Basic information 2005/0062(CNS) CNS - Consultation procedure Directive Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC) Repealed by 2013/0136(COD) Amended by 2008/0046(CNS) Subject 3.10.08.05 Animal diseases 4.60.04.04 Food safety

Key players					
European Parliament	Committee responsible	Rapporteur		Appointed	
	AGRI Agriculture and Rural Development	PARISH Neil (PPE-DE)		24/05/2005	
	Committee for opinion	Rappor	teur for opinion	Appointed	
	BUDG Budgets	MULDE	ER Jan (ALDE)	09/06/2005	
	ENVI Environment, Public Health and Food Safety	STURE	STURDY Robert (PPE-DE)		
	Committee for opinion on the legal basis	Rappor	teur for opinion	Appointed	
	JURI Legal Affairs		-ISTÚRIZ WHITE (PPE-DE)	13/07/2005	
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Council of the	Council configuration		Meetings	Date	
European Union	Employment, Social Policy, Health and Consumer Affairs		2699	2005-12-08	
	Agriculture and Fisheries		2702	2005-12-20	
	Agriculture and Fisheries		2669	2005-06-20	
	Agriculture and Fisheries		2685	2005-10-24	
	Agriculture and Fisheries		2677	2005-09-19	
European	Commission DG	Comr	nissioner		
Commission	Health and Food Safety				

Date	Event	Reference	Summary
28/04/2005	Legislative proposal published	COM(2005)0171	Summary
20/06/2005	Debate in Council		Summary
22/06/2005	Committee referral announced in Parliament		
19/09/2005	Debate in Council		
24/10/2005	Debate in Council		Summary
14/11/2005	Vote in committee		Summary
21/11/2005	Committee report tabled for plenary, 1st reading/single reading	A6-0327/2005	
30/11/2005	Debate in Parliament	\odot	
01/12/2005	Decision by Parliament	T6-0455/2005	Summary
01/12/2005	Results of vote in Parliament	£	
08/12/2005	Debate in Council		Summary
20/12/2005	Act adopted by Council after consultation of Parliament		Summary
20/12/2005	End of procedure in Parliament		
14/01/2006	Final act published in Official Journal		

Technical information				
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Legal basis	EC Treaty (after Amsterdam) EC 037			
Stage reached in procedure	Procedure completed			
Committee dossier	AGRI/6/27926			

Documentation gateway					
European Parliament					
Document type	Committee	Reference	Date	Summary	
Committee opinion	JURI	PE364.661	10/10/2005		
Amendments tabled in committee		PE362.874	13/10/2005		

Committee opinion	ENVI	PE360.235	14/10/2005	
Committee opinion	BUDG	PE364.774	14/11/2005	
Committee report tabled for plenary, 1st reading/single reading		A6-0327/2005	21/11/2005	
Text adopted by Parliament, 1st reading/single reading		T6-0455/2005	01/12/2005	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2005)0171	28/04/2005	Summary
Document attached to the procedure	SEC(2005)0549	28/04/2005	Summary
Commission response to text adopted in plenary	SP(2005)5015	15/12/2005	

Other institutions and bodies

Institution/body	ution/body Document type Refe		Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1061/2005 OJ C 024 31.01.2006, p. 0016- 0017	28/09/2005	
EU	Implementing legislative act	32006D0437 OJ L 237 31.08.2006, p. 0001- 0027	04/08/2006	Summary

Additional information				
Source	Document	Date		
European Commission	EUR-Lex			

Final act

Corrigendum to final act 32005L0094R(01) OJ L 137 04.06.2015, p. 0013

Directive 2005/0094

OJ L 010 14.01.2006, p. 0016-0065

Summary

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 28/04/2005 - Legislative proposal

PURPOSE: to update current Community measures on Avian Influenza (AI), with the objective of achieving better prevention and control of outbreaks and to reduce the health risks, the costs and losses and the negative impact to the whole of society due to this disease.

PROPOSED ACT: Council Directive

CONTENT: All is a serious, highly contagious disease of poultry and other birds caused by different types of viruses included in the very large virus family called *Influenzaviridae*. All viruses may also spread to other animals and humans, usually following direct contact with infected birds.

