



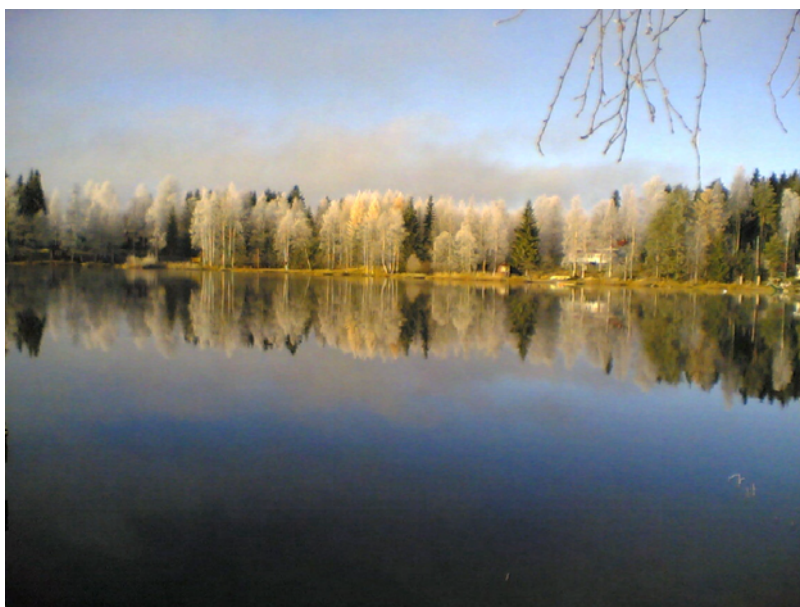
Erik Dybing • Robert Maynard • Harri Vainio

# Evaluation of the Department of Environmental Health, National Public Health Institute

Kansanterveyslaitoksen julkaisuja  9/2007

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Erik Dybing, Robert Maynard and Harri Vainio

**Evaluation**  
**of the Department of Environmental Health,**  
**National Public Health Institute**

Kuopio, April 2007

National Public Health Institute, KTL  
Department of Environmental Health, YTOS  
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## **Executive Summary**

- (1) YTOS/KTL is the only centrally funded institute in Finland that works in the environmental health area and thus has wide responsibilities. Selection of problems to address is thus critical: they should be important to Finland and within the capacity of the Institute to solve. In general the Panel feels the Department's programmes have been well chosen and well managed.
- (2) As with all institutions, appropriate selection of problems depends on the special expertise of the staff. The Department has special strengths in toxicology, microbiology, epidemiology, analytical chemistry and air pollution science. Important questions are being addressed in all these areas.
- (3) Problems in need of solution come from two main sources: the Finnish Government and from the staff within the Department. The latter source is important as the staff have a responsibility to engage in problem identification and do this by horizon-scanning, by surveillance work and by contact with experts in other countries. Such an approach has led to the Department "playing to its strengths".
- (4) Questions generated within the Department have resulted in long-lasting research programmes. In some cases there has been a reluctance to stop working on a topic of special interest to the staff even though the need for further work might be questioned. In general the Department has exercised a sensible policy of cutting programmes when the main questions have been answered. The Panel was impressed by several examples of this approach.
- (5) The Panel feels that though many of the programmes of work are clearly felt to be important there is a lack of formal analysis of why they are important. The need to justify programmes more clearly is identified as a gap in the management of work at the Department. More interaction with stakeholders would be helpful in this area. The preparation of assessments of likely benefits should a programme succeed would also be helpful.
- (6) Gap analysis is important. This is the case both within the broad programme of the Department and within individual programmes. The Panel thinks more work could be done on this. One area the Panel identified as in need of work is that of the impact on health of environmental noise.
- (7) All large research institutions run the risk of becoming inward looking. YTOS is no exception and a closer link with the Finnish medical profession is urged. The need to consult stakeholders has been mentioned above: the Panel would encourage the Department to hold regular meetings with their customers and develop the concept of "customers" throughout their work. Customer responses to the Department's work should be carefully assessed. Links with other institutions in Finland and beyond, should be developed. The development of collaborative programmes would be beneficial to the staff in the Department.

- (8) Policy makers are clearly important customers of the Department. It should be possible to develop management methods that allow the impact of the Department's research on national policies to be clearly demonstrated. This, the Panel found, was the case in some areas but not in others. An increased focus on the value of policy initiatives both in Finland and abroad would be helpful. Policy interventions often present unique opportunities to study the effects of changing levels of exposure to environmental factors: these should be capitalized upon.
- (9) In developing the Department's programmes the Panel thinks that more emphasis should be placed on a disease-based approach. This has the value of focusing researchers on the reasons for undertaking their work and is likely to lead to better links with the Finnish medical profession. In some areas this is already very well established but in others more work is needed.
- (10) The Department needs to develop further its already good record of providing advice to the public. The continued provision of web-based advice and of leaflets and booklets is important. Assessment of the impact that these measures have had should be improved.
- (11) Succession planning is a problem. In some areas of the Department's work staff are approaching retirement age and there seems to be no clear plan for how they will be replaced or for how their work will be continued. This problem is by no means unique to YTOS, but needs to be addressed urgently.
- (12) The Panel thinks that the Finnish Government should take a clear view on whether it wishes to maintain centres of international excellence in the areas addressed by staff within YTOS. If so, long term funding and a continuing confidence in the staff will be required. The Panel would like to stress that a short term approach is dangerous: losing a first class facility is easy; developing or recovering one is exceedingly difficult.
- (13) YTOS is a first class institute. Staff at YTOS has done distinguished work in a number of areas: these are explored in this report. But, YTOS has problems that need to be addressed. These problems are not unique to the Department; indeed they are common to most institutions but are, none the less, pressing. If these are addressed successfully and if long-term funding is maintained, the Panel thinks that YTOS will continue to do first class work and that the Department will maintain its fine international reputation.

**Key words:** environment, health, evaluation, report, air pollution indoor air, microbes, drinking water, chemicals, risk

## TIIVISTELMÄ

Erik Dybing, Robert Maynard ja Harri Vainio

Ympäristöterveyden osaston arviointi, Kansanterveyslaitos

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## Yhteenveto

- (1) YTOS/KTL on Suomen ainoa valtion rahoittama ympäristöterveyden alalla toimiva tutkimuslaitos. Siten sillä on laaja vastuu ja tutkimusteemojen valitseminen on tärkeää: niiden tulisi olla tärkeitä Suomelle ja laitoksen kapasiteetin puitteissa ratkaistavissa. Paneeli on yleisesti ottaen sitä mieltä, että osaston hankkeet on valittu ja hoidettu hyvin.
- (2) Kuten kaikissa tutkimuslaitoksissa, tutkimusongelmien valitseminen riippuu henkilökunnan erikoisosaamisesta. Osaston erikoisvahvuudet ovat toksikologia, mikrobiologia, epidemiologia, analyttinen kemia ja ilmahygienia. Kaikilla näillä osa-alueilla tutkitaan tärkeitä aiheita.
- (3) Tutkimusongelmien tunnistamisessa keskeinen asema on Suomen valtion hallinnolla ja osaston henkilökunnalla. Jälkimmäisen osuus on tärkeä, koska henkilökunnalla on velvollisuus osallistua tutkimuksellisten ongelmien tunnistamiseen seuraamalla alan tulevaisuuden näkymiä, ympäristöterveyden tilaa ja pitämällä yhteyttä asiantuntijoihin muissa maissa. Tällaisella menettelyllä on saatu aikaan osasto, joka optimoi vahvuutensa.
- (4) Osaston tuottamat tutkimuskysymykset ovat johtaneet pitkäkestoisiin tutkimushankkeisiin. Muutamassa tapauksessa on nähtävissä haluttomuutta lopettaa tutkimushankkeita, vaikka lisätutkimuksen tarve voitaisiin kyseenalaistaa. Osasto on kuitenkin yleensä lopettanut järkevällä tavalla ohjelmat sen jälkeen, kun pääkysymyksiin on vastattu. Useat esimerkit tästä menettelystä tekivät paneeliin vaikutuksen.
- (5) Vaikka monet hankkeista ovat selkeästi tärkeitä, paneelin mielestä sitä, miksi ne ovat tärkeitä, ei ole aina muodollisesti analysoitu. Hankkeiden oikeutuksen täsmällisempi perustelu on tunnistettu puutteelliseksi osaston työn hallinnassa. Tilannetta voisi parantaa lisäämällä vuorovaikutusta sidosryhmien kanssa. Hankkeista koituvia todennäköisiä hyötyjä koskevat arvioinnit saattaisivat olla myös hyödyksi.
- (6) Tutkimusaukkojen analysointi on tärkeää. Tämä koskee sekä osaston toimintaa yleensä että yksittäisiä hankkeita. Paneelin mielestä tällä alueella olisi vielä tehtävää. Eräs aihealue, jota paneelin mielestä tulee tutkia, on ympäristömelun vaikutus terveyteen.
- (7) Kaikki suuret tutkimuslaitokset ovat vaarassa kääntyä sisäänpäin. YTOS ei ole poikkeus, ja sitä kehoitetaan vahvasti läheisempään yhteistyöhön Suomen lääketieteen ammattilaisten kanssa. Sidosryhmien kuulemisen tarve on jo mainittu edellä: paneeli kannustaa osastoa pitämään säännöllisiä tapaamisia asiakkaidensa kanssa ja kehittämään ”asiakas” -käsitettä työn kaikissa vaiheissa. Osaston työstä saadut asiakaspalautteet tulisi käydä läpi tarkkaan. Yhteyksiä suomalaisten ja ulkomaisten laitosten kanssa tulisi kehittää. Yhteistyöhankkeiden kehittäminen olisi hyödyksi osaston henkilökunnalle.

- (8) Päätäjät ovat selkeästi tärkeitä osaston asiakkaita. Tämän vuoksi olisi voitava kehittää selkeitä hallintamenetelmiä, joiden avulla voidaan selkeästi osoittaa osaston tutkimustyön vaikutus kansalliseen politiikkaan. Paneelin mielestä tämä on toteutunut jo joillain alueilla, mutta ei kaikilla. Käytäntöjä muuttavien aloitteiden painottaminen sekä Suomessa että kansainvälisesti, olisi hyödyksi. Menettelytapoihin puuttuminen tarjoaa usein ainutlaatuisia mahdollisuuksia tutkia ympäristötekijöille altistumisen eri tasojen vaikutusta, joten niitä tulisi hyödyntää.
- (9) Paneelin mielestä osaston hankkeiden uudistamisessa tulisi painottaa enemmän sairauksiin perustuvaa lähestymistapaa. Tällöin tutkijat joutuisivat keskittymään tutkimustyön perustavoitteisiin ja yhteydet Suomen lääketieteen ammattilaisiin todennäköisesti tiivistyisivät. Joillain alueilla tämä toimintamalli on vakiintunut tapa, mutta toisilla alueilla on tehtävä lisätyötä.
- (10) Osaston tulee jatkaa arvostettua neuvontatyötään yleisölle. Verkkopohjaisen neuvonnan, lehtisten ja kirjasten toimittaminen on edelleen tärkeää. Näiden toimien vaikutuksen arviointia tulisi kehittää.
- (11) Seuraajakysymysten suunnittelu on ongelma. Joillakin osaston alueilla henkilökunta lähestyy eläkeikää, eikä selkeitä suunnitelmia näiden henkilöiden korvaamisesta tai työn jatkamisesta näytä olevan. Tämä ongelma ei koske vain YTOS:ää, mutta vaatii kiireistä käsittelyä.
- (12) Paneelin mielestä valtiovallan tulisi ottaa selvä kanta siihen, haluaako se säilyttää kansainvälisen tason osaamiskeskukset YTOS:n tutkijayhteisön aihealueilla. Jos säilyttämistä halutaan, tarvitaan pitkäjänteinen rahoitus ja jatkuva luottamus henkilökuntaan. Paneeli korostaa, että lyhyen tähtäimen lähestymistapa on vaarallinen: ensiluokkaisen laitoksen menettäminen on helppoa, mutta kehittäminen tai uudelleen käynnistäminen erittäin vaikeaa.
- (13) YTOS on ensiluokkainen laitos. YTOS:n henkilökunta on tehnyt merkittävää työtä monilla eri alueilla, joita arvioidaan tässä raportissa. YTOS:lla on kuitenkin ongelmia, joihin täytyy vastata. Nämä ongelmat eivät koske vain osastoa ja ne ovat yleisiä useimmissa laitoksissa, mutta ne ovat silti väistämättömiä. Jos ongelmat ratkaistaan ja pitkäjänteinen rahoitus säilyy, paneelin mielestä YTOS jatkaa ensiluokkaista työtään ja osasto säilyttää erinomaisen kansainvälisen maineensa.

**Avainsanat:** ympäristö, terveys, arviointi, raportti, ilmansaasteet, sisäilma, mikrobit, juomavesi, kemikaalit, riski

## SAMMANDRAG

Erik Dybing, Robert Maynard och Harri Vainio

Utvärdering av Avdelningen för miljöhälsa på Folkhälsoinstitutet

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- (1) YTOS/KTL är det enda statsunderstödda institutet i Finland som verkar inom miljöhälsoområdet, och följaktligen har det ett brett ansvarsområde. Det är därför mycket viktigt vilka frågor man väljer att arbeta med: de ska vara viktiga för Finland och vara möjliga för institutet att lösa. På det hela taget tycker panelen att avdelningens program valts ut och hanterats väl.
- (2) Som fallet är med alla institutioner handlar ett lämpligt urval av frågor om vilka specialkunskaper personalen har. Avdelningen för miljöhälsa har sina starka sidor inom toxikologi, mikrobiologi, epidemiologi, analytisk kemi och luftföroreningar. Viktiga frågor tas upp inom alla dessa områden.
- (3) De frågor som ska lösas kommer huvudsakligen från två håll: från den finska regeringen och från avdelningens personal. Den senare källan är viktig eftersom personalen har ansvaret att arbeta med problemidentifikation och gör detta genom horizon-scanning, övervakning och kontakter med experter i andra länder. Genom att arbeta på det sättet har avdelningen kunnat utnyttja sina starka sidor.
- (4) Frågor som tagits upp inom avdelningen har lett till långvariga forskningsprogram. I vissa fall har det funnits en motvilja att avsluta arbetet inom ett ämne som personalen varit särskilt intresserade av, även om behovet av vidare forskning kunnat ifrågasättas. I regel har avdelningen haft en vettig policy att avsluta program när de huvudsakliga frågeställningarna besvarats. Panelen blev imponerad av flera exempel på detta sätt att arbeta.
- (5) Även om det är tydligt att många av programmen känns viktiga, är det panelens åsikt att det saknas en formell analys av deras betydelse. Behovet att tydligare motivera programmen har identifierats som en brist i hanteringen av arbetet på avdelningen. Inom detta område vore det nyttigt med mer samarbete med intressenterna. Det skulle även vara nyttigt att ta fram bedömningar av de tänkbara fördelar som ett lyckat program skulle föra med sig.
- (6) Det är viktigt med bristanalys. Detta är fallet både inom avdelningens övergripande program och inom de enskilda programmen. Panelen anser att man skulle kunna arbeta mer med detta. Ett område som panelen tyckte att det borde arbetas mer med är hur buller påverkar hälsan.
- (7) Alla stora forskningsinstitutioner riskerar att börja blicka inåt. YTOS är inget undantag, och borde därför knyta närmare band med den finska läkarkåren. Behovet av att konsultera intressenterna har redan nämnts: panelen vill uppmuntra avdelningen att hålla regelbundna möten med sina kunder, och att tänka mer på dem som "kunder" inom sitt arbete. Kundernas reaktioner på avdelningens arbete bör nog utvärderas. Banden till andra institutioner i Finland och i utlandet bör utvecklas vidare. Det skulle vara bra för avdelningens personal att utveckla samarbetsprogram.



