Official Journal of the European Union

C 299

English edition

Information and Notices

Volume 58

11 September 2015

Contents

EN

[1] Text with EEA relevance

V *Announcements*

ADMINISTRATIVE PROCEDURES

OTHER ACTS

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Non-opposition to a notified concentration

(Case M.7498 — Compagnie de Saint Gobain/SIKA)

(Text with EEA relevance)

(2015/C 299/01)

On 22 July 2015, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ([1]). The full text of the decision is available only in English language and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes;

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/homepage.html?locale=en) under document number 32015M7498. EUR-Lex is the online access to the European law.

([1]) OJ L 24, 29.1.2004, p. 1.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COUNCIL

List of appointments made by the Council

May-August 2015 (social field)

(2015/C 299/02)

Committee	End of term of office	Publication in OJ	Person replaced	Resignation/ appointment	Member/ alternate	Category	Country	Person appointed	Affiliation	Date of Council Decision
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Ms Monika ZAKRZEWSKA	Resignation	Alternate	Employers	Poland	Ms Anna KWIATKIEWICZ	Konfederacja Lewiatan	15.6.2015
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Ms Stamatia PISIMISI	Resignation	Alternate	Government	Greece	Mr Ioannis KONSTANTAKOPOULOS	Ministry of Labour, Social Security and Social Solidarity	15.6.2015
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Mr Carl ANDERS	Resignation	Member	Employers	Ireland	Mr Michael GILLEN	IBEC	19.6.2015
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Mr Robert HUBERTY	Resignation	Member	Government	Luxembourg	Mr Marco BOLY	Ministère du Travail et de l'Emploi	19.6.2015

Committee	End of term of office	Publication in OJ	Person replaced	Resignation/ appointment	Member/ alternate	Category	Country	Person appointed	Affiliation	Date of Council Decision
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Mr Raul SCHMIDT	Resignation	Alternate	Government	Luxembourg	Mr John SCHNEIDER	Ministère du Travail et de l'Emploi	18.9.2015
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Mr Péter NESZTINGER	Resignation	Member	Government	Hungary	Mr József BAKOS	Ministry for National Economy	18.9.2015
Advisory Committee on Safety and Health at Work	28.2.2016	C 120, 26.4.2013	Mr Gyula MADARÁSZ	Resignation	Alternate	Government	Hungary	Ms Éva GRÓNAI	Ministry for National Economy	18.9.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Grazia STRANO	Resignation	Member	Government	Italy	Mr Salvatore PIRRONE	Ministero del Lavoro e delle Politiche Sociali	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Daniele LUNETTA	Resignation	Member	Government	Italy	Mr Marco ESPOSITO	Ministero del Lavoro e delle Politiche Sociali	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Iolanda VALERIA	Resignation	Alternate	Government	Italy	Ms Monica LIPPOLIS	Ministero del Lavoro e delle Politiche Sociali	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Paolo TOMASSETTI	Resignation	Alternate	Employers	Italy	Mr Fabio ANTONILLI	Confartigianato	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Armando OCCHIPINTI	Resignation	Member	Employers	Italy	Ms Serena FACELLO	Confcommercio	11.5.2015

Committee	End of term of office	Publication in OJ	Person replaced	Resignation/ appointment	Member/ alternate	Category	Country	Person appointed	Affiliation	Date of Council Decision
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Ornella CILONA	Resignation	Member	Trade Unions	Italy	Mr Giuseppe CASUCCI	UIL	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Giuseppe CASUCCI	Resignation	Alternate	Trade Unions	Italy	Mr Salvatore MARRA	CGIL	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Janina CIECIORA	Resignation	Member	Government	United Kingdom	Ms Lindsay ROOME	EU Social Security Coordination	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Radovan MAXIN	Resignation	Member	Employers	Slovakia	Mr Ján LÍŠKA	AZZZ SR — Federation of Employers' Association of the Slovak Republic	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Katalin KISSNÉ BENCZE	Resignation	Member	Government	Hungary	Ms Margit VADKERTI	Ministry for National Economy	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Mario SCHEMBRI	Resignation	Member	Government	Malta	Ms Astrid May GRIMA	Identity Malta Agency	11.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Mr Flemming DREESEN	Resignation	Member	Employers	Denmark	Ms Christiane MIßLBECK-WINBERG	Confederation of Danish Employers	28.5.2015
Advisory Committee on Freedom of Movement for Workers	24.9.2016	C 338, 27.9.2014	Ms Agnė PECIUKEVIČIENĖ	Resignation	Member	Government	Lithuania	Ms Rita ŽEMAITYTĖ-TACK	Ministry of Social Security and Labour	8.6.2015

Committee	End of term of office	Publication in OJ	Person replaced	Resignation/ appointment	Member/ alternate	Category	Country	Person appointed	Affiliation	Date of Council Decision
Advisory Committee for the Coordination of Social Security Systems	19.10.2015	C 290, 27.10.2010	Mr Flemming DREESEN	Resignation	Member	Employers	Denmark	Ms Christiane MIßLBECK-WINBERG	Confederation of Danish Employers	28.5.2015
Advisory Committee for the Coordination of Social Security Systems	19.10.2015	C 290, 27.10.2010	Ms Camilla CLEVIN	Resignation	Member	Government	Denmark	Ms Sabrija TIRAK	Danish Agency for Labour Market and Recruitment	28.5.2015
Advisory Committee for the Coordination of Social Security Systems	19.10.2015	C 290, 27.10.2010	Ms Ioanna BOUZALAKOU	Resignation	Alternate	Government	Greece	Ms Vasiliki MAMMONA	Ministry of Labour, Social Security and Social Solidarity	19.6.2015
Governing Board of the European Foundation for the Improvement of Living and Working Conditions	30.11.2016	C 358, 7.12.2013	Ms Stamatia PISIMISI	Resignation	Member	Government	Greece	Ms Despoina MICHAILIDOU	Ministry of Labour, Social Security and Social Solidarity	19.6.2015
Governing Board of the European Foundation for the Improvement of Living and Working Conditions	30.11.2016	C 358, 7.12.2013	Ms Eva PÕLDIS	Resignation	Member	Government	Estonia	Ms Liina KALDMÄE	Ministry of Social Affairs of Estonia	19.6.2015
Governing Board of the European Agency for Safety and Health at Work	7.11.2016	C 358, 7.12.2013	Ms Stamatia PISIMISI	Resignation	Alternate	Government	Greece	Mr Ioannis KONSTANTAKOPOULOS	Ministry of Labour, Social Security and Social Solidarity	19.6.2015

EUROPEAN COMMISSION

Euro exchange rates [1]

10 September 2015

(2015/C 299/03)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,1185	CAD	Canadian dollar	1,4822
JPY	Japanese yen	135,38	HKD	Hong Kong dollar	8,6685
DKK	Danish krone	7,4611	NZD	New Zealand dollar	1,7775
GBP	Pound sterling	0,72655	SGD	Singapore dollar	1,5837
SEK	Swedish krona	9,4001	KRW	South Korean won	1 327,10
CHF	Swiss franc	1,0923	ZAR	South African rand	15,4986
ISK	Iceland króna		CNY	Chinese yuan renminbi	7,1329
NOK	Norwegian krone	9,1760	HRK	Croatian kuna	7,5520
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	15 992,53
CZK	Czech koruna	27,038	MYR	Malaysian ringgit	4,8238
HUF	Hungarian forint	314,51	PHP	Philippine peso	52,388
PLN	Polish zloty	4,2125	RUB	Russian rouble	76,3445
RON	Romanian leu	4,4228	THB	Thai baht	40,387
TRY	Turkish lira	3,4067	BRL	Brazilian real	4,3489
AUD	Australian dollar	1,5831	MXN	Mexican peso	18,9163
			INR	Indian rupee	74,3061

[1] *Source*: reference exchange rate published by the ECB.

COMMISSION NOTICE

Guidelines for the prudent use of antimicrobials in veterinary medicine

(2015/C 299/04)

Table of Contents

INTRODUCTION

The extensive use of antimicrobials in human and veterinary medicine in recent years has accelerated the emergence and spread of resistant microorganisms. This situation has been worsened by the lack of investment in developing new effective antibiotics. The severity of the consequences is clear to see: it is estimated that each year, drug-resistant infections result in at least 25 000 patient deaths and cost the EU EUR 1,5 billion in healthcare costs and through loss of productivity ([1]).

([1]) ECDC/EMEA Joint Technical Report. *The bacterial challenge: time to react*. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf

Antimicrobial resistance (AMR) is therefore a priority for the Commission. In November 2011, it launched a five-year action plan designed to address the growing risks posed by AMR ([1]). The action plan is based on a holistic approach, in line with the 'One Health' perspective. It involves participation from all sectors and covers all aspects of AMR. The main aims of the plan are to strengthen the prevention and control of AMR across the human, veterinary and food sectors and to secure the availability and prolong the effectiveness of antimicrobial agents. The action plan covers seven areas and sets out twelve specific actions to be taken in the human and/or veterinary fields.

