (Control and eradication of TSE in animals that are not bovine, ovine, or caprine.)

7.1 A new Schedule 5 will be added to address the Community obligations of Article 11 (Notifications) and Article 12 (Suspect Animals) of Regulation (EC) No 999/2001 in relation to the suspicion of TSE in non-bovine, non-ovine and non-caprine animals. These measures were previously administered by regulation 78(1) of the TSE (England) Regulations (SI 2002 No. 843) but were omitted in error from both the subsequent legislation (The TSE Regulations 2006 (SI 2006 No.68) and the current TSE (No.2) Regulations (SI 2006 No. 1228).

7.2 Paragraph 1 of Schedule 5 requires the compulsory notification (by farmers, vets and laboratories) of all animals (other than cattle, sheep or goats) suspected of being affected by a TSE. Paragraph 3 of the Schedule will enable the Secretary of State to arrange for the compulsory slaughter of any TSE suspect or TSE positive animals, although we do not propose to require this for animals not otherwise intended for human consumption. Compensation would be payable for animals compulsorily slaughtered under this Schedule. As we are currently operating under these measures on a voluntary basis, there will be no additional burdens or issues for the industry.

7.3 The EU requirement for TSE testing in deer (Commission Decision 2007/182/EC) came into effect on 19 January 2007. The UK was required to test 598 wild red deer and 598 farmed red deer by the end of the 2007 hunting season. Our survey was carried out on a voluntary basis.

7.4 Paragraph 4 of Schedule 5 creates an obligation (similar to sheep and goats in Schedule 2) for the occupier of a slaughterhouse, hide market or tannery to retain a carcass selected for sampling until the test results have been received and to destroy the carcass by incineration if the test result is positive. Compensation can be requested for animals that test positive to TSE if they are destroyed because of that positive result.

7.5 The main costs for the abattoir (farmed deer) and larders (wild deer) would be the need to retain the carcasses and all other body parts until negative test results are available. As we are currently operating under these

measures on a voluntary basis, there should be no additional burdens or issues for the industry.

Schedule 6 (Feedingstuffs)

8.1 Due to the insertion of the new Schedule 5, the schedule numbered as Schedule 5 in the current Regulations, which deals with feedingstuffs, will be renumbered as Schedule 6 in the new Regulations. There are some technical changes proposed for this Schedule.

Controlling the presence of raw petfood on livestock farms, where intended for feeding to pets/working dogs on the premises.

8.2 In the 2006 TSE Regulations, 'petfood containing animal protein' is one of the list of products which may not be brought onto a livestock farm, with an exception for doing so in controlled circumstances to feed to pets or working dogs on the premises, as provided for in paragraphs 2 (2) (f), and 3 of the current Schedule 5.

8.3 The proposed addition at Paragraph 2(2) (g) of Schedule 6 will cover 'raw petfood consisting of animal protein'. This will be added to ensure that this product is clearly controlled in addition to petfood containing animal protein, with a corresponding amendment in Paragraph 3 (a). This is a clarification only, and should lead to no measurable additional burden on the industry.

Slaughter of Animals: compensation

8.4 Paragraph 6 – where compensation is payable for the slaughter of TSE susceptible animals under the terms of Paragraph 5 in this Schedule, the amount payable is to be brought into line with the amount payable for each species as laid down in the relevant Schedules of the current TSE 2006 Regulations. This means: for bovine animals, in accordance with Paragraphs 9 & 10 of Schedule 3; for ovine or caprine animals, in accordance with Paragraphs 23 and 24 of Schedule 4; and for any other animals, to the market value in accordance with Regulation 11.

Cross contamination of materials originating from premises where processed animal proteins are in use (e.g. petfood plants)

8.5 Paragraph 20, in Schedule 5 of the current 2006 TSE Regulations makes it an offence to supply an ingredient produced on premises where processed animal proteins are in use (e.g. a petfood plant) without labelling/accompanying documentation to indicate its origin.

8.6 Schedule 6, Paragraph 20 in the new Regulations will extend the labelling/documentation requirement to feedingstuffs *containing* ingredients originally produced on premises using processed animal proteins, but only where such a feedingstuff product is not specifically identified and marketed for petfood use. This should ensure that farmed animal feed compounders

cannot unwittingly incorporate possibly contaminated feed ingredients in end products destined to be fed to TSE susceptible animals.

8.7 The views of the petfood industry in particular are invited on this amendment. For the purposes of the associated impact assessment, any data which would help to quantify the category of product affected, and estimates of the cost of compliance, will be gratefully received.

