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RELATED SCIENTIFIC ACTIVITIES: The Other Half of the Federal S&T Story

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RELATED SCIENTIFIC ACTIVITIES (RSA): THE OTHER HALF OF THE FEDERAL S&T STORY

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A Paper Prepared for Health Canada and Environment Canada

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INTRODUCTION

The purpose of this paper is to examine and the nature and role of Related Scientific Activities (RSA) in federal S&T policy through case studies of four federal science-based agencies or units, two in Health Canada and two in Environment Canada.[1] The four case study agencies are the New Substances Branch and the Water Survey of Canada (both in Environment Canada) and the Veterinary Drugs Directorate and the Consumer and Clinical Radiation Protection Bureau (both in Health Canada). The analysis is set in the context of larger federal discussions on S&T policy, innovation and the role of government S&T, as well as science-based regulation and smart regulation. The paper explores the meaning of RSA as a crucial but often not well understood element of the government's role in science and technology.

RSA is one part of the federal government's classification of overall federal S&T activity. The other part is federal research and development (R&D) activity, which is by far the better known of the two, garnering much more analytical attention in debates about science policy and innovation. The very term "related scientific activity" suggests it to be a "leftover" category: not R and not D but somehow still involving science. Far from an adequate descriptor, the designation RSA begs the question: what are these activities and what are they "related" to? The implication is that RSA is related to R&D, but there is no suggestion to its more definitive relationship: providing the basis for government policy, monitoring activity and regulation.

The case studies in this paper show that RSA involves varied regulatory and service tasks such as: the direct assessment of product proposals and applications; the enforcement of rules; the drafting of science-based guideline documents for client groups and users of products; the post-market monitoring of products and effects once they are on the market; the general and targeted monitoring of activities and impacts related to environmental and health hazards and risks at numerous discrete sites and locations, many remote and dangerous; the tendering of advice to professional groups; and the exchange of knowledge, information and advice with international bodies and fellow RSA practitioners in other jurisdictions.

Indeed the central argument in the paper is that RSA is crucial to the regulatory role of government and to the monitoring of risks and health and environmental effects—thus it is crucial for policy and governance in Canada. Far from being an afterthought or something that is simply "not R&D", RSA is the quintessential core of government S&T necessary to enable the state to regulate and monitor in the public interest. The paper seeks to flesh out more clearly both what RSA is, what it is related to, and why it is a crucial and growing role for federal S&T at a time when federal policy seems focussed in its public statements mainly or solely on R&D, and where even R&D often means, in federal policy terms, having science performed as a much as possible in the private sector and in universities (see more below).

The paper is based on a review of relevant published literature and government reports, and on

1. I wish to thank the officials in the four agencies and two departments for their cooperation and helpful assistance in the interviews conducted and regarding documentation for the research. Several of these persons also provided constructive comments on earlier drafts of this paper.

25 interviews conducted by the author with officials in the four case study agencies and their parent departments, Health Canada and Environment Canada. The interviews were conducted on a confidential or "not for attribution basis". The purpose of the interviews was to garner a basic but more in-depth view of the agencies than is possible from a reading of published documents alone. The case studies of the four agencies are intended to be illustrative in nature only. They are a means to examine other ends, namely to enhance understanding of RSA. Accordingly, the case studies are by no means full-fledged accounts of the agencies either in terms of performance or in terms of the internal culture and mode of operation of each organization. The author has necessarily had to be selective about exactly what aspects of the case study agencies are drawn out for mention and commentary. But the essential purpose is to relate the formal "top-down" definitions of RSA to the reality of what it actually is when looked at from the "bottom-up" picture provided by the four case studies.

The paper proceeds in four sections. It begins with an effort to conceptualize and locate RSA in an overall definitional way but also by looking at its boundary problems and core characteristics. This includes some initial reference to a basic understanding of both *pre-market* regulatory product or substance assessment and approval activity and of *general monitoring and assessment* activity. The second section profiles the basic mandates and characteristics of the four case study agencies. The third section then analyses and compares the four agencies and the functioning of, and support for, RSA in relation to five issues or elements: a) the core decision and/or risk assessment and risk management cycles, and the volume of decision-making activity; b) the nature of external RSA or R&D partnerships and dependencies; c) RSA personnel issues and competences; d) RSA equipment/capital funding and challenges; e) other residual but not unimportant dynamics that influence the conduct of RSA in the four agencies in question.

CONCEPTUALIZING AND LOCATING RSA

To conceptualize and locate RSA in federal S&T, we need to discuss its core definition, relationships and boundary problems. We also need to see where it fits in with regard to the broad recent evolution of federal S&T and innovation policy, and how it links with the federal government's approach to regulatory governance, particularly under its Smart Regulation initiative.

RSA: Definition, Relationships and Boundaries

The federal government defines related scientific activities (RSA) as "those activities that complement and extend R&D by contributing to the generation, dissemination, and application of scientific and technological knowledge" (Canada, 2002, p. 26). It then goes on to define the sub-groupings of RSA by field of science, namely, "*natural sciences*: scientific data collection, information services, special services and studies, and education support; and *social sciences*: general purpose data collection, information, services, special services and studies, education support" (Canada, 2002, p. 26). Though this is how the report defines them, these do not relate exactly to the way RSA is grouped in departments or for reporting to Statistics Canada. The same report cited above indicated that in 2000-2001 the Government of Canada employed almost 32,000 personnel who were engaged in S&T activities and that, of these, nearly 13,000 employees were classified as scientific and professional, of which more than 6000 were engaged in conducting R&D (Canada, 2002, p. 26). The inference to be drawn is that the remaining and larger number of scientific and professional employees (7000) was engaged in RSA.

Those working in R&D (scientific research and experimental development) are defined to be those engaged in "creative work undertaken on a systematic basis to increase the stock of knowledge including the knowledge of humans, their culture and society, and the use of this knowledge to devise new applications" (Canada, 2002, p. 26). The federal R&D definitions are drawn from the main global reference, the OECD Frascati Manual. This reference was published initially in 1963, and has since undergone several revisions following assessments of it set against the changing evolution of S&T and S&T outputs (OECD, 1963, 1970, 1976, 1990, 1993, 1994, 1995, 1997). The Oslo Manual of 1970 brought more focus to technological innovation and the 1995 Canberra Manual dealt with the human resource dimensions of S&T. The 1994 Patents Manual focussed on patents and the 1990 TBP Manual focussed on technology balance of payments.