- (8) Det är tydligt att policyskapare är viktiga kunder för avdelningen. Det borde vara möjligt att utveckla metoder som gör det lätt att se hur avdelningen påverkar nationell policy. Efter vad panelen kom fram till sker detta i vissa fall, men inte i andra. Det skulle vara nyttigt med ökat fokus på värdet av policy-initiativ, både i Finland och i utlandet. När policier förändras uppstår ofta unika tillfällen att studera vad nivåförändringar av miljöfaktorer får för effekter; dessa tillfällen bör tas till vara.
- (9) Panelen anser att man borde lägga vikten mer på sjukdomar när man utvecklar avdelningens program. Det har fördelen att det får forskarna att fokusera på orsakerna bakom det arbete de utför, och det kommer sannolikt att leda till bättre kontakt med den finska läkarkåren. Inom vissa områden är detta redan väl etablerat, men inom andra behövs det mer arbete.
- (10) Avdelningen måste vidareutveckla sitt dokumenterat goda arbete med att ge råd till allmänheten. Det är viktigt att fortsätta tillhandahålla såväl Internet-baserad rådgivning som broschyrer och informationshäften. Avdelningen bör bli bättre på att utvärdera vilken inverkan dessa åtgärder har.
- (11) Generationsväxlingen är ett problem. Inom några områden av avdelningens arbete närmar sig personalen pensionsåldern, och det verkar inte finnas någon riktig plan för hur de ska ersättas eller hur deras projekt ska föras vidare. Detta är inte på något vis ett unikt problem för YTOS, men det är viktigt att ta itu med det.
- (12) Panelen anser att den finska regeringen bör bestämma sig för om de vill upprätthålla internationellt högtstående centra inom de områden som personalen på YTOS arbetar med. Om de vill det krävs långsiktig finansiering och ett fortsatt förtroende för personalen. Panelen vill betona att det kan vara farligt med ett kortsiktig sätt att arbeta: det är enkelt att bli av med en förstklassig anläggning, men att utveckla eller återskapa en är mycket svårt.
- (13) YTOS är ett förstklassigt institut. Personalen på YTOS har utfört ett förnämligt arbete inom flera områden: dessa behandlas närmare i denna rapport. Men YTOS har problem som behöver tas itu med. Det är inte problem som är unika för avdelningen, utan som är vanliga på de flesta institutioner, men de är ändå allvarliga. Om man tar hand om problemen, och en långsiktig finansiering upprätthålls, tror panelen att YTOS kommer att fortsätta utföra ett utmärkt arbete och att avdelningen kommer att fortsätta att åtnjuta ett gott internationellt rykte.

**Nyckelord:** miljö, hälsa, utvärdering, rapport, luftföroreningar, inomhusluft, mikrober, dricksvatten, kemikalier, risk

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## **Preamble**

### **(1) Introduction**

The National Public Health Institute KTL in Finland promotes people's possibilities to live a healthy life. KTL is responsible as an expert body under the Ministry of Social Affairs and Health, for providing professionals and citizens the best available information for their choices. The Institute has 9 Departments in Helsinki, Kuopio, Oulu and Turku, each of which is built of various laboratories and units.

Environmental health risk analysis forms the umbrella that covers most of the research at the KTL Department of Environmental Health (YTOS) in Kuopio. The main research themes at the Department are air pollution, drinking water, mouldy buildings, chemicals, asthma and allergies, and risk assessment.

#### **(a) The task of the International Evaluation Panel**

The Evaluation Panel should perform an overall assessment of the functions, strategic importance, scientific merits and value for money of the work of the Department.

#### **(b) Additional material requested by the Evaluation Panel**

During the first meeting of the Evaluation Panel it became apparent that additional material was needed in order to perform its evaluation. The Panel therefore requested that the following material be made available:

- (i) An analysis of the recommendations with respect to YTOS from the evaluation of KTL in 1995
- (ii) An overall strategic plan of the YTOS
- (iii) An analysis of the management of the YTOS overall, including the distribution of resources for the core processes for the period 1996-2006
- (iv) An analysis of staff competence and its development over the evaluation period
- (v) A further analysis of scientific productivity by impact factors and other relevant indices
- (vi) A vision document on international issues
- (vii) An assessment of the balance of external vs. budget funding with the full costs of the YTOS workforce
- (viii) An analysis of the maintenance of the basic infrastructure (space, personnel, equipment)
- (ix) An analysis of the expert services provided by YTOS during the evaluation period
- (x) An analysis of the value, cost and benefits of the animal facilities

#### **(c) Composition of the Evaluation Panel**

The Evaluation Panel consisted of Professor Erik Dybing, Norwegian Institute of Public Health, Norway (Chair), Dr. Robert L. Maynard, Department of Health, United Kingdom and Professor Harri Vainio, Finnish Institute of Occupational Health, Finland.

## 1. Review of the Activities of the Department of Environmental Health

### *1.1 Vision, objectives and organisation*

YTOS has formulated the following motto: ‘People must be able to breathe, drink, eat and live in the environment trusting on its safety. This is both an individual’s civil right and a prerequisite for a functioning society and economy’. The goals of the Department are (i) promotion of public health, (ii) reduction in environmental exposures, and (iii) improved decision-making on environmental risks. These goals are pursued through scientific research, risk assessment, dialogue with the decision makers, and educating the public. The main interest areas of YTOS are drinking water, chemicals, air pollution, asthma and allergies, and indoor microbes. Risk analysis forms the umbrella over most of the research done at the Department.

There are five laboratories/units at YTOS:

- Air Hygiene Laboratory (Head: Professor Matti Jantunen)
- Environmental Microbiology Laboratory (Head: Dr. Aino Nevalainen)
- Chemistry Laboratory (Professor Terttu Vartiainen)
- Environmental Epidemiology Unit (Professor Juha Pekkanen)
- Toxicology Laboratory (Dr. Hannu Komulainen)

The Head of the Department is Professor Terttu Vartiainen.

Scientific research at YTOS is conducted in collaborative research programmes across the laboratories/units. The six research programmes are:

- Air Pollution and Health (Co-ordinator: Professor Matti Jantunen)
- Respiratory Disease, Indoor Microbes and Immunotoxicity (Co-ordinator: Dr Aino Nevalainen)
- Water and Health (Co-ordinator: Dr. Ilkka Miettinen)
- Persistent Organic Pollutants and Health – Analysis, Concentration, Exposure and Epidemiology (Co-ordinator: Professor Terttu Vartiainen)
- Persistent Organic Pollutants – Mechanisms of Health Effects (Co-ordinator: Dr. Matti Viluksela)
- Risk Analysis (Co-ordinator: Dr. Jouni Tuomisto)

### *1.2 Influence of the 1994-95 evaluation*

The former Evaluation Panel made in 1995 the following six major recommendations with respect to YTOS:

- The overall strategy for the Division should be reviewed as a matter of urgency by an expert group which would report to the Director-General and the proposed Director-General’s strategy group
- The Division should develop a more structured and co-ordinated approach to studies to enable it to carry these through in a systematic manner from hazard identification to epidemiological association, to assessment of exposure and its consequences, to study of mechanism of toxicity and evaluation of factors which might modify the impact of exposure

- Major research themes for the future should include air pollution and other programmes which have a particular relevance to Finland (e.g. relating to the timber processing industries). Other major targeted programmes might be developed in neurotoxicology, immunotoxicology or reproduction/developmental toxicology – (it is recognised that the establishment of a strong programme in one or more of these fields will require considerable strengthening of the limited number of current staff members with expertise in these areas)
- A critical strategic review of the Division should be carried out in the context of its relationships with the University and the FIOH (ideally in collaboration with these other bodies). The possibility that these might be drawn together into an Institute of Environmental Health to develop a major resource and research centre in the field with a clearly defined strategy should be explored
- The contribution (of) which staff of the Division (would) make to the maintenance of bacteriological expertise within the KTL should be considered in the reappraisal proposed in the review of the Division of Infectious Diseases
- The Division should not continue to provide a toxicity testing service on a contractual basis

The present Evaluation Panel finds that YTOS has reviewed these recommendations in a thorough and diligent fashion, and acted conscientiously on all of them. The Department developed an overall strategy and thereafter evaluated 5-year strategic plans. These plans have been important for applications to nationally and EU-funded research programmes.

The research activities have been organised into specific research programmes considered to be most relevant from the public health and scientific point of view. A matrix-type organisation of the programmes has proved to be quite effective.

Major research themes have covered those recommended by the previous panel, including air pollution and its health effects, and effects of wood processing industries. Other major targeted programmes have been developed in immunotoxicology and reproduction/-developmental toxicology.

A possible establishment of an Institute of Environmental Health by merging YTOS with corresponding units of the University of Kuopio and FIOH did not come to fruition since these institutions both had different tasks and were working under different legislation and governance. There is good collaboration between YTOS, the University of Kuopio and FIOH in certain areas, but there is considerable potential for enhancement.

YTOS has maintained its microbiological expertise, focussing on organisms growing in environmental habitats and having a relevance to human health, such as campylobacteria, legionellae and noroviruses. An effective collaboration with the KTL Department of Infectious Disease has been established.

The previous toxicity testing service on a contractual basis was terminated.

### **1.3 Strategic planning**

According to the current strategy, YTOS is focusing on the following five areas of research:

- Particulate pollution in urban air and their health effects
- Respiratory disease, indoor microbes and immunotoxicology
- Drinking water and its health effects

- Persistent organic pollutants and their health effects
- Risk analysis methodology

For the next 5 years, the first research area will focus on the health effects of fine particles from different sources, including biomass combustion. In the second research area, emphasis will be given to better identifying and quantifying microbial exposures and both their harmful and beneficial effects on development of asthma and allergies, as well as the immunological and inflammatory mechanisms of these effects. The third research area will concentrate on microbial growth in water pipes and the possibility to produce safe drinking water for all people in Finland. Future research in the fourth area will focus on clarification of the significance of epigenetic alterations as a novel mechanism of toxicity of environmental chemicals potentially leading to transgenerational effects. The risk analysis methodology research was started in YTOS in 1999, and is thus fairly new. The key issues are realistic risk quantification and analysis of uncertainty in risk analysis, comparability and transparency in policy options evaluation, and rapid feedback capability in policy implementation. The ultimate aim is to develop completely new methods and processes of making risk assessments.

#### ***1.4 Management and resources***

The panel was not mandated to undertake a review of the management arrangements of the YTOS. The panel did, however, ask the YTOS staff to present a self-appraisal of (i) the distribution of resources for the evaluation period, (ii) assessment of balance of external vs. budget funding, and (iii) maintenance of the basic infrastructure.

The budgeting of the overall use of resources follows a 'management by objectives' practice. The Panel was told that the use of the existing staff was efficiently done in the matrix organisation fashion. The everyday management of the professional activities in different laboratories is operated via the decisions of the Head of the Department. Up to 90 per cent of the actual research work had to be financed from the outside external sources. The Panel recommends that this issue of the ratio between regular budget/- external funding should be carefully reconsidered.

The Panel was impressed by the good facilities the YTOS had, both in terms of the scientific equipments as well as the adequacy of the laboratory facilities. In addition, the facilities for the experimental animals were first-class.

#### ***1.5 Staff competence and renewal***

The Panel was also impressed by the quality and volume of the work produced by the relatively small research groups at YTOS. According to the analyses done in the Web of Science, the publications from the YTOS-groups in the different fields (health and air pollutants, exposure to air pollutants, indoor microbes and health, drinking water and health, and persistent organic compounds) ranked in the top positions (among the top 10 research laboratories). A high percentage (58%) of the key publications had been published in journals with impact factors above 3; 10% in journals with impact factors over 10. The current senior staff is to be commended for the effective exploitation of the research opportunities, good productivity and impressive publication record of their findings in international journals.

The Panel recognises the primary responsibility of the YTOS is to conduct research which will lead to improvements in the state of environmental health in Finland. These issues will not cease to exist in the near future, and therefore, expertise in the YTOS-field will be much needed also in the time to come. The YTOS senior staff has been successful in training and educating

students (an outstanding number of 61 PhD theses during 10 years). The Panel was, however, somewhat concerned of the obvious lack of explicit succession planning. Many of the current members of the staff are going to retire within the next five years, and the Panel considered it important to be prepared for the change. The environmental issues are also gradually changing in nature, and a careful analysis should be done in terms of the expertise needed. Also, the future use of emerging technologies (such as the different ‘omics’ technologies in environmental health research) would deserve to be considered in this succession planning.

It would be important to have a clear and concise succession plan, with leadership training included when considered necessary. The future challenges include the necessity to network outside the KTL, with research groups at universities and other institutions. The Panel considers it also important for the YTOS to continuously improve its knowledge on customers: to whom, why and for what purpose the work is done for.

Collaboration with other departments of the KTL, as well as with other institutions and the universities is one important channel for building up the knowledge and expertise needed for the future challenges.

### ***1.6 Customer/stakeholder relationships***

The expert work carried out by YTOS is mostly related to the Department’s general expertise, but in part it is also sold out on a contractual basis. The ‘customers’ for the expert work may be divided into four groups:

- The Ministry of Social Affairs and Health and other ministries, and regulatory institutions under their auspices
- Municipal and provincial authorities
- Individuals and the society more generally
- National agencies for which YTOS works internationally and international bodies such as EU and WHO

In 2004, the Department carried out a detailed survey of its expert work. About 1100 working days were used of national expert tasks, some 53 per cent of this time served the Ministry of Social Affairs and Health and the municipalities were the other main customer (27%). About 400 days were used for international tasks, 56% of which was for EU. All together 26 persons have especially been involved in expert work, on average 2.5-3 months per year.

YTOS is the main institute for knowledge on environmental health issues in Finland. They serve ministries and their underlying institutions with the following tasks:

- Ad hoc expert opinions/visits the Parliament of Finland
- National standing expert groups and committees of the ministries
- Emergency-response activities
- Preparation of national instruction/standards material
- Evaluations/analyses of specific topics
- Help in risk communication
- As experts representing Finland in the EU
- As experts representing Finland in WHO

YTOS’ service towards municipal and provincial authorities has changed during the evaluation period, with a decrease of the normative role changing into a more proactive role. This has been done through participation in training, by giving invited lectures on environmental



topics in various symposia, seminars and courses. Questions and contacts from local authorities occur daily to which the Department responds with expert opinions.

Although the resources do not allow personal service related to environmental health issues, the policy has been to answer simple questions immediately. However, more complex inquiries are referred to the Institute's web-pages and to local authorities primarily responsible for the subject.

The collaboration with national professional and health-related organisations has increased the dissemination of information on health effects and environmental risks. YTOS experts have participated in preparation of information material so that the health view has been addressed in decision making and remedial action.

Three of the YTOS seniors have been part-time professors at the University of Kuopio and most of the seniors are docents at one or more universities. On average, 6 PhD theses have been finished annually.

YTOS personnel have chaired important national scientific committees. Most of the senior researchers have been or currently are involved in some core scientific activity at the EU-level such as in the DG SANCO's Scientific Committee on Health and Environmental Risks (SCHER). Participation in such work has both impacted and enhanced the work and knowledge at the Department. Members of the staff have been regularly invited to working groups of WHO, especially related to ambient air pollutants. However, the structure of the international expert work towards international bodies is thin, for most tasks there is at present only a single competent person and no substitutes.

