

RULE OF LAW

INSTITUTE OF AUSTRALIA

RoLIA SENATE

ESTIMATES SURVEY:

AUSTRALIAN COMMUNICATIONS & MEDIA AUTHORITY
THERAPEUTIC GOODS ADMINISTRATION

OCTOBER 2010

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INTRODUCTION

The Rule of Law Institute of Australia publishes this report on the survey of two important regulators that were not covered in the main survey released in August 2010.

The Therapeutic Goods Administration (TGA) covers regulation of such important issues as medicines, medical devices, blood and tissues and is a part of the Department of Health and Ageing. It has a public health mandate of safeguarding public health through the effective and timely regulation of therapeutic products. The TGA regulates prior to a product being released to the market as well as after it is released, when the TGA will investigate reports of problems and monitor the product.

The Australian Communications and Media Authority (ACMA) is a federal statutory authority that regulates broadcasting, the internet, radiocommunications and telecommunications. The ACMA had a budget of 95.316 million in 2009-2009. It also collects revenue through licensing, taxes and other non-regular revenue. The ACMA manages content as well as access to the Internet, radio and TV and represents Australia's interests internationally.

This report sets out the results of a survey into the Estimates hearings of these Regulators from February 2009 till June 2010. Please note that the ACMA participated in hearings in May, but those Budget hearings are collectively known as the "June hearings" as most regulators are heard in June. When the October 2010 Estimates hearings occur, these Regulators will again be surveyed and included in the main RoLIA survey.

RoLIA

The Rule of Law Institute (RoLIA) is an independent non-profit association formed to uphold the rule of law in Australia. RoLIA has a keen interest in the conduct and outcomes of Senate Estimates. It receives no funds from the Government.

RoLIA's objectives are:

- To foster the rule of law in Australia.
- To promote good governance in Australia by the rule of law.
- To encourage truth and transparency in Australian Federal and State governments, and government departments and agencies.
- To reduce the complexity, arbitrariness and uncertainty of Australian laws and administrative application.

WHAT HAPPENS AT THE ESTIMATES HEARINGS?

Regulators are accountable to the Parliament on their operations and activities three times each year at the Estimates hearings of the Senate Committees. Senators are entitled to ask questions of regulators' head personnel; Senate Standing order 26(5) provides that the committees 'may ask for explanations from ministers in the Senate, or officers, relating to the items of proposed expenditure.' This is done after the budget comes out (May/June), again after the supplementary budget (October) and if necessary after additional Estimates come out (the following February).

There are several permanent Senate committees, known as 'standing committees'. The standing committee system was brought in to subdivide the Senate, as the whole cannot do it all.¹ The plan was that the Senate would become more efficient as it could deal with more work.² The Committees conduct Estimates hearings into their areas of speciality.

The two Committees considered in this report are the Senate Standing Committee on Community Affairs (TGA) and the Senate Standing Committee on Education, Employment and Workplace Relations (ACMA).

Whilst Senate Estimates hearings are held in public session, they are in some ways restricted or closed inquiries. This is so because they do not take written submissions from the general public and witnesses giving oral evidence are drawn only from the ranks of personnel employed in the Federal Public Service and its agencies.

Odgers' Australian Senate Practice 12th edition provides a very comprehensive guide to Estimates;³ describing them as:

"Estimates scrutiny is an important part of the Senate's calendar and a key element of the Senate's role as a check on government. The estimates process provides the major opportunity for the Senate to assess the performance of the public service and its administration of government policy and programs.

¹ Senator Murphy, Senate Debates, 4 June 1970, p 2050.

² Ibid.

³ <http://www.aph.gov.au/senate/pubs/odgers/chap1618.htm>

It has evolved from early efforts by senators to elicit basic information about government expenditure to inform their decisions about appropriation bills, to a wide-ranging examination of expenditure with an increasing focus on performance. Its effect is cumulative, in that an individual question may not have any significant impact, but the sum of questions and the process as a whole, as it has developed, help to keep executive government accountable and place a great deal of information on the public record on which judgments may be based.

Procedures currently applying to the consideration of estimates are as follows. Twice each year, particulars of proposed expenditure and tax expenditure statements are referred to the committees. The particulars are derived from the two sets of appropriation bills normally introduced twice each year. Portfolio Budget Statements, tabled in May, and Portfolio Additional Estimates Statements, tabled in February, assist the committees in their examination of the particulars. Statements of expenditure from the Advance to the Minister for Finance are also referred to the committees. For the consideration of additional estimates in February, committees also have access to other budget statements tabled with the particulars. Annual reports of agencies, required to be tabled by 31 October, are also available for consideration in the context of an agency's performance over the previous financial year."

While the Estimates are not the only oversight mechanism to which our regulators are subjected, they are, unarguably, the most important. Other examples of oversight of regulators include ASIC oversight via the Parliamentary Joint Committee on Corporations and Financial Services and the Economics References Committee which from time to time conducts hearings into certain matters including taking evidence from the regulatory agencies.

METHODOLOGY

The transcripts of the Estimates hearings were studied. Information gleaned from these reports was then put into Microsoft Excel files and compared.

We have selected to consider:

- How many *questions were asked of each regulator;
- Which Senator asked these questions;
- How long were the opening statements read out by each regulator;
- How many of the questions could not be answered and/or were put on notice;
- How long it takes for each regulator to answer questions taken on notice;
- How many written questions on notice were submitted; and
- The length of each oral examination for each regulator.

****Meaning of 'question'***

A 'question' is defined as a statement or question spoken to elicit a response from a regulator. This means that statements to other Senators or the chair are not included; nor are statements such as "I agree" or "I accept that" as they are not spoken to elicit a response. Requests to repeat answers are not included, nor are statements of thanks or welcome. More on the meaning of 'question' is contained in RoLIA Senate Estimates Reports 1 & 2.

OBSERVATIONS

Opening Statements

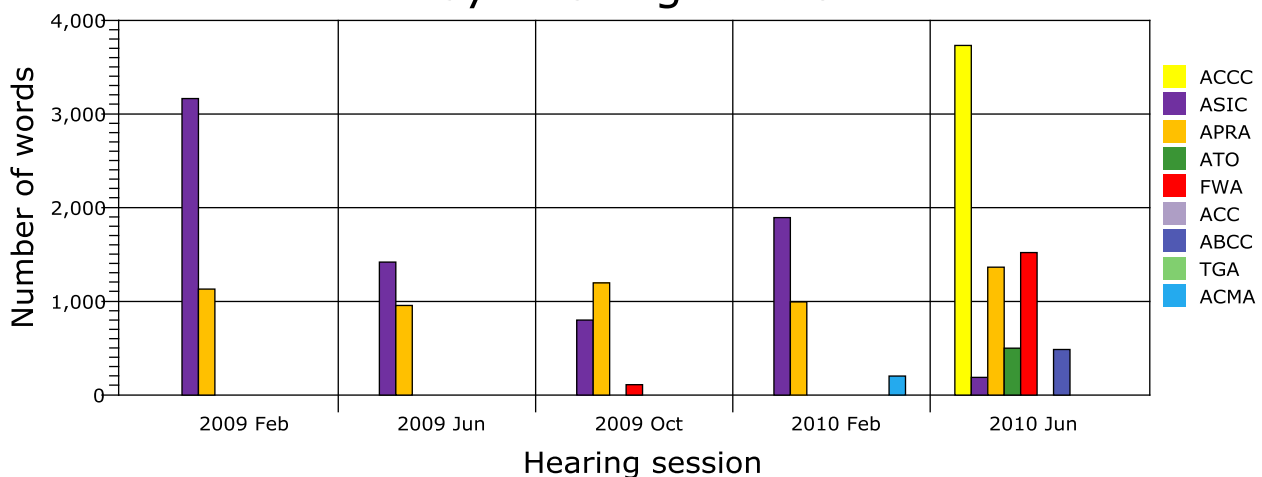
Opening statements can be very significant, especially if they take up much of the time allocated to a Regulator. This reduces time for Senators' questions. They are often useful in answering anticipated questions in a shorter amount of time.

The TGA did not use an opening statement in any of the hearing sessions surveyed. This is quite important as the TGA is given very little time in its hearings and by not speaking an opening statement have given themselves the maximum time for questions.

