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Annex to the

new Community measures for the control of Avian Influenza, in accordance with the draft Commission proposals for a new Council Directive on the control of Avian Influenza and for a Council Decision amending Council Decision 90/424/EEC as regards Community compensation for Avian Influenza control measures

IMPACT ASSESSMENT

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Executive summary

Avian Influenza is a serious, highly contagious viral disease of poultry, which can also spread to other animals and occasionally to humans. During recent outbreaks of the highly pathogenic form of this disease which have occurred in several areas of the world, including some EU MSs, more than 200 million poultry have died or have been killed and destroyed with the aim to control the disease. Massive killing and destruction of animals has, raised major concerns due to animal welfare, ethical, economic, social, and environmental reasons, particularly in the EU.

In some cases, the disease agent has also spread from poultry to humans, causing several deaths. Uncontrolled Avian Influenza outbreaks may eventually lead to the emergence of a virus fully adapted to humans and able to cause an Influenza pandemic, with major health and socio-economic consequence throughout the world.

The Commission envisages updating the current Community legislation on this disease, with the objective to achieve 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 Avian Influenza. This would be achieved by means of surveillance and control measures targeted to the low pathogenic form of disease - to prevent virus mutation into its highly pathogenic form -, by means of vaccination where appropriate and by other measures that take into account the most recent scientific knowledge on this disease, the lessons learned during recent outbreaks and the need to avoid massive killing and destruction of animals as much as possible.

The proposed changes in Community legislation on Avian Influenza control should be made in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field, to ensure adequate financial support to the MSs in relation to some of the newly envisaged control measures.

1. INTRODUCTION – PROBLEM IDENTIFICATION

The biology of Avian Influenza (AI) viruses, the animal and public health problems caused by these viruses are summarised below. Data on the impact on animal and public health as well as on costs and losses caused by AI in the EU and in other parts of the world in recent years are also provided in the table attached to this document (page 21).

AI 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*. AI viruses may also spread to mammals, including humans, usually following direct contact with infected birds. In the human host, the disease may vary from mild conjunctivitis to serious disease, sometimes fatal; during the still ongoing AI epidemic in certain Asian countries, the case fatality rate in humans has been very high (about 70% of the reported cases, see table attached).

Due to continuous genetic changes of the disease agents and their possible "adaptation" to newly infected animal or human hosts, the risks posed by the different AI viruses to animal and public health is variable and to a large extent unpredictable. However, current knowledge indicates that the health risks posed by the so-called Low Pathogenic AI (LPAI) viruses - are inferior to the one posed by Highly Pathogenic AI (HPAI) viruses, which originate from a mutation of certain LPAI viruses, namely those of types H5 and H7, and which can cause a disease in poultry with a mortality rate as high as 90%.

As regards public health, data available indicate that HPAI viruses of types H5 and H7 have been responsible for the vast majority of the cases of AI reported in humans, and of all cases of human deaths due to AI viruses. However, it has been shown that an LPAI virus of type H9 circulating in poultry and pigs in Asia has also been transmitted to humans; the threat posed by this virus on human health is unclear.

In general, domestic poultry populations are free from AI viruses[1]. However, certain wild birds (particularly migratory waterfowl, such as ducks and geese) act as a permanent "reservoir" of LPAI viruses, from which they occasionally spread to domestic poultry. No measures are currently available or can be envisaged to stop or reduce virus circulation in wild birds living in nature; this means that there is a permanent risk of introduction of potentially very dangerous AI viruses from wild to domestic birds, and ultimately to other animals and humans[2].

For unclear reasons, an increase of AI outbreaks has occurred in recent years. Serious AI outbreaks (HPAI) have been recently reported in many different species of birds – including domestic poultry, kept under different husbandry and management practices - in several different areas of the world, and across all continents. These outbreaks have caused the death or killing for disease control purposes of hundreds

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1 This is also confirmed by the surveys carried out in the MSs in recent years.

2 Very recent data suggest that the domestic duck population in south-eastern Asia is also a reservoir of certain types of AI viruses, which could spread to other poultry and animals such as pigs, undergo genetic changes, cause disease in poultry and have the propensity to cause disease in humans.

of millions of birds and very serious losses to the poultry industry worldwide. In connection with these outbreaks, several human cases of infection were also reported, some of them fatal[3].

