

**EXPLANATORY MEMORANDUM TO
THE ANTHRAX PREVENTION ORDER 1971 ETC. (REVOCATION)
REGULATIONS 2005**

2005 No.228

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

2. **Description**

These Regulations revoke the Anthrax Prevention Order 1971 (APO), the Anthrax Prevention Act 1919 (Repeals and Modifications) Regulations 1974 and the Anthrax Prevention Order 1971 (Exemptions) Regulations 1982, and make certain consequential amendments to other enactments.

3. **Matters of special interest to the House of Lords Select Committee on the Merits of Statutory Instruments**

None.

4. **Legislative Background**

These Regulations are made under powers in sections 15(1) and (3)(a) of the Health and Safety at Work etc. Act 1974 (the 1974 Act). The APO is outdated legislation and restricted in its application. The risk to workers from imports of potentially anthrax-infected material is now adequately covered by the well-established Control of Substances Hazardous to Health Regulations 2002 (COSHH). Most of the APO requirements relating to paperwork and packaging, handling and testing of these goods are now contained in the Products of Animal Origin (Third Country Imports)(England)(No. 3) Regulations 2004 (and the Scottish and Welsh equivalents), which take precedence over the APO.

5. **Extent**

This instrument applies to Great Britain. The Northern Ireland Office has been notified of the proposed revocations.

6. **European Convention on Human Rights**

Jane Kennedy, Minister of State for the Department for Work and Pensions has made the following statement under section 19(1)(a) of the Human Rights Act 1998:

“In my view the provisions of the Anthrax Prevention Order 1971 etc. (Revocation) Regulations 2005 are compatible with the Convention rights.”

7. Policy background

- 7.1 The APO was introduced to help reduce cases of occupational exposure to anthrax in the textile industry. The APO and its associated legislation, either prohibits, or places restrictions on the import of certain animal hair products, chiefly goat hair into the UK. However, the industry has changed since then both in reduction in size and work practices. The APO requires for certain products to be disinfected prior to use in the workplace. However, raw, unprocessed goat hair has not, to our knowledge, been imported for the last 5 years, and as consequence the only UK disinfection plant has closed down. Many countries now add value to their products by disinfecting prior to import.
- 7.2 There are also limitations to the APO in that it applies restrictions to specified animal products from named countries, and does not apply these restrictions to the same products from other countries where anthrax is endemic. There is therefore a danger that importers feel they have adequately mitigated the risk from the material if they just comply with the APO, which may not necessarily be the case.
- 7.3 The APO came into force before the 1974 Act, which forms the basis for all modern health and safety legislation. Health and safety concerns are now sufficiently addressed by COSHH 2002 which provides a well-established framework for assessing and controlling the risks posed by all biological agents, including anthrax, in the workplace.
- 7.4 As of July 2004, there were 9 companies importing and processing this material, and 5 importing agents. HSE has visited all these companies to explain the rationale for the revocation of the APO and will actively support these companies during the changeover.

8. Impact

A Regulatory Impact Assessment is attached to this memorandum. The impact on the public sector is negligible.

9. Contact

Ms. Madeleine Garlick at the Health and Safety Executive can answer any queries regarding the instrument.

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14 February 2005

THE ANTHRAX PREVENTION ORDER 1971 ETC. (REVOCAION) REGULATIONS 2005

REGULATORY IMPACT ASSESSMENT (FULL)

1. Full Regulatory Impact Assessment updated from the Cost Benefit Analysis provided for the consultation on the proposed revocation of the Anthrax Prevention Order 1971 (APO) and associated Regulations (see annex 1) in 1996.

