



Institute of Virology and Immunoprophylaxis Performance audit

Key facts

The Institute of Virology and Immunoprophylaxis (IVI) is the national reference laboratory for highly infectious animal diseases. It deals with the diagnosis of diseases such as foot-and-mouth disease or classical swine fever and carries out virology research, i.e. in the improvement of diagnostic tests and vaccines. Other duties carried out by the IVI are the registration of vaccines and batch controls, together with training and education. The IVI was established in the second half of the 1980s as the successor to the Federal Vaccine Institute in Basel. Investment costs at the time amounted to approximately CHF 60 million. The total cost volume of the IVI in 2003 was CHF 13.08 million.

The Swiss Federal Audit Office was commissioned by the Finance Delegation to examine whether or not it is justifiable to continue operating an institute for animal health in Switzerland. The focus of the performance audit is the IVI high security laboratory. It is the only laboratory in Switzerland to be classed as having biosafety level (BSL) 4. Level 4 signifies that the high security wing is housed in a casing and is continually under negative pressure, the animal units have been designed as gas-tight cubicles within the building. The building is equipped with special filters and has a closed sewage disposal system. The IVI high security wing only provides protection against the outside world and can thus only be used for the veterinary sector. Internally - protection of people - the high security laboratory is only designated as having BSL 2. Work with human pathogenic viruses would however require a minimum of BSL 3 both internally and externally. Ebola requires BSL 4. Along with the IVI, various other institutions are active in the field of veterinary and/or human virology. Attention is therefore drawn to the question of cooperation and/or the delineation between veterinary and human virology.

The Animal Diseases Act represents the legal basis for the IVI.

The benefits of a national high security laboratory are beyond dispute

Swiss and international scientific experts are of the opinion that Switzerland can on no account be without an institute such as the IVI. The arguments they put forward are as follows:

- The threat level concerning animal diseases will not diminish in future. On the contrary, the general opinion is that with the increasing global transportation of animals and animal products, both legal and illegal, the risk of disease outbreaks will increase.
- The IVI represents a type of insurance policy, outsourcing the required diagnostic investigations to a foreign laboratory would be linked to a loss of sovereignty.
- Rapid and reliable diagnostics is essential not just in the event of a genuine epidemic, but also in the event of a suspected case. There is uncertainty as to whether transportation abroad would run smoothly if the need really were to arise, and indeed as to whether the foreign laboratory would have the capacity to run a diagnostic investigation of foreign samples at that particular time.

The main benefit of having the IVI lies in being able to ensure a diagnostic investigation. The simulation carried out in western Switzerland in autumn 2003 did however reveal capacity limitations in the IVI in the field of diagnostics with an outbreak of foot-and-mouth disease.

Maintaining and operating the high security facility is very expensive

The cost of support services at high security BSL 4 laboratories is very high. According to information provided by the IVI, the annual operating costs for the security wing amount to CHF 3 - 4 million (including rental fees).

The IVI has a low cost recovery ratio

In the area of highly contagious animal diseases, the IVI has a monopoly position. Charges cannot be levied for the examinations for highly contagious animal diseases. Per annum there are approximately 150 cases of which 4 - 5 cases are highly suspected foot and mouth cases. However, the IVI also runs diagnostics for illnesses which do not require a high security laboratory. In this regard the IVI takes part in large scale examinations/tests (approximately 45,000 tests per annum), in which a large number of samples from all over Switzerland have to be examined to see whether or not a certain illness is still prevalent in Switzerland. For the IVI these large scale examinations/tests are important because they provide an opportunity to practice running diagnostics on a large number of samples. IVI research is financed in part from resources of the State Secretariat for Education and Research, from 2005 the money will come from the EU, together with funds from the Swiss National Fund. All told the IVI receives approximately CHF 1.3 million annually from these institutions. Concerning research, the IVI has annual operating costs amounting to CHF 6 – 7 million. The IVI's cost-recovery ratio is approximately 10 per cent.