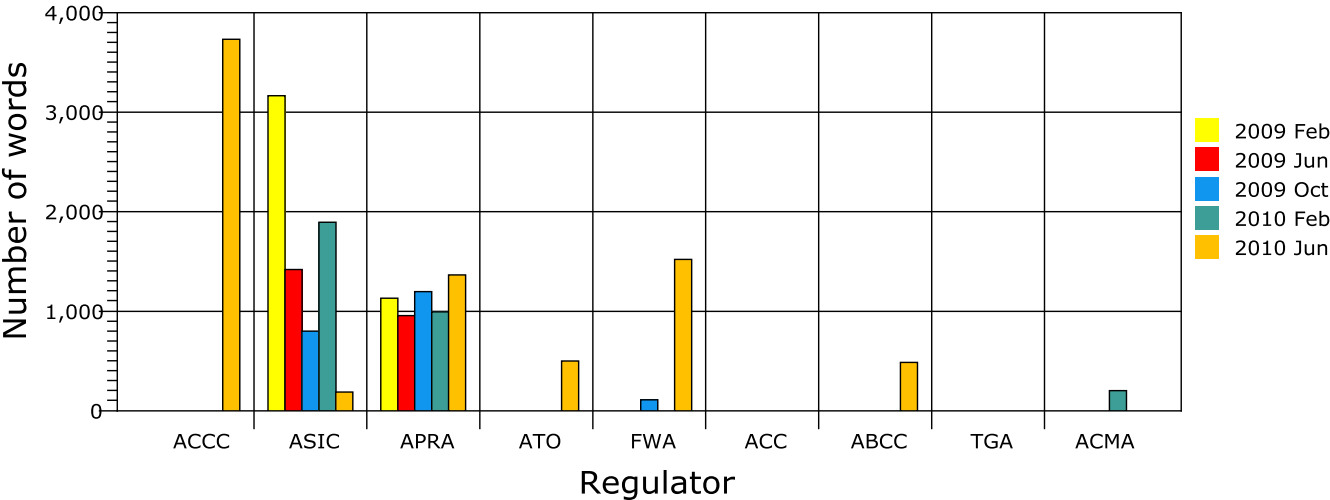
The ACMA used a short statement in February 2010, which covered a restructure of the ACMA and new appointments. All other surveyed hearings did not include opening statements.

As a comparison, the Regulators surveyed in the main Estimates reports have had their results included.

Length of opening statements:
by Hearing session



Length of opening statements: by Regulator

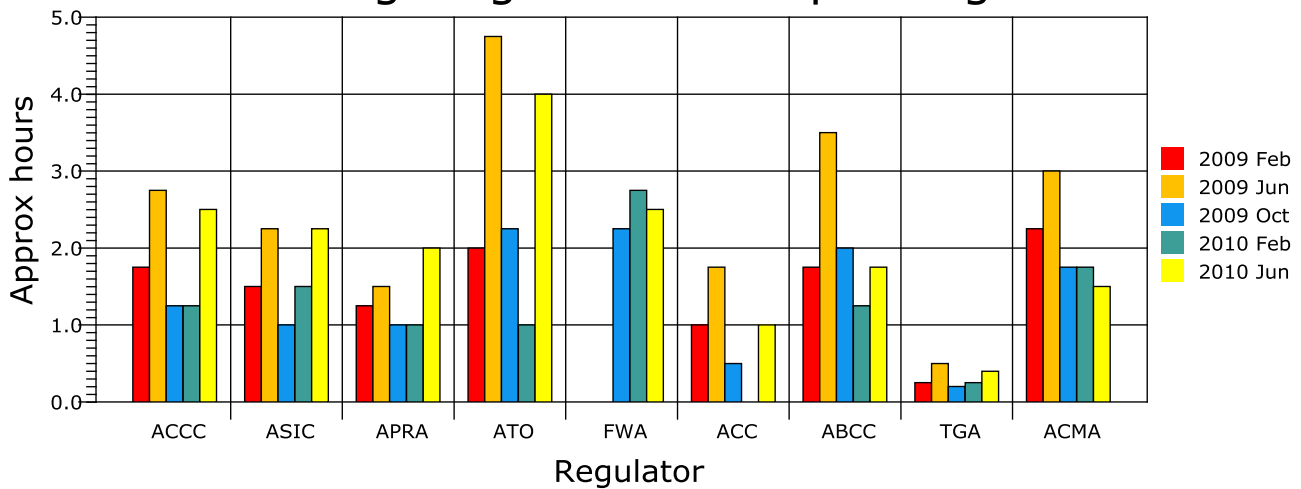


Allocation of time

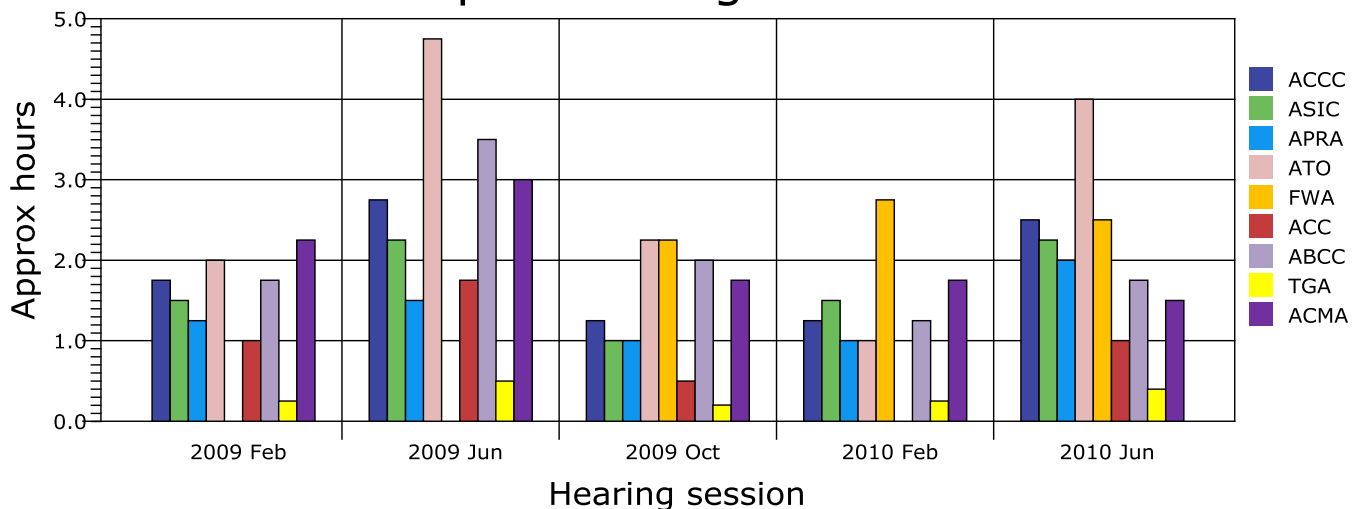
The TGA has very short hearings compared with other Regulators. As seen later in this report, they often receive many written questions on notice, which could indicate they need more time.

The ACMA receives similar time to those of the other Regulators, though its time has decreased over the survey period: it has had a large decrease in June 2010 compared to June 2009, and a smaller decrease from February 2009 in February 2010.

Hearing length in hours: per Regulator



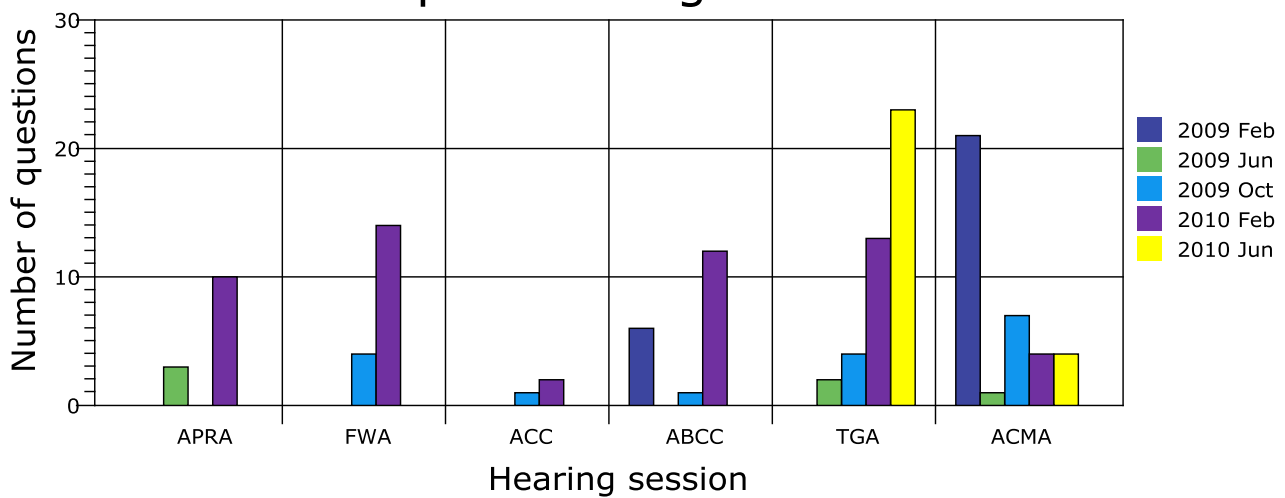
Hearing length in hours: per Hearing session