A recent paper by Benoit Godin notes that the initial Frascati manual recognized the importance of RSA for a country and that countries were encouraged to collect data on RSA. But he stresses that internationally, "numbers on RSA are almost completely unavailable because so few countries collect data on them. Besides Canada and Ireland—among OECD countries—and some developing countries—mainly in Latin America, no country measures RSA today" (Godin, 2004, p. 4). Godin goes on to argue that the lack of overall interest in measuring RSA is a classic case of "boundary-work: erecting boundaries in order to exclude things considered outside the field" (Godin, 2004, p. 5). He concedes that there are measurement difficulties involved but more basically he argues that there are two factors which explain the non-interest in RSA: ideological

and political factors. On the ideological front, he argues that "R&D was perceived as a higher order of research. No argument was needed to convince people of this hierarchy. It was taken for granted by almost everybody that 'soft' activities like market studies or design, for example were not R&D" (Godin, 2004, p. 5). On the political front, Godin argues that the non-interest was due to the "need for presenting misleadingly high science and technology performance" (Godin, 2004, p. 5). In the context of this kind of argument, Canada deserves credit for actually assembling RSA data but the analysis in this paper will show that there are further political and presentational reasons why the federal government does not draw attention to RSA in its overall public S&T policy storyline.

The authors of another recent review article have observed that, "on a theoretical level it is generally agreed that these internal and external enhancements of the Frascati Manual reflect the gradual replacement of the linear concept of innovation with an interactive concept... Thus R&D is now envisaged as an activity that can take place at any stage of a given innovation process and not just at the beginning. It can also take place independently of any clearly identified innovation process" (Djellal et al., p 416).

Djellal et al. go on to stress that the criterion of novelty in the Frascati Manual definition of R&D is the core basis for distinguishing R&D from "related activities". Paragraph 70 states that the "presence in R&D of an appreciable element of novelty and the resolution of scientific and/or technological uncertainty, ...is when the solution is not readily apparent to someone familiar with the basic stock of commonly used knowledge and techniques in the area concerned" (OECD, 1993, Paragraph 70). But notions of novelty are not an easy guide and hence boundary problems arise. To appreciate and distinguish "related" activities (including RSA) from R&D, the Frascati Manual (OECD, 1993) suggests other possible ways of differentiation such as by looking at the nature of project objectives, the methods used, and the type of personnel involved in the project.

Djellal et al. discuss the overall definitional trail because they are ultimately concerned with the need to revise the definitions of R&D in the light of the specificities of services. Their view of services refers mainly to services in the private sector where they draw attention to problems of the relational and triad nature of service innovation. According to this view a service is composed of three elements: the customer, the service provider, and the service medium. Service media can include tangible goods, codified information, and knowledge, and individuals themselves (Djellal et al., 2003, p. 418). The overall purpose of the Djellal et al. analysis is to argue that the definitions inherent in the Frascati and related manuals continue to have an "industrialist and technologist" concept of R&D and that they are unable to take into account in their definitions the systematic creation of new knowledge in services. The authors argue that they do not seek a fundamental redefinition but rather a greater recognition of "the importance of the social sciences and humanities and of design and development or organizational engineering, the composite nature of projects and so on. Our objective is to attain a certain 'psychological' threshold that would mark our emancipation from the still dominant industrialist and technological approaches" (Djellal et al., 2003, p. 415).

I cite the Djellal et al. argument and commentary for two reasons. First, it does indicate boundary problems in defining complex activities. Second, its invocation of services is of some importance

for RSA in government S&T. It is not our intention to explore services in the private sector as the Djellal et.al. analysis does. But it is of analytical interest for government RSA to take up the point that services are very relational and triad-like in nature.

If RSA is to be more fully understood and supported as a key part of the role of government and governance then the notion of service relationships and various media are important. This does not mean that the notion of services covers the full domain of action. Government RSA in the form of monitoring activity is very service-like but RSA is also very much a part of regulation and regulation in turn implies notions of sanctions, compliance and compulsion. Services on the other hand tend to evoke the notion of some voluntarily chosen benefit. But both service-style activities and regulatory ones are relational and increasingly triad-like in terms of relations and interactions. And in governmental settings RSA involves service media which include tangible goods, codified information, knowledge, and individuals themselves, including the brains, analytical judgement and regulatory and monitoring experience of RSA staff. We return to this issue later in the paper.

At this point, we simply re-emphasize the notion that official definitions of RSA define it as related, residually, to R&D and not to its other critical link which is that it is a crucial aspect of science and technology-based monitoring activity and regulatory activity, which in turn embodies both service-like and compliance-centred activity (Doern and Reed, 2000). This is partly why the four case studies considered here needed to include two RSA agencies which are largely focussed on pre-market assessment of products/substances and which are therefore more regulatory in focus, and two which are more focussed on monitoring and hence are somewhat more service-oriented.

RSA in the Federal S&T and Innovation Policy Debate

RSA must also be linked to the basic nature of federal S&T and innovation policy. These policy debates are well examined in other sources and thus no detailed discussion is presented here (Courchene, 1996; Doern and Levesque, 2002; de la Mothe, 2003; Canada, 1997, 1999, 2001, 2002, 2002a). What is stressed here is that in the larger scheme of things, this debate tends to ignore or seriously underplay the pivotal role of RSA.

The larger evolving federal policy has been characterized by four key themes and decisions. First, federal S&T absorbed significant cuts in the mid-1990s under the impetus of federal Program Review. Many federal science-based departments were especially hard hit and, despite some selected infusions of catch-up money in recent budgets, they have still not been fully restored to previous levels, let alone to meet the regulatory and monitoring mandates that have expanded in the meantime (Environment Canada, 2000, 2000a).

Second, federal S&T funding increases since the succession of federal surplus budgets began in 1997 has largely gone to universities via the Canada Foundation for Innovation and the granting councils, and to support industrial research (Kinder, 2003). This burst of considerable new funding continued the longer trajectory of federal science policy over twenty years or more which had always stated that federal preference was to get more and more R&D and S&T out of government and into industry and universities.

Third, federal policy has increasingly supported the concept of innovation policy per se. Underlying this was a desire to foster a Canadian economy that could compete in the global knowledge-based economy and which had to commercialize knowledge. Innovation policies were also explicit admissions that the old linear model of R&D or S&T was no longer a valid basis on which to anchor policy. This linear view had held that basic research leads to applied research and development and that this in turn leads to innovative new products. Innovation could occur, as noted in our discussion of R&D definitions above, in non-linear, interactive linkages at any point in the nominal continuum. National and local systems of innovation and the notion of clusters became central to how S&T innovation policy was discussed and fostered (OECD, 1998; Wolfe, 2002; Wolfe and Lucas, 2003).

A fourth feature of federal S&T policy was the emergence of more explicit concern for the nature of science advice in overall federal decision making. New governance institutions were formed and discussions were fostered about how to ensure that federal S&T advice was better linked to policy and was also transparent, independent, and engaged Canadians in direct and continuous ways (Canada, 2002a; Doern and Reed, 2000).

None of these policies were, in their time and context, wrong or inappropriate. But what is important about them in the context of this paper is that they were all crafted without much import being given to the key role that RSA plays or even to what it actually is. The federal government's report on federal science and technology for 2002 is an example of this status of RSA as an element which functions under the radar screen of federal S&T policy (Canada, 2002a). It deals with all four of the above summarized and important aspects of S&T innovation policy but leaves RSA to a bare mention.