PURPOSE AND INTENDED EFFECT

Issue

2. The APO operates by placing conditions on the importation of animal hair products likely to be infected with anthrax (chiefly goat hair, but including mohair, cashmere and wool) from countries where anthrax is endemic, eg Iran. However, the health and safety provisions contained in the APO are sufficiently addressed by the regulatory framework of the Control of Substances Hazardous to Health Regulations 2002 (COSHH). COSHH provides the mechanism for assessing the risks posed by all biological agents in the workplace, including anthrax (*bacillus anthracis*). HSE has concluded that the APO interferes with employer's duties under COSHH and it contains some provisions that conflict with overriding European-led requirements on the importation of products of animal origin. The APO was also identified in HSC's recent regulatory review as legislation which was not 'relevant or necessary'.
3. HSC consulted on the proposal for revocation of the APO in 1996, and although the majority of responses supported the revocation, HSC delayed taking this forward in the face of industry opposition. Subsequent discussions over the intervening years have now led to industry support for this proposal. HSC and the Minister have agreed in principle that the revocation should now be taken forward.

Objectives

4. The objective of this Regulation is to revoke outdated legislation, which has limited scope, contains some provisions that conflict with importing arrangements under overriding EU legislation and relevant health and safety issues already addressed by COSHH.

Risk assessment

5. Anthrax is a potentially life-threatening zoonotic disease. It primarily affects herbivorous animals although all other mammals may be susceptible. Humans are at risk of infection through contact with diseased animals, their secretions, hides, hair or other products. The human disease of anthrax can take 3 forms:
 - Cutaneous anthrax, resulting from skin contact with infected animals or products; this is the most common type of infection and affects the skin.

It accounts for more than 95% of all cases. Effective antibiotic treatment means few deaths occur from this type.

- Pulmonary or inhalation anthrax, causing virulent haemorrhagic broncho-pneumonia following inhalation of spore-containing material; the disease develops rapidly and can lead to coma and death within 24 hours. The last recorded case of pulmonary anthrax was more than 25 years ago.
- Ingestion anthrax is caused by eating undercooked meat from infected animals. This is rare in the UK.

Risk of anthrax in the textile industry

6. The first case of occupationally acquired anthrax recorded in the UK in 1847 was in the textile industry. Subsequent increases in the incidence of the disease were attributed to the importation of alpaca and mohair (goat hair). Most cases which arose from dealing with these finer wools were seen in the mills in Bradford, hence the disease became known as 'Bradford disease' or 'woolsorters' disease'.
7. There have been 17 cases of human anthrax notified in the UK since 1981. The most recent case in December 2001 involved a construction worker who contracted cutaneous anthrax, possibly from an exposure to anthrax spores in horse-hair plaster, but the source was never established. There was also a case in November 2001 of a worker at a knackers yard who contracted cutaneous anthrax from handling hides. The most recent case involving a textiles worker occurred in Bradford in August 2000; the worker was thought to have developed cutaneous anthrax after cutting his arm at work. All were successfully treated with antibiotics and made a full recovery.
8. Today, the overall risk of occupationally-acquired anthrax is low although the import, transport, storage and processing of textile materials, such as goat hair originating from countries where anthrax is endemic in the animal population can still present a risk to workers involved in these activities. The risk of exposure to contaminants varies according to how the material is handled and the greatest risk is at the early stages of animal hair treatment such as when the material is being sorted, or during blending, carding or combing.
9. The route of transmission in the textile industry is through contact with contaminated material, either by direct skin contact or through inhalation of spores liberated during the processing of the material. Person to person transmission is very rare.
10. Under the APO three categories of product are admitted to the UK:
 - material which has undergone disinfection abroad by a HSE approved method (currently only one Belgian company is approved) or which is required to undergo disinfection in an approved process in the UK (currently this option is not available);
 - material disinfected abroad by an unapproved method, which on arrival has been sampled, tested and shown to be free from anthrax; and
 - low risk materials subject to documentary controls (e.g. from China and USA).

