HEALTH COMMITTEE

Wednesday 25 June 2003
(*Morning*)

Session 2

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HEALTH COMMITTEE
3rd Meeting 2003, Session 2

CONVENER

*Christine Grahame (South of Scotland) (SNP)

DEPUTY CONVENER

*Janis Hughes (Glasgow Rutherglen) (Lab)

COMMITTEE MEMBERS

*Mr David Davidson (North East Scotland) (Con)
*Helen Eadie (Dunfermline East) (Lab)
*Kate Maclean (Dundee West) (Lab)
*Mr Duncan McNeil (Greenock and Inverclyde) (Lab)
*Shona Robison (Dundee East) (SNP)
*Mike Rumbles (West Aberdeenshire and Kincardine) (LD)
*Dr Jean Turner (Strathkelvin and Bearsden) (Ind)

*attended

WITNESSES

Tracy Boshier (Food Standards Agency)
Tom McCabe (Deputy Minister for Health and Community Care)
Helen McDade
John McKee
Lydia Wilkie (Food Standards Agency)

CLERK TO THE COMMITTEE

Jennifer Smart

SENIOR ASSISTANT CLERK

Peter McGrath

ASSISTANT CLERK

Graeme Elliot

LOCATION

Committee Room 2

Scottish Parliament

Health Committee

Wednesday 25 June 2003

(*Morning*)

[THE CONVENER *opened the meeting at 09:37*]

Subordinate Legislation

Food Supplements (Scotland) Regulations 2003

The Convener (Christine Grahame): Good morning. I open the third meeting of the Health Committee this year. I welcome to the committee petitioners John McKee and Helen McDade. Thank you for your written submission. We shall move straight to questions.

Mike Rumbles (West Aberdeenshire and Kincardine) (LD): Under European law, the United Kingdom is obliged to implement the Food Supplements (Scotland) Regulations 2003. In fact, the advice that the committee has received is that we have no option but to implement these technical measures. As a committee, we could send the regulations back to the Scottish Executive if we felt that it was not implementing the European directive properly—in other words, if it was not using all the derogations that could be used under the directive—but our advice is that the Executive is using every derogation that is available to it. What do the witnesses think the committee can and should do about that, given that the regulations are technical measures?

Helen McDade: The other question is whether it is legal in Scottish law to pass the regulations. I understand that all law that is passed by the Scottish Parliament must comply with the European convention on human rights, which gives people the right to health. We argue that the regulations will adversely affect our health, so surely it would not be legal to pass the regulations.

Mike Rumbles: Any regulation or law that is passed by the Scottish Parliament has to be examined by the Scottish Parliament's lawyers. The lawyers feel that the regulations are appropriate. Of course, anything that the Scottish Parliament does can be challenged in law, but that is a rather legal point.

I am trying to get to the nub of the question. The regulations appear to be technical measures, in respect of which the arguments have been won and lost and agreement reached in Europe. The Scottish Parliament is being asked to implement a directive of the European Union, because it is on a devolved matter. Our job is to ensure that the Deputy Minister for Health and Community Care, who will give evidence in a moment, is doing everything to implement the directive in the most flexible way. The advice that we have received is that he is doing that. Is there anything that the Scottish Executive should be doing that it is not doing?

Helen McDade: It is hard to accept that your lawyers have considered whether the regulations are legal when nobody has examined whether the implementation of the regulations will affect our health. It is not for me to sit here and argue with you. The point is that nobody has considered that. The regulations are predicated on advice on the toxicity of vitamins and minerals, but the remit of the expert group on vitamins and minerals, which considered the levels that should be set for substances, did not allow it to determine whether such substances provide non-nutritional or nutritional benefits. The issue of whether the regulations will adversely affect people's health has not been considered, so I do not see how your lawyers can have addressed our legal point. Obviously, I am not a lawyer, and I cannot sit here and debate the issue, but how can the legality in relation to the effect on our health have been considered?

Mike Rumbles: I am trying to get away from the legal argument, because that is best dealt with by lawyers. I am trying to get from you a response that I have not had. What should the Scottish Executive do that it is not doing in implementing the EU directive?

John McKee: In its report, the European and External Relations Committee asked that the potency and range of supplements that are currently available in Scotland should be available at the end of the negotiations with the European Food Safety Authority. If that is not achieved, the committee stated that the Scottish Executive should repeal the regulations. Therefore, the first thing that we ask for is a cast-iron guarantee from the Executive that it will seek to achieve that situation through the Food Standards Agency and the UK Government.

Mike Rumbles: For clarification, I asked whether the Scottish Executive should be doing anything else in making the regulations. You have not said that it should be doing anything else, except to say that we should repeal the regulations at the appropriate point.

Helen McDade: The Scottish Executive should consider the European and External Relations Committee's report. A report from a committee of this Parliament suggested four things, none of which the Scottish Executive will do. The simple

answer is that the Scottish Executive should revisit those options.

Mike Rumbles: I will take that up with the minister later if I get the chance.

Shona Robison (Dundee East) (SNP): Do the public understand the concept of passing potentially bad law into Scots law for technical reasons?

John McKee: I do not think that the public are interested. They are interested in whether the system appears to work for them. The UK has a fairly unique market in vitamins and minerals within the European Union. Any decision that redesigns that market to set up an internal market with common standards will always have to dance to the tune of the other 14 member states, and that enrages people. They do not feel that the UK Government should even have opened up discussions on the issue, because it was bound to lose.

Mr David Davidson (North East Scotland) (Con): Many of the products that the petitioners are seeking to keep on open sale are approved by the FSA, which is an agency of the Scottish Executive and Westminster. Are the petitioners asking why, if the current safety mechanisms are good enough for a Government agency in this country, we should change them because of an arbitrary comment from outside, without any scientific evidence of harm and toxicity? Is that where the petitioners are coming from in challenging the regulations?

Helen McDade: Yes, that is entirely the point. People use supplements, and many of them believe that they are essential to their families' well-being. They will wonder how on earth it can be that food supplements are being removed from them. It is not as if they will be able to get them on prescription; they will not be available at all. There are supplements that people whose children have attention deficit hyperactivity disorder, autism or ME, like my daughter, believe are important. The argument is not whether the medical profession accepts that; the point is whether the supplements are safe.

The supplements have been proved to be safe, and they are covered by food safety law, which is far more draconian than pharmaceutical law. We are trying to institute similar regulations to those under pharmaceutical law, but thousands of people every year have adverse reactions to or die because of pharmaceuticals. The Executive suggests that slight adverse reactions to food supplements are underreported tenfold, so if 10 people per year have a slight adverse reaction to food supplements, one adverse reaction to food supplements per year is reported. Those that are reported are mostly minor, causing pain for up to seven days. The FSA has estimated the cost to be £23,000 per person, which is hard to understand. People will compare that with what can happen with pharmaceuticals and wonder what is going on.

Mr Rumbles might well be right when he says that there is nothing that the committee can do. In that case, people will ask why there is a committee and why there is a Scottish Parliament.

09:45

Mr Davidson: The committee's remit is to consider the health care of the people of Scotland. As you rightly said, such products are not medicinal—they come under food regulations—and the Food Standards Agency has cleared them. Can you produce evidence that individuals in Scotland will experience substantial difficulties if many of the products are no longer available because of the way in which the directive is implemented?

John McKee: I believe that we can, but we would need more time to gather that evidence for the committee. We only had a week to get our submission together.

The Convener: How long have you had? How long has the directive been bubbling away? Can you give the committee an idea of when you were first told about it and of the time you have had to respond?

Helen McDade: As a consumer, I first heard of the directive last summer. Health food retailers have known about it for slightly longer. Consumers have had very little consultation on the matter. I rang the Food Standards Agency and asked whom it consulted. It says that it consulted consumers, but I know a lot of the people who are involved in health campaigning in different areas and they were astonished when I told them that the directive was going through. Realistically, the consumer has known about the directive since last autumn.

Janis Hughes (Glasgow Rutherglen) (Lab): I have a supplementary question on your point about the adverse effects of some of the supplements that we are talking about. I understand that there is a mandatory system under which doctors have to record the adverse effects of medicinal substances. Is that the case for vitamins and minerals?

John McKee: No, they have not sought to introduce a yellow-card reporting system for vitamins and minerals. There are a few reasons why they might not have done that, but the main reason seems to be that food supplements are patently safe and that is accepted.

Janis Hughes: Is it fair to say that if there is no mandatory system for recording such results, there are very few recorded adverse effects?

John McKee: My store has been in business for 70 years and we have been selling high-strength food supplements in quite large quantities for 30 years. We have quite a successful business. In that 30 years, we have never been contacted by a doctor, trading standards officer or hospital to complain about an adverse reaction suffered by a customer.

Janis Hughes: Do you think that that is perhaps because people perceive supplements to be safe and so do not understand that there are side effects, particularly if they take excessive dosages or take them along with prescribed medication?

Helen McDade: Doctors have a voluntary reporting system. Dr Turner will be able to answer better, but I am sure that all doctors would report anything that they thought had caused a problem. As I said, there are some reports and those are what the Food Standards Agency figure is based on. If a doctor thought that there was a suggestion of an adverse effect from a food supplement, I am sure that they would feel that it was their responsibility to report it. I do not think for a minute that such a report would not be made. There is the question whether a reaction is always recognised, but that question exists for drugs as well. There is massive underreporting in relation to drugs, so the same argument applies.

Mr Duncan McNeil (Greenock and Inverclyde) (Lab): When I was driving through to Edinburgh this morning, I heard someone from the Royal College of Physicians talking on the radio about the increase in allergies, particularly those that can be linked to peanut butter. Do you believe that there is a need for scientifically based evidence in this area, particularly in relation to children and the elderly?

Helen McDade: You are quite right. We are asking the Scottish Parliament to put money into research. Research in the area exists—we could produce lots of it—but the trouble is that there is no scientific research.

Those of us who are interested in particular illnesses read the latest research. I receive research on ME and I read some of the material on autism, of which there is a great deal. They might not be big, top-notch studies, but then I read about pharmaceutical drugs in the paper and I wonder how the reports get published, because only six people have been involved. Double standards exist.

The question is who is prepared to pay for the research. Pharmaceutical companies will not pay for research into vitamin C because it is of no interest to them to prove that vitamin C helps people to avoid illness. The only people who will pay for that kind of research are the Government. A lot of research exists and we could produce it, but it should not be entirely up to us—a small retail association and consumers—to fight for our children. That is the Scottish Parliament's job.

Mr McNeil: From a consumer's point of view, do you accept that some vitamins and minerals can cause harm? The figures that we have do not reflect the problem as you have described it. There is a problem.

Helen McDade: Is there a problem? We have asked for proof.

Mr McNeil: You suggested in earlier evidence that the problem is minute—only one incident is reported a year. Would a study and scientific evidence highlight a genuine problem? Can vitamins cause harm?

Helen McDade: Who knows what research would show? We are certainly confident that it would show that vitamins are of great benefit. We are all for research. Should politicians be introducing legislation to stop selling something before finding a problem or doing research to discover the benefits? It is ludicrous to legislate before examining the evidence.

The Convener: You might not be able to answer this, but do you know whether professional bodies such as the British Medical Association were consulted on the directive?

John McKee: I am sure that it was. The Food Standards Agency would probably consult all the usual suspects on legislation such as this.

The Convener: Perhaps we should check that out. Can you answer that question, Helen?