The contract services of YTOS have been limited. All methods used in contract service have been set up for research purposes. At present such work includes:

- Chemical analyses of organic pollutants
- Microbial analyses in water
- Microbial analyses and building inspections related to mould problem houses

## 2. Programme: Air Pollution and Health

*Leader: Professor Matti Jantunen*

### 2.1 General remarks

The Air Pollution Programme has a first class international reputation and its leader Professor Jantunen is a respected member of the international air pollution research community. He is a leader in thinking in the area of exposure modelling. Drs Pekkanen, Salonen and Hirvonen have also established international reputations in the air pollution field. The Programme undertakes cutting-edge research and should be seen as an important centre of excellence within KTL. This Programme is closer to policy development in Finland than some of the other Programmes reviewed by the Panel. Professor Jantunen [*and Dr. Salonen*] has close links with the Department of Environment and the Air Pollution Programme is able to take on urgent projects for the Government. An example is provided by work on the advantages of converting bus engines to use compressed natural gas as compared with diesel fuel.

### 2.2 Special strengths of the Air Pollution Programme

- (a) State of the art capacity in exposure modelling.
- (b) Involvement in international projects. This is a distinct strength – the Programme is involved in the leading European research programmes.
- (c) The Programme has sensibly focused on particulate air pollution. This is appropriate because of Finnish problems with the secondary aerosol and because of the national problem with fine road dust produced by studded tyres acting on gravel put on the roads in winter.
- (d) The Programme has developed methods for monitoring personal exposure to PM, CO and VOCs.
- (e) The Programme has focused on indoor air pollutants and has done important work on characterising the contribution of indoor exposure to total exposure.
- (f) Good links have been developed with clinical research on the effects of exposure to particles on myocardial functioning. Recent papers in this area are regarded as world class.
- (g) Good links with WHO and EC policy branches have been developed – [*Dr. Salonen*] and Professor Jantunen was closely involved with the Clean Air for Europe initiative.
- (h) Good work has been done in informing the public about levels of air pollutants and possible effects on health. The Evaluation Panel was not, however shown the documents provided or the website the group has developed.
- (i) The output of publications is excellent.

### 2.3 Specific challenges of the air pollution group

Note: Some of the points listed below may have been addressed but the Panel was not shown evidence of this.

- (a) The Programme is too dependent on Professor Jantunen – the impression that all the work rotates about him is easily gained. The Programme needs to consider where it will be in 5 years time and who will be leading the Programme then. Professor Jantunen reported that he was not taking new postgraduate students because of concerns about funding and continuation of the current level of support. This is worrying.
- (b) Clear evidence of:
  - (i) New policy initiatives.
  - (ii) Changes in levels of air pollutants.
  - (iii) Changes in levels of exposure to air pollutants.

- (iv) Improvements in health produced as a result of the Programmes' activities, has not been provided. This may be because the relevant studies have not been done: if this is the case the studies should be done, urgently. It is easy to gain the impression that the Programme is studying the problem rather than contributing to the solution.
- (c) The Panel did not see as much forward thinking as it had hoped. In the particle pollution area the forward look is satisfactory, but outside this area it seems less good. Gaseous air pollutants are hardly mentioned – despite likely concerns about meeting EU Limit Values for nitrogen dioxide (in urban areas) and perhaps sulphur dioxide if the latest WHO Air Quality Guidelines are adopted as a basis for new standards. The Panel heard little about exposure to carbon monoxide indoors though this is a known problem with heating devices using wood (or other solid fuel) unless they are well maintained.
- (d) There seems to the Evaluation Panel, to be a lack of emphasis on cost-benefit analysis of policy initiatives or policy proposals. The Programme is well fitted to take on such work.
- (e) The approach taken by the Programme is a “starting with the pollutants” approach. There is a case for a “starting with the diseases” approach. This was not discussed but closer links with physicians especially in preventive medicine would strengthen this and would make it a feasible and alternative strategy.

## **2.4 Assessment**

- (a) National relevance and effectiveness of activities:  
This is strong. Rating: Excellent
- (b) Appropriateness and adequacy of research, expert functions and services:  
Rating: Very good
- (c) Output and quality of research activities:  
Rating: Excellent
- (d) National and international cooperation:  
Rating: National: Very good  
International: Excellent
- (e) Resources allocation:  
Rating: Excellent  
The Programme is maintained in large part by Professor Jantunen's involvement with international programmes. Without this the resources would not be adequate to maintain the current output. Succession planning needs urgent attention.
- (f) Research fund raising:  
Rating: 4.5 million Euros in 10 years  
450,000 per annum  
Excellent
- (g) Development needs, especially regarding processes and organisation:
  - (i) Better links with preventive medicine
  - (ii) Better succession planning

## **2.5 Conclusions**

This is a first-rate Programme doing excellent work. It should be allowed to continue with work in which it has developed a fine reputation. The focus should be broadened and consideration should be given to a more disease-based approach. This is the main Finnish research programme in the area and maintenance of national expertise relies upon this Programme being strongly supported.

### **3. Programme: Respiratory Disease, Indoor Microbes and Immunotoxicity** *Leader: Dr Aino Nevalainen*

#### **3.1 General remarks**

The Respiratory Disease Programme has identified a common problem in Finland: mould growth in damp housing and has sought to investigate the nature of the mould, effects of exposure to mould on health and to develop interventions for addressing this problem. Thus, the Programme has a sharp focus on a particular problem that is has shown to be a cause of ill health. They have also tried to link exposure to mould with the rising prevalence of asthma in Finland. They have extended their work to examine the effects on health of early life exposure to antigenic materials: research on children growing up on farms has been productive. This work has led them to look at patterns of interleukin expression following exposure to moulds and associated bacterial species. The possible roles of endotoxin have been examined.

#### **3.2 Special strengths of the programme**

- (a) There is a useful focus on an important public health problem. This affects not only Finland, but seems particularly important in Finland as a result of the need for tight housing to conserve heat. The Finnish housing stock suffers from damp and mould growth and this has been shown to be linked with the risk of children developing asthma.
- (b) The scientific value of the work is high. One hundred and seventy two papers are reported as published in the international peer-reviewed literature during 10 years. This is an excellent research output.
- (c) The work has shown that remediation of damp schools leads to a significant drop in fungal concentrations and that this was associated with a decline in reported symptoms amongst students. Cough was markedly reduced as were complaints of rhinitis and “stuffy nose”. This is a useful measure of the success of the programme.
- (d) Work on early life exposure to conditions on farms (presumably a surrogate for early-life exposure to allergenic materials including bacteria) has shown that atopy is less common amongst farm children than amongst urban children. The prevalence of asthma seemed less significantly affected.
- (e) The Programme has developed advice to the public, the medical profession and to construction workers regarding the need for and value of, damp remediation. The Programme has developed a consultancy role in this area. The book “Damp Indoor Spaces” has contributed to a wider appreciation of problems in this area.
- (f) The clear links: field studies/clinical work/laboratory work are encouraging.

#### **3.3 Specific challenges in the programme**

- (a) The Programme has attacked a broad field – this raises questions about the capacity of the Programme to do world class work in all its areas. The publication record is outstanding – especially as regards epidemiological studies. The Panel was less persuaded by work on the causes of asthma. This area is under intensive study in many countries and closer links with leading research groups abroad would be useful. Some links were listed, but in such a large field this list is comparatively brief.
- (b) The Evaluation Panel was not clear about the links with policy development and about which government department had responsibility for the housing stock.
- (c) Links with physicians are clearly important and the Panel was not shown how the Programme is linked with the work of leading physicians. In the list of links with departments at Kuopio University Hospital, the departments of paediatrics and pulmonology were mentioned, but how these links operated was not clearly explained. The need for links with workers in the microbiology field in other Finnish institutes was raised and this area needs to be developed further.

- (d) In the forward-looking section the Panel was concerned that other hypotheses for the rising prevalence of asthma were not being considered in detail. Dietary factors may play a part and an association of changes in the Finnish diet over the past 20-30 years would be useful. This highlights the need for links with other areas of asthma research and the need to avoid too close a focus on a single line of attack.

### **3.4 Assessment**

- (a) National relevance and effectiveness of activities:  
Rating: Excellent
- (b) Appropriateness and adequacy of the research, expert functions and services:  
Rating: Excellent
- (c) Output and quality of research activities:  
Rating: Very good
- (d) National and international cooperation:  
Rating: National: Good  
International: Good
- (e) Resource allocation:  
Rating: Very good
- (f) Research fund raising:  
Rating: 4.6 million Euros in 10 years  
460,000 per annum  
Very good
- (g) Development needs, regarding processes and organisation:
- (i) This Programme has fewer problems as regards succession planning than the Air Pollution Programme: members of the senior staff are, the Panel believes, younger.
  - (ii) Development of links with physicians and with other institutes is important.

### **3.5 Conclusions**

This is a well focused research programme that is addressing an area of clear national importance. Their contribution:

- (i) Showing that damp and mould are common
- (ii) Showing that damp and mould are related to ill health
- (iii) Showing that remediation improves health

are obviously of first rate importance. The Programme needs to think where it is next going to focus: more work on the above issues (these could be regarded as “solved”) or an attack on fundamental causes of asthma. The latter field is very competitive internationally and the Programme needs to identify a special aspect of the area in which, as a result of personal expertise or circumstances peculiar to Finland, it can make a specific contribution. An in depth assessment of work in the area is needed.

## **4. Programme: Water and Health**

*Leader: Dr Ilkka Miettinen*

### **4.1 General remarks**

The Water and Health Programme has done its main research project in the field of chlorination by-products in drinking water. The water chlorination has been the main method of disinfection of surface water. Together with the high humic acid concentrations in raw water, considerable amounts of various chlorination by-products are formed, and chlorinated water has been shown to have high mutagenic activity in bacterial tests since the 1980s. The researchers at YTOS initiated in the beginning of 1990s a project to identify the chemicals responsible for the mutagenic activity in water, to study their toxicity in rodents and through epidemiological studies in humans. The project also made preventive interventions to diminish the formation of chlorinated by-products in waterworks. Additionally, the water and health-activities at YTOS have included studies on health effects of arsenic and uranium in drinking water. All these research questions posed by YTOS are relevant from the public health point of view in Finland. KTL scientists have been developing the work together with the customers (waterworks). The research has led to significant improvements in working practices, and diminished exposure to mutagenic components in drinking water.

### **4.2 Special strengths of the Water and Health Programme**

- (a) The KTL-programme has been a leading research entity internationally in the elucidation of chlorination by-products, especially describing the toxicities associated with MX.
- (b) The long-term rodent bioassay carried out in Kuopio has been instrumental in showing the cancer-causing potential of MX.
- (c) The chlorination by-products-project has generated important reports, which have been published in top international scientific journals.
- (d) The monitoring of water quality by mutagenic activity in bacterial tests has turned out to be a practical way of overseeing the conditions of chlorination in the process.
- (e) The interactions with water chemistry researches in universities have been exemplary.
- (f) The water disinfection project has lead to implementation of new work practices in water works.
- (g) Clarifying the limiting role of phosphorus in microbial growth and developing a very sensitive bioassay for detection of microbial-available phosphorus in water was an important scientific finding.
- (h) Collection of data related to waterborne outbreaks of microbiological disease and assisting different bodies in these cases has been very valuable.
- (i) The Programme should be congratulated with the long-term commitment to the water disinfection project and with the humble decision to finish the project when the main aims have been reached

### **4.3 Specific challenges of the Water and Health Programme**

- (a) There is a need for strategic planning of a new main research topic with clear definition of goals, tasks and milestones.

- (b) The uranium in drinking water is something which needs to be studied also in terms of its potential (chemical) toxicities in humans, and the group has already a good grip on this problem. The work probably needs to be developed with STUK.
- (c) The findings on arsenic in drinking water are also interesting, confirming the observation elsewhere. More research on this topic should be undertaken.
- (d) Further development is encouraged of the collaboration between YTOS and the KTL Department of Infectious Disease Epidemiology in epidemiological surveillance of water-borne infectious diseases.

#### **4.4 Assessment**

- (a) National relevance and effectiveness of activities:  
Rating: Excellent
- (b) Appropriateness and adequacy of research, expert functions and services:  
Rating: Excellent
- (c) Output and quality of research activities:  
Rating: Very good
- (d) National and international cooperation:  
Rating: National: Excellent  
International: Very good
- (e) Resources allocation:  
Rating: Very good
- (f) Research fund raising:  
Rating: 3.0 million Euros in 10 years  
300,000 per annum  
Very good
- (g) Development needs, especially regarding processes and organisation:
  - (i) A clear strategy is needed for new research initiatives related to chemical exposure factors in drinking water
  - (ii) Increased collaboration with infectious disease epidemiologists

#### **4.5 Conclusions**

The Programme has done solid work on a relevant topic of potential health effects associated with water chlorination. The scientific output has been good, with high impact on issues of water chlorination practices even outside the Finnish borders. This project is now coming to a successful end. The future scientific challenges have not been clearly presented. The Evaluation Panel considered that the presented sketchy plan could be more concrete and even more ambitious. It is clear that KTL/YTOS needs to maintain a readiness to provide expert advice in emergency situations related to water and health, and a basic capacity needs to be secured for the purposes of giving advice and support to those organisations responsible for surveillance and monitoring of the water quality. This is necessary both in view of the potential chemical and microbiological hazards.

## **5. Programme: Persistent Organic Pollutants and Health: Analysis, Concentrations, Exposures and Epidemiology**

*Leader: Professor Terttu Vartiainen*

### **5.1 General remarks**

This research programme has focused on analysis and exposure characterisation of chlorinated organic environmental contaminants such as PCDD/Fs, PCBs, PCDEs, PCNs and the brominated analogues such as PBDEs. Through studies of such contaminants the Programme has established a world-class analytical laboratory with advanced methodology and excellent instrumental facilities. They have applied their expertise in clarifying the contamination situation in the Gulf of Finland and the Gulf of Bothnia by analysing persistent organics in sediment, soil and fish samples. The Programme has made important contributions for the estimation of intake of dioxins, PCBs and PBDEs in the Finnish population by measuring these contaminants in fish and other types of food. By surveying Finnish breast milk, it has been observed that there was an annual decline of some 5 per cent in concentrations of PCDD/Fs and PCBs during the years of 1987 to 2000. Knowledge on exposure levels of halogenated contaminants have been coupled with information on health end-points in epidemiological studies of hypomineralised enamel tooth defects, soft tissue sarcoma, and of male urogenital malformations. The expertise within the Programme has also been used for a multi-disciplinary study of potential negative and positive health effects of fish consumption in various populations. Another group of environmental contaminants studied within the Programme are organotin compounds. The focus of these studies is both on environmental levels and population intake, as well as on internal dose assessment and coupling with potential end-points of endocrine disruption.

### **5.2 Special strengths of the Persistent Organic Pollutants and Health: Analysis, Exposures and Epidemiology Programme**

- (a) World-class quality in analysis of organic chlorinated environmental contaminants as evidenced from results in POP interlaboratory quality control studies.
- (b) Excellent laboratory facilities with up-to-date analytical equipment.
- (c) Very good output of scientific accomplishments in scientific journals and as doctoral dissertations.
- (d) Important assistance to Finnish municipalities in providing analytical expertise in assessing and remediation of soils contaminated with chlorophenols and dioxins.
- (e) Collaboration with SYKE in clarifying the dioxin contamination of the river Kymijoki and giving advice related to the consequences of this contamination.
- (f) Functioning as an expert organization for the Finnish authorities in matters concerning EU legislation of POP contamination.
- (g) Participation/leadership of various scientific bodies within Finland.
- (h) Very good co-operation with European scientific institutions through a number of EU-funded research projects.
- (i) Active participation in Nordic Council of Ministers projects with other Nordic countries on various aspects of collection and analysis of environmental contaminants.