As we have already quoted above, the basic statistical chapter in the 2002 report on federal S&T mentions RSA and defines it. It shows or infers that the *larger* part of the federal S&T staff is engaged in RSA activities. Thus in two pages of an 81 page report on federal S&T, RSA gets a direct and an inferred mention but then is not dealt with in any other way. At one level, this is simply because the federal government wishes to draw attention to its larger S&T policy storyline. But as a full treatment or understanding of what S&T actually involves, and how crucial it is, it is woefully inadequate.

RSA in the Smart Regulation Agenda

In many crucial respects RSA is about science and technology in support of public interest regulation—rules of behaviour backed up by the sanctions of the state (Doern, Hill, Prince and Schultz, 1999). Accordingly, thinking about RSA requires putting it in the context of debates about regulation and regulatory governance, and acknowledging that regulation involves both service-like relationships as well as those of compulsion and compliance (Sparrow, 2000; Solomon, 2002). In recent years, the policy debate about regulation has been increasingly cast within the rubric of *smart regulation.* The federal government's Smart Regulation initiative was announced in the September 30th, 2002 Speech from the Throne. At that time, the Chrétien Government gave the following rationale for the initiative:

> The knowledge economy requires new approaches to how we regulate. We need new regulation to achieve the public good, and we need to regulate in a way that enhances the climate for investment and trust in the markets. The government will move forward with a smart regulation strategy to accelerate reforms in key areas to promote health and sustainability, to contribute to innovation and economic growth, and to reduce the administrative burden on business (Canada, 2002b, p. 1).

The Speech from the Throne then went on to refer to a number of regulatory realms that would be a part of the reform initiative. These included: intellectual property and new life rules, copyright rules, drug approvals, research involving humans, the Canadian Environmental Assessment Act, a single window for projects such as the northern pipeline, the Agricultural Policy Framework, Canada-US smart border needs, and capital market and securities regulation.

The smart regulation initiative found its way into the Throne Speech and thus into a recognized high priority status due to several pressures and arenas of advocacy. One was certainly the federal innovation strategy paper which had emerged earlier in 2002 and whose consultation processes had generated numerous areas where current kinds of regulation were seen as an obstacle to innovation but also some areas where insufficient regulation could also be a bar to such progress (Canada, 2002). So the notion that regulation had to be "smart" or "smarter" than in the past certainly emerged from the innovation debate. But of course, there were also separate pressures emerging from the departments and stakeholder groups concerned about all the more specific areas of regulation cited above.

When seen in terms of federal policies about regulation as an overriding policy instrument, the smart regulation initiative can be cast as simply the latest in a series of periodic regulatory reform efforts. As such it joins earlier efforts in the mid-1980s under the Mulroney Conservative Government and in the late Conservative Government and early Liberal Government years of the 1992-93 period (Doern, Hill, Prince and Shultz, 1999). Both of these sought to reform regulatory decision processes, deregulate to some extent, and urged a search for non-regulatory alternatives. Economic values and ideas were certainly a part of these reform exercises but it is fair to say that neither was driven by a full-blown innovation/new economy paradigm per se. The smart regulation initiative, in contrast, is largely driven by such a paradigm. It is also driven, more than the previous bursts of reform, by a globalization agenda where a decade of NAFTA and WTO experience has heightened the pressures for the integration of rules in a North American and global context. But, as in all regulatory reform exercises, the government's smart regulation initiative necessarily and genuinely also refers to the values and ideas of health, safety, environmental protection and achieving the public good through rules.

Work on the Smart Regulations initiative is nearing completion, guided and advised by a multi-stakeholder External Advisory Committee on Smart Regulation (EACSR). This committee reports in the fall of 2004 but it has already held consultations and published several papers and reports germane to the contemporary nature of regulation (External Advisory Committee on Regulation, 2003; Hart, 2003; Health Canada, 2003; Leiss, 2003; Mendelsohn, 2003; Pal and Maxwell, 2003; Privy Council Office, 2003; Treasury Board Secretariat, 2003; Environment Canada, 2003).

The overall notion of smart regulation links directly to the issue of *risk assessment and risk management regimes* for regulation in the broad realm of health, safety and environment. This refers to a large set of regulators and their regulatory clientele whose activities are dependent on science-based regulation and on ideas centred on the *precautionary principle* (Doern and Reed, 2000; Privy Council Office, 2003; Treasury Board Secretariat, 2003; European Commission, 2000). Federal science-based departments engaged in health, safety and environmental regulation all have basic versions of a decision framework for identifying, assessing, and managing risks. For example, Health Canada's framework consists of stages/cycles of decision making including: identifying the issue and its context; assessing risks and benefits; identifying and analyzing options; selecting a strategy (a risk management plan); implementing the strategy; and monitoring and evaluating results. At all or most of these stages, the need to engage in consultation is essential since each stage involves two-way and interactive discussions with interested and affected parties (Health Canada, 2003). The entire process is to be science-based or, as often expressed in trade agreements, based on sound or objective science.

Like the debate about the policy on federal S&T and innovation, the debate about smart regulation underplays and ignores RSA. Smart regulation implies an increase in capacities to regulate in innovative but still public-interest-oriented ways but then, as a concept, it often ignores what might be crucial to actually make it happen, the S&T-based pre- and post-market regulatory science and monitoring capacities of the federal science-based departments and agencies, in short, their RSA.

RSA in Health Canada and Environment Canada

The four case study agencies examined in the paper are located within Health Canada and Environment Canada and must function within their parent department's mandate, statutes and organizational and business-line structures. We do not go into these departmental features in any detail referring to them only in so far as they are needed to elaborate on the case studies.

However, it is important to note the two department's relative compositions as between R&D and RSA. Health Canada's own breakdown shows that 75 percent of total S&T employees do RSA, with about 55 percent doing risk assessment of products and environmental risks.[2] R&D constitutes about 25 percent of the total. For its part, Environment Canada's total S&T expenditures are 72 percent on RSA, 28 percent on R&D (Environment Canada, 2000a, summary). Its percentage of S&T employees on RSA is 75 percent and 25 percent on R&D. In both expenditure and personnel terms, Health Canada and Environment Canada have by far the largest percentage of RSA focus compared to other federal science-based departments.

While these data are important and useful, it must again be stressed that department reports all stress that there are overlaps with R&D that are difficult to sort out and differentiate. It is also of some importance to note that in these reports further definitions and examples of RSA seem not to refer to the notion of *regulation* as such even though that is a fundamental part of what their RSA is related to and centred on.

2. Data provided by Health Canada.

THE FOUR CASE STUDY AGENCY MANDATES AT A GLANCE

The core purpose of this paper is not to study the four agencies per se but rather to use the four case studies illustratively as a vehicle to understand more completely the nature of RSA. Accordingly, in this section we provide initial accounts of each agency's mandate, structure, RSA versus R&D mix of activities, and an initial sense of its core operating realities. In short, we provide initial profiles "at a glance", beginning with the two agencies engaged in broad monitoring RSA tasks and then looking at the two agencies with pre-market regulatory roles and tasks. Following this, we address other particular or more detailed features of the agencies in a comparative and illustrative way, considering the extent to which an agency is involved in pre-market versus post-market or other forms of monitoring activity.