In the EU, in the last five years, major outbreaks of HPAI have occurred in Italy (1999-2000) and the Netherlands, with secondary spread to Belgium and Germany (2003). These outbreaks had devastating consequences on the poultry sector and a negative impact on the society as a whole - particularly in the Netherlands, where several human cases of disease also occurred[4]. This was despite the draconian control measures applied by the Member States (MSs) including massive killing and destruction of poultry and other birds in the affected areas, which often went far beyond the minimum requirements of Council Directive 92/40/EEC on Community control measures for the control of AI.

After previous EU animal health crises (classical swine fever, 1997-1998; foot and mouth disease, 2001) these outbreaks have prompted further criticisms in the MSs against massive slaughter of animals, due to animal welfare, ethical, social, economic and environmental reasons. The implementation of this measure has had a very negative impact on public opinion, and raised serious criticisms in particular in relation to special categories of birds, such as endangered species or breeds, or pets. The Court of Auditors has also often criticised the Commission due to the economic impact of massive slaughter on the Community budget.

Scientists deem that uncontrolled AI outbreaks, particularly those caused by certain virus types may, following transmission of the virus from birds or other animals into humans, eventually lead to the emergence of a virus fully adapted to humans and able to cause an Influenza pandemic, like the "Spanish flu" of 1917-1919. Such a pandemic could cause millions of human deaths and major socio-economic consequences all over the world[5].

Directive 92/40/EEC establishes compulsory disease control measures only in case of disease in poultry caused by HPAI. Lessons have been learnt during the recent epidemics. Outbreaks of AI caused by LPAI viruses of types H5 and H7, that subsequently mutated into HPAI viruses have caused devastating consequences. Once mutation has occurred, the virus is extremely difficult to control.

In view of the increased knowledge on the risks for human health posed by AI viruses, (which, particularly in the context of the ongoing outbreak in certain Asian countries, have prompted several actions by International organisations such the FAO, the WHO and the OIE), the opinions of the Scientific Committee and the most recent knowledge on the pathogenesis, the epidemiology and the distribution of AI, there is now a clear need to revise and update current legislation to reflect these new advances and experience and to improve disease control of both LPAI and HPAI in future. This will be of direct benefit to animal health and indirectly also human

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3 Serious HPAI outbreaks have been reported in Europe, Asia, Africa and North America in 2003-2004, see also the table on page 21.

4 Including the death of a veterinarian directly exposed to infected poultry.

5 USA public health authorities have estimated that an Influenza pandemic would cause ~ 89 000 – 207000 human deaths; ~314 000 – 734 000 hospitalizations; and an economic impact of ~US$ 71.3 - 166.5 billion, excluding disruptions to commerce and society, in the USA alone.

health. The new AI control measures would be introduced by means of a new Directive repealing Directive 92/40/EEC.

The proposed changes in Community legislation on AI control should be made in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field to bring it in line with the new Directive and ensure adequate financial support to the MSs in relation to some of the newly envisaged AI control measures.

A debate about the prevention of and response to sanitary crises is now underway. The Commission has already produced a preliminary study[6] on a risk financing model for livestock epidemics in the EU and a complementary study is programmed for 2005. The Commission has also started a process of evaluation of the whole Community Animal Health Policy, which will include questions on the cost/effectiveness of the current financial instruments to cope with animal disease surveillance, control and eradication and on ways in which producers should be induced to take all appropriate measures to reduce the risk of disease introduction onto their farms. In this context major risk factors such as density of animal populations and on-farm biohazards will be considered, together with mitigating measures and consequences on the EU budget.Based on the outcome of these studies and evaluation, alternatives to the current way Community financial support is granted to the MSs might be proposed.

Nevertheless, it has been deemed appropriate to adopt the two current proposals without waiting until the end of this process, taking into account the urgent need of revising current legislation on this major health risk. However, the concerns that have induced the Commission to make an evaluation of the Community Animal Health Policy have been fully considered in the two proposals.

[6] http://europa.eu.int/comm/food/animal/diseases/financial/risk_financing_model_10-04_en.pdf

2. OBJECTIVES OF THE PROPOSALS

2.1 Proposal for a new Directive for the control of Avian Influenza

The purpose of the first proposal is to repeal Directive 92/40/EEC and to replace it by a new Directive updating existing provisions. The new Directive will aim to improve control of AI taking into account the need to reduce as much as possible the need for massive slaughter of birds.