### **5.3 *Specific challenges of the Persistent Organic Pollutants and Health: Analysis, Concentrations, Exposure and Epidemiology Programme***

- (a) The Programme is almost exclusively concentrating on analysis and exposure characterisation of halogenated organic compounds, without giving other human chemical exposures much consideration.
- (b) It is recommended that the Programme undertakes a thorough evaluation of candidate human exposure components in addition to POPs, in order to possibly revise its future work strategy.
- (c) A new strategy may involve developing expertise and acquiring equipment for analysis of components with different characteristics than the POPs (just to mention one example: phthalates).
- (d) Also here a more disease-based approach is recommended with closer collaboration with clinical medicine. Possibilities for revealing potential environmental risk factors for major chronic diseases should be examined.
- (e) A future strategy could also include an expansion of the Programme's activities in nutrition, environment and health by developing more expertise in food intake assessment.

### **5.4 *Assessment***

- (a) National relevance and effectiveness of activities:  
Very strong for POPs.  
Rating: Very good
- (b) Appropriateness and adequacy of research, expert functions and services:  
Rating: Excellent
- (c) Output and quality of research activities  
Rating: Excellent
- (d) National and international cooperation:  
Rating: National: Very good  
International: Excellent
- (e) Resources allocation:  
Rating: Excellent
- (f) Research fund raising:  
Rating: 5.2 million Euros in 10 years  
5200,000 per annum  
Excellent
- (g) Development needs, especially regarding processes and organisation:
  - (i) Developing a strategy with a widening of the focus on human environmental exposures.
  - (ii) Exploring a more disease-based approach in selection of research priorities.

### **5.5 *Conclusions***

The Programme is of high scientific quality and has given important contributions to the characterisation of human exposures to halogenated organic contaminants. The expertise developed within the Programme has been instrumental to Finnish local authorities in coping with contaminated sites. The expertise has also been of great importance to Finnish central authorities in managing and regulating dioxin and PCB food contamination. The Programme should make a thorough review of which environmental exposures may be of importance for human health and possibly revise its strategy primarily focusing on POPs. The Programme should also address the potential for applying a more disease-based approach in its future research projects.

## **6. Programme: Persistent Organic Pollutants: Mechanisms of Health Effects**

*Leader: Dr Matti Viluksela*

### **6.1 General remarks**

The Persistent Organic Pollutants: Mechanisms of Health Effects Programme has for a number of years aimed at improving the risk assessment of 'dioxins' (PCDDs/Fs). This has been sought by identifying the key toxic effects of these environmental contaminants, clarifying their mechanisms of action and unravelling the underlying reasons for strain, species and individual differences in toxic sensitivity. Through a number of detailed molecular and genetic studies, the Programme has been very successful in delineating the structural requirements in the dioxin receptor (AHR) responsible for the wide interstrain differences in acute lethality between the TCDD resistant Han/Wistar strain and the TCDD sensitive Long-Evans strain. Further studies have revealed that there are two types of TCDD effects, type I and type II, where for the former there is no genotype variation. Further mechanistic studies have related the type II effects with liver tumour promotion and hepatotoxicity. A case-control study on soft tissue sarcoma did not give evidence of an increased risk due to general dioxin exposure. The Programme has during the later years focused strongly on developmental toxicity of dioxins and has been very successful in identifying molar tooth development as a highly sensitive target of dioxin toxicity. Thereby, developmental tooth defects were shown to be excellent biomarkers of dioxin exposure. These observations on the dental system have been extended to studies on how dioxin affects bone development, revealing that this also is a relatively sensitive developmental endpoint. The Programme is also investigating another very interesting endpoint caused by dioxin exposure, namely severely diminished feed consumption leading to severe body weight loss. So far the underlying mechanisms for this wasting syndrome have not been satisfactorily explained.

### **6.2 Special strengths of the Persistent Organic Pollutants: Mechanisms of Health Effects Programme**

- (a) Very strong mechanistic toxicological research activity with internationally acclaimed competence in the dioxin area.
- (b) Availability of a number of modern molecular, genetic and genomic methods for toxicological studies.
- (c) Production of scientific results of considerable impact on risk assessment of dioxins.
- (d) Very good publication record with a number of papers in high quality journals and good generation of doctoral dissertations.
- (e) Developed essential national competence for risk assessment of dioxin exposures, especially in relation to consumption of contaminated fish.
- (f) Participation in numerous national and international expert groups in toxicology, environmental health and risk assessment.
- (g) Contributed considerably to education activities in toxicology and environmental health.

### **6.3 Specific challenges of the Persistent Organic Pollutants: Mechanisms of Health Effects Programme**

- (a) The main focus of the research programme is on exposures which probably are not the main environmental risk factors in Finland
- (b) The Programme should examine thoroughly the potential for other environmental risk factors being of importance for chronic disease in the Finnish population

- (c) The competence in developmental toxicology could be expanded to assess the impact on children's health of other exposure factors than POPs
- (d) Neurodegenerative diseases place a considerable burden on Finnish society. Thus, examining a possible involvement of environmental chemical exposures in such diseases should be considered.

#### **6.4 Assessment**

- (a) National relevance and effectiveness of activities:  
Very strong competence in risk assessment of dioxin exposures.  
Rating: Excellent
- (b) Appropriateness and adequacy of research, expert functions and services:  
Rating: Excellent
- (c) Output and quality of research activities:  
Rating: Excellent
- (d) National and international cooperation:  
Rating: National: Excellent  
International: Excellent
- (e) Resources allocation:  
Rating: Excellent
- (f) Research fund raising:  
Rating: 4.2 M Euros in 10 years  
420,000 per annum  
Excellent
- (g) Development needs, especially regarding processes and organisation:
  - (i) Expanding Programme to address additional exposures other than dioxins.
  - (ii) Examination of possible involvement of environmental factors in chronic neurodegenerative disease.

#### **6.5 Conclusions**

This Programme is very strong in the area of dioxin mechanisms. It has made very important contributions to the understanding of how dioxins cause various health effects, especially related to developmental endpoints. The research has established very solid competence in the risk assessment of dioxin exposures. This has been essential for risk-benefit analysis of consumption of fish in the Finnish population and has thus had great societal impact in the food area. Also, general competence in mechanistic toxicology has been gained through the Programme. However, dioxin exposures presumably are not the main environmental risk factors in Finland. Therefore, the Programme should examine thoroughly the potential for other environmental risk factors being of importance for chronic disease in the Finnish population. An outcome of such an examination could point to the need for focusing on other risk factors and toxicological endpoints than those which have been studied to date.

## 7. Programme: Risk Analysis

*Leader: Dr Jouni Tuomisto*

### 7.1 General remarks

YTOS has had from the beginning of the evaluation period the idea of improving the risk assessment activities in the field of public health in Finland. The previous evaluation team in 1994/95 suggested that YTOS develop a systematic manner of approaching public health issues from hazard identification to exposure assessment, to assessing the consequences, to mechanisms of toxicity, to the evaluation of factors which might modify the impact of exposure. The relatively small staff should be used in an integrative manner in the elucidation of the public health issues, and in making risk assessment for the decision makers to consider. In the field of risk assessment, the existing legislation (the new public health law, the law on occupational health services, etc.) emphasises an increasing use of risk assessment in the practical guidance of the environmental health activities (and in occupational health). There is a great need to increase basic information and understanding of risk assessment, as well as to provide simple tools for community health care centres to use. The development of tools for these activities would be one important target of the specialists at the YTOS of the National Public Health Institute.

The YTOS specialists have taken the approach of developing a Centre of Excellence in Environmental Health Risk Analysis. This has been supported by the Academy of Finland (for the years 2002-2007), and the centre has done top quality work on some issues of the of 'risk analysis', expanding the issues beyond the traditional 'scientific' issues to the field of management, values, arguments, and political decision making. The Centre's work has been especially concentrating on two issues: dioxins and urban air fine particles.

### 7.2 Special strengths of the Risk Analysis Programme

- (a) The way the risk assessment field is tackled by establishing a centre of environmental health risk analysis, is a very interesting strategic decision making.
- (b) Devoting a specific organisational unit for risk analysis is ambitious way of addressing risk assessment problems.
- (c) Through the activities within the Centre it has been possible to tackle the whole spectrum from hazards to risk/benefit evaluation to risk communication.
- (d) As evidenced from a decision analysis-paper published in *BMC Public Health*, an interesting attempt has been provided to integrate scientific and population behavioural and societal aspects into a new theoretical traffic system.
- (e) The Programme has excellent collaboration with the corresponding centre at Harvard University. It has been well connected also in EU-projects with many important partners in various European countries.
- (f) Through collaborative contacts with the Finnish Meteorological Institute, the University of Kuopio and the Geological Survey of Finland the Programme has been able to advance the application of geoinformatics in epidemiological studies with novel possibilities for future utilisation.
- (g) The Programme was awarded the status of Centre of Excellence from the Academy of Finland.
- (h) The open method of development of risk assessment in the internet, the 'Wikipedia approach', is an interesting idea for the future.
- (i) The application of small areas epidemiology is an important tool in the surveillance of environmental hazards.

### 7.3 Specific challenges of the Risk Analysis Programme

- (a) Within a relatively small budget and resource frame, the danger of organising the risk

assessment activities in a specific programme is that important practical aspects do not necessarily get the attention they might deserve, because of the need to focus on a few important points.

- (b) The future plans are somewhat unclear. Although the questions being addressed are potentially interesting, the Evaluation Panel had some concerns about the directions of the plans. The brief oral and written presentations made it difficult to judge their quality and evaluate the future plans in depth.
- (c) Since the Programme is heavily dependent on expertise from other programmes within YTOS, it may be difficult to specifically assign scientific outputs to the Centre and thus ascribe appropriate credit for its research activities.

#### 7.4 Assessment

- (a) National relevance and effectiveness of activities:  
The centre is still under development.  
Rating: Very good
- (b) Appropriateness and adequacy of research, expert functions and services:  
Rating: Excellent
- (c) Output and quality of research activities:  
Rating: Very good
- (d) National and international cooperation:  
Rating: National: Very good  
International: Very good
- (e) Resources allocation:  
Rating: **7.4 Assessment**  
Unfortunately, the Centre a continuation of the status as a Centre of  
Excellence from the Acad
- (f) Research fund raising:  
Rating: in 10 years  
os per annum
- (g) Development needs, especially regarding processes and organisation.
  - (i) The YTOS leadership should follow carefully the development of the Programme, and make modifications to the centre approach if need be
  - (ii) The Programme should increase networking with other Finnish institutions involved in chemical risk assessments

#### 7.5 Conclusions

The relatively small Risk Analysis Programme has made important contributions in the field of developing new methods for estimating value of scientific information for decision-making (example with dioxins in fish) and a new theoretical decision analysis applied for theoretical urban traffic system. The Programme has gained appreciation in Finland (nominated Academy's centre of excellence for the years 2002-2007) and it has also been successful in raising EU funding for the development of methods used in risk analysis. Furthermore, the Programme's epidemiologists have developed useful tools such as small area statistics of health system, applied in e.g., epidemiological studies of cancer in a community air around an open asbestos mine. The geoinformatics approach has also proved to be a promising tool which could be used in environmental epidemiology studies such as studies of power lines and cancer occurrence.

The risk analysis group is heavily dependent on expertise in the other areas (exposure, modeling, epidemiology) of the YTOS. The matrix approach appears to be an efficient way of using the necessary expertise to run the risk assessment activities in the YTOS.

## 8. Overarching Evaluation Issues and Recommendations

- (1) KTL is the only centrally funded institute in Finland that works in the environmental health area. It thus has a wide area of responsibility and yet with a limited staff needs to focus on problems that are important to Finland and which it can solve. This means that the selection of work areas is critically important. Whether the selection is correct may be questioned – in general the Panel thinks the selection has been appropriate.
- (2) How have the work areas been selected?
  - (a) YTOS responds to Government questions. This is clearly so in the air pollution area. Work on the case for using compressed natural gas as a fuel for buses is an example.
  - (b) YTOS generates its own questions which it sees as important for Finland and which it thinks the Government should be interested in. This is done in several ways:
    - Appreciation of environmental problems in Finland. Thus, the Institute has a surveillance role: identifying issues. In this the staff benefit from contacts abroad – being aware of problems identified abroad and asking (investigating) whether there are similar problems in Finland.
    - The questions asked are inevitably biased by the interests of the staff. For example, Professor Jantunen's group has an international reputation in exposure assessment and thus questions about the exposure of the population to air pollutants are focused upon. This leads to a limitation of the questions that are asked and it is important in any review to decide if these are the really important questions. In general, the Panel thinks the process works well.
  - (c) As with institutes generally, there is a tendency to continue work in areas where expertise has been developed. This can continue beyond the time when the key questions that led to the work have been answered. Knowing when to stop a programme is thus important. It was encouraging to see that work on chlorination by-products was being stopped after a long and successful programme. Of course, deciding to stop a programme has implications for the morale of staff and this needs to be managed carefully. Work on dioxins may also fall into this category.
- (3) The questions:
  - (a) Why is this (any particular) subject important?
  - (b) Why should we work on it?
  - (c) Why should we work on it now?
 need to be addressed. The Panel felt there was a lack of clear analysis in some instances.

Reasons for working on a problem include:

- The impact on the population of some factor that is seen as a problem, for example air pollutants.
- The likelihood of that the problem is soluble. It is probably unwise to work on problems that have only a low probability of being solved.
- Stakeholder demand can make work on a problem necessary especially in a centrally-funded institute such as the KTL.

Better analysis of these factors for each aspect of the programmes would be useful. During the second evaluation meeting it became apparent the Department plans to utilise more quantitative estimates of health impact in the future, such as disability-adjusted life years (DALYs). The Panel supports this initiative.

- (4) There should be more open analysis of the balance between pure and applied research. This is important if the YTOS programmes are to be justified in comparison with programmes at universities.
- (5) A better analysis of gaps in the programmes is needed.
- (6) Closer links with the medical profession is needed in several areas, although this seemed to be the case in the respiratory disease area. How the YTOS work influences medical practice in Finland was not clear to the Panel.
- (7) The concept of ‘customers’ should be looked at more closely. YTOS should have a number of customers and stakeholders involved in addressing the key problems of environmental health in Finland, although at the first evaluation meeting it seemed to the Panel that the understanding of the customer concept was not well developed. For the second meeting YTOS had submitted a good analysis of its expert services. However, the Panel recommends that YTOS should initiate a project on evaluation of customer satisfaction.
- (8) Better links with other institutes in Finland are needed. Joint programmes should be developed and enhanced. This would bring fresh thinking to groups at YTOS.
- (9) The Panel thinks it is important for Finland to decide whether it wants to maintain a centre of excellence in the areas studied at YTOS. If so, long-term funding and a fairly free hand are needed – research workers will not be able to cover all areas but emphasis should be placed on those in which international reputations have been developed. Maintaining centres of excellence requires faith in the importance of the work and confidence in the belief that a long-term programme will deliver results. A short-term approach is dangerous and can lead to loss of key staff and thus of excellence in specific areas. This has been seen in institutes in other countries.
- (10) A better explained linkage with policy making is needed. The Panel feels the links are present but they could be better explained. Professor Jantunen has an excellent diagram showing the path of policy development in his area. Each group should produce such a diagram.