Helen McDade: No. However, I should have added in my response to Mr McNeil that the trouble about the evidence is that there is not much experience in nutrition in the establishment. A lot of the experience is in the private sector.

I speak as a veterinary surgeon. Twenty years ago we were giving Scottish animals trace minerals such as selenium, copper and cobalt because we knew that the animals would throughout large parts of Scotland be clinically deficient in the minerals if they did not receive them. It stands to reason that, if one grows food on the same ground, which we all eat, there might be a problem. Part of the trouble is that nutrition is not a big area of study in the establishment.

The Convener: I would like to move on after Mike Rumbles speaks.

Mike Rumbles: The briefing paper that members received tells us that there were 431 consultees in 2000, 957 consultees in 2001, and 409 consultees in 2002. That should be recorded.

The Convener: The paper is a public document so it should be in the public domain.

Janis Hughes: Will the witnesses explain their views on the probable impact of the regulations, not only at a local level, but at a wider Scottish level?

Helen McDade: There is a particular Scottish issue, although we are told that there are no Scottish differences. We are continually told that Scotland has particularly poor health: we have high levels of chronic illness and very high levels of multiple sclerosis and other illnesses for which data might not have been collected. Many of the people who will be affected by the regulations will be older people, women and the disabled—people with chronic illnesses. Having done the research for themselves, those people are going off and finding the products. I was speaking to just such a person before the meeting. People are enraged that the supplements will be taken away. On the one hand, the First Minister tells us that we must do something about Scotland's health and, on the other hand, we are told that there is no specific Scottish issue. A specific Scottish issue is involved.

Janis Hughes: You say that the supplements will be taken away, but we must be clear that people will not be unable to buy any of the items that they can buy at the moment. The concern is that there is a school of thought that says that people will never be able to buy any vitamins or minerals ever again if the regulations are passed.

You talked about Scotland's high level of chronic illness. Obviously, that is best dealt with by the medical profession. If the medical profession has advised people that they should have vitamins or minerals as supplements, that will not change.

Helen McDade: The situation will change. Many supplements are not available on prescription, but doctors still say, "If that supplement helps you, perhaps you should take it."

Many supplements will not be available. Three essential minerals are not on the list in any form. The Government accepts that those minerals are essential and the expert group on vitamins and minerals has suggested the levels of those minerals that people should have, yet there will be no way of supplementing the levels of those minerals. I ask the member to explain that to me. Is she saying that nobody who has a gut problem and does not absorb the minerals properly will have a deficiency? Some supplements will not be available. It is a misconception that only a few things will be taken away, because that is not the case.

Janis Hughes: Is it not the case that those minerals might be included on the positive list if a safety dossier were provided and they were deemed safe?

Helen McDade: So what are people who have a deficiency supposed to do in the meantime? The question is: how many people are expendable for EU legislation? Some people who have a gut problem or particular needs will be deficient in those three minerals. What is to happen to them while the issue is discussed and before someone adds the minerals to the list in 10 years?

Janis Hughes: In 10 years, someone could say that taking those supplements has a detrimental side effect that we have only just discovered. If I were taking supplements, I would rather know that proper research had been undertaken into their safety. I would rather know now if I were taking something that I thought was beneficial but which might be unsafe in the longer term, instead of discovering in 10 years' time that I am suffering detrimental side effects.

Helen McDade: What will you say to the parents of children with autism or of children with attention deficit hyperactivity disorder who are following a nutritional path to help their children? That is the question that the committee must address. What will members say to people who cannot have the supplements in the meantime? Nobody will pay for research, because it would not benefit a pharmaceutical company, so the research will never be done, but that is all right, because the committee is considering people's health interests. It is fair enough to hold that opinion, but what will you say to people such as me, who have sick children with no avenue of help from the medical profession and the national health service? If we believe that supplements help our children and us, and if nobody has proved them to be unsafe, why on earth will we not be allowed to give them to our children?

Janis Hughes: As a mother, I would rather know that something was safe in the long term before I gave it to my child, even if it had short-term benefits. I would not like to give my child something that had longer term detrimental effects and I would like to know that full research had been undertaken before I gave anything to my child.

John McKee: Janis Hughes is right to say that the mechanism for dossier submission would allow manufacturers to present evidence for safety. Unfortunately, the problem is that the rationale that the European Food Safety Authority uses is too strict and too narrow. For example, a form of selenium—a trace mineral that is essential in Scotland because its level is low in the soil—that is called selenomethionine and which occurs naturally in broccoli is not found on the positive list, because the previous European Scientific Committee on Food had no information about where selenomethionine ends up in the body when it is taken. The committee accepted that it is

safer than some other forms of selenium on the list, such as sodium selenite, but because of the lack of one piece of evidence, selenomethionine is not on the list, which seems silly when the committee accepts that it is safe. There are similar examples.

Helen Eadie (Dunfermline East) (Lab): I want the witnesses to expand on that.

While doing research I read a book about selenium, which said that—according to the old Ministry of Agriculture, Fisheries and Food—in this country, selenium is found in Essex and nowhere else. The same book covered the study in China of a particular heart disease in children. Of the 5,000 children involved, the heart condition of the 2,500 who were given a placebo did not improve, but the heart condition of the other 2,500 did improve. Are you aware of that research? Selenium is on one of the lists of banned substances. From my research, I know of its advantages, but will you comment on the risks? Why is the European Union suggesting that it is not safe?

10:00

John McKee: Selenium is on the positive list. The report of the Food Standards Agency expert group on vitamins and minerals set the recommended level for toxicity at something like 500 or 600 micrograms. Northern Europe has a real problem with a lack of selenium in the soil. Selenium is very important because it stimulates liver enzymes and helps to recycle antioxidants. Through research, it is well known that antioxidants are important in stopping low-density and maintaining high-density cholesterol, and in preventing gene damage that might lead to cancer in the long run.

It is very important that people in Scotland have access to effective selenium supplements at appropriate levels. Unfortunately, however, the levels in the food supplements directive will be established as a political fudge. That is nothing to do with the Scottish Parliament; it is to do with the fact that there are 14 other countries with levels based on the recommended daily allowance, whereas this country has been more liberal over the past 50 years.

Dr Jean Turner (Strathkelvin and Bearsden) (Ind): I want to ask Helen McDade and John McKee about the implications for people such as themselves who are very well informed about this subject—better informed than are many of us round the table. If the legislation goes through, it will be on the assumption that a reduced potency is safer, allowing us all to sit back and think that everything is fine. However, I know that you folks will continue to try to access your product. I have been reading all the information that I have been given and I want to ask, does the reduced potency mean that some people will buy double the quantity? Will the price stay the same if the potency is reduced? Will it rise? Will people stock up on the product? Are people already planning to buy the product via the internet, from America or anywhere else? If we bring in this legislation, will you still be able to get your products by other means?

John McKee: This is the moral hazard that faces the Parliament with the legislation. We have customers—some of whom are in this room—who are extremely passionate about the supplements that they take to benefit their health. In many cases, they have been taking the supplements for decades. Whatever happens here today, and whatever happens on 1 August 2005 when the legislation comes into effect, those people are not going to stop wanting the supplements. Dr Turner will not be able to prescribe the supplements for them, and they will not be able to go to a pharmacist to buy them, so they will resort to mail order, perhaps from the Channel Islands or the Isle of Man—which are nominally in Europe but seem to escape all the bits that they do not agree with, which does not seem quite right. Alternatively, people will get the products via the internet. If they got the products from America, they would be ecstatic, because the chances of the product being of a better quality would be quite good. However, they could get them from any offshore place around the world, or from Russia, and the standard could be extremely variable.

In the past week, the Food Safety Authority of Ireland and the Food Standards Agency have released warnings about a thermogenic product that is available on the internet and that contains a substance that is harmful to human health. Those agencies can only put out warnings; they cannot police the mail as it comes into the country. I do not think that the directive will help public health; it would be better to keep supplements under control and legally regulated by the Food Safety Act 1990, as at present.

Dr Turner: Given that we are told that the legislation will come into force anyway, do you have plans to monitor the situation among your consumers?

Helen McDade: John McKee's plan will be to look for a job because all health food retail shops—or at least the vast majority of them—will be shut. I do not think that anybody will monitor them.

Helen Eadie: Will you sum up briefly your argument on the inclusion and exclusion of certain vitamins and minerals from the positive lists and give your view on the projected costs of submitting dossiers in support of ingredients that are not on the positive lists?

John McKee: As I said to Janis Hughes, there is an established mechanism for submitting dossiers. The UK Government argued for an extension of the submission period from 18 months to 36 months—the period will end in three years. However, between only 10 and 20 dossiers are in production, whereas about 300 nutrient forms are missing from the positive lists. All the companies involved have complained about the cost of creating dossiers and the FSA admits that the cost could be up to £250,000 per nutrient form. I understand that even Roche Pharmaceuticals Ltd, which manufactures one ingredient that is missing from the lists, cannot afford to produce a dossier and has pulled out of producing that ingredient. The European Food Safety Authority has admitted that animal testing will be required for nutrients that we have all been happy to take for decades.

As Helen McDade's report mentions, the positive lists are flawed and sprang from another European directive that deals with powder products such as SlimFast and baby food in which minute quantities of substances such as sodium hydroxide, potassium hydroxide and calcium oxide are used as a buffer to prevent acidity. That is not a particular problem, but, unfortunately, there is a distinction between that directive and the new one, which relates to food supplements: supplements are concentrated substances that are usually supplied in pills or capsules. If the committee does not annul the regulations or if the UK Government does not get the positive lists reopened for consideration, it will be possible to sell quicklime, which is calcium oxide, in capsule form. I am sure that members would be ecstatic if a rogue manufacturer began selling such a product, which would start to burn people as soon as it touched their mucosa. Several hundred milligrams of quicklime would do a lot of damage. My submission includes a toxicology report on three caustic ingredients that are on the lists.

Helen Eadie: I understand the industry's concerns about the cost of producing dossiers. Would it be realistic for the industry collectively to finance dossiers? As I understand it, once the dossiers have been agreed, they are agreed for all time and the exercise does not have to be repeated.

Helen McDade: I will confess to ignorance on the subject. There is a real lack of clarity about whether a dossier gets confirmed for all time. There is the extension to 2009, but the only way to get an extension for all time is for the European scientific committee for foods to add substances to the positive lists. The assumption in some of the Scottish Executive answers is that that would happen automatically if a dossier were to be accepted. It might be that I have misunderstood what the Executive has said on the matter, but I do not think that I am the only person to be confused by the lack of clarity on the subject.

The people who lodge dossiers will take a realistic look at the costs involved, whether they have worked with other people to produce them or not, as was mentioned earlier. People can work with their competitors in a competitive environment to get a dossier accepted, but they will not be able to get it copyrighted. We are not talking about pharmaceutical drugs. As soon as a dossier is lodged and accepted, all the competitors who paid nothing towards the costs of producing it can go out and use the ingredient. The competitors gain an immediate benefit without having paid for it.

The lack of clarity means that the market could be reduced as a result. Manufacturers will take an economic decision that it is better to shelve all this stuff. This is an issue that matters more to the people who take the products than it does to the manufacturers. If a manufacturer has a range of products, they will be able to keep some of them. They will look at the costs that are involved in producing a dossier and decide not to keep products that do not sell in bulk—they are going to ask what the point is in producing them.

That is what is happening already—very few dossiers have been submitted to date. Manufacturers are taking an economic decision.