The action plan emphasises the importance of international cooperation in tackling AMR, given the global nature of the problem. The EU is supporting and actively collaborating with international organisations such as the World Health Organisation, the World Organisation for Animal Health, the Food and Agriculture Organisation and the Codex Alimentarius Commission, in order to ensure the development and implementation of global strategies and measures designed to restrict the development and spread of AMR. Controlling AMR is an issue that needs to be addressed at international level, in order to minimise its consequences and development, and should be compatible with international agreements, such as those of the World Trade Organisation.

The appropriate use of antimicrobials in both human and veterinary medicine is one of the main EU policy areas relevant to tackling AMR. This document is designed to provide Member States with practical guidelines for the prudent use ([2]) of antimicrobials in veterinary medicine, in accordance with Action 3 of the action plan.

These guidelines address principles of prudent use and set out measures to be considered by Member States when developing and implementing national strategies to combat AMR. In order to make these guidelines as practical as possible, a separate Staff Working Document ([3]) provides a number of practical examples of approaches used in various Member States for implementing each of the principles. These examples are provided as an illustration of possible measures that could be taken and should not be interpreted as an attempt to impose any particular approach at EU level.

These guidelines are without prejudice to provisions contained in national or EU law and are not binding on Member States or other parties. They form one part of the Commission's overall strategy on AMR, as set out in the action plan referred to above, and are complemented by other actions such as the re-assessment of marketing authorisations for antimicrobials, the strengthening and the harmonisation of surveillance systems and research activities.

There are a number of provisions relating to the use of antimicrobials for tackling the development of AMR, set out in the EU legislation and therefore binding across the EU. Some of these provisions are currently being revised, for example the legislation on veterinary medicinal products and medicated feed, as well as other legislative proposals ([4]). These guidelines will be modified if contradictions with EU legislation arise in the future. The existence of these guidelines will not prevent the Commission from putting forward legally binding requirements if these are considered more appropriate.

([1]) Communication from the Commission to the European Parliament and the Council. *Action plan against the rising threats from Antimicrobial Resistance*. COM(2011) 748.

([2]) Alternative terms such as 'appropriate', 'judicious' or 'responsible' may be used by other organisations or in other documents. In many cases, the terms are exchangeable.

([3]) http://ec.europa.eu/food/food/biosafety/antimicrobial_resistance/index_en.htm

([4]) On 10 September 2014, the Commission adopted the proposals for new regulations on veterinary medicinal products (http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm) and medicated feed (http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_en.htm). The proposals, which implement Action 2 of the EU action plan, contain specific provisions on antimicrobials. The proposal on veterinary medicinal products includes provisions on the following: a definition of antimicrobial resistance, a system to collect data on the sale and use of antimicrobials, marketing authorisation based on careful scientific benefit-risk assessment, special conditions for the retail of antimicrobials by veterinarians, post-authorisation requirements for antimicrobials, prescription for all antimicrobials, clear restrictions on off-label use (the use of a medicine outside the terms of the marketing authorisation), prohibition of use for growth promotion, stricter rules for advertising, incentives for development of new antimicrobials (extended protections of technical documentation) and a legal tool for preserving antimicrobials for human use only. The proposal on medicated feed prohibits the preventive use of antimicrobials through medicated feed. Both proposals have been introduced under the ordinary legislative procedure and discussions in the Council and the European Parliament have already started.

The guidelines should be used in conjunction with existing guidance documents provided by national authorities or stakeholder organisations, and other international standards and guidelines developed by the World Organisation for Animal Health ([1]), the World Health Organisation ([2]) and the Codex Alimentarius Commission ([3]). National guidelines are likely to be more detailed and adapted to national regulations, local circumstances, animal health status, disease control programmes and farming or veterinary systems and practices.

1. SCOPE AND PURPOSE

These Commission guidelines relate to the prudent use of antimicrobials in animals, and, in particular, how prudent usage can contribute to containing the development of AMR. They should be applied in parallel to Council Recommendation 2002/77/EC of 15 November 2001 on the prudent use of antimicrobial agents in human medicine ([4]), thus ensuring a holistic approach to the fight against AMR. They reflect the initiatives recommended in the *Council conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector — a 'One Health' perspective*, adopted on 22 June 2012, in the *Report on the Microbial Challenge — Rising threats from Antimicrobial Resistance*, adopted by the European Parliament on 10 December 2012 and in the *Resolution on Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance* adopted by the European Parliament on 19 May 2015.

Antimicrobial agents have been defined by Codex Alimentarius in its *Guidelines for risk analysis of foodborne antimicrobial resistance* ([5]) and in the *Terrestrial animal health code* ([6]) published by the World Organisation for Animal Health. In these guidelines, the term 'antimicrobial' has been used generically to encompass antibiotics and antibacterial agents, but excludes antivirals and antiparasitics. This is consistent with the wording used by the European Food Safety Authority, the European Centre for Disease Prevention and Control, the European Medicines Agency and the Scientific Committee on Emerging and Newly Identified Health Risks in the *Joint Opinion on antimicrobial resistance (AMR) focused on zoonotic infections* ([7]). The use of additional substances in limiting the growth of microorganisms for purposes other than veterinary medicine, such as for plant health, or as biocides including disinfectants, has been excluded from the scope of these guidelines.

The residues of antimicrobials in food of animal origin and the compliance with maximum residue limits and withdrawal periods are also excluded from the scope of these guidelines, as the requirements of the EU legislation on this field are aimed at ensuring food safety ([8]).

The purpose of these guidelines is to provide practical guidance for Member States on the development and implementation of strategies to promote the prudent use of antimicrobials, especially antibiotics, in veterinary medicine, in accordance with Action 3 of the Commission's action plan. These measures may also contribute to and complement the control of AMR in human medicine.

These guidelines are addressed to Member States. Some chapters or specific measures are addressed to other relevant parties, including industry, farmers, veterinarians, associations and academia.

([1]) Chapter 6.9 of the World Organisation for Animal Health Terrestrial Animal Health Code (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.6.9.htm) and Chapter 6.3 of the World Organisation for Animal Health Aquatic Animal Health Code (http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_1.6.3.htm).

([2]) http://www.euro.who.int/__data/assets/pdf_file/0005/136454/e94889.pdf

([3]) CAC/GL 77-2011 (http://www.codexalimentarius.org/standards/list-of-standards/).

([4]) OJ L 34, 5.2.2002, p. 13.

([5]) 'Antimicrobial agents: any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target.' *Guidelines for risk analysis of foodborne antimicrobial resistance* (CAC/GL 77-2011).

([6]) 'Antimicrobial agent means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of microorganisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.' *Terrestrial animal health code*.
http://web.oie.int/eng/normes/mcode/en_glossaire.htm#terme_antibiotique

([7]) An active substance of synthetic or natural origin which destroys bacteria, suppresses their growth or their ability to reproduce in animals or humans, excluding antivirals and antiparasites http://www.efsa.europa.eu/en/efsajournal/pub/1372.htm

([8]) In order to ensure food safety, food of animal origin must not contain residues of antimicrobials exceeding the maximum residue limits as established by Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ L 152, 16.6.2009, p. 11). An adequate withdrawal period therefore needs to be applied after the antimicrobial is administered to food-producing animals to ensure that the concentration of the residues remaining in edible tissues and animal products is below established maximum residue limits.

2. REGULATORY FRAMEWORK

The use of antimicrobials in animals must conform to EU and national rules. In particular, antimicrobials must be used as specified in the authorised product information (Summary of Product Characteristics (SPC), package leaflet and labelling). The SPC lists the approved indications for use of a veterinary medicinal product, as developed during the risk assessment process. In accordance with Article 14 of Directive 2001/82/EC ([1]) and Article 31 of Regulation (EC) No 726/2004 ([2]), any application for a marketing authorisation must be accompanied by the SPC which is proposed by the applicant, and assessed and, if necessary, amended by the competent authority or the Commission (centralised procedure).

For veterinary medicinal products that have been on the market for many years, new knowledge may emerge requiring amendments to be made to the terms of a marketing authorisation. This may involve, e.g. changes to the recommended dose in order to improve therapeutic efficacy. In particular, knowledge of the patterns in resistance and use of antimicrobials may change over time, and may vary between Member States.

The current legislation allows the product information (SPC, leaflet, labelling) on authorised products to be updated by means of so called referral procedure. The decision to initiate a referral could be based on the risk to human and/or animal health. Antimicrobials are one of the types of medicines for which a referral procedure can be launched. Currently, the majority of referral procedures relate to antimicrobials.