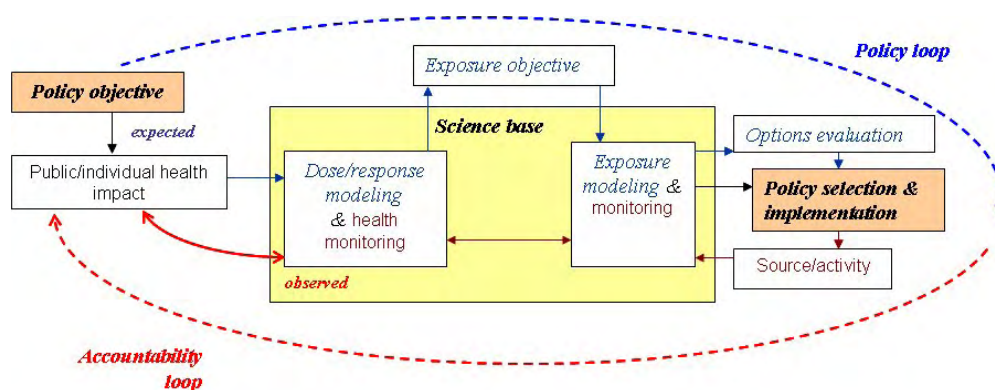


Figure 1. Science based environmental health risk management (presented by Professor Matti Jantunen)

- (11) Research programmes can be:
  - Disease based, for instance cardiovascular disease, neurological disease
  - Medium based, e.g. air, soil, water

- Linked with
  - organ based, e.g. liver, lung, kidney
  - Chemical/pollutant based: e.g. dioxins, particulates

Any of these approaches can lead to good work. A better emphasis on a disease-based approach would be useful at YTOS. Analysing the key diseases now causing concern in Finland and then looking for environmental factors should be valuable and would lead to closer links between groups.

- (12) A diagram showing groups on one axis and programmes on the other axis would be helpful. A matrix would be produced. This would identify groups with linked read-across from programme to programme.
- (13) An important environmental health area not covered by YTOS at the present time is the health effects of noise. Environmental noise does not only lead to considerable and widespread annoyance, but may also be involved as a risk factor for cardiovascular disease. The Panel recommends that the Department undertakes an analysis for the development of a programme on health effects of environmental noise.
- (14) There is a need for a better focus on coming problems. This is sometimes called horizon scanning. One example to be given increased emphasis could be ultrafine particles in urban environments. The problems could be component specific (e.g. nanoparticles) or disease specific (e.g. diabetes) or policy specific (e.g. REACH).
- (15) More emphasis on collaboration with centres of excellence in other countries is needed. Each group should produce a diagram showing links within Nordic countries and more widely. This is very important for an institute in a country of only five million people.
- (16) Product should be analysed in terms of:
- Impact: How much difference has the work made.
  - Output:
    - Advice to government: reports
    - Publications with emphasis on impact factors – though this can be misleading
    - Advice to the public: leaflets and booklets
    - Web-based advice
- Assessing impact is difficult. Falling rates of disease or reductions in rates of increase of disease are obvious measures. Links with public health physicians/epidemiologists/health statisticians are important.
- (17) More emphasis should be placed on analysing the impacts of policy initiatives. This approach has been useful in the air pollution area in Dublin and Hong Kong. It should be considered in other areas whenever change in policy leads to a variation in level or type of exposure.
- (18) Much more attention needs to be paid to succession planning. Members of the senior staff are aged between 55 and 65 (in general) and within about 5 years KTL's Environment Department will need a new senior staff team. Candidates should be identified now and plans for leadership development of such candidates should be initiated.



## APPENDIX:

### 9. Additional Material for the Evaluation

The background material for the international evaluation of the work of the National Public Health Institute, the Department of Environmental Health in 1996-2005 is published in the publication series of the National Public Health Institute (Kansanterveyslaitoksen julkaisuja) B12 / 2006.

The Evaluation Panel noted the need for additional material in order to perform its evaluation of an overall assessment of the functions, strategic importance, scientific merits and value for money of the work of the Department. For that reason, the Evaluation Panel requested the following material to be presented:

1. An analysis of the recommendations with respect to YTOS from the evaluation of KTL in 1995.
2. An overall strategic plan of the YTOS.
3. An analysis of the management of the YTOS overall, including the distribution of resources for the core processes for the period 1996-2006.
4. An analysis of staff competence and its development over the evaluation period.
5. A further analysis of scientific productivity by impact factors and other relevant indices.
6. A vision document on international issues.
7. An assessment of the balance of external vs. budget funding with the full costs of the YTOS workforce.
8. An analysis of the maintenance of the basic infrastructure (space, personnel, equipment).
9. An analysis of the expert services provided by YTOS during the evaluation period.
10. An analysis of the value, cost and benefits of the animal facilities.

The answers for the additional material are presented in the following, and numbered as indicated in the list of questions.

#### ***9.1 An analysis of the recommendations with respect to YTOS from the evaluation of KTL in 1995***

Six major recommendations of the evaluation panel 1995 are bolded and the analysis of the actions resulting from the recommendations is presented below each of them:

- (i) **The overall strategy for the Division should be reviewed as a matter of urgency by an expert group which would report to the Director-General and the proposed Director-General's strategy group**

An overall strategy development was started soon after the 1995 evaluation recommendations were available. As a result, a strategic development programme titled "Bioaerosols and Urban Air Particles" for was proposed to the Director General of the Institute to be evaluated and considered to be financially supported for the first 5

years. In total, the development programme was aimed to last 10 years, i.e., covering the period 1996-2005, and the programme covered a major part of the Division's research activity.

Although the contents of the programme was evaluated as important and relevant, no additional financial support was received from the Institute. Instead, this strategic planning could be utilized effectively and successfully in the applications to the research programme of Environmental Health of the Finnish Academy and in the applications of the EU 6<sup>th</sup> Research Framework Programme.

Since the 5-year strategic plans have been evaluated regularly by both the Ministry of the Social Affairs and Health and the Director General's Strategy Group, an additional extramural evaluation was not considered necessary at that point.

- (ii) The Division should develop a more structured and co-ordinated approach to studies to enable it to carry these through in a systematic manner from hazard identification to epidemiological association, to assessment of exposure and its consequences, to study of mechanism of toxicity and evaluation of factors which might modify the impact of exposure;**

The research activities of the YTOS have been since then organized into a few major programmes that were identified to be the most relevant areas from the public health and scientific point of view. This matrix-type organization has been used both in the administration and in build-up of ad-hoc groups for scientific projects. In each area, the activities have covered several main elements of risk assessment such as hazard identification, epidemiological association, assessment of exposure and its consequences, mechanistic studies of toxicity and evaluation of factors which might modify the exposure and its impacts.

The major research areas that were shown in the 2006 evaluation background material (1. Air Pollution and Health; 2. Respiratory Disease, Indoor Microbes and Immunotoxicity; 3. Water and Health; 4. Persistent Organic Pollutants and Health: Analysis, concentration, exposure and epidemiology; 5. Persistent Organic Pollutants and Health: Mechanisms of health effects, and 6. Risk Analysis) have mainly been developed from these fundamental areas of activity that were established after the 1995 evaluation.

- (iii) Major research themes for the future should include air pollution and other programmes which have a particular relevance to Finland (eg relating to the timber processing industries). Other major targeted programmes might be developed in neurotoxicology, immunotoxicology or reproduction/developmental toxicology –(it is recognised that the establishment of the strong programme in one or more of these fields will require considerable strengthening of the limited number of current staff members with respect in these areas);**

As recommended, the major research themes have then included air pollution and its health effects, and extensive studies on the effects of wood processing industries, especially on soils and river sediments which have a particular relevance to Finland. Other major targeted programmes have been developed in immunotoxicology and reproduction/developmental toxicology. The strength of the programmes have been based on extramural funding from the Academy of Finland and from the EU, and on effective networking with domestic and foreign collaborators.

- (iv) a critical strategic review of the Division should be carried out in the context of its relationships with the University and the FIOH (ideally in collaboration with these other bodies). The possibility that these might be drawn together into an Institute of Envi-**

**ronmental Health to develop a major resource and research centre in the field with a clearly defined strategy should be explored;**

(v)

The possibility that the Division would be drawn together into an Institute of Environmental Health was received as an interesting initiative. However, the three institutions have clearly different tasks that have mainly been defined in legislation; the University being an education institution under the Ministry of Education; KTL being a research and expert institute with clearly defined responsibilities by the Ministry of Social Affairs and Health and FIOH being a research and expert institute, respectively, but working mainly under different legislation than KTL. It has been concluded that instead of a unified unit, it may be even more productive to enhance the collaboration between these three units.

As practical examples of such collaboration are the common professorships between KTL and the University, and numerous collaborative research projects.

(vi) **the contribution which staff of the Division make to the maintenance of bacterial expertise within the KTL should be considered in the reappraisal proposed in the review of the Division of Infectious Diseases;**

The contribution of the Division to the bacteriological (and viral) expertise is focused on the environmental organisms with relevance to human health. Examples of such organisms are campylobacteria, Legionellae and noroviruses. The collaboration with other bacteriological expert bodies has been established and is functioning well today. The division of the responsibilities has been a natural one: YTOS is responsible on the research and expertise on the organisms growing in environmental habitats such as natural waters and man-made water systems, and it has also created expertise for understanding these environments and the technology necessary. The Department of Infectious Disease is responsible for identification of the pathogens in human samples, and the approach is clearly medical. Close collaboration between these expert bodies has proven effective.

(vii) **the Division should not continue to provide a toxicity testing service on a contractual basis.**

The toxicity testing service on a contractual basis has not been continued.

## **9.2 An overall strategic plan of the YTOS**

The mission of KTL is to

*“enhance people’s possibilities to live a healthy life. It ensures that the public, decision makers and other parties can base their decisions on the best possible knowledge”.*

The Department of Environmental health, KTL (YTOS), reaches even a bit further, as implied in our motto

*”Man must be able to breathe, drink, eat and live in the environment trusting on its safety. This is both an individual’s civil right and a prerequisite for a functioning society and economy”.*

Society needs us to (i) predict and warn about potential new environmental health risks (precaution), (ii) identify, explain and quantify - from sources via environment to exposure, me-

chanisms and public health consequences - the ongoing risks (assessment), (iii) rank current environmental health risks and their risk reduction potentials (prioritisation)

Our strategy, how to support these goals, is mainly based on producing, gathering, analysing, synthesising, and distributing knowledge in national and international networks, expert groups, education, in collaboration with municipalities and other parties. Our organizational structure ensures that we have in-house experts from the most important areas of environmental health, i.e. microbiology, chemistry, air hygiene, toxicology, and epidemiology, who can interpret the literature on threats to environmental health and evaluate their implications in the Finnish situation.

In the past few years, we have also started systematically to develop our formal capabilities in risk analysis. The benefits of environmental health policies should be weighed against their undesired effects and better support should be given to risk managers on choosing and implementing different policy options. Risk analysis also helps us to direct our own research on the most important topics.

We provide a limited amount of services and have some surveillance activities (see answer 9). We also help municipalities to respond to and evaluate urgent environmental health problems. For this purpose, we are developing our capabilities in GIS (spatial analysis).

In terms of our own research, Environmental Health is such a broad area that it is impossible to have experts in each area of environmental health. For that reason, we have decided to focus our own research on the most important areas in terms of public health. Some areas we have been forced to leave to the universities and some to other research institutes. Examples are health effects of noise and climate change, which may have to be reconsidered in future.

In addition to producing results from our own research, we take actively part into international collaborations and discussion, which ensures that the latest scientific knowledge is always available in Finland. Based on other countries' experiences, it is also possible to start proactive measures on newly detected environmental health problems before they become acute in Finland (good examples are fine particulate matter after American studies in 1993, and the Belgian dioxin crisis in 1999).

### **Our own research themes**

We have focused on five areas of research:

- 1) particulate pollution in urban air, and their health effects
- 2) respiratory disease, indoor microbes and immunotoxicology
- 3) drinking water and their health effects
- 4) persistent organic pollutants and their health effects
- 5) risk analysis methodology (since 1999)

In all these areas of research, we have aimed to build causal chains leading from emissions to exposure to mechanisms to health effects. Such an approach requires highly multidisciplinary collaboration, but greatest insights are often uncovered with such collaboration and our organizational structure is ideally suited for such collaboration.

These five themes are also not everlasting. Inside these themes, different projects have grown, flourished, and then ceased. An example is the large study of the strong mutagen MX: its concentrations in Finnish drinking waters; the mechanisms it appears into disinfected wa-

ter; methods to prevent its formation; its mutagenicity, toxicity and carcinogenicity in the rat; carcinogenicity in humans by epidemiological data; cancer risk of the Finnish population in the past; and risk analysis of disinfection of drinking waters versus microbial risks. Only this latest issue is ongoing since 2005.

Our own view of the strategy of these themes in the next 5 years is as follow:

Theme 1) **particulate pollution in urban air, and their health effects**, we have a fairly good understanding of the exposures and health effects in Finland, but there is great lack of knowledge on the sources and characteristics of particulate air pollution, which explain the observed health effects. This knowledge is urgently needed for the planning of future emission reductions. Therefore, future work focuses on the health effects of fine particles from different sources, including biomass combustion, which is a major source in Scandinavia.

Theme 2) **respiratory disease, indoor microbes and immunotoxicology**. This theme is a combination of two past themes, one on moisture damaged buildings and one on asthma and allergies. Basic mapping on both of these areas (prevalence, health effects, major risk factors) has been done and currently the research is focused on better identifying and quantifying microbial exposures and both their harmful and beneficial effects on the development of asthma and allergies, and the immunological and inflammatory mechanisms of these effects.

Theme 3) **drinking water and their health effects** is a “for ever” on-going research area at KTL/YTOS, because detection of waterborne epidemics is KTL’s duty. Chemical risks of disinfection by-products and the research on MX have been almost finished and focus is currently more on microbial risks. Research is concentrated on microbial growth in water pipes and the possibility to produce safe drinking water for all people in Finland. After joining the European Union, Finland has to regularly submit to the European Commission a report on drinking water quality in Finland. YTOS collects the information on monitoring results yearly and produces the report to the Commission at three-year intervals. YTOS also produces to the Commission annual reports on bathing water quality.

In the theme 4) **persistent organic pollutants and their health effects**, always new hazardous compounds seem to appear that can be found also in human tissues. Consequently, there is a continuous need for monitoring the levels of POPs and other potentially harmful compounds in the diet and in general population, as well as to study the health effects of these compounds. Surprisingly, also the requests for dioxin analyses, especially by the EU, have been still increasing during the past few years. Mechanistic studies have been focused on sensitive developmental endpoints and molecular basis of sensitivity differences between different species and individuals. The future research will focus on clarification of the significance of epigenetic alterations as a novel mechanism of toxicity of environmental chemicals potentially leading to transgenerational effects. There is also a need to study joint effects of different POPs frequently present in certain food items, such as fish.

5) **Risk analysis** has always been the umbrella concept covering all aspects of KTL-YTOS activities. However, the work on risk analysis methodology is fairly new in our department and it is likely to grow somewhat from its present size. KTL research generates data for risk model inputs, descriptive model development and for model validation, and predictive models for risk assessment and risk management. The key issues are realistic risk quantification and analysis of uncertainty in risk analysis, comparability and transparency in policy options evaluation, and rapid feedback capability in policy implementation. The aims are accountable

risk management policies and policy implementations. Much of the work is directed in better utilizing the possibilities of Internet to increase openness and participation, and for dissemination. The new computer and communication tools developed in other areas are actively applied in a new way, and the ultimate aim is to develop completely new methods and processes of making risk assessments.

### ***9.3 An analysis of the management of the YTOS overall, including the distribution of resources for the core processes for the period 1996-2006***

In the budgeting process the Director General of the KTL distributes the overall resources between the departments, after acceptance of the annual strategic plan of each department, but does not interfere with their internal allocation. The allocation takes place in the respective functional units.