The main changes that this proposal would introduce to current provisions on AI control concern the issues listed below:

(A) Change in the definition of "Avian Influenza". The definition of AI laid down in Directive 92/40/EEC restricts the compulsory control measures to be applied by the MSs in the event of an outbreak of disease caused by HPAI viruses only. This definition stemmed from knowledge that was available at the time that the Directive was drafted about 15 years ago. The new definition proposed would extend the scope of Community disease control measures also to those LPAI viruses which could potentially mutate into HPAI viruses[7]. However, it would make a distinction between the two conditions so that specific disease control measures can then be applied in relation to the different risks posed by these viruses.

(B) Compulsory surveillance and control measures for LPAI. Very often LPAI viruses do not cause any clinical signs in domestic poultry and therefore circulate unnoticed in the poultry population, due to direct or indirect contact between poultry farms or movements of poultry. Spread of LPAI viruses in domestic poultry is a major risk factor for their mutation into HPAI viruses, which then cause devastating disease outbreaks.

In accordance with the new rules, MSs would be required to submit LPAI surveillance plans for an early detection of LPAI for Commission approval[8], so that disease control measures can be rapidly applied and mutation of LPAI into HPAI is prevented. In the event of positive identification of LPAI, disease control measures applied by the MSs could either be based on stamping-out (killing and destruction) of poultry in the infected farm or on controlled slaughter of these birds if there are sufficient indications that the risks posed by the slaughtering operations

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7 These are AI viruses of types H5 and H7.

8 Since 2003 MSs surveillance plans for LPAI approved and co-financed by the Commission have been implemented in all MSs. They have been put in place following a recommendation of the Scientific Committee for Animal Health, to gain an insight into the impact of future LPAI control measures. However, the Decisions of the Commission approving and co-financing these plans have as a legal base the provisions of Decision 90/424/EEC, which establish that "the Community shall undertake, or assist the Member States in undertaking, the technical and scientific measures necessary for the development of Community veterinary legislation". It is therefore evident that it is appropriate to create a more solid legal base for a systematic LPAI surveillance.

and by the trade and consumption of the meat of the poultry in question are negligible.

(C) New and more flexible provisions on vaccination of poultry and other birds. Currently, Directive 92/40/EEC only allows emergency vaccination following confirmation of an HPAI outbreak, as a supplementary control measure. These provisions take account of the fact that, for several technical reasons[9], vaccination alone cannot ensure adequate disease prevention and control. In particular, vaccination does not prevent vaccinated birds that are infected with the AI from shedding virus and further spreading the disease, even if they do not show any clinical signs. The use of vaccine therefore requires the adoption of particular precautions, including certain trade restrictions which may make vaccination economically unsustainable.

However, recent experiences in Italy, which have been supported by the Commission, have shown that vaccines might be used in a more extensive manner, provided that appropriate surveillance systems are also implemented in the vaccination area. The 'DIVA' (**D**ifferentiating **I**nfected from **V**accinated **A**nimals) strategy of vaccination, aims to prevent AI viruses from circulating unnoticed in the vaccinated population, while maintaining a viable market for products from vaccinated animals. Indeed, in the context of the vaccination programme implemented in Italy, it has been possible to allow trade in poultry products such as meat and table eggs from the area where vaccination was applied, in the light of the health guarantees provided[10].

The Italian experience has been very well accepted at international level to the extent that the new AI chapter of the OIE Animal Health Code[11] reflects this approach and makes trade in vaccinated poultry and birds and poultry products derived from vaccinated poultry easier, provided that intensive surveillance is carried out in the vaccination area.

In the current proposal, the possibility to make use of vaccines in accordance with either "emergency vaccination" or "protective vaccination" is therefore introduced. The latter might be applied, for example, in areas at high risk of introduction of LPAI. Vaccination, however, continues to have major limits and should therefore be applied only where appropriate, under official control, and in accordance with MSs vaccination plans which must be subject to prior approval by the

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9 These include the practical problems of administration of an adequate number of doses of vaccine by repeated injections to each bird, often having a very short life.