OPTIONS

11. Three possible options have been considered:

Regulatory action. The Regulations proposed are deregulatory in purpose which will revoke outdated legislation. The APO has a very limited scope and COSHH already addresses the relevant health and safety issues. HSE believes that the APO is no longer credible as a strategy for controlling exposure to anthrax in the textile industry:

- APO was written for the goat hair trade of 30 years ago when high risk, raw or greasy goat hair made up a significant proportion of imports, Great Britain had several disinfection facilities and only a handful of sea ports were employed to handle goat hair cargoes. The trade is now very different. Raw or greasy goat hair has not, to our knowledge, been imported for about five years with the result that the only remaining company offering disinfection has recently 'mothballed' its disinfection plant. (Countries such as Iran and Pakistan now add value to their products by carrying out their own scouring and disinfection). The five ports 'designated' in the APO through which goat hair may be imported (three of which are only permitted to handle goat hair goods in containers) are unnecessarily restrictive, with the reasons for original designation having been lost in time. More importantly, two of the five 'designated ports' in the APO do not currently hold 'border inspection post' status under legislation controlling imports of products of animal origin, and importers using these ports would be liable to have the goods seized for destruction by HMC&E. HSE has had to use its powers under the APO (Exemption) Regulations to disapply the requirements on designated ports so that importers do not fall foul of superior importing requirements.
- The APO contains anomalies that weaken it as a risk control measure. It applies to imports of wool and animal hair from Egypt and Sudan yet imports of wool and (non-goat) animal hair from countries with regular anthrax outbreaks, such as Afghanistan, are unrestricted. This has led to the mistaken belief that countries and material not covered by the APO are free from risk and no additional control measures to protect employees are necessary.
- The APO imposes restrictions and prohibitions that have little to do with health and safety. For example, the ban on the importation of goat hair tops and yarns is little more than a trade protection measure. Tops and yarns are now commonly imported but it is not generally realised by importers that each consignment requires an exemption from the APO.
- The application of the APO to any material entering GB from EU Member States has been completely relaxed. This means that material entering GB that has been cleared by Customs in another EU country can avoid the APO's requirement for disinfection.
- It is also possible to avoid the requirement for disinfection in other ways. The Schedule to the APO contains a list of goods that are not subject to prohibition or restriction. For example, China cashmere with proof of origin, is exempt. There is recent evidence that goods from countries such as Iran, where anthrax is endemic, are imported into China and then legitimately exported as goods of

'China' origin. Any anthrax risk would not therefore be dealt with by the APO.

- The APO creates no offence and HSE has no powers to prosecute for non-compliance. Action could be taken under Customs law, but to our knowledge, this has never been actively pursued.
- COSHH 2002 already applies to work with material potentially contaminated with anthrax and is sufficient to ensure proper protection of workplace risks. Other equally or more serious infection hazards associated with occupation exposure (such as Bovine Spongiform Encephalopathy, rabies, and Nipah virus) are controlled by COSHH, so there is no reason why anthrax should be singled out for warranting additional legislation.
- The majority of applications to the HSE's Textiles Sector Group under the APO are for 'Certificates of Satisfaction'; these are issued to confirm that the HSE is satisfied that the documentation proves the country of origin to be one to which the restrictions and prohibitions do not apply. This is time consuming, bureaucratic and adds nothing to the control of risk.
- For imports of goat hair or products containing goat hair, Certificates of Exemption can be issued either with or without conditions depending on the anthrax risk in the country of origin. The issue of unconditional certificates is simply a paperwork exercise.

Publish supporting guidance only - Despite the publication of the anthrax guidance in 1997, inspections of premises in 2003 found that the industry was still relying on the APO, with its associated problems, to protect its workers rather than applying a COSHH based regime. Publication of guidance alone is therefore unlikely to change this position.

Do nothing - Continuation of the APO would further interfere with the more stringent requirements of COSHH and would perpetuate the misapprehension that the APO fully protects workers from exposure to anthrax from all goat hair products. HSE would also be obliged to continue to allocate resources to administer a highly flawed bureaucratic system (which also imposes an unnecessary paperwork burden on importers). The APO gets in the way of employers discharging their responsibilities to their employees under COSHH and conflicts, in part, with arrangements made under superior legislation controlling the import of goods of animal origin. Additionally, this regulation was formally identified by an HSC review in 1995 (as directed by Sir Paul Beresford the then Parliamentary Under Secretary Of State for the Department Of Environment) as not relevant or necessary. Again, the conflict with the EU legislation controlling imports of products of animal origin would remain.