In the beginning of the year, the head of Department allocates the governmental resources to the laboratories after a thorough discussion with the heads of laboratories.

The heads of laboratories and senior researchers have a strategy meeting once a year. All laboratories have their own strategy days also once a year. Because the Chemistry Laboratory is an accredited laboratory, they have several management issues during the year.

YTOS has also several special working groups, for example on gym, education, intranet and quality management which meet monthly.

YTOS has a weekly meeting every Friday morning for the whole personnel where the head of department shortly informs about timely important businesses (including meetings with the director general). Questions and comments are possible. The duration is about half an hour or less, and sometimes it may continue in form of short educational sessions (e.g. on quality, intranet, health and safety etc.). The heads of laboratories continue with their own meeting after that. It may take several hours. In those meetings, all running activities of the Department concerning budgets, equipments, personnel needs, who will give the expert opinion in the Parliament, who will give opinion for municipalities etc are discussed, but also constantly the strategic planning. The minutes of the meeting are available on Monday in the intranet.

Each laboratory has a weekly meeting on managerial subjects. The whole laboratory personnel participates that. In laboratory meetings more detailed discussions are possible than in the Friday morning meetings. Minutes from those meetings are posted to intranet (also valuable for those who are not able to participate).

Every person has discussion once a year with his/her supervisor where they discuss about personal achievements, future plans, needs for further education etc. work related subjects.

Salary agreement is discussed once a year between each employee and the immediate supervisor or unit head, within the limitations coming from the general rules of KTL and the budget available. Care is taken that the income of those paid by external funding is not different on average from those doing similar work on governmental budget.

The aim has been to make decisions as close to the actual work and as transparently as possible. Our own assessment is that it has worked fairly well.

#### ***9.4 An analysis of staff competence and its development over the evaluation period***

The enclosed example analysis has been focused on the senior researchers, but the general indexes reflect the input and competence of the whole staff.

We consider that the competence of the research staff in general has risen markedly during the last ten years. The number of the citations (containing the names of the heads of the laboratories as a consistent key word) has increased notably towards the end of the evaluation period (see the Figure 1 below), and it may be taken as a broad indication of an increased competence.

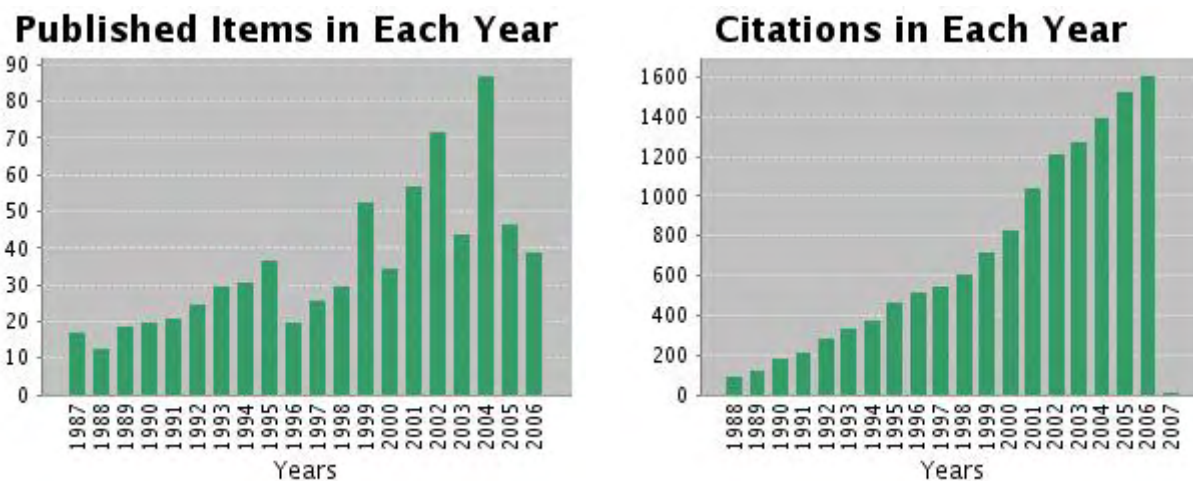
The increase is likely due to that

- 1) the scientific requirements at KTL are as demanding as in the Universities
- 2) it has been possible to do the Ph.D. thesis during working hours, as our regular research work but on the subjects relevant to YTOS
- 3) external funding has developed well. Only by governmental funding it would not had been possible to enhance and keep such scientific qualification.
- 4) the senior researchers have gained high scientific competence (most have a proven competence for professorship or are docents at Universities )

The total number of supervised doctoral theses was 61 during the last ten years (Figure 3 in the “Background material for the international evaluation”, page 17). The year 2002 was especially good because the large research program on environmental health, funded by the Academy of Finland, was finished in 2001 and much work was get ready along.

The number of post docs has increased (Table 1 in the “Background material for the international evaluation”, page 13). The percentage of PhDs of all researchers increased from 26 % to 57 % during the last ten years.




We believe that we have at present a rather good balance between the number of senior researchers, post docs and students for productive work. The role of post docs is increasingly important because they master the newest methods and techniques and are thus often most capable in instructing the practical work. Some of them are simultaneously trained for potential successors to maintain the expertise. At present that step is funded solely on soft money.



**Figure:** A result from Web of Sciences and author search (both published items and citations) of the heads of laboratories at YTOS.

*AU=(Tuomisto J or Vartiainen T or Nevalainen A or Jantunen M or Pekkanen J or Komulainen H)*

*DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1986-2007*

Results found:	737
Sum of the Times Cited 	13,470 <a href="#">View</a>
	<i>View without self-citations</i>
Average Citations per Item 	18.28
<i>h-index</i> 	50

### 9.5. A further analysis of the scientific productivity by impact factors and other relevant indices

Many instruments can be used to analyze citations and other indices of the scientific publications. The results presented below are based on Web of Science.

The results of the searches on the publications of each main research field of the KTL/YTOS are presented in Table 1. The research at the KTL/YTOS on four fields tested is ranked (based on number of publications) within the top 10, and the individual researchers on the five fields within the top 10 in the world. We chose relevant key words to be used in the searches. Due to the multidisciplinary of the research fields of the KTL/YTOS, this selection process turned out to be complicated. This was the case especially with the research fields related to air pollution (health and exposure aspects). E.g. the *exposure* –term is used in many contexts (e.g. in epidemiology, analytics, toxicology) that may not be linked to the exposure-research field at all. This will give biased result of the search. Thus, the key words used are the “best available”. However, it should be kept in mind that these searches do not reveal all publications of the department and the results presented in Table 1 should be considered as indicative.



Table 1. Ranking (based on number) of the original articles of the KTL/YTOS during 1996-2005 according to the research fields. (Source: Web of Science).

<i>Research field</i>	<i>Search terms used</i>	<i>All publications revealed by the search (n)</i>	<i>Publications of the KTL/YTOS revealed by the search (n) *</i>	<i>Ranking of KTL/YTOS: Department</i>	<i>Ranking of KTL/YTOS: Researchers</i>
<i>Health and air pollutants</i>	<i>Health AND (PM2.5 OR "ultrafine particles" OR VOC* OR NO2 OR "nitrogen dioxide" OR "carbon monoxide")</i>	2113	33	6	4
<i>Exposure to air pollutants</i>	<i>Exposure AND (PM2.5 OR "ultrafine particles" OR VOC* OR NO2 OR "nitrogen dioxide" OR "carbon monoxide")</i>	3887	35	16	1, 21, 24
<i>Indoor microbes and health</i>	<i>Indoor air</i>	3923	84	5	1, 4, 14
<i>Drinking water and health</i>	<i>Drinking water</i>	24234	152	5	4
<i>Persistent organic compounds</i>	<i>Dioxin*</i>	6388	98	9	9, 21, 25
<i>Risk analysis</i>	The research field on risk analysis is fairly new at the KTL/YTOS and is under a rapid development.				

\* The number of publications produced in this Web of Science search. It does not, however, reveal all publications of the department.

The impact factors of the publishing journals of the 15 key references listed on each research programme of the department were collected (Table 2). About half of the journals are settled between the impact factors 3-10. It should be noted that these key publications have been selected by the researchers based on their quality, not on the impact factors of the publishing journals.

Table 2. A summary of the impact factors of the publishing journals of the key references of the six research programmes of the Department of Environmental Health.

<i>Theme</i>	<i>Impact factors (n)</i>		
	<i>&lt; 3</i>	<i>3 - 10</i>	<i>&gt; 10</i>
<i>Air pollution and health</i>	12	2	1
<i>Respiratory disease, indoor microbes and immunotoxicity</i>	7	8	0
<i>Water and health</i>	4	9	2
<i>POP: Concentrations</i>	8	5	2
<i>POP: Mechanisms</i>	1	13	1
<i>Risk analysis</i>	6	5	1
<b>Sum</b>	<b>38</b>	<b>42</b>	<b>7</b>
<b>%</b>	<b>44</b>	<b>48</b>	<b>8</b>

## 9.6 *A vision document on international issues*

### *Societal requirements for our future work and products*

Our vision on international issues is interwoven with our strategic vision and plan.

Society needs us to (i) predict and warn about potential new environmental health risks (precaution), (ii) identify, explain and quantify the ongoing risks, (iii) compare and rank the current environmental health risks, (iv) quantify the risk reduction potentials of alternative control measures, and (v) follow up the accountability of policy implementations.

Societies do not and should not deal with individual risks case by case or in isolation. Instead, risks are compared, priorities set, selections made and resources allocated, and this is done in the international context of scientific knowledge and trade agreements. From us this requires capability to not only assess the current or potential risks of individual chemicals/agents or sources, but to also to express these risks as well as the associated benefits using common metrics for comparison, to assess them in their full societal context including alternative or competing risks, and to communicate our results and conclusions to the international community of risk assessors and managers. We will work interactively on all these issues.

### *International dimension*

While environmental health risks vary both qualitatively and quantitatively across Europe and the world, the causal agents, exposure pathways, media and routes of entry, as well as the effect mechanisms are similar all over. Exposure and effect models are the same – international - but input parameters, and consequently risk estimates and risk ranking vary between countries, communities and population groups.

Within this framework our roles are twofold:

- Internationally, to participate in the development of the universal science base for exposure and dose response assessment methodology and modelling and in the harmonising of the risk assessment methodologies across the different risks and countries.
- Nationally, to apply these methods for assessing specific environmental health risks, to compare and rank them in a way helpful for the political leadership in its tasks, and to provide the general public with up to date and balanced information that will help individual risk avoidance and guide civic activity.

Our international role is essential for the fulfilment of our national tasks for two distinct reasons:

I) Broad participation in cutting edge research gives us the knowledge and authority to inform and guide the people and decision makers with state of the art knowledge. Passive following of the scientific literature and reporting only would set us 2-10 years behind and thin out our understanding of the issues.

We will therefore continue to coordinate and participate in internationally funded collaborative research (training and development) projects, some of which are focussed on methodologies (e.g. intake fraction modelling), or on key scientific issues (e.g. toxicological mechanisms of action), and some of which deal with broad public health policy issues (e.g. risk analysis, risk comparison).

For the same reasons we will also continue to work in editorial boards of scientific journals, in organising of both small and focussed scientific meetings and large international conferences, as well as in evaluation panels of international research programmes and institutions.

II) Participation in EU and WHO and also U.S.EPA pre-normative expert tasks gives us influence on the international standard setting which will eventually set requirements also for the Finnish authorities and enterprises, and helps us give them a 2-5 year forewarning to prepare for the upcoming changes.

We will therefore continue to participate in, chair and contribute to international expert groups and task forces which are relevant for our national expert duties.

### *The future is in the internet*

Our work will not merely continue, we are also preparing for major operational changes, because the environment, in which we work, communicate and disseminate the benefits from our work, is changing. Our emerging and eventually central role will be the developer and provider of internet based expert services and public participation sites – ideally combining the two - both domestically and internationally. Such services should:

- digest and condense the huge quantities of more or less significant new information,
- link them to established modelling tools and databases, and
- have user interfaces, which
  - o allow the use of default data and models as well as user's own inputs,
  - o enable both narrow in depth and broad comparative analyses, and
  - o provide detailed as well as executive reporting formats.

They should empower the end users, e.g. risk assessors in government agencies, with tools and capacities for risk ranking and policy options evaluation in particular, which far exceed their current means.

Compared to our more traditional activities of field and laboratory research and publishing – which will continue and flourish – international internet expert services require a much more integrated approach, and bigger and longer term resources, which in Europe are only possible in the context of broad and committed international expert networks. Data for such services are currently being assembled and methodologies developed in large European RTD projects (Intarese, Heimtsa, ENHIS, HI-WATE etc.), but the need for the funding and commitment for long term collaboration has not yet been comprehended. Yet, we expect that (i) there will be fierce competition to provide the leading internet services on environmental health risk analyses, leaving only a few to be actually known and trusted, (ii) the lifespan of the winning services may exceed 10 years, and (iii) they will be used by international organisations, national governments, business enterprises and communities alike.

It is our sincere intent to be a part of these winning teams and concepts.

### ***9.7 An assessment of the balance of external vs. budget funding with the full costs of the YTOS workforce***

The annual governmental budget has been quite stable, about 2.95 million euros, during the last ten years, and the external funding on an average 2.4 million euros, e.g. 45% of the total funding including rents and equipments, but about 55 % if rents and equipments have not been included (Figure 2 from “Background material for the international evaluation”, page 14). That means that external funding comprises a very large proportion.

Our own analysis is that so high proportion of external funding is a high risk especially because

- 1) One senior researcher has retired and at least two other senior researchers, who have earned a big part of the external funding, will be retired during the next two or three years.
- 2) Competition of external funds is demanding, it requires internationally renowned senior researchers
- 3) Continuity in some units and programmes is endangered because their leaders are approaching retirement age, recruiting new seniors is uncertain, and there are no secondary positions in these units. Continuity is also not ensured when important research areas are maintained only by means of external funding
- 4) Many funding institutes give too short funding periods (the Academy of Finland has improved). Today's situation is significantly better.
- 5) To some extent the funding directs the research. This may sometimes be beneficial, because it would force to reassess and renew the priorities, but at the same time it may give the initiative to administrators or other competing areas of science, who do not know the needs of a particular area very well.
- 6) It is difficult to initiate totally new and high-risk research activities by external money because of difficulty of convincing granting agencies without prior results, and for reasons mentioned above under (2).

### ***9.8 An analysis of the maintenance of the basic infrastructure (space, personnel, equipment)***

The facilities of YTOS are appropriate, in good condition, and large enough for 130 workers. Laboratories are well equipped (see the Appendix list of large equipments in "Background material for the international evaluation", page 23). KTL has invested very well on good working possibilities.

The number of permanent personnel is too small. Most of the essential and strategic positions are occupied only by one researcher or in many cases, by an external funded person. That means that to fulfill the expectations of the Ministry of Social Affairs and Health, and to serve environmental health problems in Finland, external funding is fundamental for YTOS. This all also means that even post docs and some of the senior researchers do not have permanent position but are dependent on funding strategies of EU, the Academy of Finland, TEKES (Finnish Funding Agency for Technology and Innovation), and other foundations. This is more difficult to maintain by external funding than junior scientists, technical personnel and consumables. It is also more difficult to motivate good people to participate in government-given expert tasks, if the funding is from non-permanent research grants.

### ***9.9 Analysis of the expert services provided by YTOS during the evaluation period (1996-2005)***

The expert work has been addressed in several contexts in the original evaluation material report (especially in sections "Social impact" for research areas; "National impact" and "International impact") submitted to evaluators before the site visit. The enclosed analysis adds some information not previously mentioned and assesses the value and impact of the work.