10 The Italian vaccination plans have been approved by the Commission having as a legal base not only Directive 92/40/EC but also Council Directives 89/662/EEC and 90/425/EEC (see also footnotes 13 and 14 infra) which entitle the Commission to adopt exceptional animal disease control measures in case of major threat caused by animal diseases. The current proposal would reinforce and clarify the legal base for the Commission for the approval of the MSs vaccination plans not directly related to previous HPAI outbreaks.

11 The Chapter of the Animal Health Code on AI was approved under the clause "under study" at the OIE General Session in May 2004, see also chapter 6 of this document. The chapter is available on the following site: http://www.oie.int/eng/normes/mcode/en_chapitre_2.7.12.htm.

Commission. These should include the implementation of special surveillance schemes as appropriate.

(D) New and flexible provisions for the control of LPAI and HPAI in domestic birds other than poultry, such as those kept in zoos, endangered species or of rare breeds. Directive 92/40/EEC establishes Community harmonised control measures only in case of HPAI outbreaks in poultry farms, thus leaving the MSs the responsibility to adopt national measures in case of HPAI in other birds, such as pet birds, birds kept in zoos, etc…

In accordance with the proposal, MSs would also be required to apply certain control measures to such birds. It is felt necessary to establish Community harmonised rules on this matter, as the current approach has given rise to uncertainties and a reluctance in some quarters to accept the measures taken by the competent veterinary authorities during the recent outbreaks in certain MSs. However, under the new rules proposed, it would still be the responsibility of the MSs to decide on the basis of risk assessments which policy should be pursued in regard to these other birds. This may include the stamping out of the birds in question or the implementation of alternative measures, such as vaccination.

(E) New provisions to ensure co-operation between veterinary and public health authorities, in case of detection of AI, with a view to protecting human health. The proposal foresees that, in the case of confirmation of AI, animal health authorities in the MSs ensure a rapid exchange of information with public health authorities, so that the most appropriate measures to protect public health can be adopted at MSs level.

In this regard, it must be underlined that the current proposal concerns animal health, as the human health risks posed by Influenza viruses – including the human Influenza viruses regularly circulating worldwide - are primarily dealt with by other Commission actions[12], taking also into account that in accordance with the EU Treaty, the Community has much more limited responsibilities and legal powers on human health than on animal health. However, an improved control of AI in animals is of major importance to reduce the risk for humans caused by AI virus exposure and therefore it is expected that the measures envisaged in this proposal would also have a positive impact on public health.

Furthermore, the current proposal also requires that MSs' contingency plans to control AI outbreaks, which are already in place in the MSs in accordance with existing legislation, take into due account the public health risks caused by AI, in particular to workers or other persons directly exposed to infected or suspected birds.

[12] These actions include in particular the establishment of the European Centre for Disease Control, the Commission paper on Community Influenza pandemic preparedness and response planning and the establishment of the European Influenza Surveillance Scheme.

(F) Attribution to the Commission, through Regulatory Committee procedures, of the legal power to adopt further and more specific AI control measures, whenever the AI epidemiological situation requires so.

The recent AI crises in the EU and in other areas of the world have indicated how a rapid decision-making process is essential to fine tune and co-ordinate disease control measures, taking into account the unpredictability of the disease agents in question and the rapidity of their spread through movements and/or trade of animals, their products and people. In the context of Council Directive 89/662/EEC[13] and 90/425/EEC[14] and other legislation in the veterinary area, the Commission has already a legal base to adopt *ad hoc* animal disease control measures, in case of a serious hazard to animal or public health.

However, taking into account the special health risks posed by AI viruses, it is felt necessary to broaden and reinforce those legal bases, so that the most specific disease control measures can be adopted in case of AI outbreak scenarios for which it is not possible to lay down *ex ante* precise control measures in the current proposal, but for which it is possible to foresee that rapid Community actions falling within the scope of the proposed Directive might be necessary. This would include, for example, the emergence of an AI risk in animals other than birds or the occurrence of AI viruses of types different from H5 or H7 for which an animal or public health risk is identified.

(G) attribution to the Commission, through Regulatory Committee procedure, of the legal power to establish an AI vaccine bank, to which MSs may have access so that rapid vaccination of birds may proceed, when necessary.