Other technical changes in Schedule 6

8.8 Paragraph 1(3) (Paragraph 1 (2) (c) in the current legislation) – will make it clear that where animal proteins cannot be brought onto a farm keeping ruminant animals, the particular exception for premises registered to use feed containing fishmeal, dicalcium/tricalcium phosphate or blood products/meal for non-ruminants, relates only to the purpose of the registration, and is not a wider exception for the presence of other animal proteins.

8.9 Paragraph 3(2) (d) – will be amended to make a more general reference to compliance with Animal By-Product legislation on use of fertilisers / soil improvers.

8.10 Paragraph 4(2) (b) – will add powers to enable an inspector to seize cattle passports of bovine animals under movement restriction.

8.11 Paragraph 12(1) (a) & (b) – will include a technical amendment to focus sourcing requirement on blood processors only, and not to feed producers.

8.12 Paragraph 12(4) – will include an amendment to provide an authorisation requirement for blood product/bloodmeal processors where official permission is needed (i.e if ruminant blood is processed separately at same plant).

Schedule 7 (Specified Risk Material) - See also Part III of this consultation document

9.1 Previously Schedule 6 covered SRM controls. Proposed changes to this Schedule are described in Part III.

Schedule 8 (Restrictions on dispatch to other Member States and third countries)

10.1 This will remove the slaughter-date based controls on the placing on the market concerning the export of beef and beef products. Consequently, the existing provisions in Schedule 7, subparagraphs 1(b) and (c) of the current SI are deleted.

10.2 The prohibition on the offering to dispatch or on the dispatching of cattle born or reared in the UK before 1 August 1996, to other Member States or to third countries, has been retained in Annex VIII of Regulation (EC)

No.999/2001 and will be included in Schedule 8, Paragraph 1 of the new Regulations.

Part III – Summary of proposed Food Standards Agency Amendments

Changes to the General Regulations – Details

11.1 Between 26 October and 21 December 2007 the Food Standards Agency consulted on the following proposals to amend Schedule 6 (renumbered Schedule 7 in the draft Regulations) of the domestic TSE Regulations:

- (i) changes arising from the Commission's proposal to increase the age at which bovine vertebral column (VC) is classified as specified risk material (SRM);
- (ii) revocation of the Beef Bones Regulations 1997;
- (iii) introduction of a provision to allow enforcement of EU rules on trade; and
- (iv) changes to Schedule 7 (renumbered Schedule 8 in the draft Regulations) to correct references to EU legislation.

11.2 Full details of the consultation, including a partial Impact Assessment, are available on the Food Standards Agency's website at: <http://www.food.gov.uk/consultations/consulteng/2007/tseamends02eng07> and a summary of responses received is available at: <http://www.food.gov.uk/multimedia/pdfs/consultationresponse/tse06amend02engresp.pdf>.

Update on proposal to increase the age at which bovine VC is classified as SRM

12.1 The EU proposal to increase the age at which bovine VC is classified as SRM is currently subject to a three month scrutiny period by the European Parliament. The scrutiny is expected to close at the end of April 2008, if the proposal is adopted, the Community TSE Regulations will be amended to reflect the change. The change would be implemented in UK as soon as possible after it comes into force and following its publication in the Official Journal.

12.2 All these changes will be implemented by the Food Standards Agency in the Transmissible Spongiform Encephalopathies (No.2) Amendment Regulations 2008 which are expected to come into force sometime in May 2008, and will be reflected in Defra's subsequent revocation and remake of the 2006 legislation into the Transmissible Spongiform Encephalopathies Regulations 2008.

Definition of MSM

13.1 Following the amendment to Schedule 1 explained in paragraph 3.1 of part II of this document, the definition of the term “mechanical separated meat” in Article 3 (1) (b) point (n) of the Community TSE Regulations is now applicable in the domestic legislation. Although this has exactly the same meaning as that given to it in paragraph 4(3) of the current Schedule 6 to the domestic Regulations, it is no longer necessary to include provision in the domestic Regulation and it has therefore been omitted from the new Schedule 7 and a reference to the Community Regulation substituted. In addition the extension of prohibition on the production of MSM to bone in cuts from bovine, ovine and caprine animals first introduced into the Community TSE Regulations by Regulation (EC) 722/2007 becomes applicable in England.

Part IV – General Issues

14.1 These provisions may be subject to some subsequent amendment in response to comments received during the consultation period.

14.2 Separate consultations on proposals to make similar changes in Scotland, Wales and Northern Ireland are being carried out in those countries.