The expert services are divided to

- the expert work related to our general expertise
- to services sold out on contract basis.

The value and impact is evaluated for

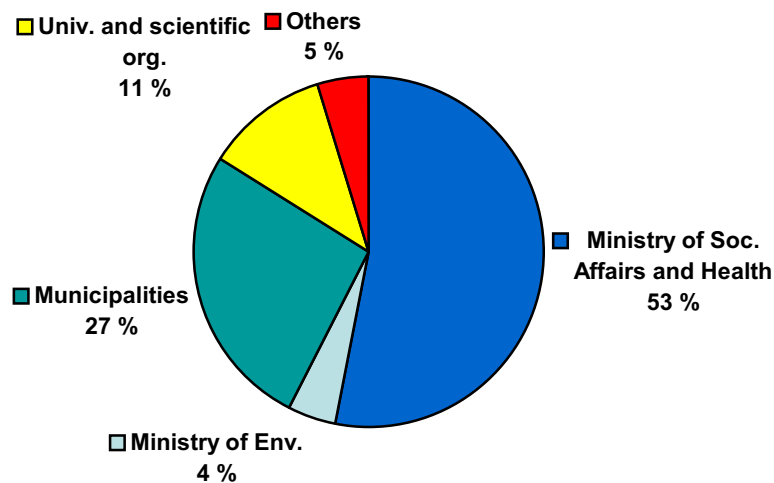
- Ministry of the Social Affairs of Health and other ministries and regulatory institutes under their auspices (national activity)
- municipal and provincial authorities
- individuals and the society more generally
- as international activity for Finland and internationally (to EU, WHO).

### 9.9.1 The expert work related to our general expertise

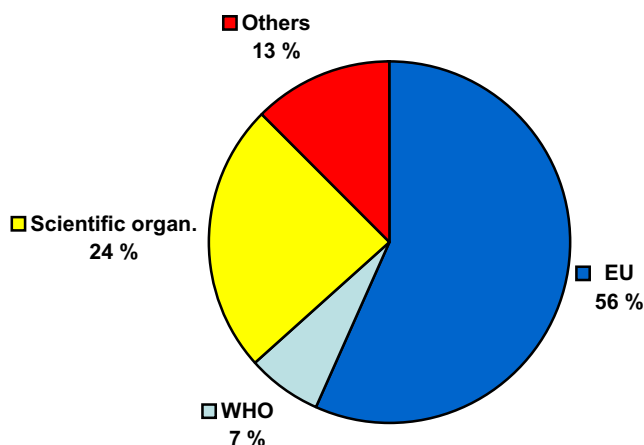
In 2004, a detailed survey on the expert work in YTOS was conducted, for the yearly strategy planning meeting of the Department. The main customers and tasks were listed and the time used for the work was asked by person.

About 1100 working days (direct involvement, not counting secretarial and other overhead type involvement) was used in total for national expert tasks on that year. Most of the national expert tasks served the Ministry of Social Affairs and Health, 53 % of the time used (Figure 1). The municipalities were the other main customers (27 %). Though there has been some variation yearly in the shares, these figures give an overall image and represent also closely the current situation. The share of municipalities has likely increased over the years due to increased permanent-type activities.

About 400 days was used for international tasks. The major share of international tasks (56 %) was for EU. That proportion has been rather steady during the recent years though the tasks and the persons may have changed. Yearly variation has been greatest in the tasks for scientific organizations because they are mostly one-time tasks (for example organizing a scientific meeting). Also the expert work for WHO is mostly in specific projects.



**Figure 1. National expert work (tasks) by the researchers of YTOS in the year 2004.** The percentages indicate the share from the working days used for the expert work (about 1100 days total).



**Figure 2. International expert work (tasks) by the researchers of YTOS in the year 2004.** The percentages indicate the share from the working days used for the expert work (about 400 days total). The tasks for WHO on that year were abnormally few and does not represent the average.

Altogether 26 persons had notably been involved in the indicated expert work, on average 2.5-3 months per year. Though the major part of the work is done by seniors in permanent positions (on budget money), important duties are on the responsibility of the project personnel (e.g. method development and maintenance). All expert work can not be covered by the budget money.

In the following, the value and impact of the work has been evaluated.

### **Tasks for ministries and the regulatory institutes under their auspices.**

The main tasks serving primarily ministries and other institutes under their auspices are:

- ad hoc expert opinions/visits at the Parliament of Finland (related to legislation or some major decisions such as those related with nuclear power)
- national standing expert groups and committees of the ministries
- emergency-response activities (water-borne epidemics, chemical incidents)
- preparation of national instruction/standards material
- evaluations/analyses of specific topics (health risks of chemicals in environment, children's health)
- help in risk communication
- as experts representing Finland in EU
- as experts representing Finland in WHO (and international scientific committees)

KTL/YTOS is the main institute for knowledge in environmental health issues in Finland. We are regularly invited to the Parliament to hearings to express our view, based on scientific evidence, during preparation of the legislation. In those occasions, the most important points for the decision are raised, also in a written form. It is difficult to assess the impact of the work, but the parliament receives an independent, science-based view on the subject.

As to ministries, we are serving mostly the Ministry of Social Affairs and Health in expert work (figure 1). There is much communication, nearly daily, directly between the experts and authorities of the ministry, on the questions raised ad hoc. When required, the answer is made in a written form. We assume that such a flexible reactivity is of great help. Sometimes immediate reactions (in hours) are needed in emergency situations (e.g. forest fires) to help in risk communication. The work in expert committees is more permanent and the benefits often directly institutes under the ministry, for example in the committee dealing regulatory aspects of pesticides in Finland.

As to other ministries, the impact has been mainly as committee members or by less official regular consultancy, to give the health risk perspective to subjects under preparation (including legislation). For the Ministry of Environment such issues have been health effects of air pollutants and pollutants in contaminated soils. We regard that work particularly important because we represent aspects of human health. Our toxicologists are also members in some committees under the Ministry of Trade and Industries involving food safety (chemical contaminants, genetically modified food).

As to other regulatory impact, we have prepared several instruction books for the ministry e.g. on standards related to air quality in residences and been involved in preparation of instructions related to drinking water treatment. KTL was heavily involved in the preparation of the Finnish Environmental Health Program (1997) and prepared a report "Evaluation on the health risks of chemicals in our environment – Report for National Chemical Programme" as a background material for National Programme on Dangerous Chemicals (2006). Such large, comprehensive, balanced summaries require wide expertise and competence in risk assessment. We are currently in the middle of preparation the respective background report on children's health in Finland for national program.

As to emergency-response activities, YTOS has had a key responsibility in taking care/treatment of water-borne epidemics in Finland in practice, since 1996. We see this activity very important. Right, timely, coordinated interference of the cases has limited and shortened the episodes and decreased the number of patients. The service has evidently been of great help for the local authorities because they face the problems seldom. The advantage of the centralized system is that the knowledge and expertise has accumulated to one place to solve and manage the cases quickly and efficiently. Concomitantly, the views for the reasons of the epidemics have accumulated for us and the information can be used in preventive work, in teaching and training of the local authorities and personnel of the waterworks.

The benefits of the Finnish Centre of Expertise on Chemical Threats remain to be seen, because the network has just started, but YTOS took the responsibility to participate to its build-up and is the other responsible party (institute) in arranging the round-o'clock emergency call-service for responsible authorities (especially rescue services and police).

As to regulatory work, the personnel of the ministries and other institutes (e.g. STTV) mainly take care of the routine EU business and the regulatory work, but sometimes our expert is asked, either to give an opinion at the preparation stage or to participate the meeting, if the substance expertise is especially essential. There are a few such meetings per year and several of them have addressed air pollutants. One expert, funded by the Ministry of Social Affairs and Health, does full time regulatory work on drinking and swimming water, mainly for EU purposes.

### **Tasks serving primarily municipal and provincial authorities**

After the ministries, municipal and provincial authorities are the main customers of our expert work. The direct contact with that level has got important after the normative role of governmental authorities has decreased during the evaluation period. Our proactive work to serve the needs has been active participation in training, by giving invited lectures on environmental health topics in national and local symposiums, seminars and courses organized by others for the authorities and writing from the same subjects in Finnish professional journals and magazines. We are not organizing the courses ourselves (though have been giving often ideas for their contents). The web-pages give information at the level suitable for local authorities. It is difficult to assess the exact impact of the work but continuing asking of such input likely indicates its usefulness.

Questions and contacts from the local authorities deal mostly practical problems they need to react for. Such inquiries are daily and they are directed to the best expert(s) on the subject. The response depends on the type of the question, from advice on the phone or a short message by e-mail to official expert opinion of the institute (signed by the Director General). From the feedback received, such service is highly appreciated, to get a quick expert opinion.

### **Individuals and the society in general**

Single citizens contact us regularly, over the phone or through the internet, with their specific questions related to environmental health. Our policy is that simple questions are answered immediately, inquirers are directed to the web-page for further information or directed to the other relevant source, but in the case the question needs further actions or work, we advice them to contact the local authorities responsible for the subject. The local authorities are supposed to contact us if necessary. The resources do not allow personal service for single citizens.

As to general education of the public, a few times a year, invited lectures are given to public on environmental health risks. Timely writings in news papers (roughly 10 – 20 per year, including fact-based articles from our research work) serve the same purpose, reaching a wider audience and also decision makers. We have the impression that some timely justified public opinions have had a great impact on how the things have gone later.

The collaboration with national professional organizations (e.g. related to air quality) and health-related organizations serving citizens (e.g. related to respiratory diseases and allergy), has increased the dissemination of information on health effects and risks by those organizations. Our experts have participated e.g. in preparation of the information material. As a result, the health view has more strongly been incorporated into decisions and some recommendations have been taken into action as such (e.g. the air quality monitoring strategy in metropolitan area). Our role has been consulting but the impact on this sector is significant because people are indeed interested in the information.

Three of our seniors have been part time professors at the University of Kuopio and most of the seniors are Docents at one or more universities. All of them give lectures in basic or postgraduate courses on toxicology or environmental health issues. In recent years the environmental health issues have largely been taught by us to students of the University of Kuopio. Even complete courses were arranged to graduate students of toxicology. Our seniors have been members of the steering groups coordinating the postgraduate training in environmental health in Kuopio Campus and arranged also specific courses. We have regarded the training very important, not only for our own graduate students but more generally to promote the



expertise in environmental health in the society. It also helps in recruiting. On average 6 Ph.D. theses have been finished in our department yearly and most post docs have found the job matching to the training received.

As to science policy, our expert chaired the scientific committee of the Academy of Finland for 6 years, and the Finnish Research Programme on Environmental Health (SYTTY, 1998-2001) of the Academy of Finland was coordinated from YTOS.

### **International expert tasks**

The survey in 2004 indicated that around 400 working days were used for international expert tasks, over 50 % for EU. Most environmental issues (for example air pollution) are European wide and the strategies to be created for their mitigation are EU-wide. The right place for impact, with the highest impact also nationally, may be the EU-level. Our role has been scientific. Most of our senior researchers have been or currently are involved in some core activity of EU (the memberships in the Scientific Committee on Health and Environmental Risks, SCHER, preparation of water directives, COST-project). The impact on preparation the EU research programmes may also be taken as an expert work and the projects aiming to improve risk assessment (for example the INDEX project). Participation in such work is not only impacting but also enhancing our own knowledge, and much of the national expert work is based on the expertise attained in international duties and networks. The expertise is based on the knowledge gained and maintained in our own scientific research and is not possible without such experiences.

Expert tasks for WHO are more global but e.g. the work related to setting of different guideline values has national impact. The work done for WHO and the WHO documents form the basis for several activities in EU. We have been regularly invited to working groups of WHO, particularly related to ambient air pollutants but there has been single tasks also in several other of our research areas.

We see the work done very important and to be even the prerequisite e.g. for external funding.

In summary on the expert work/tasks, we maintain that it is important nationally to have a place where an answer may be obtained to nearly any question on environmental health. With the current priorities the work load has been reasonable, though the work load cannot be even. However, the structure is thin, for most tasks there are at present only one competent person and no substitutes. There will be problems in maintenance of service level and training of successors if permanent positions would be cut.

### **9.9.2 The services sold out on contract basis**

The contract services of YTOS have been limited. The principles are that we do not primarily do routine services offered by other laboratories and they need to fit to daily routines of the laboratory and support the research work. All methods used in contract service have been set up for our research purposes.

KTL has fixed principles to calculate the price of the contract services, based on full costs.

The contract work includes

- chemical analyses of organic pollutants
- microbial analyses in water

- microbial analyses and building inspections related to mold problem houses

Each of these has been addressed shortly below.

By volume, **chemical analyses** of different organic pollutants have been the largest activity. Approximately 200-400 samples have been analyzed yearly. The majority of the analyses is persistent organic pollutants (POP), mainly dioxins and PCBs, from food (fish, meat, milk), feed and contaminated soil. Some water quality and organotin analyses are performed as well. The workload corresponds two to 3 person years (out of 20 persons in the laboratory). The selection of analytical services has been entirely bound to research activities in the laboratory. This has brought flexibility because the whole personnel can be employed in rush periods to either activity. The customers have been authorities in food, feed and environmental monitoring, water protection associations, companies which produce food, feed or their raw materials, and engineering or consulting offices.

The Chemistry Laboratory has been accredited since 1996, and in recent years there have not been regularly other laboratories in Finland that can perform POP analysis of food and feed according to EC food and feed directives. The availability of the service has been nationally important. We are also a national reference laboratory in dioxin analytics.

In the future, the volume of the analytical work is expected to be roughly the same and we do not have plans to expand the activity. If methods for new substances will be set up for research purposes, analyses on contract basis are possible also for them.

As to **microbiological contract services related to water**, the main customers have been water works, research institutes, industry and municipalities. The activity has changed during the last decade. In the 90's the main services included analyses of microbial nutrients, such as assimilable organic carbon (AOC), microbially available phosphorus (MAP) and microbial growth potential (HGR). More recently, the majority of the services have been analyses of waterborne pathogens.

The number of the microbial nutrient analyses (AOC/MAP/HGR) varied between 10 and 87 per year, depending on the national research programs related to drinking water research.

The number of analyses of indicator organisms and waterborne pathogens (noroviruses and campylobacteria) is directly depended on the number of waterborne outbreaks and contamination cases of drinking water, because the analyses are on those samples. Since 2003 the number of analyses has been yearly 10 to 47.

On average, 60 water samples have been analyzed for legionella yearly (the range 7-106). The number of legionella analyses has increased during the last years.

Since 1996, the income from all microbial contract service analyses has been 182 000 euros (i.e. on average 18 000 euros per year). Legionella analyses have represented about 70 % of the income. In the future, the volume of the services sold out is expected to remain at the same level, except that the number of legionella analyses may further increase.

Most of the analyses described are not available elsewhere in Finland and the maintenance and development of the methods related to drinking water is the task from the Ministry of Social Affairs and Health to KTL. Our laboratory will be a national reference laboratory for some pathogenic microbe analyses in the future.

The **services related to mold house problems** have been building inspections for moisture damage, and microbial analyses of building materials, surfaces and air (culture based methods). On both activities KTL has had an important role in developing methods which have currently been used also by others. During the years 1996-2003 about 20 building inspections were done yearly, while during the last years only a few inspections have been done. The resources are needed to research work and the demand has also decreased. The building inspection service is currently available also on private basis in Finland. The work done has kept us in touch with practical work, which is important because we participate in preparation of different instruction materials provided by the ministry.

The number of microbial analyses has been approximately 100-300 per year, corresponding the workload of one half to 1.5 person years. Most of the results have been included also to our data files i.e. have served also our research. These analyses are available also in other places in Finland but the service work helps the maintenance of the methods as reference methods.

It is assumed that the volume of our service work related to mold house problems will not increase because the services with currently standard methods will increasingly be offered by others. Our future challenge is to develop and validate more advanced DNA-based methods for microbial analytics, also for routine work. We also have plans to accredit at least some of the existing methods.

Altogether, the service work of YTOS on contract basis supports our research work, and our mission more generally. We consider it nationally important. There are no plans to expand the activity as such but to respond when necessary, with new initiations and help in the beginning their dissemination. The volume should be much larger if assumed that the service could be done as an independent work. Competition with the same services (with similar quality) provided by others (e.g. commercial providers) is either not justified.

### ***9.10 Analysis of the value, cost and benefits of the animal facilities of the YTOS***

The enclosed analysis is supplemental material, in response to questions asked during the site visit. It describes the laboratory animal facilities of YTOS and their current maintenance and function, because it closely reflects the last years and the end of the year 2005. A detailed analysis of the resources and costs has been presented for the last 5 years (2001-2005). The general analysis of the value and benefits covers the whole evaluation period. The major differences in the years 1996-2000 have been described separately where necessary.

#### ***The facilities***

YTOS has had the modern, fully equipped facilities for laboratory animals (rats and mice) since 1992. Originally (from 1985) the facilities comprised 3 rooms for animals and some lab and storage space, maintained by the University of Kuopio, by daily trafficking. In 1992, in the context of building more space to Neulanen building, the animal facilities were expanded to a full, independent unit to contain

- a barrier unit (6 animal rooms, maintenance and production facilities for Specific Pathogen Free (SPF) animals)
- conventional animal space (7 animal rooms; 2-3 of which used for experiments with laboratory animals)

- a biohazard unit with one animal room (aimed at e.g. working with pathogenic microbia, isolation of microbiologically contaminated animals from other sources)
- 5 laboratory rooms associated with animal rooms (handling of animals during experiments, necropsy)
- storages for cages, bedding, food, waste etc.
- a washing machine for cages and smaller equipments

The total floor area is 1087 m<sup>2</sup>.

At the time of expansion of the facilities, two permanent positions of animal technicians were founded by internal re-training of persons in the context of merging the previous local KTL laboratory and YTOS.

The barrier unit is a closed unit, maintained through autoclaves and by persons (1-2 laboratory animal technicians) devoted solely to that duty to keep the animals devoid of any pathogen microbes. It is aimed at breeding and maintenance of strains/animals not available commercially or for non-commercial transgenic strains. At present there are e.g. the special strains of rats used for dioxin research (A, B, C –lines, Han/Wistar and Long-Evans strains) which were cross-bred at KTL and are not available elsewhere. At present there are 6 different strains of rats and 14 strains of mice in the maintenance and breeding. This represent 50 % of its full capacity (counted from the maximum 4800 animals possible to house). The degree of capacity in use has varied between 50 to 100 % during the evaluation period of 1996-2005.

The facilities are in compliance with the OECD principles of Good Laboratory Practice (GLP). There has, however, not been an official GLP inspection since 2002, because the national GLP authorities have refused to inspect the facilities as no commercial safety evaluation studies aiming at product registration has been going on.

### ***The personnel***

The animal facilities are run by a separate personnel. The total number has been between 7 to 14 persons, depending on the number of the animals and the activities in recent years. The unit is headed (the daily activity run) by an experienced technician (a permanent position). One senior researcher is responsible as a backup and support to her in questions related to laboratory animals when necessary. The other personnel are laboratory animal technicians and technical support.

Three out of the 8 positions of the unit are at present permanent (paid fully from the KTL budget). Five workers are paid by money collected from the users of the unit (see details in the budget). The secretary of the unit is paid about 50-70 % by the animal facilities. In addition, on average one person has been as a trainee through the local employment authorities (and paid by them) in technical work. As to major changes in the personnel, one permanent position has been removed from the unit after retirement to establish new duties at YTOS (on year 2005) and replaced by animal technician positions on the soft money.

**Table 1.** Personnel by funding structure in the laboratory animal facilities during the years 2001-2005.

	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
<i>Permanent positions (from KTL budget)</i>	4	4	4	4	3
<i>Other positions (funding based on charges related to use of the facilities)</i>	6	9	9	8	7
<i>Trainees</i>	1	1	-	1	1
<b>Total</b>	<b>11</b>	<b>14</b>	<b>13</b>	<b>13</b>	<b>11</b>

The indicated personnel is the minimum required for running the unit. Some work for obligatory duties on weekends has been paid on an hour basis to persons not included in the core personnel (and Table 1).

#### ***The users and activities of the unit***

The facilities have mainly been used (over 95 %) for the research purpose during the evaluation period (for in vivo studies), conducted principally by the researchers of YTOS. Some studies have been run by/for other research groups (e.g. from the Universities of Kuopio and Helsinki) and animals bred in the barrier have been sold to other research groups outside YTOS (also to KTL in Helsinki). The unit does not primarily breed animals for selling, but extra animals not needed for own purposes are sold out. Commercially available animal strains used for own studies are bought from animal breeders.

Two notably high volume activities serving researchers / animal facilities outside YTOS may be specifically mentioned. The unit produced mice for vaccine quality control at KTL Helsinki during the years 1994-2003, 21573 animals per year. During the years 2001 and 2002 the National Laboratory Animal Center at the University of Kuopio renewed their animal facilities and their activity was partly transferred to our animal facilities, as much as the space allowed. Those years represent already overloading which would not be possible continuously.

Up to 1996, we were running also some routine toxicity testing, as a contract research, but it was finished on purpose based on a strategic decision at that time. The toxicology testing unit proved to be too small to be competitive with commercial contract toxicology laboratories, and it consumed too much permanent resources for routine work. The previous international KTL evaluation (1995) also recommended that the routine toxicity testing as contract service should be discontinued.

#### ***Budget***

The yearly costs of the laboratory animal facilities during the last 5 years have been around 400 000 euros (Table 2).

The costs consist of

- salaries from KTL budget money (for full-time permanent positions)
- yearly allocation for running costs from the YTOS budget (originally KTL budget money)
- salary for a few months for secretary from other sources of YTOS (also other duties)
- indirect costs (rents, electricity, cleaning etc. costs of general maintenance)

The costs have mainly been covered by the KTL budget money but also by incomes charged directly from the users. Such sources are (Specific incomes in Table 2):

- incomes from daily fees charged from the users of the animals (used mainly for salaries)
- incomes from selling of the animals
- charges from technical help for researchers

The portion of the specific incomes was exceptionally high during the years 2002 and 2003 when there was much activity from the university. Transfer of the savings have smoothed the yearly budgets, allowing reasonable function.

**Table 2.** The budget of the animal facilities during the years 2001-2005 (euros).

<b>Costs</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
<i>Salaries (from KTL budget) (permanant positions)</i>	91694	103619	106477	109377	105022
<i>Other salaries</i>	110893	152237	188521	173117	161211
<i>Running costs (from KTL budget)</i>	95 000	98 000	100 000	97 000	75 000
<i>Indirect costs (electricity etc.)</i>	31260	31427	32068	32000	32388
<b><i>Costs total</i></b>	<b>328847</b>	<b>385283</b>	<b>427066</b>	<b>411494</b>	<b>373621</b>
<b><i>Specific incomes</i></b>					
<i>Fees charged from customers on animal housing</i>	94527	172053	123849	49067	58662
<i>Incomes from selling of animals</i>	36573	51293	16587	6142	3455
<i>Charges from technical services</i>	6351	5546	4620	9550	15327
<b><i>Specific incomes total</i></b>	<b>137451</b>	<b>228892</b>	<b>145056</b>	<b>64759</b>	<b>77444</b>

The yearly allocation for running costs from the KTL budget has been used for daily expenses of running of the unit, including maintenance of the equipments (e.g. several autoclaves). It covers a few occasional months for salaries of the personnel, needed e.g. for replacements due to sick leaves.

From the very beginning a part of the funding of the unit has been based on the animal maintenance fees paid by the users of the facility. This principle has also very efficiently prevented inefficient use of the facility. For the whole 10 year period the users of the animal facilities have also paid their animals bought outside. The researchers of KTL have been charged an internal fee, which includes the expenses of daily running costs of the unit and the salaries of the personnel on soft money (but not the salaries of the permanent positions). The users from universities have paid an external fee, which includes in addition salaries of the permanent positions, indirect maintenance costs of the unit and around 5 % for other costs. There is a third fee for contract type work, covering all costs and some profit for contract type external users, but there have not been such customers recently.

### ***The value and benefits***

The animal facilities and the possibility to do in vivo experiments has been an integral part in the research conducted at YTOS. Some projects (e.g. the toxicology of dioxins) have been nearly completely based on the use of laboratory animals. In several other projects in vivo studies have also been an unreplaceable link between findings in vitro experiments and epidemiological studies. Understanding of the whole chain of events from molecular and cellular level to in vivo effect and health effects in exposed human populations has directed the research and produced comprehensive results, and has been a significant strength of our research.

The own laboratory animal facilities (located in the same building) have been important because in most studies samples need to be analyzed immediately, fresh, needing the lab, the necessary analytical equipments and the personnel aside. In several studies, transiently the whole staff has to be recruited to work at the time of necropsy. It would be difficult to run such studies elsewhere.

Our vision in the early 1980's was that there must be an independent and high quality governmental facility and related expertise in Finland for studying effects of relevant exposures that are not of interest for e.g. industry (dioxins as an example) in laboratory animals. Because such expertise and activity need a long-term commitment, it does not fit well to universities and it is not either their duty. This principle concerned especially toxicity testing, which was initiated at the University of Kuopio in 1982, but was transferred to KTL/YTOS in 1984, along with the key personnel. As a contract work it was finished around 1996 after a strategic decision, because the lab proved out to be too small to be competitive with the larger commercial contract laboratories.

However, the expertise gained in toxicity testing has been invaluable for us and it has been exploited by several ways. It has been important also nationally. First, some research projects (e.g. the project on toxicology of the MX, including the carcinogenicity study in rats) are solely based on this expertise and the established collaboration network (e.g. the link to histopathology). Without this expertise the project on MX toxicology most likely could not have been undertaken. Secondly, we have taken the responsibility to teach the subject (toxicity testing in practice) to graduate and postgraduate students of toxicology at the University of Kuopio (arranging special courses) and elsewhere in Finland. Thirdly, due to this expertise, we have served as the national coordinator of Finland in the OECD and EU toxicity testing guideline programs aimed to develop and update the toxicity testing guidelines. The same expertise is needed in our current work at the SCHER of EU, where risk assessment reports of individual chemicals are evaluated (two members of the SCHER currently from YTOS).

As to research, all main research projects of YTOS have used the animal facilities (i.e. done in vivo studies) at some stage. There are also some smaller projects which have not been raised to the evaluation material. The value and benefits of the animal facilities for the research projects may be summarized as follows.

- The dioxin toxicology project (currently POPs) has been based on in vivo studies in rats and mice, and some studies have yet been scheduled to be conducted. Nine dissertations, either finished or ongoing are based on animal studies and most of the papers published from the project thus far.
- The characterization of the toxicity profile of MX (a disinfection by-product in chlorinated drinking water) over the years 1990-2000 was based on rat studies.
- The indoor air group on microbes has done a pioneer work in laboratory animals, world wide. Most other laboratories in that field do not have the possibility to do in vivo studies. The findings based on cell cultures in vitro have been evaluated and verified in a mouse model (after intratracheal instillation, thus far one Ph.D. thesis). The results have created confidence that the findings made in cell cultures are true also in lungs and link the results to findings in epidemiological studies.
- The fourth main user has been the outdoor air group. Between 1996-2000 it studied respiratory effects of gaseous pollutants (SO<sub>2</sub>, NO<sub>2</sub>) in a guinea pig model, especially

interaction with cold air, which is relevant in Finland (one Ph.D. thesis). In the 2000's, effects of fine and ultrafine particles collected e.g. in the PAMCHAR-project, have been studied in the same mouse model as the microbes (an ongoing Ph.D. thesis work). As in indoor air studies, verifying the in vitro results in whole animals has created confidence on their relevance. In fact, when the correlation is known and understood, mere in vitro studies may increasingly be used to predict the toxicity.

- Several animal studies on carcinogenic and teratogenic effects of electromagnetic fields and radiofrequency radiation in rats and mice have been run in the facilities in collaboration with the researchers of the Department of Environmental Health, University of Kuopio (2 Ph.D. theses, e.g. the CEMFEC-EU project). The main responsibility of the studies has been at the University, but several studies have been run in our animal facilities and our role has been to provide the toxicological expertise.
- It should be noted that in vitro studies with primary cells (including embryo cultures) need daily living animals for the source of tissue. One group in YTOS developed in vitro methods in embryo cultures for testing of developmental effects, and participated also in the international EU/ECVAM-coordinated validation of such methods.

### *The future*

The scientific risk assessment of chemical substances will most likely be largely based on in vivo studies in laboratory animals also in the future, despite of heavy current pressure against their use, because only in vivo studies can provide the dose-response data needed in risk assessment. This is rather clear for the toxicologists and has been stated repeatedly e.g. by the scientific committees of EU responsible for environmental and health risks (currently SCHER). There is seldom enough human data for risk assessment and in vitro studies do not provide such dose-response data. It can thus be foreseen that there is a continuing need for animal experiments and facilities in general. The question remains: who has the strategy and possibility to maintain them over the years.

Currently over 90 % of the laboratory animals (rodents) used for scientific research are genetically modified (transgenic) and their number is increasing rather than decreasing, because the modified strains are efficient tools. This has meant and will mean an increasing number of different strains to be maintained. Also new demanding techniques, such as embryo transfer (which we already do), are needed in animal facilities.

Our approach in research at YTOS has been problem-solving, which means that animal experiments and animal facilities are needed in certain phase of the project, at the time when they yield the data needed. This creates fluctuation in the use of the facilities with limited number of senior researchers and projects. Originally the unit has been dimensioned to include also the toxicity testing as contract work. Therefore, there is capacity for other customers and further projects. The projects that have used much the facilities have got to the point that animal facilities will be used less (TCDD-project), if any (the MX-project). Other ongoing projects are expected to continue to use the facilities but our own use together will likely be less in the near future. But we are seeking other users to utilize the liberating capacity.

One new three-year project (ATHON) has just started on non-dioxin-like PCBs, based on animal experiments.



We see that our barrier unit will be very valuable in the future and its capacity in full use, because it serves best also outsiders, also in long distance. We already have had continuously 3-4 strains of transgenic animals in maintenance for research groups working at different universities.

The main institute of KTL in Helsinki is one natural customer to increasing extent. In the past years we already produced animals e.g. to vaccine testing (which was then finished at KTL) to be used in animal facilities in Helsinki. There are some plans to reorganize the animal facilities in Helsinki area and we have offered to take some strains of animals for breeding and maintenance from the animal facilities of KTL in Helsinki.

We have been in close collaboration with the National Laboratory Animal Center, located beside at the University of Kuopio from the beginning (exchange of personnel, our spare capacity used during their needs, a common Ethical Committee on laboratory animal experiments etc.) and had discussions on the more extensive use of our facilities for their purposes in the future. Understandably, the university is using their own resources first.

There should be a national concern, who will maintain and where the practical expertise on key areas of regulatory toxicology, such as toxicity testing, in Finland in the future. The expertise is one core subject of e.g. in implementation of REACH and national authority activities related to them. Experts understanding the subject, preferably having own experience, would be needed. There is a trend and danger that such expertise and knowledge is disappearing, and targeted strategic decisions would be needed to avoid it.