Sections of the high security animal facilities have not been used for years

Since the decision was taken by the Federal Council in 1991 not to annually vaccinate cattle herds in Switzerland against foot and mouth disease, foot and mouth vaccination inspections have to a large extent become superfluous. Since then the high security facilities specially equipped for animal experiments using cattle has seen little use by the IVI. The small animal facilities in the high security wing are used by the IVI for rabies or swine

erysipelas vaccination controls, i.e. for animal experiments using viruses which do not require biosafety level 4. The need for high security animal facilities was consequently put into question. The Austrian reference laboratory for highly infectious animal diseases currently manages without high security facilities with biosafety level 4. Austria has plans to create a new laboratory, but will, however, dispense with high security animal facilities. Ireland, however, attaches great importance to being able to work with infected animals should the need arise. But only two areas are envisaged in which in each one approximately 5-6 calves can be kept.

Experts recommend that the IVI should retain the high security animal facilities

National and international experts are of the opinion that high security animal facilities should be retained. Whether or not capacity should be maintained at current levels or reduced to a smaller scale depends on the one hand on the scale of possible savings and on the other on available alternatives. On no account should the external mantle of the high security wing be pierced as biosafety would no longer be assured.

Need for a high security laboratory for the human and military sectors

A change of use of the unoccupied areas could open up interesting perspectives for the IVI. It could be conceivable to use the high security wing of the IVI not just for veterinary purposes but also for human purposes. However, this would require investments to be made in the IVI's high security wing. In order to integrate the SARS reference laboratory, human protection of BSL 3 would be required (signifying investment costs of approximately CHF 500,000 and annual operating costs of approximately CHF 400,000). On the other hand, the DDPS's Spiez Laboratory is also planning a BSL-4 Laboratory with full body protection suits and sufficient laboratory space to provide room for BSL 3 and 2 facilities. This project no longer has plans to provide animal facilities. However, it is possible that at a later stage mice will be used. It is planned that the high security laboratory (as a civilian reference laboratory) will be used to analyse agents which can be employed in bioterrorism, including the tracing of highly pathogenic virus cultures. The new laboratory should be ready for service by 2010. CHF 25 million have been set aside for the project in real estate plans. Against this backdrop, it would appear to be very important that the full extent of this situation is analysed in greater depth and this before important decisions have to be made. In this regard, the pros and cons of merging or combining a high security laboratory in the veterinary sector with one from the human sector should be examined in greater detail. On this topic the opinions of the experts are divided. In principle increased cooperation between human and veterinary sectors certainly shows the way forward.

Several countries concentrate reference laboratories in one place

Several of the countries surveyed within the scope of an international comparison concentrate reference laboratories for different pathogens in the veterinary sector at the same location. In Ireland different institutions in the veterinary/agricultural sector are being merged in one big facility. In new developments in Austria, it is even planned to integrate

not just the animal and human sector but the military sector as well. In Canada the human and veterinary sectors are already grouped together in the same place.

Recommendations

1. Switzerland should continue operating its own high security laboratory for highly infectious animal diseases.
2. Improved utilisation of facilities in the high security wing is to be sought or the area has to be used differently. It is also worth clarifying whether larger investments (renovations) will be required for the maintenance of the high security facility in the next few years. The IVI should therefore make the necessary clarifications and submit a report to the Federal Veterinary Office by the end of 2005.
3. The IVI should be in a position, when there is an outbreak of a highly infectious epidemic, to ensure diagnostic investigations. Within the scope of the service agreement, the Federal Veterinary Office should set the number of cases to be diagnosed a day in the event of an epidemic and oblige the IVI to ensure it has personnel available from other laboratories and conclude corresponding agreements.
4. The possibility should be examined of concentrating reference laboratories for all highly infectious illnesses, in human and veterinary medicine, at the IVI. Via the Federal Department of Economic Affairs, the Federal Veterinary Office should make an application to the Federal Council to commission a requirements analysis, with proposals and variants and pros and cons. The Swiss Federal Office of Public Health, the Federal Office for Civil Protection and the Federal Veterinary Office should all be involved. The findings must be taken into consideration in the decision-making process for a high security laboratory in Spiez.
5. The Federal Veterinary Office (FVO) will provide information on the implementation of the recommendations and the results of the requirements analysis to the SFAO by the end of 2005.

In principle the Federal Veterinary Office is in agreement with the recommendations. However, it is of the opinion that a requirements analysis in which the question of the location of the Spiez laboratory will have to be discussed, cannot be carried out by the end of 2005.

The original text is in German