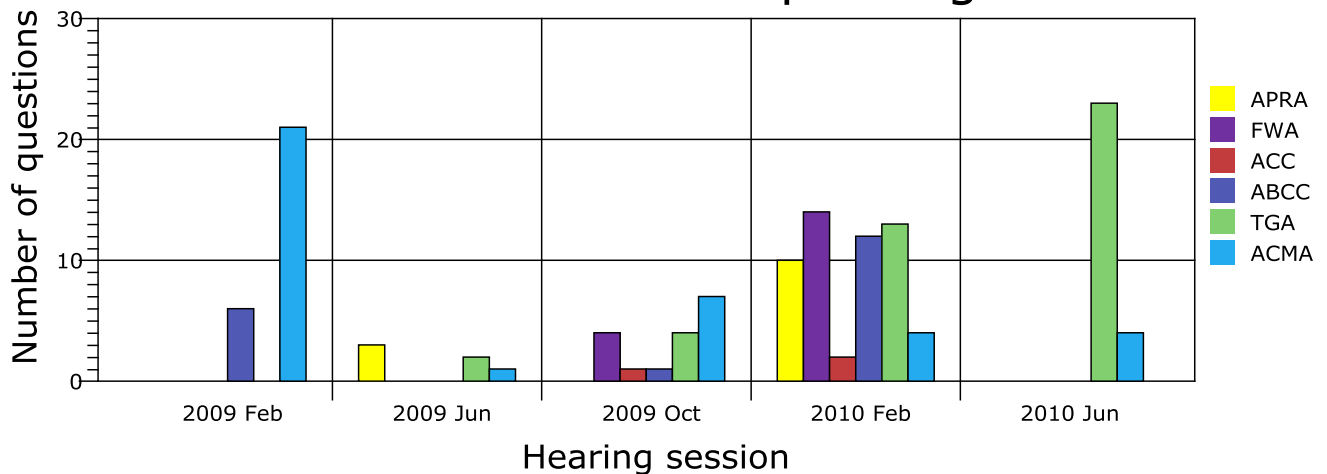
Written questions on notice

Both the ACMA and the TGA receive written questions on notice, with the ACMA receiving quite a large number in February 2009 and the TGA receiving their largest number of questions in June 2010. Written questions on notice are generally submitted when time has run out or at Senator's discretion.

Number of written questions Submitted for notice per Hearing session



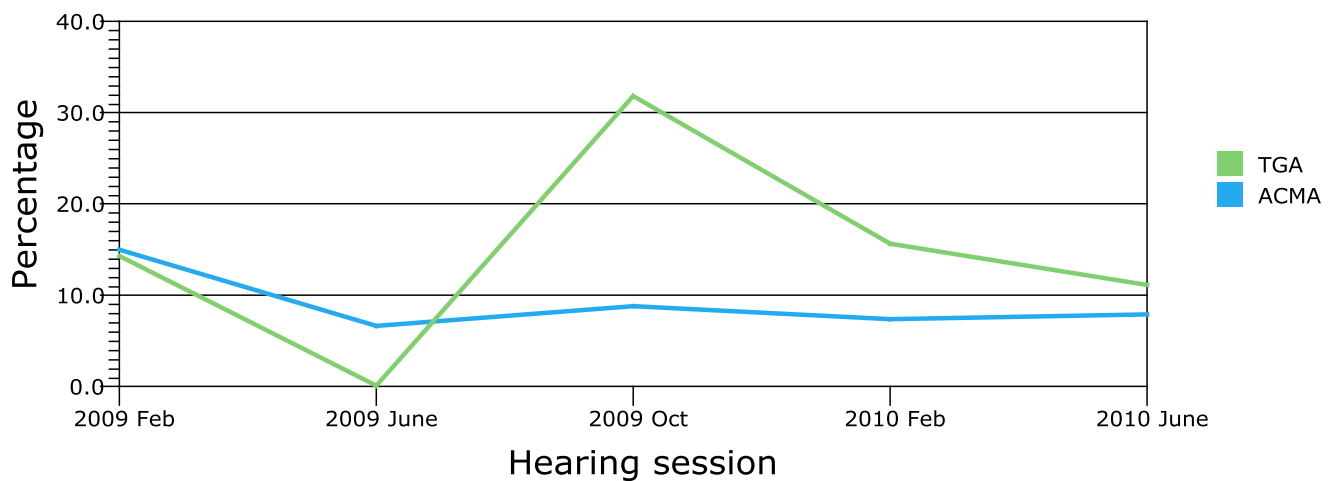
Number of written questions submitted for notice per Regulator



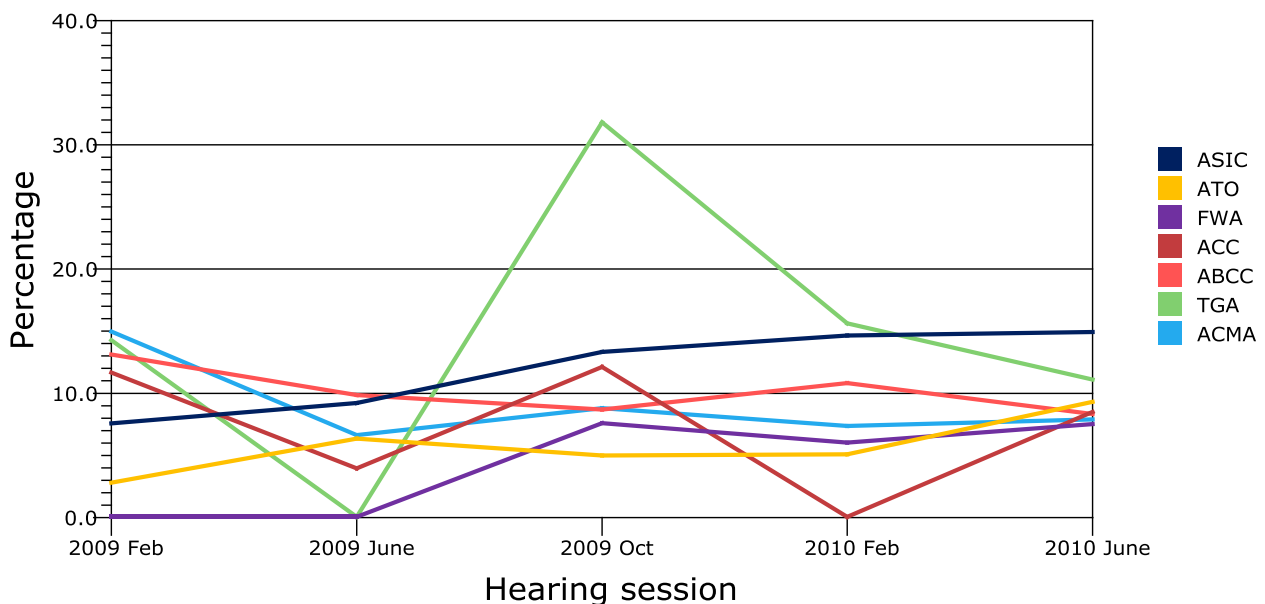
Differences in rate of taking on notice

The TGA's rate of taking questions on notice significantly varies, with them not needing to take any on notice in June 2009 while taking a great deal of questions on notice in October 2009. The ACMA does not have quite the disparity in rates, and as viewed in the second graph takes questions on notice at a similar rate to the other regulators.

Percentage of questions that were taken on notice: TGA & ACMA



Percentage of questions that were taken on notice



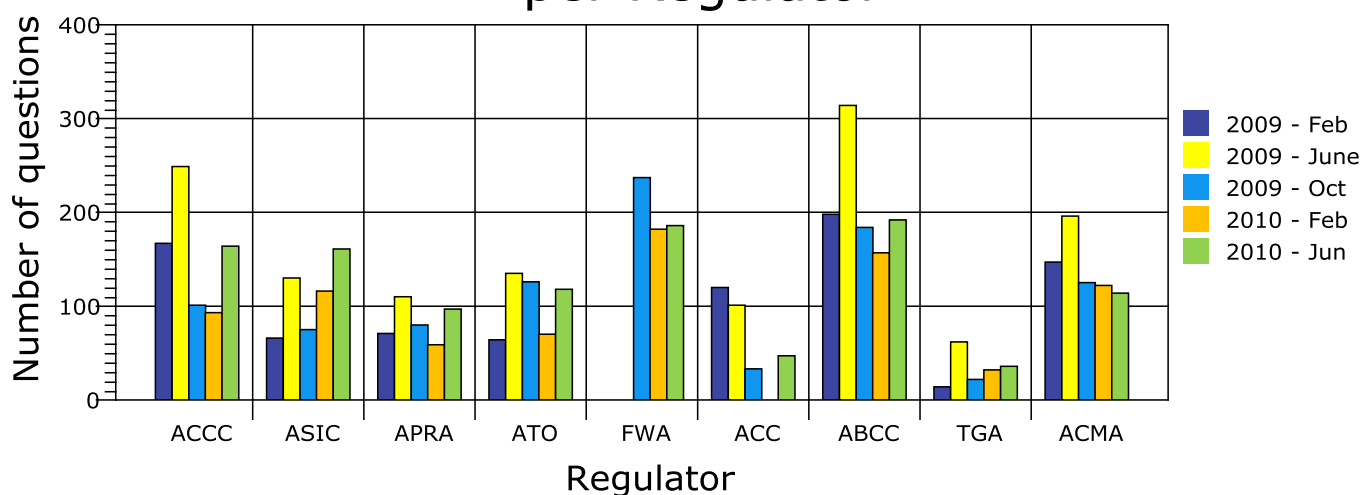
Differences in rate of questions asked

There are many variables which cause more or less questions to be asked when comparing a Hearing session to its previous year, such as long opening statements, longer questions and irrelevant comments and questions not directed at the regulator. Only very general observations can be made because of these variables.