SPC harmonisation can be achieved by means of the referral procedure laid down in Article 34 of Directive 2001/82/EC. Harmonisation may be necessary when SPC for the same or similar products are authorised with different conditions in different EU countries. The differences may relate to indications, dosage, dosing intervals and other fundamental aspects determining a medicine's effective and safe use.

SPC can also be amended through referrals made in the 'Union interest', as laid down in Article 35 of Directive 2001/82/EC. A number of referrals have already been performed to revise and update SPC for classes of antimicrobials considered critically important in human medicine. These relate to: the inclusion of warning sentences in the SPC for quinolones (including fluoroquinolones) and in the SPC for third- and fourth-generation cephalosporins used for systemic administration, the updating of the SPC for oral colistin and tylosin pharmaceutical forms administered to pigs. A stepwise procedure is in place and, taking account of the risk, other referrals will be carried out.

The Commission's decisions following referrals procedures are made public, and competent authorities and marketing authorisation holders are then responsible for the implementation. The Commission decision may include changes to the terms of a marketing authorisation, revision of the SPC, or a suspension or withdrawal of a marketing authorisation.

EU legislation on medicated feed ([3]) regulates the conditions for the manufacture (mixing of veterinary medicines into feed), placing on the market and use of medicated feed. It does not apply to veterinary medicinal products used as the medicinal component of medicated feed (the 'medicated premixes'), which are covered by the veterinary medicinal products legislation.

3. PRINCIPLES FOR THE PRUDENT USE OF ANTIMICROBIALS

Antimicrobials are essential for the medical care and health of animals and livestock populations. Any use of antimicrobials (e.g. in human and veterinary medicine) can result in the development of AMR. The risk increases if such antimicrobials are used inappropriately, for example, in an untargeted manner (e.g. mass medication or use on non-susceptible microorganisms), at sub-therapeutic doses, repeatedly, or for inappropriate periods of time.

General principles on the prudent use of antimicrobials need to be applied as a matter of routine on farms and in veterinary practices.

([1]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([2]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

([3]) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community (OJ L 92, 7.4.1990, p. 42).

3.1. **Issues to be considered before using antimicrobials**

The scientific documents ([1]) on antimicrobials produced by the European Medicines Agency provide additional recommendations on minimising the development of AMR from the use of antimicrobials in animals.

Prudent use of antimicrobials should lead to more rational and targeted use, thereby maximising the therapeutic effect and minimising the development of AMR. Taking into account cross- and co-resistance, which mean that any exposure to antimicrobials increases the occurrence of AMR, the final outcome of prudent use should be an overall reduction in the use of antimicrobials, predominantly by limiting their use only to situations where they are necessary. In these situations antimicrobials should be used as targeted treatment and according to best practices, i.e. based on clinical diagnosis and, whenever possible, on the results of microbiological susceptibility tests, and using an antimicrobial agent of as narrow-spectrum as possible.

The ultimate objective is to reduce the need for antimicrobials by preventing disease. Animal diseases and infections should primarily be prevented by ensuring biosecurity, following good production and good management practices, and implementing integrated disease control programmes to minimise the occurrence of diseases and eradicate endemic disease.

In cases where it is necessary to use antimicrobials to safeguard animal health and welfare, the following principles should be followed:

— The prescription and dispensation of antimicrobials must be justified by a veterinary diagnosis in accordance with the current status of scientific knowledge.

— Where it is necessary to prescribe an antimicrobial, the prescription should be based on a diagnosis made following clinical examination of the animal by the prescribing veterinarian. Where possible, antimicrobial susceptibility testing should be carried out to determine the choice of antimicrobial.

— Antimicrobial metaphylaxis ([2]) should be prescribed only when there is a real need for treatment. In such cases, the veterinarian should justify and document the treatment on the basis of clinical findings on the development of a disease in a herd or flock. Antimicrobial metaphylaxis should never be used in place of good management practices.

— Routine prophylaxis must be avoided. Prophylaxis should be reserved for exceptional case-specific indications.

— Administering medication to an entire herd or flock should be avoided whenever possible. Sick animals should be isolated and treated individually (e.g. by administrating injectables).

— All information relating to the animals, the cause and the nature of the infection and the range of available antimicrobial products must be taken into account when making a decision regarding antimicrobial treatment.

— A narrow-spectrum antimicrobial should always be the first choice unless prior susceptibility testing — where appropriate supported by relevant epidemiological data — shows that this would be ineffective. The use of broad-spectrum antimicrobials and antimicrobial combinations should be avoided (with the exception of fixed combinations contained in authorised veterinary medicinal products).

— If an animal or group of animals suffer from recurrent infection(s) requiring antimicrobial treatment, efforts should be made to eradicate the strains of the microorganisms by determining why the disease is recurring, and altering the production conditions, animal husbandry and/or management.

— Use of antimicrobial agents prone to propagate transmissible resistance should be minimised.

([1]) http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000384.jsp&mid=WC0b01ac058002dd37#Antimicrobials

([2]) The term 'metaphylaxis', refers to the administration of the product at the same time to a group of clinically healthy (but presumably infected) in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease. The presence of the disease in the group/flock must be established before the product is used. A metaphylaxis claim will always have to be combined with a treatment claim (EMA/CVMP/414812/2011-Rev.1).

— A number of compounds on the World Health Organisation's list of critically important antimicrobials ([1]) are only authorised in medicinal products for human use. As laid down in EU legislation ([2]), those that do not have marketing authorisations as veterinary medicinal products for use in food-producing animals may only be used off-label (following the cascade) in these animals if the substance in question is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([3]).

— The off-label use (cascade) of the compounds referred to above for non-food-producing animals (e.g. pets and animals used for sports) should be avoided and strictly limited to very exceptional cases, e.g. where there are ethical reasons for doing so, and only when laboratory antimicrobial susceptibility tests have confirmed that no other antimicrobial would be effective.

— Antimicrobial treatment must be administered to animals according to the instructions given in the veterinarian's prescription.

— The need for antimicrobial therapy should be reassessed on a regular basis to avoid unnecessary medication.

— The perioperative use of antimicrobials should be minimised by using aseptic techniques.

— When possible, alternative strategies for controlling disease that have been proven to be equally efficient and safe (e.g. vaccines) should be preferred over antimicrobial treatment.

— The pharmacovigilance system should be used to obtain information and feedback on therapeutic failures, so as to identify potential resistance issues in the case of use of existing, new or alternative treatment options.

— A network of laboratories with the capacity for performing antimicrobial susceptibility tests in zoonotic and commensal microorganisms and target pathogens should be established in each Member State to ensure the availability of susceptibility testing.

3.2. **Particular issues to be considered before using critically important antimicrobials**

Many of the antimicrobials used in animals are also used in humans. Some of these antimicrobials are critical ([4]) for preventing or treating life-threatening infections in humans. Special consideration is necessary to ensure the continued efficacy of such antimicrobials and to minimise the development of resistance.

Before using these antimicrobials in animals, consideration should be given to the following (in addition to the points already mentioned):

— These antimicrobials should only be used in situations where a veterinarian has assessed, on the basis of antimicrobial susceptibility testing and relevant epidemiological data, that there is no non-critically important effective antimicrobial available.

— In exceptional cases where the use of these antimicrobials under off-label use (cascade) is unavoidable and legally permissible, prescription and final use should be sufficiently justified and recorded. Such use should be based on clinical grounds, i.e. the prescribing veterinarian considers the use of a particular critically important antimicrobial necessary in order to avoid the suffering of diseased animals, and should also take into consideration ethical and public health concerns. The use of critically important antimicrobials should be limited to cases where no other alternative is available.

([1]) http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia/en/

([2]) Article 10, Article 11 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([3]) Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([4]) In April 2013, the Commission requested advice from the European Medicines Agency on the impact of the use of antibiotics in animals on public and animal health. The response to this request should be used to identify the antimicrobials to be considered in this chapter.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000385.jsp&mid=WC0b01ac058080a585

3.3. **Oral administration of antimicrobials to groups of animals via feed and drinking water**

Oral antimicrobial treatment is often administered to groups of animals through medicated feed or by adding the antimicrobial to drinking water or feed on the farm (e.g. top dressing).

Whenever possible, individual treatment of the affected animal(s) (e.g. injectable treatments) should be preferred to group or mass treatment. When using group treatment, the following points should be taken into account:

— Medicated feed contains a premix of veterinary medicines and requires, according to EU legislation ([1]), veterinary prescription.

— Oral antimicrobial treatment given via medicated feed or drinking water must only be administered where prescribed by a veterinarian.