Based on consultations with interested parties, the Commission proposes the introduction of the following main changes to current provisions on Al control:

- Change in the definition of AI to extend the scope of the control measures also to those LPAI (low pathogenic AI) viruses which could potentially mutate into HPAI (high pathogenic AI) viruses, however it would make a distinction between the two conditions so that specific control measures can then be applied in relation to the different risks posed by these viruses.
- Introduction of compulsory surveillance for LPAI in all MSs.
- New and more flexible provisions on vaccination.
- New and flexible provisions for the control of LPAI and HPAI in domestic birds other than poultry, such as those kept in zoos or endangered species.
- New provisions to ensure co-operation between MSs veterinary and public health authorities in case of detection of AI, with the view of protecting human health.
- Attribution to the Commission, through Comitology procedures, to adopt further and more specific AI control measures and to establish an AI vaccine bank

It is proposed to make these changes in Community legislation on Al control in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field, to bring it in line with this proposal and ensure adequate financial support to the Member States (MSs) in relation to some of the newly envisaged control measures (see CNS/2005/0063).

FINANCIAL IMPACT:

Budget lines: 17 01: Administrative expenditure of health and consumer protection policy area; 17 04 02: Other measures in the veterinary, animal welfare and public-health field; and 17 04 03: Emergency fund for veterinary complaints and other animal contaminations which are a risk to public health.

Total allocation for action: EUR 18.810 million for commitments over six years (EUR 3.135 million per year from 2006), broken down as follows:

- Objective 1 (emergency fund eradication of the disease): impossible to predict with precision.
- Objective 2 (surveillance): EUR 9 million.
- Objective 3 (establishment of a vaccine bank): EUR 9 million.
- Objective 4 (establishment of a Community Reference Laboratory for avian influenza): EUR 0.810 million.

Impact on human resources: EUR 1,170,000 (EUR 0.195 per year from 2006).

Total cost of measures: EUR 19.980 million (EUR 3.33 million per year from 2006).

BUDGETARY IMPACT: the additional annual costs for the Community budget of the adoption and implementation of the planned measures is between EUR 3 and 6 million, thus an average of EUR 5.5 million. These costs will be largely recouped by the savings generated from the reduction in the risk of HPAI epidemics breaking out. If they take as a point of reference the two recent epidemics in the EU, it can be estimated that in terms of costs, the prevention of two epidemics would save EUR 100 million or more of the Community budget over a period of ten years. This saving would be considerably higher than the additional costs planned for the new LPAI surveillance measures and the fight against this disease (around EUR 55 million over ten years).

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 24/10/2005

The Council took note of the information provided by the Commission and the remarks from several delegations on the situation regarding avian influenza

Commissioner Kyprianou stressed that avian influenza had spread in Europe, including Russia, Romania and Turkey, that suspicions were rising in Croatia and that a suspicious case was currently under examination in Greece. Indicating that this disease was mostly spread by migrant birds, he insisted on the need to tackle this issue rapidly in order to avoid any possible risks. He also announced the presentation by the Commission in the Standing Committee on the Food Chain and Animal Health (SCFCAH) of a temporary ban on imports of captive birds and pet birds. He reiterated his reluctance to consider vaccination as a tool to combat the outbreak.

Several delegations welcomed the swift reaction of the Commission and stressed the need for each Member State to take immediate action at the source of the problem and to improve communication in order to avoid large-scale panic reactions from consumers. Some of these delegations indicated that consumption of poultry had sharply declined in their countries.

In the follow-up to the information provided on avian influenza, France, supported by Italy and Hungary, submitted a document stressing the need to take into account the economic implications of avian influenza. These delegations asked in particular that all possible tools be used, including the existing export refunds in the Common Market Organisation for poultry, in order to alleviate the economic impact of the avian flu outbreak on poultry producers.

Commissioner Fischer-Boel acknowledged the influence of the media on the decreasing consumption of poultry. She emphasised the use of export refunds as the main market instrument, and stressed that the market would be closely monitored. She also indicated that, should the situation develop into a massive outbreak of avian influenza, co-financing of expenditures was possible and financial compensation for producers' inability to deliver poultry was provided for, under Article 14 of Regulation (EEC) No 2777/75 on the CMO for poultry meat.