Water Survey of Canada

The Water Survey of Canada (WSC) is a part of the Meteorological Service of Canada at Environment Canada and is the primary operator for the national water quantity monitoring network. The WSC is the main "recognized national authority and source of standardized water data, information, expertise and related technology in the areas of water monitoring and hydrology" (Water Survey Program, 2003, p. 1). Technology, as applied by the WSC through the science of "hydrometry", is the core capacity that allows the WSC to carry out its mandate and to ensure that data and information products and services are "standardized, up-to-date and delivered in a timely manner" (Water Survey Program, 2003, p. 1). As a monitoring agency with a dominant RSA role, a key challenge for the WSC is that its government, business, and recreational activity clients require and demand real-time data services as well as traditional products to be delivered via the Internet. Environment Canada also has current and new program needs which the WSC has to support and be cognizant of.

The data the WSC produces is a public good and is used routinely to develop and manage thousands of small projects, like ditches, as well as large projects such as hydropower facilities and environmental impact decisions in environmental assessment processes. It is used by cottagers and businesses and governments in myriad tasks and regulatory contexts.

The WSC mandate can be traced back to 1908 but its modern expression comes from the Canada Water Act, Part 1 Section 7, which empowers the Minister directly or in cooperation with any provincial government "...to conduct research, collect data, and establish inventories". More broadly, the mandate is to "provide nationally coherent, relevant and effective hyrologic monitoring and information services, to all Canadians, enabling wise decisions affecting security of life and property, efficiency and economy, and protection of environmental quality" (Water Survey Program, 2003, p. 3). Its current mission statement indicates that the WSC is "to contribute to the sustainable management of Canada's water and related resources" (Water Survey Program, 2003, p. 3).

In cooperation with all the provinces and territories, the WSC operates a Canada-wide network of hydrometric stations at which water levels are automatically monitored. In addition, stream-flow velocity is measured by technologists and is used to derive stream flow data and other

hydrological information. These data are also used to help Canada meet its obligations in over 30 international treaties and federal-provincial-territorial conventions, agreements and Boards. The WSC operates with an Ottawa headquarters group, five regional offices and 25 district offices located across Canada. But the network per se provides real-time and historical data on over 2411 sites plus historical data for an additional 5000 non-active sites.

The WSC has a current budget of approximately $26.3 million, $12.7 million of which comes from the provinces and territories under the water quantity cost share agreements. Its budget had been severely cut (by 30 percent) in the mid-1990s Program Review. Its professional staff of about 185 persons are involved overwhelmingly in RSA activity but some do R&D work tied closely to the core mandate. The largest part of the staff operates in the field, often in remote areas. The actual monitoring work is not easy to do and can be dangerous. Two deaths in recent years prompted action under federal occupational health and safety law which included funding for new technologies of monitoring that were safer. The WSC also operates a Regina office whose focus, on a cost-recovery basis, is on business development to take advantage of opportunities to utilize WSC expertise via CIDA and United Nations work.

The agency has enjoyed considerable stability in that staff tend to stay for long careers and also in the sense that continuity of method, technology and technique are crucial in the production of consistent and reliable time series data. But at the same time the agency faces continuous needs to adapt to the newest computer and data acquisition technologies. There are two key influences already present and destined to increase. The first is the influence of the low cost availability of new micro-processing technologies which "have progressed to the point where they can be adapted or designed to operate as part of devices that can measure velocity or flow rates directly in an open and often harsh natural environment" (Water Survey Program, 2003, p. 13). The second influence comes from clients and various users demanding greater access to real-time stream flow data. In addition, the WSC staff and technologists must have access to the same data through hand-held computers in order to manage the system. This shift to an "on-the-fly" paradigm "is all the more challenging when considering the reality that the existing tried and proven operational systems must be maintained to provide continuity of service until the new systems have proven themselves to be able to replace the current ones" (Water Survey Program, 2003, p. 13).

To function in as integrated and sustainable a way as possible, the WSC is now beginning to operate through seven management processes seen as the core components of the water quantity monitoring business. These are: network evaluation and planning; measurement of environmental parameters; telecommunication and data retrieval; data production and estimation; long term data archive; and data, information and services (Water Survey Program, 2003, p. 14). But the overall work involves extensive federal-provincial contact and coordination. Regular meetings of the federal and provincial Agreement Coordinators are held at the regional level and at the national level with the Administrators meeting on an annual basis. These activities function under the Federal-Provincial-Territorial Cost Sharing Agreements on Water Quantity Surveys signed in 1975.

Consumer and Clinical Radiation Protection Bureau (Health Canada)

The Consumer and Clinical Radiation Protection Bureau (CCRPB) is a bureau in Health Canada whose core mandate is to assess, monitor and assist in the reduction of the health and safety risks associated with different types of radiation (x-rays, ultrasound, radiowaves, microwaves, noise, ultraviolet light, lasers) emitted from radiation-emitting devices or other sources (Health Canada, 2004). It carries out its overall protection role under the provisions of the Radiation Emitting Devices (RED) Act, the Canada Labour Code, the Food and Drugs Act, Treasury Board Standards, and other related government undertakings.

Located within the larger Healthy Environments and Consumer Safety (HECS) Branch, the CCRPB is in turn composed of several smaller divisions on: Acoustics, Electromagnetics, Radiobiology, Medical X-Ray and Mammography, Lasers and Electro-Optics, and X-Ray Inspections and Non-Medical X-Rays. These divisions produce numerous standards and guidelines for any number of persons (employees, patients, health professionals) using or subject to the use of these radiation-emitting devices. For example, the Acoustics Division provides and implements standards for protection against occupational and environmental noise, largely through the use of its state-of-the-art acoustics chamber.

The Electromagnetics Division sets regulations for the safe use of microwave ovens and enforces their compliance. This core task involves the need to investigate and monitor external research on the biological effects of electromagnetic fields. The Radiobiology Division focuses on evaluating and managing the risks of radiation on human health by investigating the biological effects of exposures to internal and external sources of radiation. The other divisions of the CCRPB similarly have their core tasks.

Located in Ottawa, the CCRPB has a staff of 36 persons including some research scientists and considerable technical support personnel. Its RSA roles predominate, but compared to the Water Survey of Canada described above, the CCRPB has a more varied realm of regulatory science tasks to perform. Its tasks include direct regulation, guidelines, public outreach, and compliance, as well as monitoring. It does little product approval regulation given that most radiation-emitting devices are imported into Canada but it has to be up to date and aware of how devices are made, used and being changed by new technologies. Moreover the RED Act mandate deals with the importation, sale, use and resale of such devices. The Bureau's capacity to do its work is highly dependent on links and partnerships with the provinces at thousands of health facility sites and other places of work where devices are used. It is the Bureau's safety codes and standards that are referenced and used in provincial legislation and regulations regarding occupational health and safety and other related health matters. The Federal-Provincial-Territorial Radiation Protection Committee meets annually for a week to coordinate issues and take into account new health and technological developments.