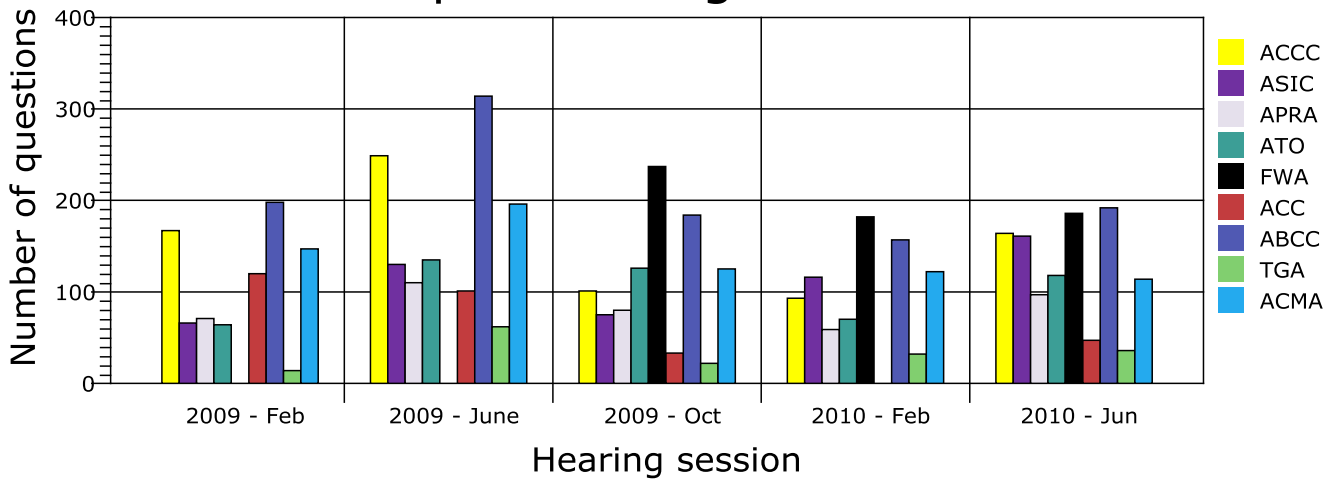
For example, the ACMA did not receive as many questions in June 2010 compared to June 2009, and this may be explained by the drop in time allocated for their hearing. They also received fewer questions in the shorter February 2010 hearing compared with February 2009, with the inclusion of an opening statement in February 2010 also having the potential to reduce questions.

The TGA's short time allocation results in them being asked far fewer questions compared with other regulators. They also took less questions in June 2010 compared with the previous June.

Number of questions asked: per Regulator



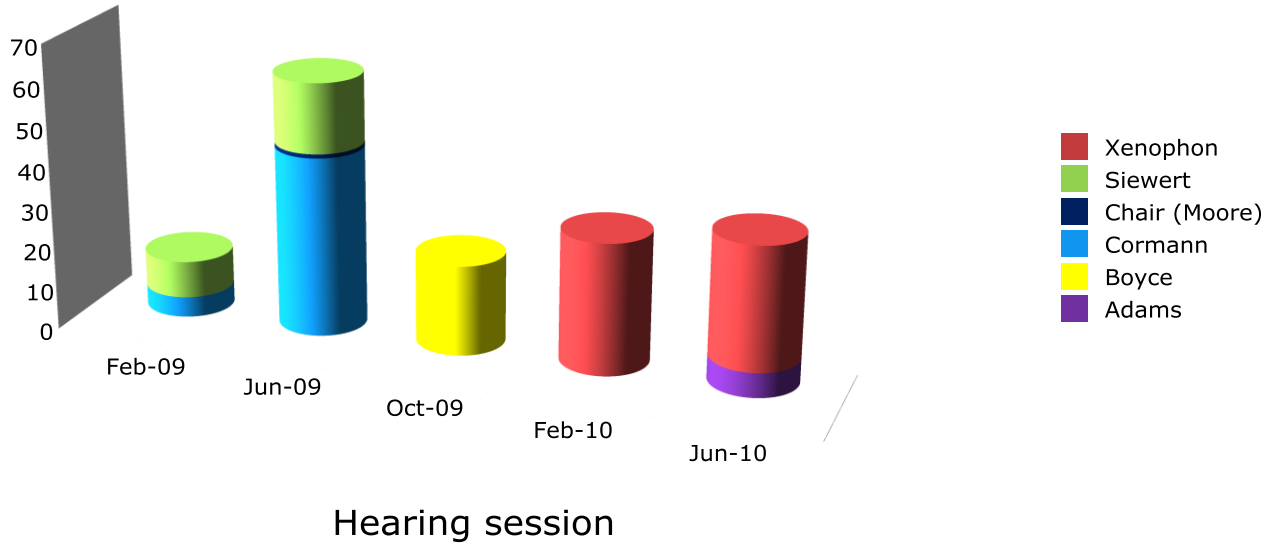
Number of questions asked: per Hearing session



Which Senators focus on which regulators?

Senators who question the TGA

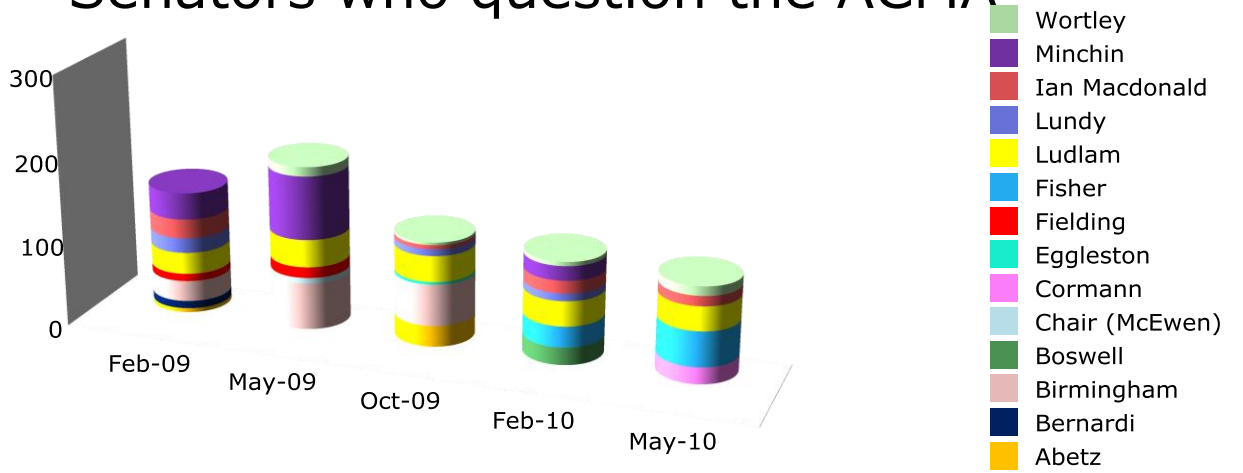
Number of questions



	Feb-09	Jun-09	Oct-09	Feb-10	Jun-10
Adams	0	0	0	0	6
Boyce	0	0	22	0	0
Cormann	5	44	0	0	0
Chair (Moore)	0	1	0	0	0
Siewert	9	17	0	0	0
Xenophon	0	0	0	32	30

Senators who question the ACMA

Number of questions



Hearing session

	Feb-09	May-09	Oct-09	Feb-10	May-10
Abetz	5	0	25	0	0
Bernardi	9	0	0	0	0
Birmingham	25	56	50	0	0
Boswell	0	0	0	21	0
Chair (McEwen)	0	7	0	0	0
Cormann	0	0	0	0	20
Eggleston	0	0	3	0	0
Fielding	9	13	0	0	0
Fisher	0	0	0	25	42
Ludlam	26	33	31	30	29
Lundy	18	0	8	9	0
Ian Macdonald	23	0	5	15	12
Minchin	32	76	0	17	0
Wortley	0	11	3	5	11

RULE OF LAW VIGNETTES

ACMA

May 2010

Senator IAN MACDONALD—So, it will not be before the election. Mr Chapman, bearing in mind what the minister has indicated, has ACMA been doing any work towards the installation within Australia of an internet filtering service as proposed by the government in a policy sense? Have you been doing any work towards it?

Ms O’Loughlin—I will defer to my colleague Ms Booyar as well. We certainly are aware that currently we are enforcing the current legislative provisions under the Broadcasting Services Act, which allows for our material that we have found to be prohibited content to be passed to the filter providers, who provide those to people at no cost. We recognise that the move to mandatory filtering will require some significant changes to our current processes.