The Presidency intends to return to the issue at one of its forthcoming meetings in particular in the light of the discussions within the Council preparatory bodies on the Commission proposal for a Council Directive on Community measures for the control of avian influenza. It recalls its intention to reach an agreement on the Commission proposal as soon as the European Parliament delivers its opinion (in December).

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 04/08/2006 - Implementing legislative act

ACT: Commission Decision 2006/437/EC approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC.

CONTENT: Directive 2005/94/EC provides for certain preventive measures relating to the surveillance and early detection of avian influenza. It also includes control measures which need to be applied in the event of an outbreak of avian influenza in poultry and/or other captive birds.

To help implement these measures the Commission has developed a Diagnostic Manual for avian influenza, which is attached to this Council Decision. The manual lays down common diagnostic procedures, sampling methods and criteria for evaluating laboratory test results, which can confirm the outbreak, or not, of avian influenza.

The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health. They also take account of new tests which have been recently developed on the quick diagnosis of avian influenza.

ENTRY INTO FORCE: The Member States must apply the diagnostic manual from the date on which they transpose Directive 2005/94/EC or from 1 July 2007 – which ever date is earlier.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 20/12/2005 - Final act

PURPOSE: to introduce new measures for the control of avian influenza and to repeal Directive 92/40/EEC.

LEGISLATIVE ACT: Council Directive 2005/94/EC on Community measures for the control of avian influenza and repealing Directive 92/40/EC.

CONTENT: influenza is a highly contagious disease of poultry and other captive birds caused by different types of influenza viruses, which can spread to other mammals, in particular pigs and humans. Certain influenza viruses of avian origin may in certain circumstances affect humans which in turn may pose a serious risk to public health. The purpose of this Directive, however, is to focus on fighting the disease in farmed animals only. At a Community level, the human health risks posed by influenza viruses are primarily dealt with through other Community initiatives such as the European Centre of Disease Prevention and Control, (ECDC) and through the European Union Early Warning Response Mechanism. In light of the inter-linking nature of the avian virus the provisions in this legislative act specify that any public health or workers' health, which complement the animal provisions of this Directive, will be assessed by the Commission together with the ECDC.

The rapidly evolving nature of the avian influenza has resulted in the need to repeal Directive 92/40, which has hitherto regulated the control of avian influenza in the EU. In repealing outdated legislation the new Directive has developed provisions capable of countering the threat to animals and humans, which avian influenza can pose. Provisions in the Directive take account of the most recent opinions delivered by the Scientific Committee on Animal Health and Animal Welfare and the European Food Safety Authority. It also takes account of changes in the "Terrestrial Animals of International Office of Epizootics" (OIE).

The Directive marks a departure from previous provisions by making a distinction between, on the one hand, "Low pathogenic avian influenza (LPAI)" and, "Highly pathogenic avian influenza (HPAI)" on the other. In the case of detecting a virus of a low pathogenic nature, control measures may differ from those which should apply in the case of detecting a virus of a highly pathogenic nature. Disease control measures and in particular the establishment of restriction zones have been modulated to take account of the density of the poultry population as well as other risk factors in the area in which it has been detected. Such an approach allows for the enactment of measures that are both proportionate and flexible, taking account of the

various levels of risk posed by the different virus strains. Given the potential of low pathogenic avian influenza to mutate rapidly into a more pathogenically dangerous variety, the new provisions have an in-built mechanism for active and early surveillance, which are based on general quidelines.

A further feature of the new Directive is its vaccination provisions. The Directive recognises that vaccination can be an effective tool to supplement disease control measures and to avoid mass killings of poultry or other captive birds. At the same time vaccinated poultry, although protected against any clinical signs of the disease, may become infected thereby contributing to the further spread of the disease. Hence the need to provide appropriate surveillance and vaccination restrictions established at a Community level through provisions listed in the Directive.