However, it appears appropriate that the cost of protective vaccination should be left to the responsibility of MSs and/or industry/owners, as is the case for another major disease of poultry (Newcastle disease) for which Community harmonised control rules are in place (Council Directive 92/66/EEC). Therefore, before taking any decision in this regard, the Commission should launch a debate and then issue guidelines on the use of the vaccines within the bank, to ensure that Community vaccines are only used for emergency vaccination and not for long term protective vaccination.

(H) This proposal would also introduce several technical adaptations to existing provisions, to take into account the lessons learned during the most recent outbreaks. However, these are not worth detailing in this document.

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13 Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.

14 Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market.

2.2 Proposal for a Council Decision amending Council Decision 90/424/EEC

Council Decision 90/424/EEC provides for a Community financial contribution (50%) to be granted to the MSs for some of the expenditure which they may incur when eradicating HPAI[15], namely for reimbursement to farmers who have had their birds slaughtered and destroyed to eradicate the disease, for cleansing and disinfection, and for the destruction of eggs, feedingstuff and other materials likely to be contaminated. The Community may also reimburse 100% of vaccine costs.

The second proposal envisages the following changes to Decision 90/424/EEC:

– to foresee a financial contribution (30%) to MSs, for the costs which they incurred in case of a stamping out policy being applied following LPAI outbreaks. The reduced contribution compared with HPAI outbreaks is justified by the fact that MSs should keep the option not to apply a stamping-out policy in case of LPAI, and a higher Community contribution might induce them not to make adequate use of this option. On the other hand, the Community co-financed surveillance programme should allow the detection of LPAI in a timely manner and thus the need for extensive stamping out should be reduced, with a positive impact also on MSs budgets;

– to foresee a financial contribution (up to 50%) for the MSs surveillance programmes to be implemented annually in accordance with the first proposal (see also footnote 8).

[15] Decision 90/424/EEC uses the very old terminology “avian plague” for HPAI.

3. POLICY OPTIONS

The policy options considered in this assessment are the ones identified by the Scientific Committee on animal health in its report of June 2000 "The Definition of Avian Influenza - The use of Vaccination against Avian Influenza".[16]

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

Option 1: not to change the definition of AI and the control measures laid down in Directive 92/40/EEC, with a recommendation that MSs impose restrictions to limit the spread of LPAI;

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;

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.

[16] The report is available on the web site: http://europa.eu.int/comm/food/fs/sc/scah/out45-final_en.pdf.

4. IMPACT - POSITIVE AND NEGATIVE

The advantages and disadvantages of the three options and the reasons to follow option 3 are hereby summarised.

Option 1

To maintain the *status quo* would not reduce the risk for the Community of future HPAI outbreaks due to uncontrolled circulation of LPAI viruses in poultry farms. The simple recommendation to MSs to adopt national measures for LPAI control would not give sufficient guarantees for improved disease control and a reduction of the related health risks, taking also into account the resistance of operators against stricter control measures which may not be equally imposed to their competitors in other MSs. The implementation of national measures for LPAI surveillance and control by each individual MS may thus lead to serious disturbance to trade in poultry and poultry products and to unfair competition between poultry producers in a market where competition is very high.

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 all the subsequent negative consequences on animal health and welfare, the economy and the environment mentioned in chapter 1.

Option 2

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 (see also chapter 5).

Option 3

It is the option on which the current proposals are based and is therefore discussed in more detail.

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 recent experiences with HPAI in Italy and the Netherlands indicate that at least the Italian epidemic would have been most likely prevented if the measures laid down in the current proposal on AI control had been in force and applied at that time. Indeed, the Italian HPAI epidemic in 1999-2000 originated from an LPAI virus which circulated in poultry farms for several months without effective control and this finally lead to the emergence of an HPAI virus which caused a major epidemic. One of the reasons for the Italian authorities not to apply adequate LPAI control measures at that time was that, given the definition of AI laid down in Directive 92/40/EEC, no legal base appeared to be available in the Italian legal order for such measures[17].

Conversely, the outbreak in the NL was caused by an LPAI virus which probably circulated in poultry farms only for a few weeks before mutating into HPAI. Thus, the unpredictability of the possible mutation of LPAI into HPAI does not make it possible to guarantee the detection and control of such a rapidly evolving event in all circumstances. However, the experience that will be gained in the future thanks to the implementation of LPAI surveys could help in better identifying the risk factors linked to the introduction of LPAI into poultry or other domestic birds, and this would lead to a more targeted surveillance and better chance for earlier detection of any LPAI infection in these birds.