The minister has indicated that the government has been consulting on transparency and accountability arrangements, and we have obviously been in discussions with the department about how those accountability and transparency arrangements would flow through if the government agrees to them. Certainly we have looked very carefully at some of our security arrangements for the list. When we move from a system that has been on a voluntary basis to a mandatory basis, we are aware that there will need to be stronger security around the list and how that is transferred to a larger number of ISPs. That is the type of background work that we have been doing.

Senator XENOPHON—You said if you ‘receive a valid complaint’. Would it be defined as a valid complaint if there had been published either images mocking the death of someone or images of a deceased person who was murdered? Is that the sort of thing you would have jurisdiction to act on?

Ms Booyar—Yes. A valid complaint basically needs to have a name, a URL about which that person is complaining, and why they think it is prohibited content.

Senator XENOPHON—You may want to take this on notice. In terms of complaints that you have had, say, in the past 12 months, what volume of complaints do you get and under what circumstances do you act in relation to those complaints?

Ms Booyar—I can take that on notice in broad terms, but since the scheme was introduced we have had more than 10,000 complaints and we have actioned about 8,000 complaints in the last 10 years.

Senator LUDLAM—Can you tell us, under the system that we have currently with the blacklist, when you receive a referral from the public, how long does it take to get from the referral to the stage where it is being evaluated, refused classification and put on the blacklist for content?

Ms Booyar—When we receive a complaint it normally takes us one or two days to refer it—if we feel that that complaint is at the RC level or prohibited content level—to the Classification Board. It can take between five and 20 days for us to receive the classification. It would probably take around about 20 to 25 days.

Senator LUDLAM—So one to two days for a referral to the board or in the event that you judge it does not need a referral because it is pretty obvious where it lies then it can take up to five days. As I usually do, I am just going to ask whether you can provide us with a breakdown of the current blacklist as it stands at the moment by category.

Ms Booyar—As at 30 April our current prohibited content list contains 1,421 URLs. Of those URLs, 54 per cent are refused classification items; 37 per cent are X18+ items; nine per cent are 18+ items, which are not subject to restricted access.

Senator LUDLAM—I would like to go to the 54 per cent, which is roughly 700 URLs, that are in the RC bracket. What proportion of those are related to children or child sexual abuse material?

Ms Booyar—Thirty-one per cent would be related to that.

Senator LUDLAM—At the risk of the minister tipping a bucket on me, is that the origin of the sorts of numbers that you quote around 355 child porn websites? Is that roughly the number?

Ms Booyar—At the moment it is 435.

Senator LUDLAM—That is fine. I am not seeking that, because I realise they are getting referrals from the public, which is not the same as when something first goes online. What I am wanting to know is when it is first going up on the blacklist to the point that it disappears because of law enforcement or for whatever reason it has gone. Are these the same sites that are hanging around for months and years at a time? You must be able to tell us what the turnover rate is on the blacklist rather than on the web itself.

Ms O'Loughlin—We advised that we do not have any automated monitoring of the URLs on the list, so it is difficult for us to do that breakdown. I can say that in general we review the list on a very regular basis, and so you will find that things come off, some material is not there when we actually go back to look at it, and other material may have been removed by the site owner when we get to it. We do not have an automated one and, therefore, it is difficult for us to give you any further detail on that.

Feb 2010

Senator BOSWELL—What role did the ACMA play in having removed from the draft code the requirement for a member of the public to have actually viewed a program in order to register a complaint?

Ms O'Loughlin—The role of the authority is to make sure that the code meets a number of tests, including that it provides appropriate community safeguards. We did not agree with Free TV that the removal of that clause was appropriate because we consider that a complaint is just a prompt for inquiry for us. We consider that it is not necessary for somebody to have viewed or listened to a program to be able to come to us with a concern.

Senator BOSWELL—I think you would concede that the code is weaker now than it was before. My question is: why did the ACMA effectively ignore the concerns of a large number of Australians in approving a new Free TV Australia code of practice with significantly weaker standards when people, including the minister, wanted these standards strengthened?

Mr Chapman—That is a proposition you have put to us that the authority would not agree to. We do not consider—

Senator BOSWELL—You do not think the standards are weaker?

Mr Chapman—We do not concede that the code is weaker. We could presume that in the sense that it offers fewer consumer safeguards—

Senator BOSWELL—You concede—

Mr Chapman—Like all considerations of codes there are lots of checks and balances.

There are a lot of new initiatives that need to be dealt with. The introduction of the digital channels needed to be addressed. There were a number of major safeguards introduced into the code on this occasion: electronic dealing of complaints, the protection of participants in reality programs, a very significant provision to encourage broadcasters to correct significant factual errors in a timely fashion and the strengthened classification criteria for sex and nudity in MA programs. They were significant consumer enhancements in this code. At the same time, the code needed to deal with the introduction of the digital channels. The authority, consistent with the exhortations contained in the explanatory legislative material at the time of the introduction of those amendments in 2006, sought to be flexible in the way in which it addressed the multichannels in their initial phase. When we worked our way through all those permutations we came up with a code that we were satisfied we could register prior to that. In part, the code took a long time to work its way through the system—the system being the interaction between Free TV, their stakeholders and their engagement with us— because there are a number of complex matters to deal with. At the end of the day we feel comfortable with the final position we came up with in the code. I

do not agree with your proposition, nor do I make the concession, that it is fundamentally a weaker code as a result of those consumer safeguards that we introduced.

...

Senator BOSWELL—You have a minister sitting beside you who is taking on a mammoth task to clean up the internet and it seems to me that you are weakening this code by allowing advertising of MA products on kids programs. To me it does not seem as strong as the previous code.

Mr Chapman—I would put to you that, with respect to all the elements that you might raise as constituting a weakening, we sought to address and build in caveats and qualifications to that in a way that provided some appropriate checks and balances on the matters that you are no doubt alluding to.

When weighed as a totality of debits and credits, if you like, in the whole code process, we think that the four principal consumer/citizen safeguards that I have touched on do not ultimately represent any diminution in the strength of those codes.

We think the authority has been very resolute and consistent in its approach with Free TV and that that consistency is borne out in a number of benefits that have been derived; in particular I will refer again to the introduction of electronic complaints for commercial free television.

...

Senator LUDLAM—Yes. If this is not your area, that is fine and I will move on. Does the ACMA have a policy research capacity at all? Is that part of your brief?

Mr Chapman—The ACMA does have a comparatively extensive research and analysis capacity, yes.

Senator LUDLAM—Is there anything you can point me to that would illuminate the question of accidental or inadvertent exposure to refused classification material online? Is there any evidence pointing to the frequency with which that occurs?

Mr Chapman—Are you talking in the occupational health and safety capacity of those classifiers who work for the ACMA?

Senator LUDLAM—No, although that would probably be a really interesting line of questioning. What is the likelihood of Australian children online stumbling across refused classification material inadvertently or by accident?

Ms O'Loughlin—We do not have any research internally but that might be a question you could also ask the department, which has recently undertaken some research that might touch on that.

Senator LUDLAM—I think they might have done; we are meeting up with the department later in the day. So, there is nothing that you are aware of that you have either commissioned or come across recently that would be relevant?

Ms O'Loughlin—No.

Mr Chapman—No, but you having put the question to us we will see what we are aware of.

Ms O'Loughlin—Of course, apart from the complaints that have come to us where people have come across material online and reported back to us as being of concern.

Senator LUDLAM—That would certainly give you some kind of record, I suppose, but I am just wondering whether there has been any kind of either quantitative or qualitative research at all—but I guess you will take that on notice. Have you been directed by the minister to undertake any such research?

Ms O'Loughlin—No.

...

Senator LUDLAM—In the last few iterations of this process I have asked you to table a breakdown of the material that currently lies on the black list. Could you give us a very brief overview? Maybe in order to not tie up the committee's time I would ask you to table anything supporting that?

Mr Chapman—We are happy to table it. We have got a brief shorthand, if you like.

Ms O'Loughlin—I can give you a summary. The last data I have is from 30 November.

The list at that stage contained 1,254 URLs of which 51 per cent were refused classification items, 40 per cent were X18+, 8 per cent were R18+ and there were no MA15+ without a restricted access system items on the list.

Senator LUDLAM—My understanding was that last year subsequent to the leaking of the black list you actually suspended distribution of that list to filter providers. How long did that suspension go for and can we presume that that was lifted during the course of last year?

Ms O'Loughlin—I will seek some advice on that. It went for some months, approximately about six months.

Senator LUDLAM—Has that been lifted now and you are back to business as usual?

Ms O'Loughlin—Yes, for those filter providers that we were satisfied that they had appropriate security in place.

...

Senator LUDLAM—My last question is a research one. You may direct me to the Australian Federal Police. Do you have any idea what proportion of the child sexual abuse material that is online, in total, is available on the public internet, thus subject to the kind of filtering that we are discussing, as opposed to the proportion available on the dark net essentially—encrypted networks, peer-to-peer networks and so on?

Ms O'Loughlin—That is probably something that the AFP, who are dealing with the actual crime scene called Child Sexual Abuse Online, would be better placed to comment on.

Senator LUDLAM—It is not research that you conduct or are aware of?