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

12. To complete the CBA for the 1996 consultation 8 firms, of which 3 employed less than 50 workers, responded to the impact questionnaire (10 firms contacted). These firms covered virtually all of the 150 certificates of satisfaction issued by HSE in 1996. HSE has provided up-to-date information on the number of certificates of satisfaction and exemption issued in the year

to July 2004. HSE also provided information on the costs of sampling during the year to July 2004 which it is obliged to undertake for material disinfected abroad and on the costs of administering the APO.

13. It is assumed that there is less than 100% compliance with the APO because some ports have not routinely required the presentation of Certificates to permit the import of goat hair and, because of a lack of awareness of the APO's complex requirements, some importers are not aware of requirements such as the prohibition on the import of tops and yarns or on the import of wool from Egypt and the Sudan.
14. In line with Treasury guidance, costs and benefits have been discounted at 3.5% a year. Earnings have been uprated by 1.8% a year.

EQUITY AND FAIRNESS

15. There are no differential impacts from the proposed policy.

Atypical workers

16. Not relevant for this industry.

BENEFITS

Health and safety benefits

17. HSE does not expect there to be any relaxation of control following the revocation of the APO. There should not be any increased risk to health from this proposal. Moreover, HSE believes that there is a danger that the APO may give misleading impression that countries and materials not covered by the APO are free of risk and that if the only procedures followed are those laid down by the APO then nothing more need to be done.
18. Because of the industry reliance on the APO, and evidence of their failure to take on board the 1997 anthrax guidance, HSE believe that the alternative options will continue to perpetuate the misapprehension that the APO fully protects workers from exposure to anthrax in all goat hair products.

Other benefits

19. There will be financial savings to HSE, as it will no longer have to administer the APO and its exemption schemes, which currently take up approximately 1-4 hours per week of a Band 6 time, and between 0.25 and 1 hour per week of a Band 2 time. This amounts to an annual cost of £2,200 to £8,800, and a ten year present value of £21,000 to £82,000¹.
20. HSE would also not have to pay for sampling and testing of certain imported goat hair, which costs approximately £4,500 a year plus around 3 days per year of HSL Scientific Officer time. There are additional costs of transporting equipment to HSL for decontamination after each set of sampling. This involves a day of the HSE driver's time for each sampling occasion.

¹ The hourly cost of an administrative Band 6 HSE is £29, and for a Band 2 it is £57. Both include non-wage labour costs.

However, although HSE currently bears these costs, under the deregulatory proposal, similar costs would be borne by the dutyholder. Consequently, this represents a transfer of costs within society and should therefore not be counted as an overall benefit.

21. There are likely to be some savings to industry in the form of transport and storage costs. Goods that are disinfected abroad using an unapproved process, are required as a condition of the exemption certificate to be transported to bonded warehousing in the Leeds area for sampling by HSE. (It is difficult to put a figure on transport costs because it will depend on the port of arrival and whether the goods are destined to come to the Leeds area anyway.) The importers are then charged demurrage costs for goods held in bonded storage pending satisfactory test results. Estimates of the cost of storage vary but in practice, it is expected that savings will be small. For example, one bonded warehouse charges 45p per bale per week plus a handling charge of around £1 per bale. The usual time taken by the test centre is ten to fourteen days. Based on the total number of bales imported during the last year, where HSE carried out sampling, the savings on storage are likely to be less than £1,000 per year, which has a ten year present value of £9,000.

Total benefits

22. Total annual benefits are estimated to lie between £3,200 and £9,800, while the total ten year present value is between £30,000 and £91,000.

COSTS (of all options)

Business sectors affected

23. This proposal affects a small (and reducing) subset of the textiles sector which import goat hair and goat hair products. As of July 2004, there were 14 importing companies involved in processing goat hair, (9 of whom are currently active) and 5 importing agents. All but 3 of the processing companies employ fewer than 50 people.