Helen Eadie: Is it not the case that, if the associations were to form a legal entity—I am thinking of some sort of association co-operative—that legal entity could register for the copyright? Surely the dossier would become the property of the business entity and not of those who had not financed it?

Helen McDade: That is not the way in which it works. It is not possible to copyright natural substances, which is what these things are. They are freely available to all.

Kate Maclean (Dundee West) (Lab): I want to ask John McKee what might seem to be a simplistic question, but it follows on from something that Helen McDade said earlier. I want people to get a sense of what the effect will be on your shop. Helen McDade said earlier that, if the regulations go through, people like you will be looking for a job. What is the percentage of goods that are sold in the shop at the moment that are not included on the positive list? I am looking for a ballpark figure—I do not expect you to have an inventory.

I have received a lot of representation from constituents and businesses in my constituency on the issue. I want to get an idea of what the impact on jobs would be. Although I am concerned about the health impacts, I am also concerned about the job impacts. What percentage of goods that you sell at the moment will you not be able to sell because they are on the positive list?

John McKee: I am glad that you asked that question. I did an impact assessment about a year ago. I took account of the positive list—as it stood a year ago; it will not change substantially over the next two years—and used a potency level of about 1 x RDA. Hazel Blears, the Parliamentary Under-Secretary of State for Public Health, admitted at the beginning of this month that that was the way that it was going and that we should get used to that. Based on the ingredients that are missing from the positive list, I calculated that I would lose about 300 products, which amounts to about 25 per cent of my annual turnover. Taking the RDA basis into account, I calculated that I would lose about another 12 per cent. There is, however, some overlap, so about 30 per cent of my annual turnover would be lost as a result of the directive.

The worry is that the directive will be extended in future to cover probiotics, amino acids, essential fatty acids, and products such as glucosamine sulphate, which so many people take nowadays because their general practitioners recommend it. The Commission is publishing a sports supplements directive at the end of this year. There is also the herbal medicines directive, which the committee is aware of. The combined effect of those—even the effect of the regulations in front of us alone—would be catastrophic, particularly in city centre locations. We would be pushed close to the line—we would probably close. Many health food stores will close.

Kate Maclean: If you were not able to sell 1,000mg of vitamin C, you could still sell 500mg. Is that correct?

John McKee: The amount would be much lower. The likelihood is that the maximum amount of vitamin C that we will be able to sell will probably be between 100mg and 200mg.

Kate Maclean: I was referring to your inventory: you just took these—

John McKee: You are absolutely right. I took them out of the equation. The implications of the directive mean that only so many 200mg vitamin C products can be on the market. I am sure that Sainsbury's or Boots could sell it a lot cheaper than we could, albeit without the advice that we give. The effect would be to genericise the market. People with specialist needs who go to specialist health food shops would no longer be able to get the products, which would be gone. They would be left with buying low-potency, low-effectiveness products from multiple retailers.

10:15

Dr Turner: Let us return to the dossier. It seems that the emphasis has been on putting in the money to publish a dossier. Once the status of an item has been decided upon, other people can benefit from that. If small companies have paid for a dossier, the bigger manufacturers can take over and benefit. To some extent, that happens with the pharmaceutical industry. Licences are held for, say, 10 years for a particular drug that has been developed. Then, everybody moves in and can sell that drug. It would seem unfair if the smaller companies that seem to be affected had to put up the money, only for the bigger companies to take advantage later. That is what I have understood from the information that I have been given.

John McKee: That is broadly right.

The Convener: You mentioned a directive on herbal remedies. I am not sure what stage that is at. What are your views on that? Does it flow on from the food supplements directive?

John McKee: I would rather you had not asked me about that—I have not done my homework on it that well. The effect of the herbal medicines directive will be quite catastrophic, too. There are two reasons for that. First, there is a 30-year rule. If a product has not been around for 30 years—if it was not available in 1973—then it will not be permitted to sell it. For example, a perfectly safe combination of bilberry and lutein, which a lot of people currently take for macular degeneration, would not be available. It would not be possible to get glucosamine sulphate with ginger.

The costs to manufacturers of good manufacturing practice—GMP—and the licensing costs associated with the current draft of the herbal medicines directive will drive all but a very small number of manufacturers out of the market. At the moment, people who go into a health food store expect to have a choice of echinacea. It might be available in a tincture, in a capsule and in other forms, and some of it will have been organically grown. People also want to have that choice in future.

The Convener: What legislative stage has the herbal medicines directive reached?

John McKee: I cannot remember exactly.

The Convener: Is it just at the consultation stage?

Helen McDade: I think that it is coming up for a second go-round. It is at some stage of consultation. I think that it has been through one stage and that it is now back in committee, but I am not sure.

The Convener: I will ask a final short question, because we should not really be talking about the herbal medicines directive. When the Parliament deals with the herbal medicines directive, will that reopen consideration of the food supplements directive?

John McKee: There is a bit of a link with combinations, but the herbal medicines directive

falls within the scope of medicines licensing, so it is reserved to Westminster.

Helen McDade: John McKee mentioned essential fatty acids and amino acids, which are planned to be dealt with and are linked more directly with vitamins and minerals. It is clear from several replies from the UK Government and the Scottish Government, which say that they will consider in a few years how the food supplements directive is working, that they mean to consider the legislation with a view to extending it to those substances. That is in writing.

The Convener: David Davidson can ask a very brief question, as I want to move on to questioning the minister.

Mr Davidson: John McKee talked about the number of people in Scotland who use food supplements and the low incidence of problems. Do you know what percentage of the population in Scotland uses supplements? I do not mean only those who tell me that they depend on supplements, but those who use supplements generally. Do genuinely few reactions occur?

Helen McDade: The Food Standards Agency conducted a UK-wide study of 22,000 people, of whom, on average, 40 per cent took supplements. More women than men take supplements, so about 47 per cent of women take something.

Mr Davidson: What is the incidence of problems?

John McKee: If there are any problems, the incidence is very low, and in many cases, effects are reversible.

The Convener: I thank both witnesses for their evidence.

I welcome Tom McCabe, who is the Deputy Minister for Health and Community Care, and Lydia Wilkie and Tracy Boshier of the Food Standards Agency. As we are taking evidence, civil servants, Food Standards Agency employees and others can speak to the committee.

Janis Hughes: I understand that UK members of the European Parliament secured derogations during discussions on the food supplements directive. Will the minister explain the rationale behind the Executive's using those derogations when it compiled the regulations? Are any other derogations available to the Parliament to deal with the petitioners' concerns?

The Convener: I am sorry; I should have referred members to the Executive's response in committee paper HC/S2/03/03/2, of which I am sure they are aware.

The Deputy Minister for Health and Community Care (Mr Tom McCabe): Good morning, everyone. The threads that ran through the United Kingdom's approach to the negotiations were those of the protection of public health and consumer safety, accompanied by a desire to eliminate any unnecessary restriction on trade and to promote the maximum consumer choice.

The negotiations were difficult and it is fair to say that the United Kingdom view was not in the ascendant. The Commission only just secured a qualified majority for its proposals, so it is extremely unlikely that there would be a successful return to negotiations on the issue. All the information that is available to me suggests that, were an attempt to reopen the negotiations to prove successful, we might find ourselves in a more restrictive situation.

A number of derogations were secured during negotiations at the insistence of the UK. Article 4 of the directive allows continued use until December 2009 of vitamins and minerals that do not appear on the positive list. Use of those vitamins and minerals are permitted up to that date, provided that three essential conditions are met. First, the substance must have been in use in a food supplement prior to July 2002. Secondly, if a retailer or manufacturer wishes to continue selling or producing a substance until 2009, they should submit before July 2005 the safety dossiers that have been mentioned this morning. Lastly, no unfavourable safety opinion on the substance should be issued by the European Food Safety Authority. If those three conditions are met, that substantial derogation allows use of products that are not on the positive list until 2009.

The other derogation provides the facility to submit a safety dossier prior to 2005.

Janis Hughes: Are you satisfied that no other derogations are available to the Parliament that would enable it to address some of the concerns raised by the petitioners?

Mr McCabe: I do not believe that there are. I return to the point that I made earlier: further derogations could be secured only by reopening negotiations. As I said, the negotiations were very difficult and the United Kingdom view was not in the ascendant. There is a real risk that if negotiations were reopened we might end up with a more restrictive set of regulations.

Shona Robison: You have described the actions of the UK Government. What has the Scottish Government done? Have you or the Minister for Health and Community Care had any direct contact with Brussels in response to the concerns that were raised previously, as well as those expressed recently by the European and External Relations Committee? Did officials from the Health Department have any input into discussions on the directive at the time when it was possible to influence those discussions?

Mr McCabe: Discussions were taken forward on behalf of the United Kingdom through the Food Standards Agency. As members know, the Food Standards Agency is a UK-wide Government body. Officials from the Health Department have discussions with the people from the Food Standards Agency who conduct negotiations.

Lydia Wilkie (Food Standards Agency): It is important to remember that the FSA is a separate Government department. It is not part of the Executive and it is not an agency. We were involved in the very difficult negotiations to which the minister referred. We will now negotiate on a case-by-case basis on the safe levels for vitamins and minerals. We will also negotiate on the basis of recommendations by the expert committee on vitamins and minerals. We know that those negotiations will be very difficult because of the attitudes of some other member states.

Shona Robison: You said that you were involved in negotiations. To what extent was Scottish expert advice sought to influence the discussions? We have heard about the particular Scottish perspective on this issue, because of public health concerns and so on. I am trying to tease out the extent to which the Scottish perspective influenced the negotiations.

Mr McCabe: I think that the negotiations were mainly guided by the recommendations in the report by the expert group on vitamins and minerals. I have no doubt that the group took account of the situation not only in Scotland, but throughout the United Kingdom.

Shona Robison: Did it?

Mr McCabe: Yes. My information is that it did.

Shona Robison: Did the expert group take evidence from Scottish experts?

Mr McCabe: I think that the group arrived at its conclusions by using all relevant available data.

Lydia Wilkie: The FSA was set up on a UK basis to reflect the need for the best scientific advice to support the raft of issues covered by our remit. We have a nutrition committee that is UK in nature. We do not specifically seek to have proportional representation for any UK country. We seek the best scientific advice. We also ensure that we have full consultation throughout each UK country. The paper that is before the committee has figures that show the number of consultations that took place from 2000 to this year and the number of consultees in Scotland.

10:30

Mike Rumbles: In your letter to us yesterday, minister, you said that the UK is obliged, under European law, to implement the directive. You also said, regarding the regulations that you have presented to Parliament, that we must implement the directive's provisions and have the regulations in place by 31 July. It seems to me that the key question is not about the rights and wrongs of the detail. The issue that faces the Health Committee is whether the Executive has produced regulations that implement the directive appropriately for Scotland. My understanding of the advice that was given to the committee is that the Executive used every possible derogation. Is that the case?

Mr McCabe: Yes.

Mike Rumbles: It strikes me that, if you are presenting to us the best possible regulations—perhaps you will confirm whether that is the case—there is no point in the Health Committee delaying or throwing out the regulations and asking you to return with different regulations.

Mr McCabe: I believe that we have produced the best possible regulations. I reiterate the point that I made earlier, which is that the Parliament has the right and the opportunity to make its own decisions. However, if the Scottish statutory instrument were not confirmed and the UK Parliament did not pass similar regulations into UK law, our firm view is that renegotiation could place us in a far more restrictive position than that provided by the current regulations.