Furthermore, the current proposal introduces provisions on the vaccination of poultry and other birds and to fine tune control measures in the case of HPAI outbreaks.

By means of better prevention of HPAI thanks to improved LPAI measures and subsequent better control of HPAI outbreaks, it is expected that massive killings of birds in relation to HPAI could be reduced in the future, should an outbreak occur.

Option 3 is the only approach which would match the new Chapter of the O.I.E. Code, which is expected to be finally adopted in May 2005[18], 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.

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17 National measures have since been introduced by Italy.

18 A debate has been ongoing at O.I.E. level on AI in recent years, to which the Community has given its active contribution. Indeed, the contents of the current proposal also reflect the debate already held between the Commission and the MSs to prepare the Community position at the O.I.E..

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. The approximate costs for the Community budget can be anticipated as follows:

(a) LPAI surveillance: 1-2 M€ per year. These figures take into account the costs of the programmes for AI surveillance which have been put in place in the MSs in 2003 and 2004[19]. However, it is envisaged that in the future it might be appropriate to reinforce these programmes and this should lead to incremental costs;

(b) LPAI control by means of stamping out: ~1-4 M€ per year. This figure is based on:

– the results of the surveillance for AI carried out in (all) the MSs in 2003 and the preliminary data available on the LPAI surveillance carried out in 2004[20];

– the average cost of any single AI outbreak for which a stamping out policy has been applied in the Community in recent years (~150,000 € per poultry farm); and

– the costs for the EU budget of these outbreaks (30% of co-financing, that is 50 000 € per farm).

Assuming ~80-320 LPAI outbreaks per year in the whole EU, it is envisaged that it will be necessary to apply a stamping out policy on 20-80 LPAI infected farms each year, that is on 25%[21] of the farms in which LPAI would be detected[22];

(c) AI vaccine bank: if the decision to establish an AI vaccine bank is finally taken, the establishment and maintenance of this bank would cost approximately 1-2 M€ per year. This figure has been estimated taking into

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19 600 000 € and 1 M€ from the Community budget have been allocated for these surveys in 2003 and 2004, respectively.

20 In 2003 about 320 poultry farms were found infected or serologically positive for LPAI, about 300 of them in Italy. However, in 2004 the number of LPAI outbreaks in Italy has been much lower (28). Based on this historical data, it is assumed that in the next years from 80 to 320 LPAI outbreaks could be detected annually, even if it is possible that the real number will be much lower. However, to make use of the data of the 2003 and 2004 survey as a reference to assess the risk for future outbreaks of LPAI in the EU should not lead to an underestimation of that risk. Conversely, the further experience which will be gained in the EU thanks to the new LPAI surveillance and control policy could lead to a reduced number of LPAI outbreaks in the future, leading in the long term to a decreasing cost of the proposed LPAI control measures.

21 In the last LPAI outbreaks in Italy in 2002-2003, a stamping out policy has been applied on about 40% of the infected poultry farms. However, this figure should be considered higher than the expected future average, as the recent outbreaks in Italy have occurred in an area with a very high density of poultry where there are several risk factors, that have induced the Italian authorities to apply stamping-out quite widely to prevent further virus spread.

22 It can be estimated that if option 2 was followed (stamping out compulsory in each LPAI infected poultry farm), the annual cost for the control of LPAI would increase up to 15 M€ per year, making the cost/benefit of this option highly questionable.

account the costs of the existing Foot and Mouth Disease antigen bank for the formulation of vaccine.

The annual additional cost for the Community budget (related to the adoption and implementation of the measures indicated in a), b) and c) above would be ~3-8 M€, that means ~5-6 M€ on average.

As explained below, it is expected that the above costs will be counterbalanced by the savings related to the reduced risks for future HPAI epidemics. Of course, it cannot be precisely indicated to what extent the proposed measures would lead to a decrease in the number of future HPAI epidemics, the occurrence of which is still largely unpredictable and can never be totally excluded, given the nature of the risk in question. However, if the envisaged measures had been already in place and implemented in the EU in the last five years, one of the two major epidemics which have occurred in the Community would have been most likely prevented. Based on this, it may therefore be estimated that the implementation of the proposed measures could successfully prevent two major epidemics of HPAI in the next ten years.