In other measures the Directive:

- Establishes a reserve of vaccines against avian influenza to be used in poultry or other captive birds.
- Outlines harmonised procedures and methods to be used for the diagnosis of avian influenza. This includes the use of both the Community's and Member States' reference laboratories.
- Requests Member States to draw up contingency plans.
- Sets out procedures for cleansing and disinfection.
- Requests Member States to lay down penalties applicable to infringements of the Directive's provisions.
- Allows for the possibility to amend the Annexes of the Directive without delay in case of an emergency.
- Lays down the possibility to adopt swift Community measures to control any infection of poultry and other animal species.
- Sets out the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry or other captive birds. Member States are free to take more stringent measures should they wish to do so.

TRANSITIONAL PROVISIONS: contingency plans for the control of avian influenza based on Directive 92/40 and in force at 1 July 2007 shall continue to apply for the purpose of this Directive. However, by 30 September 2007 Member States must submit amendments to the Commission to those contingency plans in order to bring them into line with the new Directive's provisions.

TRANSPOSITION: at the latest by 1 July 2007 Member States must make sure that their laws, regulations and administrative provisions comply with this Decision.

ENTRY INTO FORCE: 3 February 2006.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 28/04/2005

COMMISSION'S IMPACT ASSESSMENT

Revision and updating of current legislation to improve disease control of both Low Pathogenic Avian Influenza (LPAI) and High Pathogenic Avian Influenza (HPAI).

Further information concerning the context of this issue may be found in the summary relating to the Commission's proposal COM(2005)0171.

1- POLICY OPTIONS AND IMPACT

The Commission's Scientific Committee examined three possible options for disease control, which can be summarised as follows:

1.1- Option 1: not to change the definition of Al and the control measures laid down in Directive 92/40/EEC, with a recommendation that Member States (MSs) impose restrictions to limit the spread of LPAI.

The advantage of this option would be that it does not involve any cost for LPAI surveillance and control for the Community budget. On the other hand, it is evident that this option does not offer sufficient guarantees that the risks posed by AI viruses are properly tackled, with the subsequent negative consequences on animal health and welfare, the economy and the environment.

1.2- Option 2: to change the current definition of AI to also include LPAI in it, thus establishing the same disease control measures for LPAI and HPAI.

To apply the current HPAI control measures also in case of LPAI would be disproportionate to the risks posed by LPAI to both animal and public health; this could also result in massive killings of animals, with a major negative impact on public opinion and very high costs for disease control, in circumstances where such massive killings and costs may not be justified nor sustainable. In the case of LPAI, the implementation of a compulsory and systematic stamping out policy, which would lead to massive killing and destruction of animals, does not appear necessary, although in certain cases it can still be a valid option taking into account its costs and risks vs. its benefits. Furthermore, several other ancillary disease control measures that are necessary for HPAI should be applied in a more flexible manner in the case of LPAI, also reducing disease control costs.

1.3- Option 3: to change the definition of AI to also include LPAI, but to foresee control measures taking into account the different type of virus and animal host involved.

The current proposals specifically address the LPAI risks by introducing Community harmonised surveillance and control measures for LPAI and developing a broader legal base for the Community co-financing of MSs expenditure related to LPAI control. In the new measures that would be introduced, emphasis is given to the rapid detection and control of LPAI, which should be achieved without necessarily making recourse to massive killing and destruction of poultry or other birds. This approach would reduce the risks of HPAI outbreaks in animals and ultimately also offer risk reduction benefits for public health.

The expected major benefit of option 3 would therefore be to reduce the risk of HPAI outbreaks in poultry and other birds by means of a better control on LPAI and by building on an approach that is proportionate to the risk posed by the two conditions.

The current proposals would entail additional costs for the MSs and the Community budget, due to the measures being introduced for the surveillance and control of LPAI.

Thanks to the adoption of other disease control measures envisaged under the current proposal, including vaccination, savings should result from the expected reduced size of future AI epidemics. It is, however, extremely difficult to quantify these savings.

a decrease in the AI risk in poultry and other birds in the Community is bound to indirectly but significantly reduce the public health risks posed by AI viruses, including the one of an Influenza pandemic, since the circulation of AI viruses in domestic birds is the main source of the AI risk for humans. The implementation of regular surveillance would also have the positive effect that circulation of any AI virus in domestic poultry having a potential impact on public health could be rapidly detected, so allowing the adoption of any appropriate preventive measures, by both animal and public health authorities.