Compliance costs for a 'typical' business

24. It is not possible to assess what impact revoking the APO will have on the costs to firms that currently put consignments through a disinfection process. The need for disinfection of consignments will be determined by risk assessment under COSHH, but is not expected to diminish.
25. Those companies that are obliged to submit consignments for sampling and testing will have to pay for this once the APO is revoked. In the year to July 2004 HSE has undertaken sampling on 6 occasions for one company only at a cost of approximately £4,500 plus staff costs. (Three other companies whom HSE has issued with APO period exemption certificates already undertake their own sampling and testing as a condition of the certificate and so they will not face any additional costs). Assuming that these tests will still have to be conducted under COSHH risk assessments, and that the cost of conducting the tests will remain the same, the company will have to bear the same costs that HSE currently bears. However, as noted above, HSE will benefit from the new arrangement, and hence the cost to society would be neutral.
26. Under a COSHH risk assessment regime, the amount of sampling and testing that will need to be done may be less than that currently required under the APO. The APO requires sampling and testing of every consignment that has been disinfected abroad using an unapproved process: a COSHH regime could allow sampling to diminish once a satisfactory level of quality assurance has been obtained. However, some firms may need to sample some higher risk goods that, due to gaps in coverage of the APO, are not currently required to be sampled. This would include cashmere from countries such as Iran and Afghanistan which is imported into China and exported as 'goods of China origin'.
27. Administrative savings to industry are likely to be very small. During the year to July 2004, applications were made to HSE for 54 Certificates of Satisfaction and 9 Certificates of Exemption. If we assume completing each application costs around £3² (one company suggested it would take about ten minutes) then cost savings would be £189 per year.

Total compliance costs to business

28. The impact on industries' costs is uncertain. The transfer of the costs of sampling and testing from HSE to industry would suggest that the most likely outcome would seem to be an increase in costs to industry. If so, this increase would be very small and would represent a small fraction of the overall cost of the goods.
29. It is likely that any additional costs from sampling will be recouped when the goods are sold on. However, those companies for whom HSE conducts sampling are at a competitive advantage compared with those who arrange their own sampling and revocation of the APO will remove this inequity.
30. British companies compete mainly with Italy, which is regarded as the world centre of the cashmere market. Removal of the APO would, in terms of health

² This assumes the labour cost (including non-wage elements) of the employee is fifteen pounds. An allowance of 50 pence has been made for postage.

and safety, allow British companies to compete on the same legislative basis as their Italian counterparts.

Costs to HSE

31. There will be some initial costs of inspectorial support to the industry to ease the transition from an APO regime to a COSHH based regime which could include a round of visits to the importing companies. This would take up approximately 4 days of B2 time plus travel and subsistence costs of around £400. Thereafter, monitoring and enforcement would be dealt with by operational inspectors at routine visits. Overall, costs to HSE are expected to be absorbed within existing budgets.

Other costs

32. None.

Environmental impacts

33. There should no environmental impacts from the revocation of the APO. All imports of animal hair and by products are controlled by EU legislation (Regulation 1774/2002) which requires that it comes from animals not showing clinical signs of disease, that it is securely packaged and is dry. These requirements are similar to those in the APO.

Total costs to society

34. Costs to society are difficult to quantify but are deemed to be negligible.

SMALL FIRMS' IMPACT TEST

35. The 1996 cost benefit analysis of the industry included three firms with 50 employees or less, satisfying the requirement of the small business litmus test. As of July 2004, of the 14 firms engaged in processing goat hair, almost all employ less than 50. Removing the APO will therefore impact more on small than large firms. It is difficult to draw conclusions on any differential impact on small firms from the limited information provided in the 1996 survey. However, two of the three small firms made comments criticising the existing system. One stated that the certificates of satisfaction appeared to serve no useful purpose. Another stated that the system should be more comprehensive with administration kept as simple as possible. The other small firm saw the system as "OK". It is likely that small firms would benefit from reduced paperwork requirements. In summary, we have little evidence to suggest revoking the APO will have significantly disproportionate effects on small firms.