Ms O'Loughlin—It is not research that we conduct. As I said, we can only indicate that material that comes to us as complaints, either from the public or from the police themselves.

...

Senator MINCHIN—I want quickly to come back to this issue of classification and raise with you correspondence you have had with Mr Mark Newton with respect to the availability to minors of MA15+ movies via the i-Tunes online store using gift cards, which is of some concern. Mr Newton, I declare, is a constituent of mine resident in the state of South Australia. He complained to you in January of last year about this matter and got a response from Mr Richard Frazer in September of last year. Is there someone at the table who is familiar with this case and who can answer questions on it?

Ms O'Loughlin—Yes.

Senator MINCHIN—Could you indicate to me why it did take eight months to deal with this matter and respond to Mr Newton?

Ms O'Loughlin—It certainly was a longer time frame than we usually have for our online complaints, but it was a very technical investigation which came to looking at the ACMA's restricted access system declaration which we did in 2007. It was really the first time that we had an investigation before us that went to looking at whether or not that restricted access system determination was being complied with by the provider of the service. In our defence, I would note we did about another 700 investigations during that period, so it was not as if we were only focused on this particular investigation. It also took quite a long time because we had to gather quite a lot of technical information about how the system actually worked, what measures were put in place by i-Tunes, whether in fact those technical aspects that had been put in place by i-Tunes complied with that determination. There were quite complex legal issues arising as well. Sometimes when we have a first investigation it does take us a little longer because we are testing all of these things. We think that we did a very thorough job on the investigation. As I said, we continued our work in other areas while we were on the case.

Senator MINCHIN—It was not the determination of the content as being prohibited content that was time consuming, it was more this issue of the restricted access system which they are required to have in place?

Ms O'Loughlin—MA15+ without an appropriate restricted access into the system is currently prohibited content.

Oct 2009

Senator BIRMINGHAM—Ms O'Loughlin, in that nine-day period, did the ACMA observe requests for donations to the al-Emdad charity?

Ms O'Loughlin—We looked at the content, which included material involving the al-Emdad charity. But, as I have mentioned, al-Emdad is not a listed organisation.

Senator ABETZ—But do you know what al-Emdad actually collects money for?

Ms O'Loughlin—We understand or it is reported to us that there is some link between al-Emdad and Hezbollah, but that is not something that we as the regulator could opine upon.

Basically, our standard covers listed terrorist organisations. Currently, that includes 'Hezbollah overseas operations' but it does not include al-Emdad.

...

Senator BIRMINGHAM—On the issue of vilification, which is where I was about to go, Mr Chapman, what consequences are there for Australian networks that engage in any form of racial vilification and is there any difference in those consequences for a satellite network such as al-Manar?

Mr Chapman—Would you just excuse me, Senator? The consequences that flow from a breach of the standard is different to what might flow from the breach of a code. In this particular code, there are understandable and necessary constraints on vilification. So, if on the next occasion we find a breach of the code with respect to vilification, the avenues open to the ACMA there are narrower than they are with respect to a breach of the standard. We have many occasions in our broadcasting investigations where we find a breach of the code and we have found historically that that provides fewer immediate remedies for us to pursue than a breach of the standard, and that would be the case here.

...

Senator BIRMINGHAM—What is the worst penalty that can be applied for systematic and ongoing breaches and cumulative breaches of the code?

Mr Chapman—In the ordinary course and in the ordinary commercial television broadcasting sense, consistent and repeated breaches of the code lead to one of two outcomes:

a discussion with the particular licensee or network encouraging them to provide us with an enforceable undertaking that is detailed and prescriptive and seeks to go to the heart of the matter to redress behavioural issues within the licensee or network—that has been an increasing trend with the way we have liaised with licensees and networks, and there have been a number of examples of that over the last two years in particular—or, in the absence of an enforceable undertaking being offered or with the inappropriateness of an enforceable undertaking, as an enforceable undertaking is not a magic bullet for all circumstances, we would seek to impose a licence condition on the licensee. More serious consequences would then flow from any subsequent breach of the licence condition, which in the ordinary course would probably reflect in a licence condition what exists in a code provision.

....

Ms O’Loughlin—I can provide that to you now. As at 30 September there were 1,175 URLs on the black list. Fifty-four per cent of those were URLs where we had found prohibited content at the refused classification level. Of that 54 per cent, approximately 33 per cent was child sexual abuse material.

Senator LUDLAM—Was it one-third of the RC?

Ms O’Loughlin—It was one-third of the 54 per cent, yes. Forty-one per cent was X18+ and five per cent was R18+, which was commercial product where there was no appropriate restricted access system in place.

May 2009

Senator WORTLEY—I have some questions that are not on this issue. Would you be able to tell us how many complaints about child sexual abuse material ACMA receives?

Ms O’Loughlin—I am not sure that I have the absolute breakdown in front of me on child sexual abuse images but, for example, the total number of complaints received by the ACMA in relation to online content from 1 July 2008 to 30 April 2009 was 1,002. We have actioned 775 individual child sexual abuse items out of those 1,002 complaints.

...

Senator BIRMINGHAM—Can you tell me how many sites are currently on the ACMA blacklist?

Ms O’Loughlin—At 30 April ACMA’s blacklist contained 977 URLs.

Senator BIRMINGHAM—How does that stand against where ACMA was over the past six to 12 months?

Ms O’Loughlin—That is a lower number than has been the case in the last six to 12 months. As part of our normal processes, we go through a regular process of updating the URL list to get rid of URLs that are no longer there. We have done a recent review of that, and the current list is 977.

...

Senator BIRMINGHAM—Where have you gone in terms of investigating the apparent or alleged leaking of the blacklist?

Ms O’Loughlin—In what regard?

Senator BIRMINGHAM—Referring to the apparent posting on the Wikileaks website of the blacklist back in March this year?

Mr Chapman—We have referred that matter to the AFP.

Senator BIRMINGHAM—Have you been provided with any recent updates in terms of their investigations?

Mr Chapman—No. It was a relatively recent referral. I would not expect to hear for a month or two.

...

Senator BIRMINGHAM—Why was there a delay between the March leaking of the list and the referral to the AFP?

Mr Chapman—I do not think there was any reason for it other than the process that we went through in going through the right protocols and getting the paperwork together and satisfying ourselves it was a matter worthy of referral. We have referred it. It is with the AFP.

...

Senator BIRMINGHAM—One of the government’s policy commitments was to ensure the ACMA blacklist is more comprehensive. I am assuming this is the key means by which that is being achieved.

Ms O’Loughlin—There are a couple of means. We also want to concentrate on raising public awareness of the capacity for the public to complain to us about material that they see online. Obviously, the more things that we are looking at that come to us in the complaints mechanisms available to us the more we can make sure that the blacklist is reflecting community concern.

...

Senator LUDLAM—I will go to either of them because no-one has any way of checking how closely they matched the original, having not seen them. What is the process of getting off the blacklist for somebody who finds themselves on there? Can you appeal your appearance on there or is a site notified? There are a couple of examples that have been used.

Senator Conroy—This is the blacklist that has existed for nine years that you are talking about?

Senator LUDLAM—That is correct, yes. What is the process for getting off that if you are put on it inadvertently or if somebody has hosted material on your website that you were not even sure was there?

Ms O’Loughlin—Generally, if somebody came to us in the first instance to say that they felt that they were on the blacklist for a reason that they did not understand then, of course, we would look at the matter.

Senator LUDLAM—How would they know that they are there? The list is secret and we are not meant to know what is on the list.

Ms O’Loughlin—That is an issue. There are two parts to the scheme itself. Firstly, for those sites we find prohibited located in Australia, their hosts receive a takedown notice, so they are very much aware.

Senator LUDLAM—That is right. It is the overseas hosts.

Feb 2009

Senator BIRMINGHAM—To start with perhaps you could tell us how many URLs are currently on the ACMA black list.

Ms O’Loughlin—We did an update recently. There was a question on notice that looked at the number of sites to the end of November and at that stage there were around about 1,300.

We constantly have a look at those because obviously URLs change from time to time. We are constantly reviewing that. My advice is that currently—at the end of January—there are around about 1,100.

Senator BIRMINGHAM—Around about 1,100?

...

Senator BIRMINGHAM—How many staff does ACMA have dedicated to the assessment and classification of websites and the monitoring and updating of the blacklist?

Ms O’Loughlin—It is a shared responsibility in an area which deals with classification issues both in online content and also in broadcasting. There are around about eight people in that area. It is a complaints based system under the Broadcasting Services Act so we respond to and investigate complaints that are put to us.

...

Senator LUDLAM—Over the course of a year or so, the blacklist went from roughly 800 sites to 1,370 or thereabouts in November. I understand that there is a fair bit of churn, so a lot of material that turned up has gone. However, what was the reason for the substantial expansion of that list over that period?

Ms O’Loughlin—I think it is probably a combination of things. It is probably an increase in the complaints coming to us and it probably was not washed as rigorously as we have been doing over the last eight or nine months.

...