14.3 The Food Standards Agency has been fully involved in the preparation of these consultation papers.

14.4 The partial Impact Assessment (IA) for these proposals can be viewed at <http://www.defra.gov.uk/corporate/consult/tseregs-2008/>. This provides further detail on the above measures in terms of their impact on stakeholders. **We invite your comments on the proposed changes plus any additional estimates on benefits and costs likely to result from the changes.**

14.5 **Responses to this consultation are required by 26 June 2008.** When responding, please state whether you are responding as a private individual or on behalf of an organisation or company.

Annex 1 - Spongiform Encephalopathy Advisory Committee (SEAC) Guidance

The Beef Bones Regulations

Background

1.1 The Beef Bones Regulations 1997 prohibited not only the sale of bone-in beef to the consumer but also the use of beef bones for manufacturing food products. In 1999 the regulations were amended to lift the ban on the sale of bone-in beef and beef bones direct to the consumer, but kept the ban on the use of beef bones and bone-in beef in manufactured and processed products.

1.2 Keeping the manufacturing ban was considered prudent as it was thought bone marrow might be infective and that consumers wishing to avoid any associated risk should be protected in circumstances where they might be unable to make a fully-informed choice.

1.3 In November 2005 the ban on OTM cattle entering the food supply was replaced by BSE testing which means that OTM cattle that test negative for BSE may enter the food supply. Measures that manage any risk from dorsal root ganglia associated with the vertebral column have been taken at EU level with the designation of bovine vertebral column (from cattle aged over 24 months) as SRM. In principle, therefore, the UK bones ban deals with any risk from infectivity in bone marrow.

Risk considerations

- i. SEAC do not discount that infectivity may occasionally occur in the bone marrow of clinically affected cattle
- ii. Clinically affected cattle are removed from the food chain
- iii. The number of infected cattle entering the food chain is very low
- iv. Any infected cattle not exhibiting clinical signs but close to clinical disease should be identified by BSE testing
- v. The risk from dorsal root ganglia associated with vertebral column is dealt with under the EU SRM controls
- vi. Any remaining risk from bone marrow, if any, is extremely low
- vii. The ban prohibits the use of UK bones but not imported bones, which may come from countries with the same BSE-risk status as the UK
- viii. The ban is illegal under EU law and therefore could be subject to infraction procedures

SEAC

2.1 SEAC reviewed data on infectivity in bone marrow in November 1998, which at that point derived from the Veterinary Laboratory Agency's pathogenesis study using mouse bioassay on cattle orally infected with BSE. SEAC suggested three possible alternative interpretations for the results,

which were positive for bone marrow samples taken at 38 months after exposure, when clinical disease was evident in the cattle, but negative for samples taken at earlier or later times:

- i. infectivity may occur occasionally in the bone marrow of clinically affected animals;
- ii. the test is able to detect infectivity only above a certain level and, for BSE infectivity in the bone marrow of cattle, it is operating on the borderline of its sensitivity;
- iii. the positive in the case of the group of cattle killed at 38 months may have been due to accidental contamination during post mortem procedures.

2.2 SEAC concluded that there was insufficient evidence to determine which of the interpretations is correct, but that the risk, if any, from bone marrow is likely to be very small and does not have the same significance as infectivity in dorsal root ganglia.

2.3 The FSA put the issue back to SEAC in November 2003, in the light of results which had become available from the BSE pathogenesis study using cattle bioassay, which is estimated to be approximately 500-fold more sensitive than the mouse bioassay. Bone marrow samples taken at 32 and 36 months (plus those taken at 22 and 26 months) post exposure had been inoculated into five 4-months old cattle which were at that point still alive at 55-56 months post inoculation with no clinical signs of disease (and subsequently remained so).

2.4 The negative evidence from the more sensitive cattle bioassay did not cause the Committee to discount the single positive result from the mouse bioassay. However, SEAC did conclude that the risk estimate had been reduced by the results from the cattle bioassay.

Links

FSA Guidance Notes on the Beef Bones Regulations:
www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/beefbonesregsgeng

Beef Bones Regulations 1997: www.opsi.gov.uk/si/si1997/19972959.htm

Beef Bones (Amendment)(England) Regulations 1999:
www.opsi.gov.uk/si/si1999/19993371.htm

Public Summary of SEAC meeting 9 November 1998 and Report to Ministers "A review of infectivity in bone marrow and Dorsal Root Ganglia in cattle infected with BSE"
www.seac.gov.uk/summaries/summ_1198.htm

Public Summary of SEAC meeting 26 November 2003 (Agenda Item 3)
www.seac.gov.uk/minutes/final80.pdf