COMPETITION ASSESSMENT

36. Given that the costs to industry are negligible, there is no reason to believe that the revocation of the Anthrax Prevention Order will have any affect on competition.

BALANCE OF COSTS AND BENEFITS

37. On the basis of the limited analysis that has been possible, benefits have a ten year present value of between £30,000 and £91,000, while costs are probably substantially less than this.

Uncertainties

38. There are a number of uncertainties in this analysis, in particular whether firms take up more or less disinfection and as a consequence of a full and thorough risk assessment under the COSHH legislation. However the costs are small.

ENFORCEMENT AND SANCTIONS

39. The APO is not enforced by HSE but through HM Customs and Excise. HSE already has powers under COSHH to take enforcement action if duty holders fail to adequately protect workers from anthrax exposure. These include the issue of improvement notices, and in extreme cases, prosecution. There is a risk that some importers may view the removal of the APO as a removal of the requirement for disinfection. This will be dealt with by preparing a model risk assessment in consultation with the industry and by ensuring that each importing company is provided with a copy.

CONSULTATION

40. The Department for Environment, Food and Rural Affairs; HM Customs and Excise; Cabinet Office; Home Office; Foreign and Commonwealth Office, Ministry of Defence and LACoRS have all been consulted on this proposal.
41. The 1996 consultation generated 9 responses: most were in favour of revocation but two responses representing employers and employees (the Wool Industry Health and Safety Committee (WSHSC) and the Confederation of British Wool Textiles (CBWT) Ltd respectively), expressed opposition to the APO's removal, mainly on health grounds. The HSC agreed in September 1996 to revocation, but owing to industry opposition did not set a date.
42. More recently HSC's Textile Industry Advisory Committee considered these options. The representative of the Wool Industry Health and Safety Committee advised that members of the CBWT involved in goat hair importations had voted overwhelmingly, 10 votes to one, for the revocation of the APO. The Confederation considered that revocation would not reduce the level of protection for employees. The Lancashire Textile Manufacturers Association also supported the revocation. The representative of the Transport and General Workers Union (TGWU) also supported the revocation of the APO and related legislation.

ARRANGEMENTS FOR MONITORING AND EVALUATION

43. Ongoing monitoring of the proposals would be dealt with by operational inspectors at routine visits, and analysis of any reports of occupationally acquired anthrax in the industry.

SUMMARY AND RECOMMENDATION

44. It is clear that the APO and its associated legislation is an outdated law which fails to adequately protect all workers from all imported goat hair which could be potentially contaminated with anthrax. Removal of the APO is the only effective way of ensuring the industry uses a consistent risk based approach as required by COSHH to all these products. Guidance issued in 1997 failed to convince the industry to move fully to the COSHH approach, and doing nothing would perpetuate the misapprehension that the APO fully protects workers. The total costs to society from this proposal are deemed to be negligible, while administrative benefits are probably modestly larger. Unquantifiable health benefits may also accrue from the revocation.
45. The recommendation is that the APO and its associated legislation are revoked.

MINISTERIAL DECLARATION

46. I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs

Signed by the responsible Minister

Jane Kennedy

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Date6 February 2005.....

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Annex 1

The Anthrax Prevention Order 1971 (APO) is the principal piece of current legislation dealing specifically with the importation of goods likely to be contaminated with anthrax. The Act of 1919 was repealed by means of the Anthrax Prevention Act (Repeals and Modifications) Regulations 1974 and at the same time modified the APO to enable the transfer of functions under it from the Secretary of State to the Health and Safety Executive.

The APO operates as control measure to prevent the importation of certain animal hair products declared 'likely to be infected with anthrax' (chiefly goat hair, including mohair and cashmere). Associated legislation is the Anthrax Prevention Order 1971 (Exemptions) (APO(E)) Regulations 1982 by which the HSE may exempt any person or any class of persons or any goods of any description from any requirement or prohibition imposed by the APO provided that the health and safety of those likely to be affected would not be prejudiced.