We have fully complied with the directive. The advice that I received is that it would not be in the best interests of the industry not to confirm the regulations and that renegotiation could present certain dangers.

Mr McNeil: I will follow up Shona Robison's questions. Is there a specifically Scottish dimension in terms of products that might be more popular in Scotland and which might have different dosage levels compared with levels in other parts of the UK? Are Scottish consumers of such products losing out? Is there a Scottish impact?

Mr McCabe: I am not aware of a particularly Scottish dimension. The supplements industry is a substantial one. I think that, at 2000 prices, the industry was worth around £335 million in the UK. Surveys show a substantial rise from 1996 to 2002 in the number of people—men and women—who take supplements. Those are UK rather than Scotland statistics.

Lydia Wilkie: During our consultations, we also went to the consumer associations. We got a response from the National Consumers Council, which has supported the general terms of the directive as far as mandatory labelling and clarifying issues for consumers is concerned. We did not get a separate response from the Scottish Consumers Council.

Shona Robison: I will ask the minister a simple question. Do you have any concerns about the directive?

Mr McCabe: As I said, the United Kingdom worked hard to achieve a position that ensured that the directive focused as much as we could possibly achieve on public health, public safety, minimum restrictions on trade and maximum consumer choice. The negotiations have achieved the best possible situation relative to all those matters.

Shona Robison: Do you still have concerns that this may not be best law to introduce in Scotland?

Mr McCabe: No, I do not.

Shona Robison: You have no concerns.

Mr McCabe: No.

Helen Eadie: We heard earlier from the petitioners that glucosamine sulphate is one of the items with which there will be a problem. Like many people throughout the UK, I am concerned about that, as I am a user of glucosamine sulphate. Any arthritis sufferer would tell you about the result of the evaluation that was carried out at St Thomas' hospital in London. It is a major product and has a real impact on us. I wanted you to hear that comment from me.

I quote from paragraph 118 of the report that I prepared for the European and External Relations Committee:

"Additionally, the Scottish Executive and its agencies, perhaps through the UK Government, should encourage the European Commission to have recourse to Article 4 (8) which provides that the Commission must report to the European Parliament and the Council on the advisability of making 'any proposals for amendments to this Directive, which the Commission deems necessary'. This report must be submitted no later than 12 July"—

so we do not have a lot of time.

The report continues:

"Therefore, an approach to the Commission to that effect might be appropriate and should be encouraged by the Scottish Executive and its agencies, if the European Commission is not minded to repeal the Directive."

I say that with the knowledge, which I also mention in my report, that any of us can go to the internet and buy any product from America or the Channel Islands. Will you comment on that paragraph of the report?

Mr McCabe: I will comment first on the substance that you mentioned. My information is that that is not a mineral or vitamin and that it is therefore not affected at this time.

I think that, in quoting paragraph 118 of the report, you were driving at a comment that I made earlier about the possibility of making a fresh approach to the Commission. I have already made my view on that reasonably clear. Our firm view is that that would not be an advisable course of action.

Was there another question that you wanted me to answer?

Helen Eadie: Any of us would be able to buy substances over the internet. For example, we cannot buy melatonin in this country, but we can buy it from America.

Mr McCabe: The technological development of tools such as the internet has impacted on many aspects of life, from highly undesirable activities, such as child pornography, through to being able to source different items that one can purchase from different countries. The fact that that happens does not necessarily make the case for avoiding the proper regulation of particular products or services through the retail sector in our country. It is an unfortunate situation, and it is clear that there are developing issues. The wider global community is still spending time thinking about how to develop a response to those issues, but that would not necessarily negate our proper desire to ensure that proper regulation and proper levels of consumer safety and choice exist in Scotland.

Mr Davidson: I will take the minister up on his use of the phrase "consumer safety and choice". I understand from the Food Standards Agency presentation that we had recently that manufacturers of the products that we are discussing have a duty of care under law anyway. Those products are not medicines. As far as medicines are concerned, the Medicines Commission is rigorous in putting safety first. If it finds signs that a product that has been on general sale as a medicine is causing side effects it reinvestigates the product. In this case, regulations are being proposed that seem to restrict choice without dealing with safety.

As many of the items that will no longer be on the positive list have been approved for sale in this country under the law as it stands, I ask the Food Standards Agency whether, had a directive not come from the European Union, it would have been proposing to limit or control those products.

Lydia Wilkie: Under general food law, we do not licence or positively approve foods. It is up to the manufacturers and the retailers, through due diligence, to ensure that they are selling something that will not be harmful. That is the current situation.

As has been explained, we have still not negotiated on the levels for the specific vitamins and minerals that are to be covered. We now have the report of the expert group on vitamins and minerals, which took five years to develop. The independent board of the FSA has already raised concerns about some of the information and about some of the levels of products that are on sale. The board has asked agency officials to have

discussions with parts of the industry about those concerns. Our independent board believes that, on a precautionary basis, we should not wait for the safety dossiers and for the full implementation of the directives. We are considering the levels closely.

Mr Davidson: So the agency, under its current remit, was going to take action that is separate from any European-led initiative. You were dealing with those products and were going to come back with recommendations about levels of specific substances.

Lydia Wilkie: I go back to the expert group on vitamins and minerals, which predates the agency. The developments that were taking place in Europe and the UK—using expert scientific advice to set recommended safety levels for the raft of vitamins and minerals that have come on to the market—have been running hand in hand. The expert group's report, which was published earlier this year, raised concerns about the safety levels of certain products. Therefore, on a precautionary basis and in accordance with its duty and remit, the agency will discuss those concerns with the manufacturers.

Mr Davidson: Does that mean that you would be doing independent scientific research on individual items? Does it also mean that there would not be a blanket ban, as appears to be proposed by Europe, but that any ban would be specific to products that may have a problem?

Lydia Wilkie: Yes.

Mr Davidson: I am trying to clarify the matter. I am not being hostile.

Lydia Wilkie: That is okay.

Mr Davidson: You are operating on the same basis as the Medicines Commission operates, but for different product ranges.

Lydia Wilkie: It might be helpful if I say that the way that the expert group operated was that it looked at individual vitamins and minerals in turn and negotiated with and consulted industry and other experts over the five years. It took each one in turn and examined the scientific advice that was available. My colleague may be able to help me on that point.

Tracy Boshier (Food Standards Agency): The expert group considered as much evidence as it could on each vitamin and mineral. That evidence is presented in its report. As has been said, where concerns have been raised over particular vitamins and minerals, we will meet manufacturers shortly to discuss the concerns and the measures that we can take in the interim before the EU proposes to set limits. Where there are concerns about public health, we will have discussions on the specific limits that are available for those particular vitamins and minerals.

On the concerns that there may be extra evidence that the expert group did not consider or take account of in its report, I advise that other evidence is being welcomed—in one case such evidence will be submitted later this year to the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment. The expert group has disbanded, so where further evidence comes to light the agency will call upon relevant experts. We can call on various advisory committees to provide extra advice.

Mr Davidson: The limits are possibly going to be different from those in other countries, as you are using UK-based evidence and UK-based population requirements.

Tracy Boshier: The evidence considered would be internationally based. The report lists the evidence that was considered for each vitamin and mineral. Our report will be used in the UK's negotiations when it comes to discussions on vitamins and minerals. Some other member states have set up similar groups to present evidence on the matter; however, that is not a requirement and not all member states have done so. As was mentioned earlier, the Scientific Committee on Food considered a number of vitamins and minerals, but now that that committee no longer exists a new scientific panel of the European Food Safety Authority will continue with the rest of the considerations. Once those are complete, the Commission will be in a position to draw up proposals for maximum limits, which will involve a whole new set of negotiations.

The Convener: Could you move your microphone slightly? You have a very gentle voice and we are not used to that. No politicians have gentle voices.

Mr Davidson: Can I ask a brief question of the minister? We have heard in evidence—

The Convener: The minister was wanting to speak anyway. Do you want to come in first, minister?

10:45

Mr McCabe: On a point of information for Mr Davidson, it may be helpful if I inform him of the terms of reference of the expert group on vitamins and minerals. There are essentially three parts to its remit. First, the group was to establish principles on which controls for ensuring the safety of vitamin and mineral supplements that are sold under food law can be based. Secondly, the group was to review the levels of individual vitamins and minerals that are associated with adverse health effects. Thirdly, the group was to recommend maximum levels of intakes of vitamins and minerals from supplements, if appropriate. The group's recommendations will, in large part, guide the UK's approach in any future negotiations.

Mr Davidson: I am grateful for that clarification from the minister, which is the sort of comment that I was hoping to hear. It shows that the Government has a mind of its own and is looking at the issue from a UK perspective.

We have heard that about 40 per cent of the population use supplements. Is the Government inclined to give any assistance with dossier production to smaller manufacturers or groups of manufacturers on the basis that there is no patent protection when they produce a product, as these are natural products?

Mr McCabe: Several issues impact on that specific area. It would be possible, under a de minimis rule relative to state aid, to provide some assistance to certain small and medium-sized enterprises. However, there is some debate over what the cost of dossiers may be. The figures that have been quoted range from £80,000 to £250,000, but those are industry figures, not Government figures. It is important to remember that there could be issues of market distortion relative to the European Union and the open market if Government aid was made available, depending on how much an individual dossier cost.

Evidence is emerging of collaboration in the industry on the cost and production of the dossiers. If a dossier is submitted to the Commission and is approved, it makes that substance available to any manufacturer anywhere in the European Union. Therefore, there is a disproportionate cost to be borne by the individual manufacturer. However, there is evidence that manufacturers in the industry are coming together to collaborate on the cost and production of the dossiers.

Mr Davidson: Is the Executive worried that this is a first step towards controlling alternative therapies?

Mr McCabe: We are dealing with a specific directive, and the Executive has not expressed a view on what you suggest.

The Convener: I am sorry, David, but can we move on? I feel that this is becoming a conversation at the far end of the room.

I detect a difference between what the minister and the Food Standards Agency are saying about the Scottish input. I may have got it wrong, and I can check the *Official Report*. However, I am concerned about the recommendation in paragraph 107 of the European and External Relations Committee's report. It says:

"It is for this reason that the Committee recommends greater consideration of the regulatory impact of such legislation at Scottish and local level, in addition to anything which is done at UK or EU level. The Committee notes, with dismay, that the Commission's original proposal appears not to have been accompanied by any Regulatory Impact Assessment."

Minister, you have floated the issue of the costs to the industry and the need for assessments and so on. What is your comment on that recommendation of the European and External Relations Committee?

In its report, the European and External Relations Committee also states:

"The Committee recognises the very real financial impacts to the industry, potentially threatening a continued ability to trade, as a result of the need to submit safety dossiers, perhaps reformulate products and to label."

The committee was clearly concerned and I would like to hear the minister's comments.

Mr McCabe: We consulted on the regulatory impact assessment and we received no information to indicate a specific impact on Scotland.

The Convener: Should you have received such information?

Mr McCabe: One can only ask for information, not demand it.

The Convener: Apart from considering the physical impact of changing food additives, one might consider also the financial implications, as has been suggested by the petitioners. Why was that not done for Scotland?

Mr McCabe: The consultation was UK-wide. We heard earlier that, although the Consumers Council for the UK responded, the Scottish Consumers Council did not.

The Convener: So are we to blame it?

Mr McCabe: Those are your words, convener.

The Convener: Perhaps we should ask the council why it did not respond.