The cost and the impact of an Influenza pandemic would be so serious that even a slight reduction of the overall risk stemming from the proposed measures should not be disregarded in the overall cost/benefit evaluation of such measures.

The economic impact of these new proposals on the poultry sector is also expected to be favourable, as major epidemics of HPAI have also lead to severe indirect losses to the industry, for which they receive no or minimal compensation from MSs and no compensation at all from the EU.

The impact of the proposed measures on zoos and owners of pet birds and rare breeds or species of birds, etc. is also expected to be positive, due to both the reduced risk of HPAI epidemics, which may require the adoption of unpleasant measures for these birds, and because it would be possible to control the AI risks in these birds without necessarily making recourse to killing the birds in question. Prophylactic vaccination of rare birds in areas at high risk of AI would also be possible.

CONCLUSION: Option 3 is the only approach which would match the new Chapter of the O.I.E. (World Organisation for Animal Health) Code, which is expected to be finally adopted in May 2005, and this would prevent EC disease control measures having a negative impact on international trade. Also for this reason, the introduction of new or more detailed LPAI and HPAI control measures cannot be left to the responsibility of individual MSs, as envisaged in option 1, but needs the adoption of harmonised rules at Community level. In summary, option 3 is the one giving the best guarantees that the risks posed by AI viruses for the economy, the environment and society as a whole are tackled in the best possible manner, by means of proportionate measures that are the most advantageous in terms of cost-risk/benefit ratio.

2- FOLLOW-UP

The Commission will have at its disposal several ways to evaluate the impact of the proposals:

- from the occurrence of future HPAI epidemics on poultry, it will be evident whether the measures put in place have been effective to prevent and control those epidemics;
- from the results of the regular LPAI surveillance programmes, future programmes could be better modulated to ensure that the resources allocated are proportionate to the risks posed by LPAI; this would prevent under- or over-expenditure both for the Community and MSs in connection with surveillance:
- from the control measures applied by the MSs in relation to future LPAI outbreaks and related costs, it will be more clear what the real impact of the new financial measures introduced in relation to LPAI control will be.

The Commission has already in place the necessary basic tools to gather and analyse this information in the proper manner, such as the Standing Committee for the Food Chain and Animal Health and the network of Community and National Reference Laboratories, whose role will be confirmed and strengthened by the current proposal. However, in the future, new scientific opinions could also be useful to assist the Commission for policy formulation and fine tuning of legislation, as well as for MSs when implementing disease control measures.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 08/12/2005

The Council held a debate focusing on the need for clear and evidence-based information to the public and for steps to be taken both at national and at EU level to prepare for a possible outbreak of human pandemic influenza.

The debate covered the following issues:

- sharing of information and coordination (e.g. between Member States, the Commission, the European Centre for Disease Prevention and Control and with the World Health Organisation) about the communication to the public about pandemic influenza;
- specific contribution that Member States envisage that EU action, especially the research and development programmes, could make to prepare for a pandemic;
- other specific actions at EU level that Member States believe would add value to work already in hand (for example through the World Health Organisation) to improve both production capacity and speed of access to antivirals and vaccines.

In its conclusions, the Council insisted on the need to distinguish between avian influenza, where the World Health Organisation (WHO) has stressed that the risk is very low for the general human population; seasonal influenza which occurs every year but for which annual vaccination is available; and the risk of human pandemic influenza.