Senator MINCHIN—I note that some of the conservative family groups that support mandating filters are great proponents, of course, of the anti-abortion cause. They might be interested to know that anti-abortion sites can be blacklisted.

Ms O’Loughlin—Individual URLs or pages, yes.

....

Senator BERNARDI—I have one other question regarding the blacklist. The minister has referred on a number of occasions to illegal content. You have talked about what is restricted content and about the classifications and things of that nature. Any number of illegal websites or websites with illegal content, which is not limited to visual content, are out there. I am referring to illegal MP3 download sites and things like that. Do you blacklist any of those?

Ms O’Loughlin—We concentrate on the requirements under the Broadcasting Services Act around prohibited content. As I have described previously, they are ‘refuse classification’, X18+ and R18+ with an RAS. They are our main focus of attention. It is a complex area because, under state and territory laws, different types of material may be considered illegal. But ACMA’s major focus with what we are charged with is to look at the online content scheme.

Senator BERNARDI—Thank you. Perhaps I will refer this to the minister: what do you describe as illegal content, Minister?

Senator Conroy—I think there is a very straightforward legal definition for it. In terms of the mandatory ISP filtering that we have been talking about, I would argue that there is a very strong case for blocking RC or ‘refuse classification’ material that includes child sexual abuse imagery, bestiality, sexual violence, detailed instruction in crime, violence or drug use and/or material that advocates the doing of a terrorist act. I understand that we are all engaged in significant public debate around the inclusion of other categories. This is a decision that has not yet been determined and it will be determined, as we have always said, following the live pilot trial to give us advice—

Senator BERNARDI—But surely—

Senator Conroy—if I can just finish—about what is technically feasible. So, as we have said consistently, the RC illegal material under the classification act, not under other arguments that others have put forward, will be included. But no other decision has been made and it will be determined on the basis of the trial.

...

Senator LUNDY—Speaking of that, I am feeling a bit of deja vu myself because I would like you to just go through the issue of the blacklist and why it is not made public. I do recall asking the same questions, I have to say, of the previous government when these laws were being discussed and debated, but I think it is important to make it clear.

Ms O'Loughlin—The Administrative Appeals Tribunal in 2002 looked at considering an application, under the FOI Act, to access the blacklist. It came to the view that it would have a substantial adverse effect on the proper and efficient administration of the regulatory scheme for online content and that the disclosure of such information, on balance, would not be in the public interest. In that regard, the parliament subsequently amended the FOI Act in 2003. The reasoning was that in the offline environment, if a book or a film is refused classification under the same classification scheme or is assigned a restricted classification, the distribution of that book, DVD or publication is effectively banned or restricted so that distribution cannot happen. You may be able to publish the title of the book, but effectively it is not really going to be able to be obtained. However, if you are publishing the title or an internet address of online material, that material actually still exists and would potentially allow a person to locate, view, download and pass it on. That was the reasoning of the AAT. From our point of view, we also believe that, as the list is compiled mainly of URLs relating to online material depicting child sexual abuse images, publication of the list would obviously provide a ready source of new material for adults who have a sexual interest in children and would continue that abuse. So, as I mentioned earlier, the blacklist itself is based on what is in the Broadcasting Services Act and defined under the classification act, whereas the list itself is not made public for those reasons.

...

Senator LUNDY—Is political content banned?

Ms Wright—Political content does not mesh in any way with the National Classification Code. The National Classification Code looks at individual elements of violence, sex, coarse language and child sexual abuse; it does not cover political speech. We are not like China.

...

Senator FIELDING—There have been calls to toughen the laws in regard to cyberbullying. Have you looked at toughening the laws up at all?

Senator Conroy—We have been very conscious of cyberbullying and that is why we released a policy prior to the last election on these matters and have been implementing it as we go. I do not always believe everything that I read in the newspapers, particularly from some individuals. But I think Ms O'Loughlin outlined before, perhaps before you were in the room, a whole range of initiatives we are actually doing on the ground to combat it. I might just get her to quickly review them again for you. These are programs in schools on the ground with teachers, parents and kids.

...

Senator MINCHIN—I am not—and I do not know whether anybody else in the community is—clear as to what the current state of the law is. That is what I was trying to get at. Is there a legislative prohibition on the use of mobile phones? If I use my mobile phone on a plane, am I liable to be prosecuted under the law or am I simply breaching some sort of implied or written contract with the airline conveying me?

Mr Tanner—You will not be prosecuted by us. I would have to take your question on notice. I am not aware that you are breaking one of our laws by doing that.

TGA

June 2010

Senator XENOPHON—Would you agree that it is preferable that the TGA either conducts the investigation or outsources it to an independent body rather than the manufacturer as a general principle?

Dr Hammett—I do not think they are actually mutually exclusive. I would certainly agree with the premise that it is important that there is an independent scientific regulatory agency such as the TGA to ensure the safety and efficacy of the products that are available for as the Australian people. That is

certainly the case. A balance that needs to be struck between having that independent scientific body that can investigate issues and at the same time allowing appropriately well-defined investigations to occur in other settings as well. There are standards about how an investigation into a product issue should be conducted, whether it is by industry or by the TGA.

...

Senator XENOPHON—Thank you. I will just move on. You also stated in response to my question on notice about high revision rate for the device that:

The TGA first became aware of these revision rates when Johnson & Johnson Medical Pty Ltd contacted the TGA in July 2009 with concerns raised by hospitals in Australia over current batches of the LCS Duofix femoral component.

My question is: why were hospitals reporting to the manufacturer and not the TGA?

Dr Hammett—In Australia we operate reporting systems for adverse events for all types of therapeutic products. As I think we have discussed previously, there are obligations that apply to manufacturers of products to report problems to us. There are stated time frames for that. In addition, there are mechanisms by which anyone—you, I, the hospital or the treating clinician—can report such events to the TGA. That can occur via telephone, on our website, by email or by written communication. So all of those avenues for reporting are open. How an individual chooses to report a particular incident is not a matter that the TGA can actually control.

...

Senator ADAMS—I would just like to ask questions about the equipment used by some of the complementary medicine providers for breast scanning. This is creating quite a stir in Western Australia at the moment. The equipment involves thermography or electrical impedance. It has been advertised as an alternative to mammograms. It is creating quite a stir because there are a number of women who think that they do not have to go through the pain of their mammograms and therefore they are going to this. Do the devices that are used go to TGA? Are they equipment that you look at before or approve?

Dr Hammett—In general terms we might approve a device like a thermal scanner. Unless it was supported by appropriate evidence, we certainly would not be supporting the use of that device for the diagnosis or screening of breast cancer. Dr Kelly will correct me if I am wrong but to my knowledge we have not approved any such devices for the screening or diagnosis of breast cancer. That being the case—

...

Senator ADAMS—It really does concern me that people think that they can go and have this done and that it is the same as having a mammogram, because it is not. But misleading advertising can do that, and that is really what has happened.

February 2010

Senator XENOPHON—I am talking about implants: artificial joints, heart valves and pacemakers. Would it be fair to say that the level of testing is not as rigorous as for prescription medication?

Dr Hammett—No, I do not think it would be fair to say. The regulatory framework for those implantable devices is again an internationally harmonised framework called the global harmonisation taskforce framework for regulation of medical devices. It is the same framework that is applied in similar countries to Australia, the US, the EU. Again, it adopts that risk-based approach.

Senator XENOPHON—Can I go to a specific case. It is someone I have spoken to. In the case of Karen Carey, and you are no doubt familiar with the case, she suffered multiple strokes and other very serious health complications as a result of a faulty St Jude medical heart valve. What steps did the TGA take to independently ensure that the product was still suitable to be used in Australian patients, what were the processes involved in terms of, firstly, the approval, and what knowledge did you have of that device having problems?

Dr Hammett—I am a little uncomfortable talking about an individual case but I am aware that Ms Carey has in fact raised this matter publicly.

Senator XENOPHON—She is not uncomfortable about me raising it publicly either.

Dr Hammett—It is important to note right at the outset that there are some erroneous premises in your questions. You referred specifically to Ms Carey's problems relating to a faulty heart valve although that remains an assertion, and indeed when she pursued litigation I note and I quote from the extract of the judgment in that case:

... the applicant has been unable to establish liability in any of the respondents. It has not been shown

that the St Jude medical valve was defective or unfit for its known purpose.

That is in contradistinction to the premise your question was based upon.

Senator XENOPHON—So what is your understanding of the strokes and health complications she suffered?

Dr Hammett—There are different types of heart valve. There are tissue heart valves and there are metallic heart valves. The particular type of valve that Ms Carey had at that time was a metallic heart valve, and it is a known complication of metallic heart valves that they cause increased propensity to form blood clots on the leaflets of the valves. Occasionally in a small percentage of patients those blood clots break off and go to the brain and cause a stroke. It is a recognised complication of the type of heart valve—

Senator XENOPHON—Two to five per cent?

...

Senator XENOPHON—Sorry, can we go back a step. The analysis of the valve was carried out by whom?

Dr Hammett—I do not know the individuals. The treating clinicians—

Senator XENOPHON—But it was cleared up by the manufacturer, wasn't it?