The expenditure incurred by the MSs concerned for compensating farmers, for stamping out measures and for cleansing and disinfection (expenditure that are in principle eligible for a 50% Community co-financing in accordance with current provisions of Decision 90/424/EEC) in relation to the two major epidemics which recently occurred in the EU has been between 101 and 174 M€. It can therefore be estimated that at the current costs the prevention of two major epidemics would lead to savings for the Community budget of 100 M€ or more over a ten year period. This would largely outweigh the additional costs foreseen for the new LPAI surveillance and control measures (~50-60 M€ in ten years).

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

As seen above in this document, 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[23].

However, it is not possible to quantify more precisely the benefit of the proposed measures on public health.

As regards the prevention of an Influenza pandemic, this event may have its origin in any country in the world and may then spread into the Community due to human-to-

[23] In accordance with this proposal, Community animal health measures might also be adopted through Regulatory Committee procedure in case of detection of AI virus of types different from H5 or H7, if it is deemed that the virus in question is posing unacceptable risks for animal and/or public health.

human transmission of virus via movements of people. In this case, animal health control measures in place in the Community would have no effect in reducing that risk. However, 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. Furthermore, if such a catastrophic event originated in the EU in the absence of appropriate and scientifically updated Community legislation on animal health, the Community, as well as MSs, would be exposed to very serious criticisms, probably not inferior to the ones made in the past in relation to the emergence and spread of Bovine Spongiform Encephalopathy.

From all the data above, it emerges that both the Community as a whole and the MSs have a clear interest in the updating of Community policy on AI control, in line with the two proposals

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.

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.

5. MONITORING THE RESULTS AND THE IMPACT OF THE PROPOSALS

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[24] 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.

[24] In accordance with Regulation (EC) No. 178/2002 the delivery of scientific opinion in the animal health area is a task of the European Food Safety Authority, see also chapter 6.

6. STAKEHOLDERS CONSULTATION

The two proposals are to a large extent based on a policy paper on AI control and international standards on trade drafted by the Commission services in late 2003, following the major outbreak in the NL, BE and D. The opinions delivered by the Scientific Committee on animal health and welfare on this disease in 2000 and 2003 were duly taken into account in the preparation of that document.

After discussion with MSs veterinary experts, the final version of the policy paper was formally sent by the Commission to the Council in the context of the preparatory work for the General Session of the OIE of May 2004. The paper was endorsed by the Council and sent by the Commission and the Council to the OIE as a working document for reflection, within the overall Community position documents for discussions held at the General Session, and in accordance with the current procedure. On that occasion, the policy paper was also made public on the EUROPA web site[25].

The OIE General Session decided to approve the new international standards on AI to be included in the OIE Code, although in a provisional manner under the clause "under study". This outcome was the consequence of the general agreement reached between OIE members on future AI standards. However, some further developments and improvements of the approved text were still deemed necessary[26] before final adoption, which is foreseen for May 2005.

The preliminary draft proposal for a new Directive on AI control was then drafted taking into account the outcome of the OIE General Session. The preliminary draft was discussed as a working document with MSs experts in two working groups in July 2004. In this context, some MSs have expressed their opinions after consulting their national poultry industry and other stakeholders.

In October 2004, other stakeholders have been consulted by the Commission services. These have been:

– the members of the of the Advisory Committee on poultry meat and eggs of DG AGRI, representing the EU poultry producers and retailers (COPA-COGECA, AVEC, CPE, AEH, EPEGA, EPEXA, EUROCOMMERCE);

– animal welfare organisations (EUROGROUP for animal welfare);

– consumers organisations (BEUC, EUROCOOP);

– animal conservation organisations (SAVE);

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[25] This is document SANCO/10076/2004 REV. 1 (16/2/2004), that is attached to the Community comments sent to the OIE. These comments are available on the following site: HYPERLINK http://europa.eu.int/comm/food/international/organisations/ah_pcad_oie6_en.pdf

[26] The issues for which the text still needs some improvements concern surveillance, trade in certain commodities and "compartmentalisation". These developments in the OIE Code are not expected to have any impact on the measures being proposed by the Commission for AI.

– organisation of European restaurants and caterers (EMRA);

– the Federation of Veterinarians of Europe (FVE).

The Commission services have throughout the drafting and consultation process maintained continuous contacts with the experts of the Community Reference Laboratory for AI, Weybridge, UK, for technical and scientific advice.

Many comments have been received during the above consultation process. In summary, these comments have highlighted the need:

– to have the possibility to apply special disease control rules for particular categories of birds such as pet birds, zoo birds, birds of rare breeds or racing pigeons, that may pose an AI risk inferior to the one posed by commercial poultry and in general have an intrinsic material and immaterial value much higher than commercial poultry; and

– to foresee disease control measures that are proportionate to the different risks posed by LPAI and HPAI.

These comments have been duly taken into account for the finalisation of the proposed legislation, as explained in particular in 2.1 (B), (C) and (D) above. Furthermore, all parties have agreed that each particular disease scenario may require the adoption of tailor-made measures and have welcomed the elements of flexibility in the proposal.

At the request of the Commission and also as a self-motivated task, the European Food Safety Authority (EFSA) has started some work on AI, which would update and extend the recent opinions of the Scientific Committee. It is expected that the incoming EFSA opinions will not have any impact on the basic changes in the AI control policy envisaged with the current proposals. However, EFSA work will most likely produce results that can be of help for MSs when implementing the new legislation and managing AI outbreaks in the future. Furthermore, if appropriate, the Commission may also make full use of EFSA opinions for the fine tuning of the envisaged AI control measures, through Comitology procedure.

ANNEX

INFORMATION ON MAJOR

HIGHLY PATHOGENIC AVIAN INFLUENZA OUTBREAKS[1]

Country affected	Year	Poultry and other birds dead/killed and destroyed	Direct costs[2]	Indirect losses[3]	Impact on human health
Canada (British Columbia)	**2004**	**17 Million**	**M€ 45.6**	**M€ 144**	**2 cases of conjunctivitis**
East Asia[4]	**2003 - 2005**	**>125 Million**	**no data available**	**US$ 10-15 billion[5]**	**69 cases – 46 deaths (in Vietnam, Thailand and Cambodia)**
Belgium	**2003**	**2.7 Million**	**M€ 17.9**	**no data available**	**-**
Germany		**419 000**	**M€ 0.5**	**no data available**	**-**
The Netherlands		**30.7 Million**	**M€ 155.5**	**M€ 350**	**83 cases[6] (conjunctivitis, influenza-like syndrome) – 1 death**
Italy	**1999 - 2000**	**14 Million**	**M€ 101.7**	**M€ 400**	**-**
USA (Pennsylvania)	**1983**	**17 Million**	**M€ 50**	**M€ 204**	**-**

1 The data provided in this table are updated as at 11 March 2005.

2 Direct eradication costs (compensation for birds killed and destroyed, cleansing and disinfection, etc.). The figures concerning Member States are those provided to the European Commission by the Member States concerned. The amounts indicated in the table are in principle eligible for Community co-financing (50% rate) in accordance with existing provisions of Council Decision 90/424/EEC.

3 Estimate of the losses incurred by farmers and industry as a result of restrictions imposed on movement of poultry, marketing of their products and other negative impacts for the poultry sector.

4 Outbreaks of HPAI caused by virus type H5N1 have been reported in Cambodia, Indonesia, Japan, Malaysia, Republic of Korea, Laos, People's Republic of China, Thailand and Vietnam. After an epidemic wave, the disease seems to have become endemic in some of the above Asian countries. This situation is unprecedented. The FAO and OIE have defined it as "a crisis of global importance". Its social and economic impact has been enormous, both on commercial and non-commercial poultry farmers in the affected areas. Thailand, in particular, being a major producer and exporter of poultry and poultry products, has been suffering major economic losses, also due to the restrictions imposed by many countries including the EU on their export of poultry/poultry meat. The WHO has warned on the risk of a human pandemic originating from this epidemic. The FAO, OIE and WHO are currently engaged in supporting the efforts of the countries concerned to control the disease. The EU has provided aid to some of these countries, Vietnam in particular.

5 Estimate of the total 2004 GDP losses (source: Oxford Economic Forecasting).

6 In accordance with recent information, a much higher number of people, mainly poultry workers and their relatives, seem to have been in contact with the AI virus, as shown by the detection of AI specific antibodies.