— Antimicrobials should only be administered to groups of animals via feed or drinking water where there is evidence of microbial disease or infection; such treatment should not be given as a prophylactic treatment. The administration of antimicrobials via feed or water should be limited to the animals requiring treatment, and the drug delivery systems should be appropriate for the intended treatment.

— The quantities of antimicrobials administered in feed or water should be monitored and documented on a continuous basis, especially in intensive food production systems.

— The instruction given in the product information (SPC, leaflet, labelling) and by the veterinarian must be complied with, both in terms of dosage and duration of treatment.

— Where an antimicrobial is administered through feed, it is important to ensure the homogeneity of distribution of the drug, in order that each animal obtains the required therapeutic dose for treating the disease in accordance with the veterinary prescription.

— Off-label (cascade) use should be limited to the necessary minimum and to exceptional occasions where no other authorised treatment options are available.

— Adequate, clean storage facilities should be available on the farm to ensure proper storage of the medicated feed. Access to these facilities should be restricted.

3.4. **Responsibilities**

Controlling AMR requires cooperation between public health, food, veterinary and environmental authorities, industry bodies, veterinarians, farmers and other parties, who all have a responsibility in this area.

The primary responsibility for the prudent use of antimicrobials lies with the prescriber and the person administering the antimicrobials.

3.4.1. *Prescriber*

The prescriber of the antimicrobial should be a veterinarian familiar with the history of the herd, flock or animal being treated ([2]).

It is necessary to ensure that the prescriber can make the treatment decision in an independent way, so as to avoid a conflict of interest. The position or status of the prescriber in relation to the farmer should therefore be such as to ensure independent decisions, primarily based on expert knowledge.

([1]) Article 67 of Regulation of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([2]) In some Member States, however, other professionals may, in exceptional and well-defined circumstances, be permitted by national legislation to issue a veterinary prescription.

This can be achieved in a number of different ways:

— by introducing measures to limit financial incentives between veterinary practitioners, suppliers of antimicrobials and the pharmaceutical industry, and to restrict potential conflicts of interest that could facilitate the inappropriate or unnecessary prescription and sale of antimicrobials, whilst still allowing for balanced systems of veterinary health care;

— by putting in place contracts or arrangements between the farmer and a veterinarian for a specific herd or flock, such that the veterinarian can develop a better understanding of the overall health status of the herd or flock, and thereby reduce the prevalence of disease and the use of antimicrobials.

Where it is necessary to prescribe an antimicrobial, the prescribing veterinarian should ascertain himself by means of an on-site clinical examination that the symptoms indicate a bacterial infection.

Whenever possible, the prescriber should take appropriate samples from which he/she can identify the pathogen and measure its antimicrobial susceptibility. In acute cases, when treatment needs to be started immediately to avoid animal suffering or to limit the spread of infection, it is still advisable to collect samples. If samples are collected immediately prior to the start of treatment, susceptibility testing can be carried out whilst treatment is being given. The results of this can then be used to validate the choice of antimicrobial and to inform epidemiological follow-up. Where treatment is being given on an ongoing basis, repeated culture and sensitivity testing allows antimicrobial sensitivity trends to be monitored, and the treatment revised subsequently if necessary.

The prescriber should follow national and/or regional recommendations for prescribing and administering antimicrobials. Particular attention should be given to:

— up-to-date treatment guidelines provided by national authorities or veterinary professional bodies to assist veterinarians in selecting the appropriate antimicrobial and fixing a suitable dosing regime and route of administration;

— practice-based protocols for common infections, which take into account regional and local trends in antimicrobial sensitivity. These can help veterinarians to make optimal prescribing decisions in the absence of susceptibility data. Timely publication and availability of up-to-date national surveillance data facilitates the development of local protocols.

The prescriber should ensure that the most appropriate antimicrobial is selected, based on the most accurate and up-to-date information on pharmacodynamics and pharmacokinetics and on accurate and up-to-date information on the functioning of the different classes of antimicrobials.

The prescriber should always consider using single substances instead of combinations of antimicrobials and should ensure that, where a combination of antimicrobials is prescribed, all the substances in the combination are active against the target pathogen(s).

The prescriber is responsible for providing correct information to the person administering the antimicrobial. This should be based, in the first instance, on the information from the product information (SPC, leaflet, labelling) relating to the dose, the indications, the withdrawal periods and prudent use warnings.

Veterinarians should report the lack or reduced efficacy of an antimicrobial product to the authorities without delay. Reporting should be carried out within the existing pharmacovigilance system.

In view of the risk of AMR, the prescriber should always give serious consideration to alternative — including long-term — solutions, which could prevent recurrence of the disease.

3.4.2. *Administrator of the antimicrobial*

The person administrating antimicrobials to companion animals is usually the veterinarian and/or the owner of the animals, whilst for food-producing animals, aquaculture animals and animals bred for fur, it is often the farmer or staff working on the farm. These are the people responsible for closely following the prescriber's instructions on administering antimicrobials and alternatives. They also play a critical role in observing and monitoring sick animals and animals that do not need antimicrobials. Farmers who use good quality feed and appropriate feed management and biosecurity measures can influence their animals' health for the better and reduce the potential need for antimicrobials.

Any person administering antimicrobials should always follow the prescriber's instructions, the product information (SPC, leaflet, labelling) on the product and any available government guidelines or guidelines from other organisations on administering antimicrobials prudently, especially when treating animals with oral medication (antimicrobials added to feed or water).

In particular, when administering antimicrobials to a group of animals, farmers or any other person administering antimicrobials, should ensure that the correct group of animals is treated, at the required dosage, and for the specified duration of the treatment.

The appetites of diseased animals can be depressed, so farmers or any other person administering antimicrobials should monitor whether all animals ingest the adequate/full quantity of the medicated feed containing the therapeutic dose, to avoid under-dosing. Where there is a risk of this occurring, farmers should inform the prescribing veterinarian who should assess the need to modify the treatment regime (e.g. by switching to parenteral treatment).

In accordance with relevant national and EU legislation, those who administer antimicrobials:

— must obtain the antimicrobials from authorised sources, based on a veterinary prescription;

— must ensure the safety of the food production chain, by respecting instructions given by the veterinarian on administering antimicrobials, and ensuring that withdrawal periods are observed, so as to avoid residues of antimicrobials appearing in meat, milk or other products.

Those who administer antimicrobials should also:

— cooperate with the veterinarian who regularly visits the animals and knows the history and current health status of the herd, flock or animal, to allow him/her to put in place disease prevention measures that also take account of animal welfare;

— ensure that the correct dose, treatment duration and dosing schedule is followed;

— be aware of the general aspects of prudent use of antimicrobials and AMR, including the need to take samples and perform antimicrobial susceptibility testing on target pathogens.

3.4.3. *Pharmaceutical industry, pharmacists, retailers and wholesalers*

EU legislation specifies that, in some circumstances, a veterinary prescription is required for dispensing veterinary medicinal products. This is the case, for example, for food-producing animals. Member States shall therefore prohibit the advertising to the general public of veterinary medicinal products that are available on veterinary prescription only ([1]).

Stakeholders who supply antimicrobials to the end-user, such as pharmacists and retailers, are responsible for ensuring that a valid prescription is presented at the time antimicrobials are supplied, including in the case of internet sales, and for providing clear and correct information on product use.

The pharmaceutical industry and wholesalers should limit their advertising to veterinarians to objective information, which is in line with approved SPC. The information provided should also highlight the risk of AMR and the need for prudent use. Promotional campaigns involving economic or material benefits for prescribers or suppliers of veterinary medicines should be avoided.

The pack size and the strength of the available antimicrobial formulations should be adapted as far as possible to the approved indications of use, so as to avoid, for example, improper dosing and overuse.

In addition, the pharmaceutical industry, wholesalers and those involved in the sale of antimicrobials should cooperate to implement measures to monitor and control the supply and use of antimicrobials, such as providing information on veterinary sales and the results from industry monitoring programmes to competent authorities.

([1]) Articles 67 and 85 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

The pharmaceutical industry should prioritise and focus on developing and marketing alternatives to antimicrobials, such as vaccines and rapid and affordable diagnostic tests. Pharmaceutical industry should also prioritise tasks like dose optimisation (based on relevant pharmacokinetic and pharmacodynamic data), modern formulations of old classes of antibiotics such as penicillins (which are still effective against many animal diseases) and antimicrobials for minor use/minor species. The development of fixed combinations of veterinary antimicrobials should be avoided unless adequately justified.

3.4.4. *Feed business operators*

Feed business operators must comply with the legal requirements for feed hygiene ([1]), implement best practices in the production of safe and nutritionally balanced feed, and ensure adequate feed formulation. They must also ensure that all ingredients meet the required standards and that the manufacturing process does not allow the feed to be contaminated with deleterious agents, which could compromise the safety of the feed.