Veterinary Drugs Directorate (VDD)

The Veterinary Drugs Directorate (VDD) is a new directorate in Health Canada. Established in 2001 it is a part of the Health Products and Food Branch of Health Canada. It had been a bureau within the Food Directorate prior to becoming a Directorate itself in 2001. The VDD's mandate

is to ensure "the safety of food such as milk, meat, eggs, fish, and honey from animals treated with veterinary drugs...(and) also ensure that veterinary drugs sold in Canada are safe and effective for animals" (Veterinary Drugs Directorate, 2004, p.3). Functioning under the Canadian Food and Drugs Act and Regulations, the VDD assesses and approves veterinary drugs which manufacturers submit for possible sale in Canada. The VDD also establishes the Maximum Residue Limits (MRLs) for veterinary drugs used in food producing animals. Manufacturers are required to submit data to "demonstrate/establish the safety of any residues in food from treated animals, as well as the safety and efficacy of the products for the treated animals" (VDD, 2004, p. 5).

Compared to the first two case studies, the VDD's RSA activity is geared more to regulatory product approvals rather than monitoring. Thus the VDD is extensively involved in the evaluation of industry submissions and in the establishment of MRLs. However, its RSA activity also involves monitoring through its pharmacovigilance program, as well as related activities including Health Risk Assessments (HRAs), research and surveillance, science-based policy and regulatory development, issues management, international cooperation/harmonization and public involvement and outreach. The VDD provides HRAs at the request of the Canadian Food Inspection Agency (CFIA) when violative residues are found in food derived from animals. The CFIA then undertakes the appropriate compliance measures. The growing international role is centred on the Veterinary International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medical Products (VICH), a trilateral (EU-Japan-US) program. The VDD leads Canada's "observer" role in the VICH process and it also heads Canada's delegation to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) (VDD, 2004, p. 8).

Based in Ottawa, the VDD is composed of a multi-disciplinary staff of about 80, of which approximately 50 are engaged in RSA. Its budgetary allocations are approximately 80 percent for RSA and 20 percent for R&D. The research is purchased from other Health Canada and university research centres. The VDD's policy and regulatory development roles are based on evidence-based decision making and a Smart Regulations approach "which emphasizes appropriate instrument choice in order to protect Canadians, the public interest, and enable innovation" (VDD, 2004, p. 7). It is anchored within Health Canada's Decision Making Framework for risk assessment and risk management (Health Canada, 2003), referred to above.

New Substances Branch (Environment Canada)

The New Substances Branch (NSB) of Environment Canada co-administers, with Health Canada, the new substances provisions of the Canadian Environmental Protection Act (CEPA), including the New Substances Notification Regulations (NSNR). CEPA was originally promulgated in 1988 and was replaced by CEPA 1999. It has always had provisions whose key purpose is to ensure that "no new substance is imported into or manufactured in Canada without a formal review, prior to market introduction, of its potential risks to human health and to the environment" (Health Canada and Environment Canada, 2002, p. 3). New substances include chemicals, polymers, biochemicals and biopolymers as well as animate products of biotechnology. The case study of NSB in this paper refers only to Environment Canada's role but in all of our discussion it must be kept firmly in mind that the program depends on Health

Canada's RSA capacity as well.

The CEPA provisions referred to above prohibit the import or manufacture of new substances unless importers and manufacturers notify Environment Canada in accordance with the requirements of NSNR. The notification information "typically includes test data relating to physicochemical properties, environmental fate and behaviour and/or toxicity" (Health Canada and Environment Canada, 2002, p. 3). Crucial to the regime is the determination of what is new and therefore notificable. CEPA relies on the Domestic Substances List (DSL): if a substance is not present on this list, then it is considered new. There are also other factors in determining the need to notify including whether importation/manufacture quantities equal or exceed prescribed regulatory triggers or comply with stated exemptions and exclusions in CEPA 1999. Substances which do not require notification include those listed on DSL, substances regulated by other Federal Acts that appear in CEPA schedules, and substances meeting a number of other tests or characteristics. There is also a Non-domestic Substances List (NDSL) which is a compilation of substances other than animate products of biotechnology that are not on the DSL but are believed to be in international commerce. These are still subject to notification but the information requirements are reduced because of previous U.S. experience. It is the U.S. list that was chosen as the basis for determining that the substances were in use in international commerce because they have had a notification regime in place since the late 1970s and therefore could be a source of expertise. Notifiers are responsible for providing the information packages and any associated costs. The New Substances Program costs are mainly taxpayer funded through the budgets of Environment Canada and Health Canada but also through a lesser contribution through fees prescribed under the New Substances Fee Regulations.

The assessment process is a joint one with Health Canada and must be completed within a limit of from 5 to 90 days depending upon the extent of introduction into Canadian commerce. It results in either a determination that the substance is not suspected of being "toxic" or capable of becoming "toxic", a suspicion that the substance is "toxic" or capable of being "toxic", or a suspicion that a significant new activity (SNAc) may result in the substance becoming toxic if there was adequate information available to assess it. If the substance is suspected of being toxic then the risk may be managed through measures on import and manufacture, its outright prohibition, or prohibition pending submission and assessment of additional information. There are also *post-notification* responsibilities imposed upon notifiers, including correction of information, notices of excess quantity, and submission of any new information available to the notifier that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic.

It must be stressed therefore that the NSB does not "approve" substances. It cannot formally be described as a pre-market approval agency the way the Veterinary Drugs Directorate can. It can, however, be called a pre-market regulator. It also has some post-market monitoring and compliance activities because of the post-notification features of CEPA. The New Substances Branch consists of several divisions for the various risk assessment and regulatory compliance phases of CEPA and the NSNR. These divisions provide: strategic planning and program coordination; the processing of notifications and risk management measures, delivery of client services; new chemicals evaluation; and biotechnology evaluation and policy development.

Environment Canada's 45 person professional staff consists of 50 percent engaged in RSA and the other 50 percent on other regulatory/policy work. The Branch receives over 800 submissions per year, about 20 of which result in some form of risk management measures.

MAPPING RSA: A CLOSER LOOK AT KEY ISSUES AND ELEMENTS

The above initial profiles of the mandates and core tasks of the four case study agencies provide us only with an agency/institutional context to look at RSA activity. We now need to look more closely and analytically at RSA issues and elements by comparing the agencies in relation to the five issues/features set out in this paper's introduction.

Core Decision and/or Risk Assessment and Management Cycles and Volumes of Activity

The first issue regarding the nature of RSA is that of appreciating the core cycles of decision making and risk assessment/management and the volume of activity inherent in those cycles. In a sense the very notion of *cycles* or rhythms of business for the case study agencies is bound to be an inexact designation. It is probably a clearer concept for the two agencies with pre-market product/substance regulatory roles. The nature of the RSA already emerges in that RSA staff interact with mainly firms and commercial organizations and their S&T staff as information and applications are submitted to be assessed. RSA staff draw on their own knowledge and training and also seek out research and related studies to make decisions and judgements about the product, substance, or activity in question. For the two agencies which are RSA practitioners of monitoring, the notions of cycles of decision making are less easily detectable to the outsider. There are certainly notions of regularity in monitoring to obtain consistent data but there are also more complex types of behaviour in answering queries from the public and dealing with clientele and service users which can easily include other governments, employees/workers, community groups, and site-specific towns and cities.