Mr McCabe: Again, convener, it is for you, not me, to decide the list of people from whom you take evidence.

Shona Robison: I want to ask about positive and negative lists. Is the minister happy with the positive list model as opposed to the negative list model?

Mr McCabe: My understanding is that there is no negative list. There is a positive list that remains open and can be added to on the production of safety dossiers.

Shona Robison: Let me then ask you about what is not on the positive list. Your letter to the committee dated 24 June states:

"The Executive's position is that any restrictions to the range of products available should be justified on public health, rather than on trade grounds."

Three minerals missing from the positive list are boron, silica and sulphur, which were listed as essential by the expert group on vitamins and minerals. What were the public health grounds for not including those three minerals on the positive list?

Mr McCabe: Scientists tell us that there is no known human deficiency in those three minerals.

Shona Robison: That runs counter to evidence that we have heard from people who use food supplements. Some of those products have been used for decades to control epilepsy. Have you any information on that?

Mr McCabe: That is a medical condition and not one that we would expect people to buy supplements to treat.

Shona Robison: Do you not accept that people with conditions such as multiple sclerosis use food supplements to alleviate their condition?

Mr McCabe: I do not accept that it is appropriate to make claims about what these products can do to cure particular medical conditions. That would be dangerous.

Shona Robison: Nobody is making that claim.

Mr McCabe: I thought that that was what you were saying, but if I misunderstood you, I misunderstood you. It would be dangerous if someone with epilepsy who was being treated by their general practitioner for their condition was adding to their treatment without knowing the effect of combining the treatments.

Shona Robison: For the record, I am not saying that food supplements would cure a condition; I am saying that people have found over the decades that certain minerals help to alleviate the symptoms of their condition. Do you dispute that?

Mr McCabe: It is not for me to dispute that, but my view and, I think, the view of the Executive would be that, if an individual felt that a particular supplement added to the alleviation of a medical condition, they should take advice from their GP.

Dr Turner: I think that we have already touched on it, but I was wondering about monitoring. Are mechanisms in place, or planned, to monitor the impact of the regulations locally and nationally, and to consider options—such as financial assistance—for those who might be disadvantaged by implementation of the regulations? It seems that small businesses, especially in Scotland, will be well and truly damaged by the regulations—although I am trying not to look at this from a doctor's point of view.

We need look only to the big retail and wholesale outlets to see what a business the vitamin business is. People might find that the potency of products that they buy will be reduced, so they might double up and buy more of them or stock up on them. There is a good opportunity to have some research done on the matter, although it appears that the matter is a foregone conclusion, because legislation is to be introduced. Indeed, I do not know why the matter is before the Health Committee now; we have had so little evidence to go on and it has been over such a short time.

Mr McCabe: Dr Turner made two points; I think that I have already addressed the second one on financial assistance. I hope that I explained it earlier.

On monitoring, we will continue to accept scientific advice as it becomes available. That will inform our approach to the whole area, now and in the future. That is how we intend to go about things.

Dr Turner: What about monitoring? Have you thought about how you will approach it and about how you will acquire research evidence?

Mr McCabe: Research continues in the scientific community on the impacts of different nutrients, minerals and vitamins. That work continues to inform the work of the Food Standards Agency. That has always gone on, and will continue to go on in the future.

Dr Turner: Does Lydia Wilkie of the Food Standards Agency have anything to add?

Lydia Wilkie: We always welcome new scientific evidence's being brought to our attention. We take such evidence to our expert scientific committees in order for them to take a position on it. Where necessary, we take evidence to Europe for discussions to be held at that level.

Monitoring of the industry would not be a matter for us because we are a consumer-oriented food body.

Dr Turner: So—you have no plans to get involved with consumers to find out about how things develop. It seems that there will be a large number of consumers who will no longer be able to access the products that they have been accessing. Either the products will be changed, or they will have to access them in different ways. It might even mean that they will not get them.

Lydia Wilkie: We do not know what the end effect will be. A lot depends on what dossiers are brought forward, on which are accepted and on where the European negotiations go on the various individual levels. Our stance is clear; we will—in order to ensure maximum consumer choice—push for the levels to be set according to the safety levels that have been provided to us.

Mr McCabe: Some claims have been made this morning about the impacts of the directive on the industry and on the consumer. In line with the

answer that has just been given, I would say that such claims are difficult to make at the moment, mainly because negotiations on maximum limits are still to take place. I hope that I have reassured the committee that the UK's approach is guided by the recommendations from the expert group on minerals and vitamins. The utmost will be done to try to restrict any regulations that would restrict trade or consumer choice, as long as that is guided by the overriding principle of consumer safety.

Dr Turner: It seems as if you are already restricting choice by accepting the European legislation.

Mr McCabe: That is not our view. Much has been made of the 300 nutrient sources that are used in the UK and are not on the positive lists. Those sources are mainly different sources of 19 vitamins and minerals that are on the positive list. There has been a fair amount of speculation and allegation with which we do not necessarily agree. Perhaps a parliamentary committee has a job to do—although it is not for me to suggest which committee should monitor the impact of the regulations and inform itself about the claims that have been made.

11:00

Mike Rumbles: I return to consultation through the Food Standards Agency. Our previous witnesses' view is that consultation was lacking, but our briefing note says that three tranches of consultation took place in 2000, 2001 and 2002 and involved 1,797 individual consultees. We were told that the Consumers Association in Scotland did not reply to the consultation, but that the UK Consumers Association did. Will the Food Standards Agency confirm that? The Executive's paper says:

"The Food Standards Agency Scotland issued the following consultations",

which resulted in 1,797 consultees. Is that correct? Did every agency, organisation and individual in Scotland have the opportunity over those three years to be consulted?

Lydia Wilkie: I should clarify that we are a UK agency with four distinct arms, including the Food Standards Agency Scotland, which is based in Aberdeen. On such issues and on most food matters, we issue consultations from Aberdeen in order to ensure that we pick up any Scottish nuances and feed them into the UK picture. We also have two Scottish members of our independent board and there is an independent Scottish Food Advisory Committee. The figures are on consultations that were issued in Scotland from the arm of the agency's office that is based in Scotland.

Mike Rumbles mentioned the Consumers Association. I should clarify that the National Consumer Council responded to the consultation. On many issues, that council responds on behalf of all the consumer councils in the UK. If a specific Scottish issue is involved, it is normal for the Scottish Consumer Council to respond in its own right. In this case, it did not do that.

Mike Rumbles: Therefore, you are content that the Scottish perspective was covered adequately in the three consultation phases.

Lydia Wilkie: Our list of consultees was as wide as we could make it and was on our website. We make information as open as we can and we are always prepared to go out to speak to groups, which is one reason why we spoke to MSPs earlier this year.

Kate Maclean: I ask the minister to clarify his answer about nutrients. Much of the correspondence that we have received from individuals and businesses has said that about 300 nutrients will no longer be available, but the minister gave the impression that the nutrient sources will not be available. How many nutrients are not on the positive list?

Mr McCabe: The concise answer is that six minerals are missing. The 300 nutrient sources that have been mentioned are mainly different sources of 19 vitamins and minerals that are on the positive list. I am sure that that is pretty confusing, but the point is important.

Kate Maclean: That clarifies the matter.

The Convener: Lydia Wilkie said that she spoke about the directive to MSPs earlier this year. Was that evidence to the then European Committee? We are a new Health Committee, but to the best of my knowledge, our predecessor committee did not take evidence on the issue. Is that correct?

Lydia Wilkie: The Food Standards Agency and ministers provided evidence to the then European Committee. I was referring to a letter—which we issued to all MSPs following the elections—that gave a factual briefing on the directive. We received a reasonable response at the time.

The Convener: With respect, I would not say that sending a letter that would have come in with a batch of others soon after the election means that you "spoke to MSPs".

Mr McCabe: A specific briefing session for MSPs was held in the past week or so.

The Convener: Fine—I was seeking clarification.

I have a sense that the committees of the Parliament are being railroaded. Directives such as this come to us and there is very little that we seem to be able to do about them. If the

procedural position is that the directive has gone through and the Executive has got its derogations, what is your view on how the Parliament should be involved with the next issue that will come along, which will be herbal remedies? I take it that a directive will come in on that matter. How will the procedure change so that the committees of Parliament—specifically the European and External Relations Committee and the Health Committee—feel that they have more say within the consultation procedure and evidence taking?

Mr McCabe: With the greatest respect, I disagree with you on your first point about committees of the Parliament being railroaded.

The Convener: I said that that was a personal view.

Mr McCabe: Yes; we will agree to differ on that.

On future directives on herbal medicine or anything else—using herbal medicine as a specific example—it would be open to any committee of the Parliament to take advice from the Food Standards Agency, which will in effect be our lead negotiator.

Lydia Wilkie: That will not be the case in relation to herbal medicines.

Mr McCabe: I am sorry. The FSA will not be the lead negotiator on herbal medicines. The relevant parts of the UK Government that deal with herbal medicines could receive a request from a parliamentary committee to give evidence. However, I stress that, as that particular issue is a reserved matter, it would be for United Kingdom ministers to decide whether they or their civil servants would give evidence.

The Convener: With respect, my point is that the committee could be part of the consultation procedure. I understand the point about reserved and devolved matters, but committees of this Parliament should—as part of the consultation procedure—be involved earlier. Do you agree that they should give a view, if there is a Scottish dimension that could be absorbed or otherwise or taken in in part by UK ministers?

Mr McCabe: The consultations are now regularly placed on the worldwide web so that people from round the globe can view them and comment if they so choose. I am sure that the clerks to this or any other parliamentary committee would, if they felt that it was appropriate, bring a consultation to the notice of members and invite them to consider whether they want to make a response.

The Convener: I was pushing you on the issue because you have responsibility for health matters in Scotland, which are fully devolved. In those circumstances, I would have thought that when a directive impacts on health matters—as this one has and as will the next one, on herbal remedies—you would be a prime mover on the issue and might want to bring the matter before the committees in order to assist you.

Mr McCabe: You tread a dangerous line—far be it from me or any other minister to suggest what the work programme of this or any other committee should be.

The Convener: That is not what I was suggesting. It might be of interest to you to pursue the issue of herbal remedies along a line that conjoins with ours—there is an issue that requires to be addressed.

Mike Rumbles: Convener, may I interrupt this private conversation? This is meant to be an evidence session for the committee, not a discussion between the convener and the minister.

The Convener: With respect, Mr Rumbles, the discussion reflects the subject that we are moving on to, which is consideration of European legislation.

Mike Rumbles: You seem to be making statements that represent the views of the committee, but they do not.

The Convener: I beg your pardon. I stated at the beginning of the discussion of this point that I am expressing a personal view. I think that you will accept that; it is on the record. I am pursuing in my questioning the issues that come before the committee, although I am expressing personal views.

Mr McCabe: I think that I have made my point about how such consultations are brought to the attention of a wide audience in this day and age. All consultations are also forwarded to the Scottish Parliament information centre. I am sure that the clerks of this and other committees will consider that information and decide whether they wish to discuss the matter with the relevant politicians.

Mr Davidson: The evidence that you and the FSA have given this morning suggests that a lot of work is being carried out, although we are nowhere near receiving any outcomes. Indeed, we have heard that products are being considered individually and so on. Did the Scottish Executive appeal to Europe for more time to consider the matter, given that work had already been commissioned in Scotland and was, I presume, being co-ordinated throughout the UK? It appears to be the case that Government bodies and agencies are working to establish where we need to go on the matter and what the safety issues are, but the European directive has, in effect, railroaded the Executive into an early decision before it has reached any conclusions. Can any evidence be sent to Europe on that basis?