Feed businesses operators producing medicated feed must be approved for the manufacture of medicated feed. They must follow all legal requirements for medicated feeds ([2]) and may only produce medicated feed from authorised veterinary medicinal products and in accordance with a veterinarian's prescription. They must follow good manufacturing practices and ensure appropriate mixing to guarantee the homogeneity of antimicrobials in the feed. They must take steps to avoid cross-contamination and minimise the transfer of antimicrobials to subsequent batches of feed.

In accordance with EU legislation, medicated feed must be appropriately labelled and only be supplied to the end-user on presentation of a valid veterinary prescription. Detailed records should be kept of the antimicrobials used, the medicated feed produced and the destination.

3.4.5. *Food business operators*

Food business operators, including retailers, should favour food produced in accordance with quality schemes and systems of production and supply that apply the principles of prudent use, i.e. that minimise the use of antimicrobials and promote high standards of animal welfare. They should not make claims that could confuse or mislead consumers (e.g. 'antibiotic-free') when marketing meat and other products from animals reared under 'prudent use' conditions (as antibiotics can be used legally in accordance with SPC indications). Consumer organisations should proactively support such initiatives.

3.4.6. *Veterinary faculties and agricultural schools*

Veterinary faculties and agricultural schools or colleges should ensure that sufficient attention is given to the problem of AMR and the prudent use of antimicrobials in their undergraduate and post-graduate programmes, and that knowledge relating to these areas is kept up to date. Under- and post-graduate programmes should also focus on developing learning materials and techniques relating to ways to improve and promote breeding and husbandry practices that promote animal health. Such practices may include biosecurity measures, good farming practices and herd health planning that prevent infections and therefore reduce the need for antimicrobials.

Providing information on antimicrobials and AMR should even be considered in basic education on public health and food safety, e.g. in secondary schools.

Universities and other research facilities should give priority to research in the area of AMR. In veterinary medicine, focus should be given to:

— developing alternative, preferably preventive, tools for infection control;

— evaluating the impact of the use of antimicrobials in animals on public health and the environment;

([1]) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

([2]) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community (OJ L 92, 7.4.1990, p. 42).

— further investigating pharmacokinetic and pharmacodynamic data and using models to simulate the effects of different dosing schedules (based on different combinations of: disease, pathogen, target tissue and animal species). The results from modelling should provide a scientific background for setting effective dosing schedules in practice;

— further investigating co-resistance and cross-resistance, including the co-resistance of disinfectants and antimicrobials and the co-resistance and development of resistance of antimicrobials to certain metals;

— developing new classes of antimicrobials.

Veterinary faculties should provide information on the risk of nosocomial infections in veterinary practices and clinics, on the use of monitoring procedures to detect and report occurrence of infections and on the use of infection prevention and control measures to minimise occurrence.

Scientific publications should promote the principles of prudent use.

3.4.7. *Veterinary professional associations*

Veterinary professional associations should continue developing guidelines for the prudent use of antimicrobials and promoting their implementation. Veterinary professional associations and statutory bodies should provide specific training for veterinary practitioners on AMR and the prudent use of antimicrobials.

They should include principles on the prudent use of antimicrobials in their codes of conduct for veterinarians.

3.4.8. *Industry stakeholder associations*

Industry stakeholder associations should continue to support the development and implementation of initiatives to tackle AMR and to promote the prudent use of antimicrobials. They should develop appropriate communication materials and provide adequate information about the risk of AMR to their members. They should also support national initiatives involving the collection of data on sales of antimicrobials.

Industry stakeholder associations should promote quality schemes and systems of production and supply that implement the principles of prudent use, i.e. that minimise the use of antimicrobials and promote animal welfare.

3.4.9. *Farmers' associations*

Farmers' associations should promote the principles of prudent use of antimicrobials among their members. They should inform farmers of the implications of the use of antimicrobials in animals for the risk of AMR, and thus help to minimise the use. Other aspects such as the risk of AMR due to direct contact with animals should also be publicised.

Training courses and guidance materials given to farmers should include information on preventive measures that promote animal health, in particular implementation of biosecurity measures, good farming practices and herd health planning. Such practices can help to reduce the need for antimicrobials. Training should also cover the administration of antimicrobials and environmental risks.

3.4.10. *Competent authorities*

Competent authorities at local and national level are responsible for pursuing a proactive approach to developing appropriate risk-based measures to ensure the prudent use of antimicrobials, verifying and enforcing their application, and evaluating the results. They are also responsible for providing sufficient resources for implementing these measures and for research and awareness campaigns. In particular, competent authorities (or, where relevant, the responsible veterinary statutory bodies) should:

— ensure that national strategies are developed and implemented as described in Chapter 9. Such strategies should be based on cooperation between the veterinary authorities, the human health authorities and other relevant authorities (e.g. environmental authorities);

— monitor the implementation of the national strategy, in order to evaluate and assess the impact and effectiveness of measures taken under it;

— carry out, where appropriate, targeted checks on veterinarians with high levels or concerning patterns of prescription. Obligatory educational courses may be considered for veterinarians with questionable prescribing practices. Farm inspections should also be carried out in order to evaluate animal husbandry and animal health conditions;

— consider the introduction of mandatory herd health programmes promoting best practices, and ensure that hygiene standards are improved on farms where problems have been identified;

— support and promote research into alternatives to antimicrobials, diagnostic tests and the prudent use of antimicrobials;

— fund and support the development, dissemination and implementation of guidelines for both the prudent use of antimicrobials and hygiene measures; fund and support awareness and training campaigns on AMR and the prudent use of antimicrobials aimed at farmers and veterinarians;

— develop control measures to limit the spread of resistant bacteria when a type of AMR is low or emerging. This may include increased biosecurity measures, identification of carriers, animal quarantine, restrictions on the movement of people and investigations.

Competent authorities are also responsible for setting up compulsory surveillance programmes and supplementary programmes, and for monitoring their enforcement (see Chapters 6 and 8).

3.4.11. *Laboratories*

The official network of laboratories for monitoring AMR comprises the European Reference Laboratory for Antimicrobial Resistance ([1]) and the national reference laboratories appointed by the Member States. The main duties of the European Reference Laboratory are to provide scientific advice and assistance to the national reference laboratories, to organise annual proficiency tests for susceptibility testing for the national reference laboratories and to harmonise the implementation of antimicrobial susceptibility testing methods. Each Member State's national reference laboratory oversees the work carried out by the official laboratories responsible for AMR testing in the Member State. The national reference laboratory is responsible for organising proficiency tests for susceptibility testing between the official national laboratories. They also provide scientific and technical assistance to the competent authorities in the Member State on monitoring AMR.

A network of laboratories performing antimicrobial susceptibility tests and providing results on target pathogens is essential in order to guarantee that susceptibility testing is available to practitioners in every Member State.

Laboratories should provide the practitioner with the results of testing and any other relevant information which may be useful (e.g. resistance to narrow-spectrum antimicrobials).

Results should be based on:

— (preferably internationally) standardised methodologies;

— (preferably internationally harmonised) clear interpretative criteria.

Laboratories should take part in external proficiency tests for antimicrobial susceptibility testing and other relevant microbiological tests, in order to ensure that their results are valid.

([1]) http://www.crl-ar.eu/143-introduction.htm

4. AWARENESS RAISING

It is only possible to minimise the development of AMR through the prudent use of antimicrobials if all parties involved are well informed. Awareness campaigns therefore play an important role, and need to be regularly repeated and updated.

— Prudent use campaigns in the veterinary sector can be targeted at specific groups, in particular farmers, veterinarians, other professionals involved in animal production and pet owners. These campaigns may include a number of approaches, for example, providing sectoral guidelines on good practice, holding seminars and displaying posters in veterinary practices.

— Relevant networks and stakeholder organisations play an important role in the success of such campaigns and they should also be supported by the competent authorities. Guidelines should not be limited to information on minimal legal requirements, but should also provide practical tools for implementation and should encourage the parties concerned to be proactive in taking steps to reduce the threat of AMR.

— (National) guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.

— Campaigns aimed at pet owners, designed to increase their awareness of the importance of prudent use of antimicrobials and of hygiene, are also encouraged.

— Campaigns may also be targeted at consumers, to encourage them to demand food that is produced in accordance with standards which require the amount of antimicrobial agents used to be kept as low as possible. Positive examples of best practice in animal husbandry can strengthen consumer confidence and increase public demand for food produced with minimal use of antimicrobials.

5. ENFORCEMENT AND SANCTIONS

Member States must ensure compliance with national and EU legal requirements relating to antimicrobials (see Chapter 3 on the regulatory framework).

Member States must perform official controls on the distribution, prescribing and use of veterinary medicines, in accordance with the requirements of the EU legislation on veterinary medicines and with Regulation (EC) No 882/2004 ([1]).