The Water Survey of Canada and the Consumer and Clinical Radiation Protection Bureau as monitoring RSA bodies show the more seamless or embedded nature of decision cycles. The WSC seeks and practices a sustainable monitoring approach and seeks to operate in relation to the six elements of its business framework. The former involves its RSA staff in regionally deployed and site-specific offices and many remote locations. But new technologies and the demands of clients/users are also requiring the WSC to monitor away from sites. The WSC also monitors water level and flows but pressures are emerging about concerns and needs regarding the *quality* of water. Its core business framework also seeks to ensure that RSA activities and capacities are up to date in possessing the right kinds of new computer and information technologies and the ability to deliver data and information to many different kinds of users.

The CCRPB's cycles are also harder to pin down than those of pre-market approval RSA bodies. It brings science "off the bench" to the public domain in various ways. It is after all a *consumer* and a *clinical* radiation protection body. The notion of "off the bench" can mean acquiring it and using it from many published research sources and professional contacts/networks but it can also come from the acquired knowledge, education and training of its staff. The CCRPB obtains access to research about the many radiation and related devices it must monitor and their effects on target populations. Its RSA is brought to bear to draft and develop information documents and guidelines for various clientele groups/populations/users. It also needs and uses RSA to obtain feedback from its inspection system that can be tied back to research that it partly does itself or that other bodies and institutions might do. The CCRPB's cycles and rhythms of monitoring also

vary among the different technologies and product lines of its divisions (e.g. acoustics, electromagnetics).

The New Substances Branch and the Veterinary Drugs Directorate in the first instance have clearer notions of cycles and volume but the different nature of the products each has to regulate make for some differences in how they have to think about their main cycles of business. It is also important to note that though we have cast them in our larger pre-market approval and assessment category for selecting them as case studies in the first place, they are also agencies which have some post-market or other monitoring tasks to perform as well. When firms and product or substance approvals are involved, there is also the inevitable ticking of the regulatory clock. This means that the RSA must be brought to bear in a timely way with time limits for decisions specified.

The NSB has a high volume business to contend with, about 800 submissions per year in the main chemicals assessment process, although considerably fewer (about 10 to 12) for biotechnology substances. It broadly functions under Environment Canada's framework for environmental risk assessment and management and its volume of assessments must be coordinated with Health Canada whose RSA personnel look at the health effects of new substances. Like all pre-market regulators, its staff must also apply its RSA in the context of rules regarding the protection of a firm's proprietary interests. Thus, as it assesses and regulates, it cannot reveal information or data that might publically disclose such interests.

For its part the VDD's notion of core cycles for RSA practice is somewhat less straightforward than that of the NSB. The notion of volume is somewhat more varied because an approval can involve a change of dose, the addition of a new species, or a new veterinary drug per se. But truly novel veterinary drugs are quite rare. As mentioned above, the agency does conduct its assessment work in the context of Health Canada's decision making framework for risk assessment and management. But the VDD also has a growing role in post-market monitoring under the concepts and processes of pharmacovigilance. For this aspect of its work, RSA involves elaborate networks of information and reporting from numerous groups and individuals including farmers, veterinarians, doctors, and milk, poultry, and other food producers. Overall, the VDD's RSA is brought to bear in risk assessment, devising risk management options and decisions, in labelling, in setting residue limits in food, and in suggesting non-regulatory options and approaches.

Nature of External RSA or R&D Partnerships and Dependencies

In our discussion above of the core cycles it is almost impossible not to have to discuss RSA in relation to an agency's external (non-agency) RSA, R&D relations, partnerships and dependencies. This is where our earlier reference to service triads becomes important in understanding RSA from a realistic agency or "bottom-up perspective" rather than the top-down definitional views of R&D and RSA. When properly thought of as "regulatory and monitoring science", RSA is almost always relational and networked. RSA is embedded in the brains, education, training and experience of RSA staff but they constantly have to reach out on a daily basis to other points, people and sources of R&D, other people's RSA, and other kinds of organized knowledge. We saw this in the previous section where the two pre-market regulatory

agencies have primary relations with the R&D and technical staff of applicant companies. But it is equally true that these other sites and sources also need and relate to the RSA of the agencies' front line staff.

Beyond these core relations that lie at the heart of RSA in action, the four case studies show the larger wide array of partnered relations and dependencies to achieve the day-to-day needs of regulatory science and monitoring activity. The Water Survey of Canada calls on and has links with other members of the Canadian Water Resources Association, an organization which contains most of the professional community involved in hydrological activity in the consulting industry and in other governments and firms needing survey data. The WSC's RSA staff also works with and draws on links with the National Research Council (NRC), the Department of Fisheries and Oceans (DFO), Environment Canada's National Water Research Institute at Burlington, and provinces such as Quebec which have an active core expertise and related experience. It operates with U.S. RSA and R&D expertise, including the United States Geological Survey (USGS) through a formal MOU and with U.S. border station personnel, and also through the International Joint Commission (IJC), the joint Canada-US body which manages Great Lakes and other cross-border water resource issues.

The other monitoring-style RSA case study agency, the Consumer and Clinical Radiation Protection Bureau (CCRPB) also works through and with a wide array of sources and sites of relevant complementary knowledge. It has always had to work with manufacturers and distributors of devices even though it does not approve products in any pre-market sense. It often faces situations which arise because of the fact that many devices are not made in total and then sold, but rather the component parts are shipped and the device is then assembled at the site in which it is used. It produces some situations where manufacturers and distributors quite literally do not know as much about their own products as they used to. As we have seen already in our initial profile of the CCRPB, it also works closely with a provincial advisory body and it also has numerous daily contacts with the medical profession and with radiologist professionals and X-ray technicians. Its university network includes researchers at the University of Ottawa. Internationally, there are ever increasing needs to draw on the research, meetings and contacts of the World Health Organization (WHO).

The two pre-market assessment RSA case study agencies also have links with external RSA and R&D sources beyond their core dealings with experts in the applicant firms. The Veterinary Drugs Directorate engages regularly with its core stakeholders to get a regular updated sense of the different risk situations and practices. It works with the veterinary colleges which are of course educating the new veterinarians and also engaged in updating professional practice. In its recent/current work on antimicrobial resistance (AMR) where new risk management strategies have to be developed against a serious health threat, the VDD worked through an advisory multi-stakeholder committee which reviewed national and international scientific reports on AMR (Health Canada, 2002). It also built its AMR evidence base through collaboration with the Health Canada National Microbiology Laboratory in Winnipeg, the Canadian Institutes of Health Research, the provinces and territories, and a formal Canadian Committee on Antibiotic Resistance (CCAR). Internationally, the VDD, on the AMR issue and more generally, is closely tied in with the work of the CODEX Committee on Residues of Veterinary Drugs in Food, the

WHO, and other international regulatory agencies.