Mr McCabe: With respect, I disagree again: we have not been railroaded in any way, shape or form. At the start of this evidence session I mentioned some of the very significant derogations that we had achieved. For example, some of the timelines for implementation in relation to the submission of safety dossiers, and the final timeline for maximum implementation of the directive were a result of the negotiations that the UK delegation pursued.

Mr Davidson: Does that mean that the work that is being carried out by the FSA has almost been discounted in Europe?

Mr McCabe: No, I would say that the exact opposite is the case. The FSA has played a very important and full part in the UK negotiating team and has managed to secure the derogations.

Mr Davidson: But we are still where we are.

Mr McCabe: As far as the directive is concerned, we might not have secured the derogations and timelines that we have secured had the FSA—on behalf of the UK—not made certain representations.

Helen Eadie: I agree with the minister. The European Committee flagged up the issue more than 18 months ago, which has given the public a lot of time to become involved. After all, we are now inquiring into the matter and, as the committee knows, I have done some in-depth work on the subject.

I agree that something positive is emerging from this morning's discussion. However, I say for clarification that the minister mentioned that negotiations on maximum limits are still to take place. Indeed, I think that Tracy Boshier highlighted the same point. That is very encouraging, because I know that the petitioners have been seriously concerned by the matter. I ask the minister to expand on that, because it indicates that a very important door might be opening.

Mr McCabe: Yes. It has already been made clear that negotiations on maximum limits have still to take place. I mentioned earlier that the UK's position will be pushed on the basis of public safety, minimum restriction on trade and maximum consumer choice. Some of the current speculation, on, for example, the maximum levels of vitamin C does not reflect the UK's position, which is that 1,000mg is acceptable. I know that some people have alleged that the eventual figure will be much lower than that; however, that will be our negotiating stance on this particular issue.

Helen Eadie: How might the committee play a role in that process? I am very heartened that the minister appears to be taking on board the concerns of the people of Scotland on the matter. However, you said earlier that it was not up to you to determine which monitoring committee ought to examine the impact of the directive. Will you expand on that important comment? After all, Parliament's committees have a monitoring role.

Mr McCabe: Again, I stress strongly that it is not for me to suggest how the committee should go about its business. However, both the committee and the Executive are aware of the negotiations that will take place on the setting of maximum limits. The Food Standards Agency will play a major part in those negotiations. It is, of course, open to this or any other parliamentary committee to invite the people who will be involved in the negotiations to explain the approach that they will take, and perhaps to say what the views of politicians are on the various different approaches that they might wish to be taken during those negotiations.

Helen Eadie: Thank you—that is helpful. Irrespective of which committee it is, there is a role for a committee of the Parliament to do as you suggest.

The Convener: It appears that there are no further questions. I wish to ask the committee whether it now wishes to move to the debate, or whether members wish to take further evidence—as is open to the committee—and postpone the debate on the regulations until after the summer recess, which would still be within the stipulated time limits. I think that members will probably have made up their minds on the matter, but I will allow a short debate.

Mike Rumbles: There is little point in delaying further what we are here to do—the regulations are on our agenda for today. The key point is that we are obliged under EU law to implement the directive. The simple question is whether the Executive is doing what it can. Is it using all the derogations that it can? The evidence suggests that it is. If we took more evidence and decided to throw out the regulations, it would simply not be possible to ask the Scottish Executive to come up with better ones. There is absolutely no point in delaying what we are doing; we must really get on with it.

11:15

Shona Robison: I disagree fundamentally with that. I do not think that we have done justice to the directive. There is an issue of credibility for the Health Committee: our role is to scrutinise adequately and to report on the health impacts of the regulations. Our role is not to tie ourselves up with the technicalities. I do not think that we have given the matter adequate scrutiny and I do not think that we have done our job.

Helen Eadie's point—that negotiations on maximum limits are still taking place—was

pertinent. The negotiations will take place whether or not we decide today to approve the regulations, but it would send out an important message if we decided to take further evidence on the health impacts of the measures, especially on the maximum limits, on which debate continues. That would be an important task for the committee over the recess and we could finalise our conclusions after the summer. I think that we should do that

Mr Davidson: I spoke to you before the meeting, convener, about the fact that some of the papers came into my possession only this morning, which did not give me an opportunity to look at them carefully or—had it been necessary—to carry out any research, follow-up library work and so on. I do not think that the committee should be seen to be operating in that way. In the first session of Parliament, committees had cut-off lines for information, which only in an emergency did not apply. As the regulations are very important and will affect preparations that are used by a large—and increasing—number of people, and because there is a lack of evidence of their harm, I think that we need to consider the matter more carefully.

I am not applying that view so much to the evidence that we have taken today, which has been useful. I understand the FSA's role far better now, even though I had also attended its seminar. We need some time in which to examine the paperwork. We can consider seeking some written evidence over the summer to clarify some of the points that have been raised this morning. I look to the convener to direct the clerk to produce a brief note on where the areas of confusion seem to lie. As far as the procedure is concerned, I could not support going ahead with the regulations at the moment.

Helen Eadie: We have a number of roles as politicians. We have the role of passing legislation and we have the role of monitoring legislation. We also have the role of listening to what the public are saying. We have a duty this morning to ensure that we do not raise public expectations to the extent that we cannot deliver on them. We must take that on board.

If I could see a chink of light whereby we were able to avoid the regulations' going through, then I would support whole-heartedly our taking whatever action we could. I am an avid supporter of the public's having the right to access food supplements, minerals and herbal medication. I am a regular user of all those things, and I have extreme concerns. I need to see a chink of light, but no one this morning has been able to show me one that shows how to change the legislation.

However, as the minister has pointed out, we could have a monitoring role. Tablets of stone in the EU can be changed. We should not raise expectations this morning; we should allow the legislation to go through, but we should in future monitor what happens. What we do today should not prevent the committee from making further inquiries. I would be happy if the matter became continuing work for the committee. Minerals and supplements bring benefits to people, but I would not want to raise those people's expectations this morning. I hope that the minister will come back diligently to us—I am sure that he will—to report on negotiations in the EU on raising the maximum permitted dosage levels. It is important that we do that.

Because of the furore, any politician at Mr McCabe's level or any other level would be very remiss if they did not listen to those concerns. I know that Mr McCabe will not fail to listen.

Mr McNeil: I support Helen Eadie's view. We have a responsibility to be honest with people when they challenge us on our role. We are in a difficult situation and we have no right to raise people's expectations. As Helen said, we must be honest. However, I take comfort from the remarks of the minister and of the representatives of the Food Standards Agency. We can commit ourselves to continuing to look into the differences between the different sets of evidence that we have heard this morning.

The committee will have to consider its work programme for the next session. We could accept the responsibility of a continuing role in this process and we could faithfully monitor what happens. I hope that that would be a two-way process that would allow us to call back the petitioners in future when we have new information. That would at least allow the petitioners to engage honestly with the committee in this difficult situation.

Kate Maclean: I agree. I do not like the directive; personally, I am very much in favour of food supplements. However, if we decide to take more evidence and to continue discussions until after the summer recess, we will be misleading people and putting individuals and organisations to some bother and expense—through their putting together submissions and coming here to give more evidence—when we know that we are obliged to implement the directive. That would not be fair; rather, it would be patronising and unhelpful. We have to decide today, one way or the other.

The Convener: Speaking as an individual and not on behalf of the committee, I do not think that there is a conflict between the inevitability of the implementation of the directive and our taking further evidence. Our doing so would not raise expectations; it would allow us to comment on the health issues that arise from the directive, which is within our remit. Whether that would be

procedurally competent is another matter, but I feel that it would be possible for us to do both things. The petitioners and others are well aware that the directive is inevitable, but the Parliament, through this committee, may want to comment on the health implications. I do not think that there is a conflict.

Dr Turner: I agree, convener. I am new to the Parliament and the committee and it astonished me that we were to have a say on what seemed to be a foregone conclusion. There was very little time in which to gather good evidence and do good research. My background is as a doctor, and I would like to have delved into many matters and spoken to an awful lot more people. We do not seem to be listening to our constituents. Why are we here?

I do not believe that we should take too many vitamins: I believe that one should have a good diet. However, people might not be able to have a good diet because the soil is terrible and we can do nothing to fix it. We always encourage people to look after themselves, but the national health service cannot cope and does not provide the service that those people need, so they are trying to provide that service themselves.

It looks as though we will railroad the regulations through. I would like to deal with the legislation separately and have a Health Committee whose on-going function it is to consider health issues. I do not know enough about the rights and wrongs or the technicalities, but I hope that we can deal with both matters.

The Convener: After I call Janis Hughes, I will not call anyone else to speak, as we will all have had our say.

Janis Hughes: I agree with some of Jean Turner's comments, but I disagree with the suggestion that we would not raise expectations by pursuing the matter. We must acknowledge that the regulations are intended to implement a European directive, which was not made in this Parliament. I say with all due respect to Jean Turner that she talked about our scrutiny of and full investigation into legislation, but that relates to legislation that is initiated by this Parliament. The regulations implement European legislation and we are being asked to consider whether the Scottish Executive has complied with the European legislation.

We would raise expectations if we took more evidence in the hope of changing the directive, because it was not our directive in the first place. We have heard a lot today. I disagree with the convener's comment that the Health Committee would be remiss if it did not consider the health implications. We considered those implications today. It is clear from what the minister said that we can have continuing input on the legislation in relation to the recommended maximum dosages. As Duncan McNeil said, I hope that we can put that in our work plan for discussion and monitoring. To continue to take evidence would be inappropriate.

The Convener: I thank everybody for their interesting comments. I suggest that Mike Rumbles should make a formal proposal.

Mike Rumbles: I am keen for us to stick to procedures. I do not advocate changing the agenda—that is what other people advocate. Agenda item 1 is evidence on food supplements, which we have heard, and item 2 is Shona Robison's motion that nothing further be done, which we are supposed to debate and then agree or disagree to. I thought that that was what we would do.

The Convener: The committee has the right to decide whether to continue the debate. We have been informed of the procedural options. To be clear about what we are doing, I seek a formal proposal from someone who supports the idea that we should take no further evidence and move straight to the debate. Will you make such a proposal?

Mike Rumbles: I am happy to make that proposal, if that is what you would prefer. I just want to get on with the debate. The proposal would be that we should take no further evidence on the regulations and do what we are expected to do, which is to recommend that Parliament should implement the regulations. Everybody in the room has problems with the regulations, but we cannot do anything practical about them. We should get on with the debate.

The Convener: We have a motion to annul the regulations, so we must debate that, if Shona Robison insists on it.

Mike Rumbles: Shona Robison might not move her motion.

The Convener: Does Shona Robison want to reserve her position or make a decision now?

Shona Robison: We should debate the motion.

The Convener: In that case, the proposal must be decided on.

Mike Rumbles: I still do not understand. If Shona Robison wants to continue with agenda item 2, surely we must proceed with it—the situation is as simple as that.

The Convener: It is open to Shona Robison to postpone the debate on the motion.

Shona Robison: I do not know how we have managed to become so tied up. I understood that we would decide first whether to have the debate

now or after the summer and I do not see why we cannot take that decision.

The Convener: That is the point of the proposal, which I would be happy for someone to put.