Member States should consider adopting national legislation and creating national systems to control the distribution and use of antimicrobials, in particular to prevent illegal sale of antimicrobials, including over the internet.

Member States should take appropriate measures to discourage practices and behaviours that contribute to the emergence and spread of AMR and reduce the effectiveness of the fight against AMR.

6. DISEASE PREVENTION AND REDUCING THE NEED TO USE ANTIMICROBIALS

6.1. General

AMR is not only an animal health and economic concern, with implications for decreasing the efficiency of antimicrobial treatment in animals, but is also a public health concern due to the transmission of antimicrobial-resistant bacteria through the food chain and the transmission of resistance from animal bacteria to human bacteria.

To be effective in mitigating the risk of AMR, and taking into account co-resistance and cross-resistance, the prudent use of antimicrobials needs to bring about an overall reduction in the use of antimicrobials.

([1]) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

Preventing infections in the first instance is the best way to achieve this reduction and to minimise the need to use antimicrobials, as reducing the number of infections reduces the number of treatments needed. This approach is supported by the new Animal Health Strategy ([1]), as it is fully in line with the principle promoted by this strategy that prevention is better than cure. A reduction in the incidence of animal disease and zoonotic infections should also minimise the need for, and use of, antimicrobials.

The objective of reducing the use of antimicrobials is also in line with animal welfare, aims to reduce the density of the farm animal population. This is believed to be a major risk factor in the emergence and spread of infections that require the use of antimicrobials to reduce the suffering of sick animals.

In general, the following measures can help to prevent diseases and reduce the need to use antimicrobials in all species:

— implementing hygiene and biosecurity measures (including measures designed to prevent the introduction of infections), such as: keeping separate clothes and boots for each unit; limiting access; making hand washing and hand disinfection facilities (with liquid soap, hot and cold water) available close to the workplace; ensuring quick removal of and prevention of access to dead animals; applying the 'all-in all-out' system in each unit; following a strict schedule for cleaning and disinfection; and performing regular disinfection controls;

— producing clear protocols for the prevention of infectious diseases and infection control and hygiene; making these available on farms;

— improving husbandry systems by providing appropriate housing, ventilation and environmental conditions for animals and appropriate and clean facilities during transport (e.g. the lairage area and vehicles);

— establishing integrated production systems which avoid the need to buy and mix animal populations and to transport animals with unknown disease status;

— avoiding stressful situations which can weaken animals' immune systems and make them more susceptible to infections, e.g. limiting the transport of animals, minimising transport time and ensuring that the recommended animal population density is adhered to (i.e. avoiding overcrowding);

— implementing other zootechnical treatments to minimise disease and decrease use of antimicrobials;

— introducing herd-specific health plans designed to achieve a consistent stepwise improvement in herd health and avoiding and discouraging health programmes in which animals are systematically treated with antimicrobials prophylactically;

— implementing programmes to control specific animal diseases (both viral and bacterial) by means of vaccination;

— using scientifically proven, effective and safe alternatives to antimicrobials;

— using only safe, high-quality feed and water;

— providing incentives to farmers to encourage them to adopt effective preventive measures, to improve animal health and welfare standards and to monitor pathogens and their sensitivity at herd level, with the ultimate objective of ensuring evidence-based use of antimicrobials in individual herds in line with the prudent use principles set in this guideline.

([1]) http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm

6.2. **Pigs**

Antimicrobials are most often used in pigs to relieve weaning diarrhoea, intestinal infections associated with *Lawsonia intracellularis* and respiratory diseases often associated with transport and the stress caused when pigs originating from different farms are brought together or when animals are housed in holdings with inappropriate ventilation systems, unsuitable feeding methods and/or insufficient biosecurity measures.

When an infection requiring the use of antimicrobials is found in certain holdings, an in-depth analysis of the problem should be carried out, and steps taken to limit the spread and prevent the recurrence of the infection. Possible measures to be taken include:

— avoiding the prophylactic use of antimicrobials in new-born piglets (and after weaning), as a part of a herd health strategy;

— implementing an 'all-in all-out' system of production, thoroughly cleaning and disinfecting production units when animals move into, within and out of the herd;

— isolating the pathogen and considering a vaccination strategy where available (e.g. atrophic rhinitis);

— checking and ensuring that the ventilation system and general housing environment are functioning correctly and making sure it is possible to change the conditions if there is a high frequency of recurring respiratory diseases or environmental conditions are poor (e.g. in summer, when there can be a dramatic increase in temperatures and in the ammonia concentration in the environment, which, if the ventilation system is not adjusted, exacerbates respiratory conditions);

— establishing appropriate feeding strategies based on the pigs' age, especially at weaning;

— avoiding mixing within the herd, or quarantining stock for an appropriate period prior to mixing;

— reassessing weaning management in cases of recurrent weaning diarrhoea (considering in particular hygiene, the age of the pigs, the use of 'all-in all-out' systems, ways of reducing the stress suffered by the animals and alternatives to the prophylactic use of antimicrobials);

— eliminating recurrent cases of post-partum dysgalactiae syndrome by ensuring appropriate selection of sows, good hygiene at parturition and adapted feeding;

— limiting the trading and movement of pigs to mitigate the spread of infections and organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA).

There is an increasing need to establish integrated pig production systems that avoid the mixing of animals and minimise long-distance transport (e.g. closed farms and an integrated approach between breeding and fattening farms).

In addition, breeding targets should focus not only on production parameters but also on the increased resistance to infections. A holistic approach to disease prevention should be adopted.

6.3. **Poultry**

Action is needed to avoid the prophylactic and often recurrent group medication of poultry, which is frequently carried out immediately before or after transport of day-old chicks, or in some cases to address losses of productivity.

The injection of antimicrobials into eggs or day-old chicks in hatcheries should be avoided entirely, unless justified for exceptional reasons that are clearly described in national or regional guidelines.

Hatcheries should keep records of any use of antimicrobials in eggs and should provide their records to competent authorities on request.

Antimicrobials should not be used routinely on the arrival of day-old chicks at the farm. The prophylactic use of antimicrobials at this stage can be avoided by ensuring good hatchery hygiene and through good management of day-old chick production (e.g. temperature control, hygiene and stimulation of drinking and eating).

Vaccination management should include measures to avoid a stress reaction and improvements to the availability of autogenous vaccines.

The use of antimicrobials for non-infectious diseases with limited secondary infections should be avoided. Husbandry, management and breeding policies should be evaluated to avoid the recurrence of such diseases.

The use of 3rd and 4th generation of cephalosporins in poultry (including eggs) should be prohibited, in accordance with the Commission's decision following the referral procedure of 13 January 2012 ([1]) and in line with the European Food Safety Authority's scientific opinion on the public health risks of bacterial strains producing extended-spectrum beta-lactamases (ESBL) and/or AmpC beta-lactamases in food and food-producing animals ([2]) due to the risk of AMR spreading to humans.

In accordance with the Commission's decision following the referral procedure of 1 July 2010 on quinolones for food producing animals and Commission's decision following the referral procedure of 28 February 2014 ([3]), fluoroquinolones should be reserved for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antimicrobials and, whenever possible, should only be used where susceptibility testing has first been carried out.

Specific animal welfare programmes should be introduced, potentially including footpad scores.

Antimicrobials shall not be used as a specific method to control *Salmonella* in poultry as set out in Article 2 of Regulation (EC) No 1177/2006 ([4]). In order to ensure that EU targets for reducing *Salmonella* are met, all Member States' national control programmes should include biosecurity measures designed to prevent *Salmonella* infection on poultry farms. The introduction of such measures also has a positive effect in terms of preventing other diseases. Specific EU guidelines have been published by the Commission services for farms where broilers and laying hens are kept ([5]).

6.4. **Bovines and small ruminants**

Mass or group medication of cattle is rare, although veal calves can be subjected to group treatment using antimicrobials. Treatment given to cows at drying-off is of particular importance. The measures to be taken include:

— avoiding the prophylactic use of antimicrobials in new-born calves (e.g. antimicrobials added to milk replacers) by instead implementing good farming practices (e.g. to ensure high standards of hygiene);

— developing preventive strategies (e.g. vaccinations and feeding colostrum to calves), especially for the allotment of veal calves and beef cattle;

— avoiding the systematic treatment of cows at drying-off, and considering and implementing alternative measures on a case-by-case basis;

([1]) Commission Implementing Decision C(2012) 182 of 13 January 2012 following the referral procedure by the European Medicines Agency's Committee for Medicinal Products for Veterinary Use. http://ec.europa.eu/health/documents/community-register/html/vo22101.htm

([2]) http://www.efsa.europa.eu/en/efsajournal/doc/2322.pdf

([3]) Commission Decision C(2010) 4684 of 1 July 2010 and Commission Implementing decision C(2014) 1484 of 28 February 2014 following the referral procedures by the European Medicines Agency's Committee for Medicinal Products for Veterinary Use http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/quinolones_35/WC500094631.pdf http://ec.europa.eu/health/documents/community-register/html/vo25077.htm

([4]) Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry (OJ L 314, 1.12.2007, p. 153).