For its part, the New Substances Branch (NSB) also has key RSA and R&D links with many players outside the boundaries of its own organization. Links to the US Environmental Protection Agency (EPA) are virtually daily in nature. A growing issue in the nature of RSA in the field of new substances is the EPA's promotion of the use of modelling approaches as a complement and an alternative to direct scientific data as evidence. Designed to support the regulatory process, the use of modelling not only raises key concerns about efficacy and certainty but it also places potential new demands on the training and equipment needed for RSA personnel (see more below). Domestically, of course, the NSB has links with other parts of Environment Canada, Health Canada and some universities with relevant research expertise. Given its core relationship with applicant firms, it also has regular meetings with core stakeholder groups in the chemical and now increasingly the biotechnology industries as well.

RSA Personnel Backgrounds and Competences

The third aspect of RSA that warrants illustrative comment across the four case study agencies is the core backgrounds of RSA personnel and the changing competences needed to meet the changing regulatory and monitoring challenges they face. As previously noted, RSA is not just research related activity. It is also something which crucially depends upon a stock of brain power and experience of front-line assessors and monitoring personnel. They bring their knowledge and skills to bear and they also have capacities to obtain other kinds of research and information.

For the New Substances Branch, core RSA expertise centres on staff with backgrounds in chemistry, biology and engineering. But the expertise must also increasingly involve more detailed regulatory knowledge of particular classes of compounds. As mentioned earlier, there are also greater needs for computer-based modelling skills and competences. It is often difficult for the NSB to find the particular expertise it needs, in part because universities and colleges do not necessarily produce them "ready made" but also because experience and training must be acquired on the job, and because government salaries may not be competitive in attracting the right people. In the NSB's biotechnology mandate, the core competences are more complex as is the information and analysis the assessor has to deal with and interpret. Accordingly, in this growing realm, RSA expertise is harder to attract and retain, given fast-moving R&D changes and opportunities in the private sector.

In the case of the Veterinary Drugs Directorate, the traditional core RSA staff come with backgrounds in chemistry, biology, and veterinary medicine. The VDD has grown quickly from 30 to 80 staff in the last 3 years and continues to attract qualified persons. Indeed, the relative newness of the agency and its composition of many new people, has also meant that it has been able to forge its own culture consistent with its new mandate rather than being bound by a long history of previous program practice. In its work on antimicrobial resistance (AMR), the VDD is developing new risk management strategies against a serious public health threat. To develop a common understanding of AMR from Canadian perspectives, the VDD worked closely with Health Canada's AMR Advisory Committee, which presented its final report following its in-depth review of national and international reports on AMR (Health Canada, 2002). The VDD is

also building the evidence base for risk management decision making through ongoing collaboration with the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) as well as supporting research activities in Health Canada's laboratories. To further address the issue of AMR, the VDD has been collaborating with several international regulatory agencies, such as the US FDA, APVMA, Codex, WHO and VICH.

The Consumer and Clinical Radiation Protection Bureau has a considerably smaller staff complement than the other units being examined, combined with quite diverse kinds of products/devices that it must monitor and on which it must develop consumer/user guidelines. Accordingly, its core competences are more varied. It has staff with backgrounds in radiation biology, electrical engineering, and medical physics. It also needs people skilled at technical inspection. Its inspectorate staff have had to change from an era of "clipboards and ticks on a chart" to one where they have to be more analytical. The need for IT capacities is also crucial for almost all RSA jobs. For years, the CCRPB has also had to acquire persons who could deal with new devices as they came on to the market. This included the emergence of cell phones and also the need to deal with controversies regarding issues such as radio-frequency towers, the various uses and effects of ultra-sound technology, and acoustics and noise as it affects the quality of life rather than outright risk.

The Water Survey of Canada has core RSA competences centred on engineers augmented by considerable staff with technical backgrounds for work in the field. The WSC has gone through a cycle of personnel development in which it started with core engineering backgrounds, added technical capacity, lost some core engineering due to budget cuts in the mid-1990s and then retirements, and then has begun building back more core engineering capacity. The WSC has also had considerable staff continuity. RSA staff who joined tended to stay for their whole careers in the WSC. Numerous training programs were needed to keep staff up-to-date as new computer technologies were used, and, as noted earlier, as user groups demanded more real-time and varied water data. Also as mentioned earlier, RSA staff faced physical risks in field work that resulted in two deaths and the need to develop new technologies for monitoring that were safer in terms of occupational health and safety.

RSA Equipment/Capital Funding and Challenges

The conduct of RSA clearly needs competent people but it also requires up-to-date capital and equipment to enable core tasks to be carried out successfully, whether these are in the context of pre-market approvals or post-market or other general monitoring. RSA typically does not occur in agencies which are "laboratories" in a front-bench science fashion, although the CCRPB's acoustics testing facility is a partial exception to this. But, as we have seen in earlier sections, they do need access to more capital-intensive laboratory facilities either in other parts of their home department, the federal government as a whole, or outside in academic or private research establishments. These larger laboratory operations in the federal government have been subject to quite serious problems of "rust-out" as aging equipment was not replaced or modernized due to budget cuts in the mid-1990s whose effects still resonate a decade later. As indicated earlier, the largest part by far of S&T federal funding increases from about 1997 on have gone to universities, including capital funding via the Canada Foundation for Innovation (CFI) which federal S&T bodies were ineligible to take part in. Our four case study RSA agencies do have

other capital and equipment needs and their experience in getting funding for these needs has varied in recent years. These are basically small-scale and not necessarily big budget needs but they are nonetheless crucial to what they can or cannot do.

The present study did not address this question in any detail but some observations can be made across the four agencies. The CCRPB used to have an explicit capital replacement program but this no longer exists. Accordingly, it has had considerable experience of getting by with quite old equipment for some of its monitoring functions for various devices. Each year represents a struggle to persuade departmental authorities to provide the funding. Its core acoustic lab, however, has tended to be backed with adequate funding. And so the experience does vary across even a smallish agency such as the CCRPB.

The other monitoring-focussed RSA agency, the Water Survey of Canada, has also had capital and equipment needs. We have already seen this in our discussion of its need to massively computerize its monitoring operations and equipment and its data retrieval and data provision services. Recent budgets have begun to address these problems but there is still a considerable distance to go. WSC staff stress, however, that the agency's needs are never just money. Needs also centre technically on exactly what kind of data can be acquired and used.

As for the two pre-market case study RSA agencies, the situation with respect to capital equipment varied. The Veterinary Drugs Directorate seems to have few concerns about this issue. It has sought and obtained core funds but it largely uses its funds to resource R&D from other Health Canada and federal labs. This may simply be another byproduct of the fact that the VDD has almost tripled its staff and been quite well supported overall as the federal government sought to demonstrate nationally and internationally that it was dealing properly with the global controversies of animal health and food chain health and safety links. As with other agencies, it faces continuous needs to upgrade its core IT equipment as technologies change and improve.

The New Substances Branch's main equipment and capital needs focus more on developing greater software modelling capacity to assess substances, and information management and exchange. In the case of the latter, the NSB also experiences significant difficulties in sharing information between the two departments that would aid in implementing its core mandate efficiently. This is a challenge because solutions are constrained by broader IT policies and services of the departments.

Other Dynamics Impacting on RSA Agencies

The above four issues and aspects of RSA in the case study labs represent important features for understanding RSA as it occurs in complex organizational and institutional settings. In this final section we refer to some other dynamics which affect RSA, some of them unique to the agency (and which do not easily fit the first four analytical categories) and some reflecting the larger dynamics of the two parent departments, Environment Canada and Health Canada or of the state of support for government science as a whole.

The interviews with case study agency staff highlighted various unusual or impending challenges that may be more particular to the given agency. For example, the New Substances Branch drew

considerable attention to the pressures to use software modelling as a way to assess toxic or other effects as opposed to animal or other direct tests and data. The Clinical and Consumer Radiation Protection Bureau faces interesting challenges from the additional use of ultrasound where private firms are offering it as new forms of family memorabilia where ultrasound images of a child in the womb are sold but obtained in ways which may subject both mother and child to longer than normal ultrasound exposure. The Water Survey of Canada interviews tended to bring out the degree to which the survey and monitoring work is geographically dispersed and remote and also the new challenges of work at existing sites but also increasingly *away* from these core sites. The Veterinary Drugs Directorate interviews brought out the positive impacts that simply arose from the fact that it had recently become a Directorate rather than its former status as a bureau. It had also received a significant political impetus for new resources and a new organization in the fall of 2000 when a quite critical European Union audit of the Canadian system of veterinary drugs had been made public and got significant media attention.

This latter VDD example points to a larger dynamic which we can only take note of but which is often quite important for different agencies. This refers to the factors which might trigger budgetary and political support or produce new political lenses though which such issues might be viewed. The VDD profited from a public controversy as new resources were sent its way both from Health Canada and from the central agencies. The WSC had its work indirectly impacted by the Walkerton inquiry into drinking water in Ontario. New attention was brought to the issue of water quality but also to linked issues of water flows. Recently, the Ontario Government approved funding to expand the water quantity network in direct response to the issue.

In an overall sense, all four agencies have to be seen in the context of the larger set of sister agencies in their parent departments all competing for scarce resources and all seeking attention and support "up the line". This paper cannot deal with these detailed dynamics but it is certainly the case that they play a role in the perceptions of agency RSA staff about whether RSA activity is generally appreciated or understood by those further up the departmental hierarchy. Within the four agencies there is certainly a high degree of scepticism about whether RSA is properly understood and whether there is sufficient political and budgetary support and recognition for this as a crucial and growing aspect of federal S&T.

The five issues and elements explored across the four case study agencies are only initial samplings of what RSA actually involves. But they do provide a closer look at RSA through a brief analysis of decision cycles, core relationships, RSA personnel capacities and needs, and technological features and funding issues as well.

CONCLUSIONS

The purpose of this paper has been to examine the nature and role of Related Scientific Activities (RSA) in federal S&T policy through case studies of four federal science-based agencies. The analysis has been set in the context of larger federal discussions on S&T policy, innovation and the role of government S&T, as well as science-based regulation and smart regulation. The paper has explored the meaning of RSA first in a definitional sense and then by relating the "top-down" definition to the nature of RSA in the four case study agencies.

It must again be stressed that the paper is very much a stock-taking and illustrative analysis. The agency case studies were not intended as studies of the performance of the agencies but rather as illustrative glimpses into what RSA is. RSA is one half of the federal government's S&T but is more than half of its S&T personnel. For Health Canada and Environment Canada, the home departments of our four case study agencies, RSA is of the order of 75 percent of its S&T. Despite this, in terms of official federal definitions, RSA seems at times to be a leftover category, not R and not D but somehow still involving science. Moreover, as we have argued, the designation RSA does not immediately help to describe what the activity is and what it is "related" to. The implication is that RSA is related to R&D, but there is no suggestion to its more definitive functional relationship: providing the basis for government policy, monitoring activity and regulation.

The most general conclusion of this analysis is that RSA is a critical feature of public-interest monitoring and regulation. Far from being an afterthought or something that is simply "not R&D", RSA is the quintessential core of government S&T necessary to enable the state to regulate and monitor and manage risks in the public interest. In pure definitional terms, the current definition of RSA is misleading in conveying what is actually involved. RSA is without doubt related to R&D. But it is also at the heart of regulatory and monitoring activity and hence to the core public-interest tasks within the role of government.

The four case studies illustrate more clearly what RSA is. The complex set of service-oriented and regulatory tasks emerge quite clearly. RSA involves: the direct assessment of product proposals and applications; the enforcement of rules; the drafting of guideline documents for any number of Canadian client groups and users of products; post-market monitoring of products once they are on the market; the monitoring of activities and impacts of environmental and health hazards and risks at numerous discrete sites and locations, many remote and dangerous; the tendering of advice to professional groups; and the exchange of knowledge and information with international bodies and fellow RSA practitioners in other countries and jurisdictions.

The analysis has shown that the case study agencies vary as to the mix of pre-market regulatory and monitoring activities they undertake and to the volume of decisions they must manage. Regulation is a task that involves both the enforcement and sanctioning authority and power of the state, but regulation also involves numerous service relationships as well. The varied RSA tasks need to be cast in ways similar to the manner that services and service relationships and innovation are being viewed in the private knowledge-based economy, namely as varied triads of service relations including the service provider, the service client, and the service medium. The

case study agencies operate very much in this kind of complex relational world: RSA emerges out of the education, training, knowledge and experience of front-line assessors and monitoring personnel, and out of their ability and the agencies' ability to obtain timely inputs from R&D and other kinds of knowledge sources. It also depends on capital equipment and technologies that are constantly changing.

The federal government is certainly not internally unaware of the importance of RSA and indeed on a yearly basis it makes more and more legal and policy-regulatory commitments requiring more of it. But in public debates, in funding, and in its core publications about federal S&T and innovation policies, the federal government basically obscures RSA and deliberately and seriously underplays it. RSA is simply not central to its larger S&T and innovation policy storyline which favours overwhelmingly academic and private sector S&T and innovation rather than the S&T needed to underpin the public-interest monitoring and regulatory tasks that government must carry out.

The smart regulation agenda of the federal government has so far not been much clearer about where RSA fits in. RSA again is the unmentioned non-subject in the smart regulation debate. But RSA is at the heart of whether government can actually regulate "smarter", that is, can regulate with continuous innovation in mind, coupled with the need to effectively and transparently ensure the health and safety of Canadians and the sustainable development of the Canadian economy and society.

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