Dr Hammett—The treating clinicians who removed the valve sent the valve back to the company that produced it.

Senator XENOPHON—As a regulator, as a gatekeeper of these devices, if there is a question mark over the efficacy and the safety of a particular medical device, wouldn't it be preferable for that to be independently assessed rather than to go back to the manufacturer?

Dr Hammett—As the regulator our interest is certainly in ensuring that the best possible public health protection occurs, and we have within the TGA well-established processes for investigating faulty medical devices.

Senator XENOPHON—But in this particular case, if you are looking at the best possible safety outcomes how can those be achieved if the valve in question went back to the manufacturer for assessment rather than being assessed independently? Isn't there a role for the TGA to intervene in that?

Dr Hammett—Potentially, when clinicians choose to send devices to the TGA for investigation, the TGA will willingly undertake an investigation. In fact we investigate those sorts of events on a daily basis. We do not have powers under the Therapeutic Goods Act to compel doctors, nurses or other healthcare professionals to refer these devices to us. That is not within our powers under the act.

Senator XENOPHON—In terms of best practice, wouldn't it be desirable for there to be an independent assessment and investigation of the actual device in question? Don't you accept that the manufacturers of these sorts of devices have billion-dollar reasons not to tell the truth, in the sense that you have situations where it is a multibillion-dollar market?

Dr Hammett—In fact the manufacturers of many of these devices actually share the same public health interest that you and I as concerned citizens might share for public health and wellbeing. Indeed, the TGA subsequently investigated the assessment of the heart valve that was undertaken by the manufacturer and found that their assessment was appropriate. This was confirmed subsequently in the legal case, where all of these issues were tested and examined forensically, with lawyers arguing the exact case that you are arguing, and the judgment found that there was no fault in the heart valve.

Senator XENOPHON—You are talking to an old civil litigation lawyer. Isn't there a problem here in the sense that the forensic evidence was based on a forensic examination by the manufacturer and that there was never an opportunity for a completely independent assessment of the heart valve that was the subject of the court case? Furthermore, wasn't it the case that there were hundreds of similar reports overseas expressing concerns about the efficacy and the safety of the St Jude valves?

Dr Hammett—I am unaware of reports of hundreds of similar concerns. I am aware of reports by Ms Carey that one of the officers of the company that conducted the assessment of that device had looked at similar surgically removed heart valves as part of the company's quality assurance program. So, whenever one of their valves was taken out of a patient for whatever reason, the company, quite rightly, would examine it to see if there were any problems. That is good practice.

...

Senator XENOPHON—Is there an obligation on manufacturers, sponsors or importers to report safety concerns with a device to the TGA, including any reports or concerns from overseas? And, subsequent to that, if a manufacturer or sponsor does not report safety issues with a device, what are the penalties?

Dr Hammett—Absolutely there are requirements for them to report adverse events to us. I will have to take on notice what sanctions we have available, unless any of our officers here are able to enlighten us. But we can certainly take that on notice. I could perhaps clarify some of those time frames. The mandatory

time frames under the legislation for reporting are as follows. In the case of an adverse event that would or could result in a serious public health threat or concern, such as supply of a contaminated or non-sterile device which is in common public use, sponsors are required to report to us within 48 hours. If it would or could result in serious injury or death, it is 10 days. Or, if it was just a near adverse event—if something might have gone wrong—they have to report that within—

Senator XENOPHON—Has anyone been prosecuted for not complying with that?

Dr Hammett—I would have take that on notice.

Senator XENOPHON—Can you explain this to me: why is it that Sweden, which has a different regime for dealing with these, has a revision rate—just for artificial hips and knee joints—which is about half, as I understand it, of the revision rate here in Australia, which costs our health system, for just hips and knees, for those revisions, about \$156 million a year? Isn't there something wrong in the way that we deal with the issue of hip and knee joints alone if they have a revision rate much higher than in other jurisdictions?

Dr Hammett—There are a lot of theoretical and potential causes for that difference. First of all, the data could have anomalies and we could be looking at different statistical factors affecting that result. Alternatively, it may be related to the relatively narrow range of joint prostheses available in Sweden, which has a very different health system with very different controls. You and I, as we approach the ages where we may seek orthopaedic intervention—

Senator XENOPHON—I just had neurosurgery over Christmas.

Dr Hammett—will probably appreciate the vast number of devices that are available in Australia to meet the needs of particular patients. Some orthopaedic prostheses work better in particular patients. The problems with looking at the sorts of national data you are talking about is that it does not necessarily always account for the individual and appropriate clinical specifics that we are dealing with.

October 2009

Senator BOYCE—Would you also not be aware that RISS is a not-for-profit company that was set up in July 2007 to assist companies to obtain good manufacturing practice licences from the TGA?

Ms Halton—What is the point of this question, Senator? You are talking about an individual who is not an officer of the Commonwealth who is allegedly undertaking private activity. That is not a matter that we can make any comment about.

Senator BOYCE—I am surprised, though, that there is not knowledge of a company that is specifically established for the purpose of assisting companies to obtain good manufacturing practice licences from TGA.

Ms Halton—There are any number of people who offer services in that respect. I would not expect TGA—

Senator BOYCE—Do you have a register of companies that do that? How do you interface with these companies, Dr Hammett?

Dr Hammett—There are regulatory affairs companies in all parts of the therapeutic products industry related to—

Senator BOYCE—This one particularly functions in the cellular therapies area.

Dr Hammett—We do not have a register of regulatory affairs companies or consultants; that is beyond the purposes of the Therapeutic Goods Act.

...

Senator BOYCE—Ms Rita Maclachlan is listed as a member of the RISS's expert advisory committee in that 30 September 2008 annual report. Was Ms Maclachlan an employee of the TGA at 30 September 2008?

Ms Halton—I will have to take that on notice.

Senator BOYCE—So you do not know whether she worked for you then?

Senator Ludwig—I think we said we would take it on notice.

Ms Halton—We will take it on notice.

Senator BOYCE—I understand that she no longer works for the TGA; could you please advise me at what date she left the TGA's employment.

...

Senator BOYCE—In general, if an employee of the TGA wants to work on the board or as an outside expert for a company that has dealings with the TGA, do they have to seek approval from anyone?

Dr Hammett—The TGA has very strict probity and conflict of interest guidelines. Certainly we would expect any of our officers undertaking activity in any company that had direct relationships with the TGA to declare that and seek approval for that involvement.

Senator BOYCE—Who would they have to seek that approval from?

Dr Hammett—In the first instance from me, but, in a matter of that nature, I would refer it to the secretary for her consideration.

Senator BOYCE—And you would be the ultimate arbiter, Ms Halton? Could you advise me if that procedure was followed in the case of Ms Maclachlan?

Ms Halton—No, but we have already indicated that we will have to find out what the circumstances were at the particular date that you have given.

...

Senator BOYCE—Would you be able to tell me then, Dr Hammett, whether any comment was sought from the TGA in relation to a \$7½ million grant over four years that was given to RISS in 2008?

Dr Hammett—I would have to take that on notice. I have no knowledge of that whatsoever, but I will make inquiries for you.

...

Dr Hammett—Mr Cesarin is currently the acting head of the Office of Prescription Medicines.

Senator BOYCE—Briefly, what are the tasks of that office?

Dr Hammett—That office evaluates applications for prescription medicines to be included on the Australian Register of Therapeutic Goods.

Senator BOYCE—Is it normal practice for a qualified medical practitioner to be in that role? Has a non medical practitioner been appointed to the head of the Office of Prescription Medicines before?

Dr Hammett—Again, I will have to take that on notice, because I am not sure whether in the distant past it has always been a medical practitioner. The previous incumbent in that role was a medical practitioner who had been in the role for a decade, so in the recent past it has certainly been a medical practitioner. The office is staffed with large numbers of medical practitioners, who are delegated with decision-making responsibilities around those prescription medicines.

June 2009

Senator CORMANN—Thank you very much for that. There was an article in the *Sunday Telegraph* on 3 May which talked about 1.9 million doses of Tamiflu stockpiled by the federal government in case of a national emergency which were close to the expiry date. I am led to believe that there was a decision made to extend the expiry date by two years and the TGA was involved in that. Is that right?

Dr Lopert—Yes. The company applied for an extension of the shelf life of the product to seven years. That was evaluated and approved by the TGA on 1 May.

Senator CORMANN—Can you talk us through the process that you have gone through in making that decision to agree to the extension of the shelf life?

Dr Lopert—Yes. Typically, when a product is first approved for marketing, an appropriate shelf life is determined. That will be based on the stability data available on that product at that time. It is quite often the case thereafter that the company will come back to the TGA when they have longer duration stability data and will seek to extend the shelf life of the product.

Senator CORMANN—Are you saying that that is something that is not unusual?

Dr Lopert—No. We would process between 50 and 100 applications for extension of shelf life in any given year.

Senator CORMANN—Is it usually by two years?

Dr Lopert—It is not common that a shelf life in excess of five years would be approved.