([5]) http://ec.europa.eu/food/food/biosafety/salmonella/impl_reg_en.htm

— establishing thorough hygiene measures and good farm practice and management strategies to minimise the development and spread of mastitis in dairy cows;

— promoting the use of rapid diagnostic tests (e.g. standardised tests with chromogenic media) for identifying mastitis-causing pathogens, in order to minimise the use of both intramammary and injectable antimicrobials in milking cows;

— avoiding feeding calves with waste milk from cows that have been treated with antimicrobials.

6.5. **Aquaculture**

The same strategies as are used for reducing the use of antimicrobials in other farm animals should also be considered in aquaculture. The use of vaccines to tackle some of the bacterial diseases most commonly occurring in fish has been demonstrated to be particularly effective.

The following actions should be implemented to prevent and reduce the need to use antimicrobials in aquaculture:

— encouraging production systems that provide appropriate environmental conditions for aquaculture animals kept on farms, in particular with regard to water quality, water flow rates, oxygen levels and nutrition;

— encouraging the use of antimicrobial sensitivity testing prior to treatment, wherever possible;

— encouraging the development of specific disease surveillance programmes to identify and help prevent possible outbreaks of disease;

— implementing specific hygiene and biosecurity measures, including measures to prevent the introduction and spread of infections, such as:

  — operating an 'all-in all-out' system per unit or farm, applying single bay management where possible, ensuring proper cleaning and/or disinfection of units and farms between production cycles, and carrying out fallowing of sites between production cycles;

  — keeping separate equipment, clothes and boots for each unit or farm and enforcing restrictions on access to the farm;

  — quickly removing dead fish and ensuring systems are in place for handling, disposing of and treating by-products;

  — ensuring a system is in place for collecting blood and/or water when slaughtering on site;

  — developing systems to avoid the spread of diseases by transport (e.g. treatment of transportation water and avoiding contact with other aquaculture animals during transport);

— encouraging the development and use of effective vaccines for aquaculture;

— recommending adequate welfare parameters, e.g. for stocking density.

6.6. **Rabbits**

The two main indications requiring group medication in rabbits are weaning diarrhoea and respiratory problems. Preventive measures include:

— optimising ventilation (avoidance of cold drafts) and vaccinating against pasteurellosis;

— avoiding overcrowding and fighting between animals and making sure rabbits do not come into contact with sharp objects;

— ensuring that dietary changes are made gradually;

— ensuring thorough cleaning and disinfection of pens;

— quarantining newly purchased rabbits before introducing them into the main group.

6.7. **Other species (pets, animals kept for fur and other non-food-producing species)**

The following should be considered:

— When clinical infection with methicillin-resistant *Staphylococcus aureus* (MRSA) or methicillin-resistant *Staphylococcus pseudintermedius* (MRSP) is suspected or detected in horses and companion animals, they should be monitored for MRSA/MRSP with a view to possible quarantine. It is very important that the risk of the infection spreading in animal hospitals and veterinary clinics is minimised. Animals showing clinical signs should therefore be handled separately. In dog kennels or in daycare for dogs, dogs showing clinical symptoms should not be kept with other animals.

— The off-label (cascade) use of antimicrobials not authorised in veterinary medicine to treat non-food-producing animals should be avoided, especially when the drugs are of critical importance for human health (e.g. carbapenems and tigecycline). Their use should only be considered in very exceptional cases, e.g. when laboratory susceptibility testing has confirmed that no other antimicrobials will be effective and where there are ethical reasons to justify such a course of treatment.

7. **SURVEILLANCE AND MONITORING**

Harmonised and comparable data on the use of antimicrobials and AMR in the food chain is necessary for carrying out risk assessment, for research purposes, and for evaluating the effectiveness of the measures taken to tackle AMR. Harmonised monitoring and surveillance systems should be used across the EU, in order to collect comparable data on countries and animal species, and so as to allow comparison with human data.

Member States are encouraged to timely provide data on the use of antimicrobials in veterinary medicine for the European Surveillance Veterinary Antimicrobial Consumption project ([1]).

Member States are encouraged to support the initiatives launched by the European Surveillance Veterinary Antimicrobial Consumption project. Their aim is to collect representative and comparable data on the use of antimicrobial agents in individual animal species and to establish technical units of measurement for reporting the use of antimicrobial agents in animals.

Member States are encouraged to analyse and publish the data on antimicrobial use collected at national level. This should preferably include data on usage by species and age group, and should be compared to AMR monitoring data. Member States that are able to collect detailed data on the use of antimicrobials by age group are encouraged to use these data to set benchmarking values for each age group, which could then be used by all Member States.

As technology evolves, the systematic collection of data on the use of antimicrobials, and its subsequent analysis, should become easier. This will allow prescribers, dispensers and users who do not comply with prudent use principles to be detected more easily, facilitating the education and, if necessary, sanctioning of the individuals involved.

Member States must monitor antimicrobial resistance in zoonotic and indicator bacteria taken from food-producing animal populations and their meat, and report the data in accordance with Commission Implementing Decision 2013/652/EU ([2]). Member States are also encouraged to implement the non-compulsory provisions on monitoring AMR contained in that Decision.

Under the harmonised monitoring system set out in Commission Implementing Decision 2013/652/EU, Member States are encouraged to perform additional sampling and analysis to monitor AMR in other bacteria (e.g. MRSA and animal pathogens), at other points in the food chain and in other food and animal species not subject to the EU harmonised monitoring regime.

([1]) http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

([2]) Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (OJ L 303, 14.11.2013, p. 26).

8. NATIONAL STRATEGIES

All Member States should develop and implement national strategies or action plans for tackling AMR. These strategies or action plans should have a holistic approach, and should cover all sectors and aspects of AMR (e.g. public health, animal health and welfare, food safety, consumer safety, the environment, research and non-therapeutic use of antimicrobials). They should involve the relevant competent authorities and all other parties concerned.

In addition to all elements addressed in these guidelines, when developing national strategies, the following aspects should also be taken into account:

a) national animal production;

b) the prevalence of foodborne pathogens and animal pathogens;

c) the patterns of resistance observed in pathogens isolated during cases of infection in humans and animals, and in commensal organisms isolated during the screening of animals; and

d) data on the current use of antimicrobials in both animals and humans.

Animal health and welfare and the availability of relevant authorised veterinary medicinal products should also be taken into account.

Several Member States already have national strategies in place. These may be useful to other Member States in providing information and examples of how to implement an AMR strategy.

National strategies should set out a comprehensive set of actions. They should cover at least the following areas: the monitoring and surveillance of AMR and antimicrobial use in both humans and animals, risk management measures, risk communication strategies, guidelines on prudent use, treatment and husbandry management, education and training and research.

National control programmes or strategies could include targets or appropriate indicators for monitoring progress and assessing the effectiveness of measures taken. Care should be taken to ensure that targets for reducing the use of antimicrobials do not result in inadequate prescribing practices which may have an effect on animal health, and/or on the development of AMR (e.g. under-dosing and the use of broad-spectrum antimicrobials).

Preventing diseases is, in the first instance, the best way to reduce the need for antimicrobials. Member States are therefore recommended to focus their AMR strategy primarily on species that are commonly treated with mass or group medication (pigs, poultry, veal calves and rabbits), but not to the exclusion of other food-producing and non-food-producing species.

Further risk-based targeting could be considered in a national strategy. For example, some Member States have introduced strict provisions on specific antimicrobials included in the World Health Organisation's list of critically important antimicrobials, for example on the use of third- and fourth-generation cephalosporins and/or fluoroquinolones.