Mike Rumbles: I am happy to propose that we take no further evidence and stick to the agenda.

The Convener: The question is, that the committee agrees to take no further evidence on the Food Supplements (Scotland) Regulations 2003 and to move to item 2. Are we agreed?

Members: No.

The Convener: There will be a division

FOR

Eadie, Helen (Dunfermline East) (Lab)
Hughes, Janis (Glasgow Rutherglen) (Lab)
Maclean, Kate (Dundee West) (Lab)
McNeil, Mr Duncan (Greenock and Inverclyde) (Lab)
Rumbles, Mike (West Aberdeenshire and Kincardine) (LD)

AGAINST

Davidson, Mr David (North East Scotland) (Con)
Grahame, Christine (South of Scotland) (SNP)
Robison, Shona (Dundee East) (SNP)
Turner, Dr Jean (Strathkelvin and Bearsden) (Ind)

The Convener: The result of the division is: For 5, Against 4, Abstentions 0.

The proposal has been agreed to, so we will move on to the debate on Shona Robison's motion to annul the regulations. I call Shona to speak to and move the motion.

11:30

Shona Robison: I am sure that members will not want me to go over exactly the same arguments that we have heard all morning, and I will try not to do so.

I found it strange to hear members say that individuals and organisations would feel patronised if they were asked to come before the committee and give more evidence, even though the technical point about the directive has been made. If we were to take a straw poll of people in the public gallery, we would find that, instead of feeling patronised, they would say that they would like to have the opportunity to give more evidence—

Kate Maclean: On a point of clarification, I did not say that people would feel patronised if we asked them to give more evidence. I said that it would be patronising of us to do that.

Shona Robison: If a thing is patronising, someone has to feel patronised.

Let me move on. I think that the public will find it difficult to understand why a parliamentary committee is not taking the opportunity to examine fully issues that lie within its remit. That is the strongest argument for seeking to annul the regulations. The Health Committee has a responsibility to consider all the health issues that are involved, particularly the issue of maximum limits. That debate has still to take place. All those aspects could be examined at the same time.

The European and External Relations Committee report, on which Helen Eadie was the reporter, was drawn up in March and concluded that the directive as it stood was flawed, on the basis of concerns about some widely used supplements being banned and maximum permitted levels being set too low. The committee stated that the debate on the issue should continue and recommended that the Scottish Executive should take certain action. The Executive then published the regulations before even responding to the committee's concerns.

Finally, at this late stage, we have received the minister's response, which contains nothing new. I do not think that the minister can claim that he has acted on the European and External Relations Committee's suggestion that the Executive should take action. Nowhere in his response does he say that the Executive has raised any of the committee's concerns with the Commission or the UK Government. That is the minimum that should have been done.

We have unfinished business with the directive, particularly from a health perspective. If the implementation of the directive as it stands will change the whole market for consumers and producers, there is still no evidence that Scottish consumers want such a measure and plenty of evidence that Scottish producers will be put out of business by it. It is also likely to force some producers to go to markets that are outwith regulation, which will make supplements more—not less—dangerous.

We should not lose sight of the point that this directive is about harmonisation, not consumer safety. A number of outstanding questions remain to be answered. Before we agree to the regulations, we should seek those answers and leave no stone unturned. After all, we have the time. The regulations are subject to annulment over the whole recess and we should take evidence on the directive from a health perspective.

Yesterday, a Labour member of the European and External Relations Committee said that the directive was "absurd" and "unjustifiable" and would cause problems

"for a number of our citizens."

He also stated that if a health case could be made against the directive by

"our colleagues in the Health Committee … we should support them".—[*Official Report*, *European and External Affairs Committee*, 24 June 2003; c 15.]

I agree totally with him.

I move,

That the Health Committee recommends that nothing further be done under the Food Supplements (Scotland) Regulations 2003 (SSI 2003/278).

The Convener: Thank you. Whom were you quoting?

Shona Robison: John Home Robertson.

The Convener: Helen Eadie will be the first to speak in the open debate after the minister has responded, then David Davidson will be able to pitch in.

Mr McCabe: I will be brief. I have listened to the comments that have been made on the committee's approach. I hope that, both this morning and beforehand, the committee will have taken cognisance of the view that there is a danger and a difficulty in reopening the negotiations. If the committee feels strongly that the industry is being disadvantaged by the regulations as they stand—I am not necessarily saying that that is the case—our advice is that there is a danger that reopening the negotiations might further disadvantage the industry. I have already tried to stress that the negotiations were very difficult and that the United Kingdom's view on how to approach the issue was not in the ascendancy. That should indicate to members that reopening the negotiations would present a danger.

Much has been made of the impact on the industry of the setting of maximum levels. It is important to re-emphasise that those levels have not been set—they are the subject of entirely separate negotiations. A separate piece of amending legislation will be consulted on and a separate regulatory impact assessment will be carried out. That point is vital in the context of the present discussion.

Much has been made of the impact on an industry that, as I have said, was estimated to be worth around £335 million in the UK in 2000. By any measure, that is a substantial industry. I stress again that it is not for me, or for any other minister, to make suggestions on or to dictate the work programme of any parliamentary committee. However, over time, the committee might wish to inform itself about what actually transpires with regard to the impact of the directive on the industry, compared with what has been claimed.

Helen Eadie: I was not here last week, but I know from my work on the previous session's European Committee that the Executive was advised that simply ignoring the directive was not an option, as we have an obligation to transpose and implement its provisions. We must also bear in mind the fact that if Scotland failed to transpose the directive, the UK would have the right to do that in any case, which would mean that we would not have a basis for taking the matter forward.

There is an important issue that I want to separate out, because Shona Robison has conveyed to the public the impression that, as a Labour member, I am not sympathetic to people's views on the implementation of the directive; I am whole-heartedly sympathetic to their views. We can continue to work on the issue. At the beginning of this part of the procedure, the convener said that she would support that, on the basis of our not taking a decision now. Although it is possible to take a decision now on the specific issue at hand, we could conduct a continuing investigation to inform and feed back into the European process our views as a Scottish Parliament.

Rather than be hasty, over the next year or two we could produce a thoroughly researched piece of work that would inform European parliamentarians, such as Catherine Stihler, who have worked very hard on the issue. I speak to Catherine Stihler regularly on European matters and I know that she has taken a keen interest in the implementation of the food supplements directive. Like me, she believes that safety must be paramount for all of us.

The most encouraging aspect of this morning's discussions has been the minister's key point that the upper levels have not been set. There has been a long debate during the past year and all the politicians and civil servants at senior level, and the European parliamentarians, have got the message—they understand the public's concern. We should continue to press them on the concern that exists. If there is a possibility legitimately to have the directive revised, we should pursue that.

We have explored all the derogations. In my report, I sought to establish what derogations might be possible. All of the agencies and the minister have reassured me that every derogation has been examined. I thought that because soil in Scotland does not contain adequate levels of selenium, a derogation in that area might be considered. I note that that issue has been flagged up to the minister and the agencies. Matters of that sort can be dealt with on an on-going basis. It is wrong to suggest that we are not sympathetic to the petitioners. I commit myself to continuing discussions with the agencies and the petitioners in order to progress this issue.

Mr Davidson: I remind the committee that, as a pharmacist, I am committed professionally to patient safety and consumer care. Those are the issues on which we need to focus this morning.

The Convener: Should you not have made a declaration of interest at the beginning?

Mr Davidson: I have made all my declarations. I am not a practising pharmacist, so I am not involved. I have some expertise, albeit a bit faded.

The Convener: Like the rest of us.

Mr Davidson: We are dealing with a measure that would create consumer disadvantage and that is not backed up by evidence. It would remove choice, but there is no evidence before us about safety. We have heard that again this morning. There is no reason for the legislation to be agreed to now, because research is still under way. The minister said that safety levels are not set. We expect to have that sort of information before we agree to any piece of legislation, regardless of whether it is a member's bill, an Executive bill or legislation from Europe.

The committee must focus on the health aspects of the measure as it affects Scotland. Health is a devolved matter, so why can the Parliament not decide within the UK—which is an open market—to deal with the work and to get the research done? This morning we have offered to consider real evidence on consumer safety and risks to health. If we accept these regulations right, left and centre, we are supporting interference in human rights in Scotland by a Parliament many of whose members disagree totally with the directive. Many Scots MEPs are particularly concerned about the regulations. They also share our concern about safety—no one should avoid that issue. The point is that the regulations will produce an unregulated market that poses an even greater risk to public health than the current situation.

I would like us to take written evidence over the summer on the safety and risk aspects of supplements, as well as the benefits. This morning we have again heard evidence that much of the scientific work on this issue has not been done.

I feel that we are being rushed. The minister says that there will be a new set of regulations dealing with safety levels. That implies that we accept in principle that Europe has the right to introduce this measure in the UK—even though we have not raised the issue of supplements—and that we will be left to tinker around the edges on safety levels. If the minister can make clear this morning that we will be able to obtain derogations that allow the UK to set safety levels independently of Europe, I will feel somewhat assured. However, I do not believe that real evidence will be produced within a time scale that is compatible with decent, honest decision making on a piece of legislation that will have long-term effects. This is not a short-term measure with which we can tinker easily. Once the regulations are approved, it will take years of evidence gathering and committee work in Europe to have them changed.

I want the Health Committee to put the interests of the Scottish people first and to ensure that we have exhausted every possibility that is in their interests. If we then decide that the regulations are in the UK consumer's interest and should be agreed to, that is fine. However, we have not reached that point. We have not had time to deal with this matter—we have not even had a chance to discuss from whom we might take evidence. On that basis, I support the motion in the name of Shona Robison.

Mike Rumbles: I listened carefully to what David Davidson said. His line sounds like his line last week, when he was the only Health Committee member to oppose the Food Protection (Emergency Prohibitions) (Amnesic Shellfish Poisoning) (Orkney) (Scotland) Order 2003, on which he forced a vote in the chamber. He takes the same view about the regulations.

Mr Davidson: No.

The Convener: That is not really the debate.

Mike Rumbles: Unless I misunderstood him, that is what David Davidson was saying.

The key point is that the directive is EU law. As an EU member state, the UK is required to implement EU directives, which all member states have agreed to do. We are examining the regulations because they relate to a devolved issue. They are the mechanism for implementing the directive, which each member state must implement. If we agreed to Shona Robison's motion and recommended that nothing further should be done, as Shona Robison asks us to, the UK Parliament could step in and say that the Scottish Parliament was not fulfilling its duties. That would be a disaster for us. We must show that we are up to scratch and doing our duty. The issue involves implementation.

11:45

The debate that we had this morning also took place in Brussels, in the Council of Ministers and in the European Parliament. Members of my party and others argued against the regulations at those times, because those were the appropriate places for those arguments. I agree with the Scottish Executive and the minister when they say that the Executive's view, which the UK presses strongly in Brussels, is that maximum limits for nutrients in food supplements should be set at levels that protect public health. The issue is about public health and the intention is not to restrict consumer choice or to restrict trade unduly. The argument is supposed to be made in Brussels. We are being asked to implement the directive.

If the minister had brought to the committee regulations that implemented the directive

defectively, I would be the first to argue that we should throw them out and ask him to return with proper regulations. However, as we have all heard in the evidence—which is what we must go on, rather than our prejudices or views—he has used all the available derogations. That is also the legal advice that the committee has received. We would abdicate our responsibility as a committee and a Parliament if we agreed to Shona Robison's motion. I oppose her motion and I suggest that we recommend approval of the regulations.

Mr McNeil: I support most of that. We are debating Shona Robison's motion, which says:

"That the Health Committee recommends that nothing further be done under the Food Supplements (Scotland) Regulations 2003".

Even the European and External Relations Committee, which was drawn on to the field of play this morning, has said that it

"**does not recommend that the Executive simply ignore the Directive and the need to transpose and implement its provisions**. Such blatant disregard of the rule of law will only lead to (potentially) a case in the European Court of Justice against the Scottish Executive".

We must face up to that situation.

How we keep faith with the petitioners is a more interesting question. We can engage with those people not only over the summer but over the years. Despite the difficulty with European legislation, we can try to meet some of their aspirations. The petitioners asked in a letter to the European and External Relations Committee

"that the Executive explore various options to preserve the variety and strength of vitamin and mineral products currently legitimately on the UK market."

Can we work with the petitioners and the Food Standards Agency to try to achieve that objective? I suggest that that honest approach to the problem is a better option than the posturing in the committee this morning.

The Convener: Speaking once more as an individual member, I say that I am not posturing. I have serious concerns about—

Mr McNeil: You are not moving the motion.

The Convener: As a member of the committee, I support Shona Robison because I am not satisfied that I have had the opportunity to consider the health implications. Mike Rumbles is right to say that there is no debate about the legal procedures, but there are other issues that this committee could address. Those were perhaps lost in my previous submissions about why I want to take more evidence.

I understand that, if we were to agree to Shona Robison's motion, the matter could be debated in the chamber. Although the debate would be short, it would allow the Parliament to appreciate the health policy issues that are involved. I am not dealing with the constitutional matters; I am thinking of the remit of this committee. As a new member of the committee who received papers on the subject late last night and this morning, I am not satisfied that I am aware of the health impact of the regulations. I accept the sincerity of individuals who use supplements—I do not think that I do. My concern is that the committee should consider the health implications of the matter, and I cannot say what those might be at the moment.

That is why I support the motion, which would allow Parliament to consider the issue. I accept the constitutional points that Mike Rumbles has made but I think that those can be separated from the other issues.

I ask the minister to respond, if he would, to all the matters that have been raised.

Mr McCabe: I will be brief because, when I spoke to Shona Robison, I summarised many of the points that have been made around the table.

I take issue with the point that you raised about the shortness of time available to consider the information. You mentioned that you had received a letter from me in the past 24 hours. That is a result of the fact that the Scottish Executive received short notice that the motion had been lodged. I want to correct the impression that might have been created that the Executive unnecessarily rushed matters.

The Convener: Do you want to respond to any other points that were made? This is a debate and you are summing up for the Executive.

Mr McCabe: Mr Davidson made a point about the levels in the UK differing from the levels that apply across the European Union. We have an open and regulated market. That sort of arrangement would contradict the rationale behind having an open and regulated market. I have already made the point strongly that negotiations will take place about the maximum permitted levels.

Much of the debate has focused on this being a pendulum that is swinging one way only: against the UK. However, open markets have assisted many sectors of the UK's economy. The UK market that we are concerned with at the moment is somewhat older and more experienced than similar markets in the EU, which suggests that, through the operation of the open market, the consistency of levels and other regulation, the UK market might gain an advantage.

The Convener: I call Shona Robison to sum up.

Shona Robison: Mike Rumbles made an interesting comment. He said that we have to show that we are "doing our duty" in relation to our European responsibilities. I think that our role

should be to do our duty by the Scottish public and to listen to their concerns first and foremost. I do not think that the Scottish public will understand the concept of passing potentially bad law into Scots law for technical reasons. I do not think that they will get that at all and I can see why they would not, because it seems bizarre.

Duncan McNeil's comment about posturing could presumably be applied equally to his colleague, John Home Robertson, who said that the directive is

"absurd, unjustifiable and will give rise to difficulties for a number of our citizens".—[*Official Report*, *European and External Relations Committee*, 24 June 2003; c 15.]

The only difference between us is that I have chosen to do something about it and move a motion so that Parliament can decide on the matter in the chamber.

The Convener: The question is, that motion S2M-118, in the name of Shona Robison, that the Health Committee recommends that nothing further be done under the Food Supplements (Scotland) Regulations 2003 (SSI 2003/278), be agreed to. Are we agreed?

Members: No.

The Convener: There will be a division.

FOR

Davidson, Mr David (North East Scotland) (Con)
Grahame, Christine (South of Scotland) (SNP)
Robison, Shona (Dundee East) (SNP)
Turner, Dr Jean (Strathkelvin and Bearsden) (Ind)

AGAINST

Eadie, Helen (Dunfermline East) (Lab)
Hughes, Janis (Glasgow Rutherglen) (Lab)
Maclean, Kate (Dundee West) (Lab)
McNeil, Mr Duncan (Greenock and Inverclyde) (Lab)
Rumbles, Mike (West Aberdeenshire and Kincardine) (LD)

The Convener: The result of the division is: For 4, Against 5, Abstentions 0.

Motion disagreed to.

The Convener: I thank the minister for his contribution, and committee members for their robust contributions, which, I am sure, will continue.

Mr McCabe: I hope that they do.

Hepatitis C

The Convener: Members have in front of them a letter from me, as convener, to the minister and the minister's response. I would like the views of the committee on where we go from here. Possible options are to write to the minister seeking details of the meetings that have been held and the arrangements for future meetings, or to ask the minister to give evidence to the committee after the recess.

Janis Hughes: As members who have been on the committee for some time know, the matter has been the subject of a long and protracted discussion. We have been seeking answers from the minister for some time now. The two options before us today are not mutually exclusive. Given that this is our last meeting before the parliamentary recess, we are restricted in what we do in the short term. I suggest that we do both: we write again to the minister seeking details of the meetings that have been held and the arrangements for future meetings, and we ask the minister to attend the first committee meeting after the recess, or if not the first meeting, an early meeting.

Shona Robison: I agree with Janis Hughes. It is important that we do both those things. However, we must try to pin the minister down about whether progress is likely to be made. I was disheartened by his response—little or no progress seems to have been made. By the time we return after the recess, people will have been waiting ever since the announcement was made, which is a period of about nine months. Expectations will have been raised about financial assistance. The situation is ridiculous. I am sure that many members have constituents asking them what is happening and when can they expect to hear something. That is difficult.

The committee should find out what the process is vis-à-vis the Privy Council. The minister referred to that in his letter. He says that he would rather that the issue be resolved by negotiation. I think that we would all agree with that because we want an outcome for the people concerned. However, we also need to furnish ourselves with the facts about how that process would work and how long it would take, so that we will have the information when we come back after the recess. We could perhaps ask the minister some questions about that if we were well briefed on it in advance.

The Convener: It would be handy if the clerks provided a note on the procedures for that.

Mr Davidson: We need to respond to the minister. I have outstanding a long letter that I sent to him about the problem. Although the letter has been acknowledged, I have not had a reply, and I

would like to know what the minister has to say when he replies. We need to take evidence from the Ross committee. It is the recommendations of that committee that the minister was minded to do something about. I am not sure whether there have been any changes to what has gone on behind the scenes over the nine-month period. Is there any new evidence?

The blood production people and others are willing to come to the Parliament to address the problems. We need to have a good briefing, and I am happy that the clerks can do that. We need to have the minister back, but we need to discuss matters in a briefing before he comes back, and not on the same day. We could perhaps have a briefing for one of the meetings, and the minister could attend the following meeting, so that we are up to speed. If we are writing to the minister, we could give him notice that we will require him to come on a particular date and that he should bring the latest information from whoever he has had to deal with in Westminster. The minister also has the evidence from Ireland. I found the way in which the Irish decided on claims interesting. Perhaps the briefing note could outline whether there are lessons to be learnt from that.

12:00

Dr Turner: I think that, this morning, we have learnt a lesson about how speedily legislation from Brussels can be introduced. However, now that we have our own devolved Parliament, legislative goings-on between Westminster and the Scottish Parliament are very sluggish.

I am only a new member, so please correct me if my understanding is wrong, but I am embarrassed and saddened by the fact that, although people who have hepatitis C know that the minister is willing to pay out and, although there has already been a decision about people in England who were given bad blood, we cannot make things happen in Scotland. Devolution is no good if it does not do our people any good. After all, those people do not deserve their illness; most of them happened to get it through treatment. It is not their fault, and they should not be penalised. I agree with all the comments that have been made. I do not know enough about the ways and means of getting the speediest resolution to the problem, but it is urgent that we do so, given that the minister essentially agrees that the pay-outs should be made.

Mike Rumbles: It is clear to me that the previous Health and Community Care Committee decided that that should happen in 2001, and the decision was endorsed by the expert group that the minister set up. According to our briefing note, the minister indicated that the Executive was minded to provide the money for those who are seriously ill. As a result, the decision has already been made.

It strikes me that the issue is a simple one of competence. Protocols already exist between the Scottish Executive and UK Government ministers by which competence issues can be resolved by both sides deciding to reach agreement without referring the matter to the Judicial Committee of the Privy Council for adjudication. Thankfully, we have not had to use that neutral body. I think that the minister intends to ensure that the UK Government and the Scottish Executive reach such an agreement.

However, now that five or six months have gone by, I feel that we have waited long enough. There is no need to take any further evidence, because the issue is closed as far as we are concerned. We know the right thing to do. Therefore, I ask that the committee responds to the minister directly, at this meeting, to urge him to reach the necessary agreement speedily. I hope that the committee will back my suggestion that, if the UK Government and the Scottish Executive have not reached agreement when we come back in September, we urge that the matter be referred to the Judicial Committee of the Privy Council. Nine months should be quite sufficient to reach an agreement.

The Convener: I think that we are going to wind up with a consensus on this matter, which would be a nice way to end the meeting.

Mr McNeil: It was a difficult time when all the hard work was done and the previous Health and Community Care Committee should be congratulated on the work that it did for hepatitis C victims. It was a massive breakthrough. After all, we are talking about a no-fault compensation scheme.

Anyone who has been involved with asbestos victims—as I have—knows that those people die waiting. They wait for nine or 10 years for compensation and go through an adversarial process that kills their spirit. I do not want to let the fact that a great job has been done for hep C victims go unsaid. We are bumping into issues such as the benefits system and clawback which impact on all other victims of perceived negligence or of circumstances such as hep C infection. We are dealing with a pretty big matter, so we should not be blasé about it.

The achievements so far have been great, but there are serious implications for the health service, GPs and clinicians. We must avoid an American-style system in which people consult their insurance agents before receiving treatment. Although I support the comments that we should put maximum pressure on the minister to respond to us as early as possible, I feel that the committee needs to examine various other issues that arise from the decision that we have taken.

The Convener: In that case, are members content for the clerks to draw up a briefing note that details the procedures that might be available to us if there is no consensus—such as referring the matter to the Judicial Committee of the Privy Council—and what has happened with hepatitis C elsewhere in the UK, in Ireland and perhaps in Europe? Are members also content that we circulate for approval a draft letter to the minister, asking him about the number of meetings that have been held and informing him that we seek to call him to the second meeting of the committee after the recess?

Finally, are we content to call the minister to that committee meeting? That will keep some pressure on him.

Members *indicated agreement*.

The Convener: I am pleased that we have ended up happy at the end of the meeting. You are a robust team.

Meeting closed at 12:05.

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