The Council states that scientific advice remains that the risk of avian influenza being directly transmitted to humans from birds is still very low at the present time. A vital first step in protecting human health from risk of pandemic is for Member States to complete their national plans in accordance with WHO guidelines. National plans also provide the foundation for international cooperation at a global and EU level. It also recognises the important role of the European Centre for Disease Prevention and Control in providing scientific advice to the European Commission and to Member States. It highlights the importance of strengthening coordination between Member States and the European Commission on a range of issues using, where possible, existing coordination Mechanisms. There is a need for clear and objective communications with the public to reduce the likelihood of confusing messages to the citizens of Europe. The Council agrees that the need to build up production capacity for antivirals that will be required to maximise protection of populations is an urgent priority. It notes that this is primarily a matter for Member States but that there could be further action at EU level to help to address this and that there should be further consideration of the available options for dealing with an outbreak including the feasibility and added value of the EU holding a targeted strategic stockpile of antivirals.

The Council also notes the importance of building up production capacity for vaccines and notes the importance of increasing the research effort into the development of new vaccines, in support of which the European R&D Framework programmes can play a valuable role.

The Council calls upon the Commission to:

- 1) come forward with its proposals for rapid implementation of the Community aspects of the International Health Regulations as soon as possible;
- 2) strengthen the existing coordination mechanisms between Member States and the European Commission in close collaboration with the European Centre for Disease Prevention and Control in ways that allow Member States to share information about proposed responses and to consider how to avoid giving confusing messages to the general public; and
- 3) consider proposals on further practical action that would add value at EU level to action at national level and in international organisations, especially the WHO.

The Member States are called upon to :

- 1) ensure that national planning is stepped up and completed;
- 2) to share with each other, and with the European Commission, information about the messages being given to the public about pandemic influenza and about action to protect human health from the risks of pandemic influenza; and
- 3) take action to implement the International Health Regulations as quickly as possible.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 20/12/2005

The Council unanimously adopted the revised avian influenza and entered in its minutes a Commission statement. The Council also reached unanimous political agreement on the text regarding the Decision setting the EU contribution for eradication measures on the basis of a compromise drawn up by the Presidency and endorsed by the Commission. The text will subsequently be formally adopted at a future Council.

The thorniest issue at stake concerned the Decision, as it determined the appropriate share of the financial burden between the Member States and the Community. At technical level, several delegations suggested they would support a 50% co-financing rate for both HPAI and LPAI, bearing in mind the risk of the virus mutating from a benign to a severe status.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

The Council took note of the technical progress made during Luxembourg's Presidency and noted that the future United Kingdom Presidency intended to press ahead with work so that a decision could be taken on the proposals for a Directive and Decision on Community measures to combat avian influenza, submitted at the beginning of May 2005, as soon as the European Parliament's opinion was received.

The Polish delegation stressed the possible danger, in its view, of mutation of the low-pathogenic virus into a highly pathogenic virus and called for an appropriate level of financing.

Animal diseases and public health: measures for the control of avian influenza (repeal. Directive 92/40/EEC)

2005/0062(CNS) - 01/12/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the resolution drafted by Neil **PARISH** (EPP-ED, UK) making several amendments to the Commission's proposal. (Please see the summary of 14/11/2002.) The resolution called for tougher measures to control bird flu, improved early warning systems, the development of low-cost vaccines for poultry and a coordinated emergency plan in the event of human contamination. The main amendments were as follows:

- -The Commission must provide the European Centre for disease prevention and control with information on implementation of the annual surveillance programmes. It must also provide the Centre with summary data on the submission of the reports and notifications referred to in Annex II. Parliament went on to adopt a series of amendments providing for closer cooperation with the European Centre for Disease Prevention and Control.
- -Member States must provide for the immediate reporting of any cases of suspected or actual infected birds whatever the nature or pathogenicity of the virus that has caused them .
- -No eggs at all may leave the holding. Parliament deleted the relevant clauses enabling authorisation to be given for eggs to be sent directly to a processing plant for thermal treatment. Following on from these amendments, it also deleted Annex III which dealt with such authorisation. They did, however, introduce new clauses allowing eggs from holdings within protection or surveillance zones established in cases of outbreaks of HPAI, or within restricted zones established in cases of outbreaks of LPAI, to be sent directly to a processing plant.
- -A new clause states that, immediately following an outbreak of HPAI in a poultry holding other than a commercial poultry holding, the competent authority may establish a protection zone and a surveillance zone, on the basis of a risk assessment and taking account of at least the criteria set out in Annex V.
- -Density of poultry is an important factor which should be taken into account when establishing protection and surveillance zones in the event of HPAI outbreaks and when taking measures to deal with LPAI outbreaks.
- -If the outbreak of HPAI is confined in a non-commercial holding/pet bird holding, circus, zoo, pet bird shop or wildlife park, or in a fenced area where other birds are kept for scientific purposes or purposes related to the conservation of endangered species, the competent authority may, following a veterinary risk assessment, derogate to the extent necessary from the provisions concerning the establishment of the protection and surveillance zone, provided that such derogations do not jeopardise disease control.
- -Parliament introduced a new Chapter Va on measures to be applied in cases of serological detection of LPAI or HPAI which cannot be confirmed through virus isolation or polymerase chain reaction (PCR) tests. Appropriate measures must be taken, based on risk assessment, and the Commission must be informed. Prior provision must be made for emergency plans in the event of human contamination. Such emergency plans shall seek to: secure the necessary coordination between Member States; avoid panic among the general public; combat any trafficking that may arise should serious risks actually emerge; determine the areas to be isolated as a priority; identify the population groups to be vaccinated as a priority, and ensure fair and universal distribution of anti-epidemic products.
- -In the event of an outbreak of an influenza pandemic in the EU or in neighbouring countries, the Commission must be able to take crisis measures within 24 hours, such as quarantine and disinfection measures at airports in connection with flights from certain regions and travel restrictions.
- -A new clause further states the Commission shall take steps to help ensure that sufficient antivirals and vaccines are available for those exposed to the virus in the event of an outbreak in one or more Member States.
- -Member States and the Commission shall see to it that, in the event of a pandemic, the available antivirals and vaccines are effectively distributed among the Member States and countries neighbouring the EU.
- -There are new provisions on preventive measures for poultry cullers, and there must be proper risk communication to farmers, workers in the poultry sector and the public:
- -Member States must ensure the availability of an emergency stock of antivirals so that prophylactic protection in the case of a pandemic can be extended rapidly to all persons most at risk of exposure within the EU. They must also ensure sufficient vaccine production capacity to ensure that all persons most at risk of exposure in the event of a pandemic can be pre-emptively vaccinated against the strain in question, if necessary by increasing uptake of the seasonal human influenza vaccine.
- -The Commission must draw up Community-wide pandemic preparedness plans for the distribution of vaccines and antivirals between Member States in the case of a pandemic, in accordance with the prescribed procedure. Those plans shall be made public within one year of the adoption of the Directive.

- -Member States with birds of high conservation, genetic or scientific value shall have authority to acquire and use preventative vaccines with permission of the Committee and without reference to the Commission.
- -A new clause is introduced for specific protective vaccination plans for zoo animals and officially registered rare breeds of poultry or other birds, in order to prevent unnecessary killing of such animals. Such vaccinated animals may be subject to specific restrictions on movement.
- -Supermarkets and other undertakings shall be prohibited from advertising and/or labelling meat on the basis of the avian influenza vaccination characteristics of the animals from which the meat originates.
- -Where it is in the interest of the Community, the Commission may supply vaccines to third countries, and shall number among its responsibilities the provision of assistance by all available means, where possible in cooperation with international organisations, to third countries which are unable or insufficiently able to combat an outbreak of avian influenza effectively
- -An action plan shall be drawn up specifically for European institutions in the event that travel restrictions prevent international meetings, such as those of the Council and European Parliament, from taking place.
- -In addition to the contingency plans, Member States must draw up effective human pandemic preparedness plans, to include rules for the production, stocking and distribution of antivirals to the persons most at risk, the coordination of efforts for the development and mass production of vaccines as well as provisions for mandatory real-time alert exercises, including cross-border cooperation in crisis management, for instance systematic virological screening of air filters from aircraft. The national preparedness plans, the results of real-time simulations and the updates of the plans following real-time simulation must be communicated to the Commission and made public within six months following the adoption of the Directive.
- -The competent authority must carry out a socio-economic impact assessment of the consequences of the contingency plan for the wider rural economy.
- -A new clause is introduced on liaison with the OIE.