The following are some examples of measures (as discussed in the preceding chapters) that could be included in a national strategy:

— applying the 'One Health' perspective by means of a joint action plan developed by the authorities responsible for food, agriculture, environment, human health and animal health;

— monitoring the use of antimicrobials, overall and by species and/or farm; introducing systems for registering and identifying herds and flocks to facilitate monitoring;

— setting up an integrated surveillance system (for the human, food and veterinary sectors) to monitor AMR in selected bacteria; developing databases for storing the results of this monitoring;

— setting targets for reducing use of antimicrobials, in accordance with the 'One Health' perspective;

— introducing measures restricting the prophylactic use of antimicrobials and minimising metaphylactic use;

— introducing financial measures to promote the prudent use of antimicrobials and the use of alternatives (e.g. differentiated taxes on sales and differentiated fees for granting marketing authorisations for certain medicines);

— introducing measures for resolving potential conflicts of interest that may occur where parties are involved in the prescription, supply and/or sale of antimicrobials;

— implementing measures strengthening the position or status of the prescriber in relation to the farmer (e.g. setting up registered contracts between farmers and veterinary practitioners which include scheduled regular visits by the veterinarian to the farm; introducing guidelines including requirements to perform susceptibility testing);

— carrying out controls on the biosecurity standards in herds and flocks;

— developing treatment guidelines covering the choice of treatment and issuing of prescriptions by veterinarians, and the administration of antimicrobials to animals by farmers;

— introducing restrictions on the use of some antimicrobials considered critical for public health, such that they are only used as a first choice if an antimicrobial susceptibility test indicates that no other antibiotic can be used for treating a particular disease in a particular herd, flock or animal, and, where relevant, the choice of antimicrobial is supported by relevant epidemiological data;

— setting maximum acceptable levels of use of antibiotics in herds and flocks, and developing action plans for reducing antibiotic usage in herds or flocks where it is currently above this limit; developing a similar system of usage limits and action plans for prescribing antimicrobials to non-food-producing animals;

— setting up a benchmarking system to identify farms with high antimicrobial usage and obliging these farms to take measures to reduce their levels of usage;

— setting up 'risk warning' systems for individual veterinary practitioners who prescribe relatively high volumes of antimicrobials, and farmers who administer high levels of antimicrobials to their herds or flocks;

— introducing incentives to encourage the animal production and marketing industries to take steps to improve animal health on an ongoing basis, including by preventing diseases and improving hygiene standards;

— introducing animal health programmes based on good hygiene practices and other preventive measures, and discouraging routine prophylaxis;

— introducing control measures to prevent the spread of antimicrobial-resistant bacteria, including emerging antimicrobial resistance; this should involve the participation of the environmental protection sector;

— applying risk-based controls and other measures provided for by legislation; following guidance (e.g. codes of practice) on the prudent use of antimicrobials;

— developing methods for evaluating and assessing the effectiveness of the measures taken under the national strategy on AMR.

COURT OF AUDITORS

Special Report No 10/2015

'Efforts to address problems with public procurement in EU Cohesion expenditure should be intensified'

(2015/C 299/05)

The European Court of Auditors hereby informs you that Special Report No 10/2015 'Efforts to address problems with public procurement in EU Cohesion expenditure should be intensified' has just been published.

The report can be accessed for consultation or downloading on the European Court of Auditors' website: http://eca.europa.eu

A hard copy version of the report may be obtained free of charge on request to the Court of Auditors:

European Court of Auditors
Publications (PUB)
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1
E-mail: eca-info@eca.europa.eu

or by filling in an electronic order form on EU-Bookshop.

V

(Announcements)

ADMINISTRATIVE PROCEDURES

EUROPEAN COMMISSION

Call for expression of interest — invitation to present products suitable for use as a marker in gas oils and kerosene

(2015/C 299/06)

Notice is hereby given of the launch of the call for expression of interest inviting applicants to present products suitable for use as a fiscal marker in gas oil and kerosene.

The call for expression of interest including the documents to be submitted and the procedure to be followed is available via this link:

http://ec.europa.eu/taxation_customs/taxation/excise_duties/energy_products/other_energy_tax_leg/index_en.htm

OTHER ACTS

EUROPEAN COMMISSION

Publication of an application pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2015/C 299/07)

This publication confers the right to oppose the application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council [1].

SINGLE DOCUMENT

'AYDIN İNCİRİ'

EU No: TR-PDO-0005-01116 – 11.6.2013

PGI ( ) PDO (X)

1. **Name**

Aydın İnciri

2. **Member State or Third Country**

Turkey

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product*

Class 1.6. Fruit, vegetables and cereals fresh or processed

3.2. *Description of product to which the name in (1) applies*

Aydın İnciri is the name given to dried *Sarılop* figs. *Sarılop* figs are a variety of *Ficus carica domestica* (female fig). They are a type of *Ficus carica erinosyce*, a subspecies of *Ficus carica* L., a subgenus of *Ficus* L.

Physical characteristics:

Shell: whitish yellow, thin and soft.

Seed: the seeds are filled.

Size: the number of fruit per kg should be at most 90.

Chemical characteristics:

Composition of 100 grams of dried figs: water (maximum) 20 %, energy (minimum) 213 kcal, total sugar (minimum) 50 %, calcium (Ca) (minimum) 120 mg.

Organoleptic characteristics: the kernel is smooth in texture, quite honeyish and viscous; leaves a particularly sweet flavour and has a sweet smell.

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

—

3.4. *Specific steps in production that must take place in the identified geographical area*

All processes from the production to the harvesting and drying of Aydın İnciri must be carried out in the geographical area specified in point 4.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

—

[1] OJ L 343, 14.12.2012, p. 1.

3.6. *Specific rules concerning labelling of the product the registered name refers to*

The following information must be written or printed legibly and in an indelible manner on the packaging of Aydın İnciri:

— the trade name and address, short name and address, or registered trade mark of the company,

— the lot number,

— the name of the goods — Aydın İnciri, and

— the following logos:

4. **Concise definition of the geographical area**

All districts and villages of the province of Aydın

5. **Link with the geographical area**

Aydın İnciri is a variety of dried fig. The ecologic and human factors that characterise its ripening and drying process give it its thin skin, soft texture and whitish-yellow skin colour. The method of drying the figs used to produce Aydın İnciri distinguishes it from dried figs produced in other regions. The figs are dried in the sun, by skilled and experienced workers, using traditional methods and in a completely natural environment.

The region where Aydın İnciri are produced is characterised by deep, sandy-clay soils, enriched by organic materials and lime originating from gneiss or schist and gneiss parent rock. The sandy-clay nature of the soil limits the amount of water retained, as a result of which the growth of bacterial and fungal diseases is prevented and high quality fruit produced.

Winters are warm and summers are hot and dry. The annual average temperature is between 18 °C and 20 °C. The temperatures of up to 30-32 °C recorded during the ripening and drying periods are essential for drying the Aydın İnciri. Average annual precipitation for the region is 625-675 mm. It is important for the weather to be dry and cloudless during the ripening and drying seasons, as rain is the major factor causing a deterioration of the quality of dried figs. Low humidity results in thick fruit skin, while high humidity leads to a darkening of the fruit colour and causes the fruit to split, thus reducing the quality. The Aydın region sees significant rainfall in November and June, but the average rainfall in August and September is around 41-98 mm. The topographical structure of the region allows the humid weather to move from the sea to the hinterlands, and the arid weather to flow from the hinterlands to the coastline, with mountains running perpendicular to the sea. The wind systems prevalent in the Büyük and Küçük Menderes valleys are critical to the production of high-quality dried figs in this region, and thus delimit the area where the figs can be grown. The north-east wind, which blows in the mornings, is very important for the ripening and drying of the figs. The humid sea breeze blowing from the west in the afternoons, meanwhile, makes the figs grow large and thin-skinned. The concurrent blowing of both winds, from different directions, means that the figs are dried in such a way as to produce a high-quality product.

Aydın İnciri have been produced in this area for thousands of years. Reference to figs being grown in Caria in west Anatolia by the botanical name *ficus carica* L. proves the antiquity and importance of the fig-growing culture in the Aegean region. Production, harvesting and drying of figs have been performed following the same traditional, natural methods for many years. Figs have always been part of people's daily life. Fig production has become such an art for the people of the region that they taught and continue to teach the techniques of fig growing to their children at an early age. Producing high-quality dried figs depends on the work of skilled and experienced fig growers, who check the drying figs early in the morning and late in the afternoon. The figs are piled up in the evening and covered with a thick sheet to protect them from insects and possible dew. This process is repeated every day until the figs have dried to the correct level of moisture.

Aydın İnciri are of particular importance for the province of Aydın, and are a symbol of the area. Fig patterns often appear in the decoration seen in village and town squares in the province. There is also a statue in one of the main squares featuring figs. There are many festivals in Aydın celebrating the fig, including the Germencik fig festival and the İncirliova gold fig festival. Such festivals are traditionally organised yearly, with various events being held in the town or village.

Reference to publication of the specification

(the second subparagraph of Article 6(1) of this Regulation)

The Turkish Government launched the national objection procedure with the publication of an application to recognise Aydın İnciri as a product with PDO in the Official Gazette of the Turkish Republic, No 26234 of 20 July 2006. Aydın İnciri was subsequently officially registered with the Turkish Patent Institute.

The specification text can also be found on the Turkish Patent Institute's website http://www.tpe.gov.tr/TurkPatentEnstitusu/geographicalRegisteredList/ by clicking on 'Aydın İnciri'.

ISSN 1977-091X (electronic edition)
ISSN 1725-2423 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN