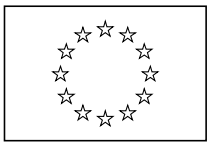

EUROPEAN COMMISSION
DIRECTORATE-GENERAL JRC
JOINT RESEARCH CENTRE

Technical Assessment of Pectin as Food Additive for Radiotoxicity Decontamination in Belarus

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EXECUTIVE SUMMARY

European surveys undertaken in the context of the EU/CIS co-operation programme to evaluate the consequences of the Chernobyl accident (1991-1995) provided an extensive assessment of the living conditions in the contaminated territories in Ukraine, Belarus and Russia. A key feature of the post-accident situation is the multiplicity and interdependency of the objectives at stake, namely (a) radiological protection of the population, (b) public health care, (c) restoration of acceptable living conditions and (d) long-term economic rehabilitation of the contaminated territories.

15 years after the Chernobyl accident, ^{137}Cs remains the most important radionuclide[1] in the environment and the food chain in Belarus. Radioactive fallout (1 or more Ci/km^2 of ^{137}Cs) still affects 23% of the country.

A number of surveys and pilot projects have already focused on assessing and improving the quality of the environment and living conditions of the population in the most heavily contaminated areas. These include efforts to educate local people (both children and adults) in radiological protection, to reduce the risk posed by the food chain by improving agricultural practices, and to instil radiological protection practices in households. An evaluation of the results obtained has shown that such multidisciplinary approaches hold good potential for the reduction of the risk posed to public health due to the radiological (mainly ^{137}Cs) contamination of the environment and the food chain.

Environmental rehabilitation and radionuclide removal from the environment is certainly the most effective way for long-term improvement of life quality in the contaminated areas of Belarus. Their results, however, will produce a significant reduction to the level of total effective exposure to radioactivity of the population only in a time frame of ten years. Reducing, therefore, the effective exposure of vulnerable parts of the population in the most contaminated areas (such as the children of the area of Gomel) as soon as possible is a short-

[1] M. De Cort et al, 1999, Atlas: Caesium deposition on Europe after the Chernobyl accident, European Communities, Luxembourg.

to medium-term objective that is expected to alleviate the health burden on children due to post-Chernobyl radiological contamination.

This report is aimed at investigating the possibilities for using food additives as agents for decorporation of artificial radionuclides such as ^{137}Cs in the immediate future, in particular from children living in the most highly contaminated areas of Belarus such as Gomel. A variety of food additives has been used to promote the decorporation of radioactivity and of heavy metals: pectin, spirulin, seaweed, and ß-carotene amongst others. Pectin in particular, has a demonstrated record of accomplishment in binding heavy metals such as lead and subsequently facilitating its excretion from the human body. Currently used alternatives to food additives include Prussian blue (ammonium-ferric-hexacyanoferrate; the active ingredient in Giese salt) and zeolites. The former is the official substance used in emergency contamination by radionuclides; the latter has been used widely in Sweden to remove the radioactivity from the body of moose and deer, in order to protect animal health and to avoid the introduction of hazardous radionuclides in the food chain.

The JRC was asked to provide a scientific evaluation of the project Test, proposed by a research team led by Profs. Nesterenko and Fernex. The project regards a double-blind with crossover trial of administering Vitapect, an apple pectin-containing food additive, to a cohort of children in selected villages of the area of Gomel in Belarus. In this context, the JRC has undertaken a technical assessment of the quality of Vitapect, the food additive that the team of Prof. Nesterenko suggests using in order to decontaminate the children of the area of Gomel in Belarus. A chemical analysis concerning non-radiologic toxic contaminants showed presence of lead in values ranging from 1.7 to 2.6 ppm. This result is based on multiple measurements performed by the JRC and an external laboratory. The average value of lead existent in the Vitapect samples furnished by Prof. Nesterenko was on the order of 2.0. However, the large variability of the measurements shows that the product is not homogeneous; significant effort should be made to improve the manufacturing process in order to produce a consistently low-lead output. As the lead content in the pectin product is dependent on the lead content in the apples used that, in turn, depends on growth conditions, e.g from environmental contamination, the apples should be controlled prior to production or at least the final product must be checked for lead contamination. Tests for patulin and other non-radiologic contaminants resulted negative.

Gamma spectrometry tests of the Vitapect samples used in the chemical analyses described above showed that the level of radioactivity was negligible. No artificial radionuclide was found. Only ^{40}K was present in the samples tested.

The chemical composition of the samples were analysed at an external laboratory specialised in analysis of pectin and pectin preparations. The results showed that the Vitapect content in pectin was 12%[2]; the substance was highly esterified (degree of esterification DE = 77.4%). Such a DE is typical of pectin found naturally in apple and apple pomasse. Highly esterified pectin would not be expected to have a good binding capacity for heavy metals and, in particular, caesium. However, the team of Prof. Nesterenko has repeatedly reported very encouraging results regarding the efficacy of using Vitapect as a food additive for rapid decorporation of artificial radionuclides (particularly ^{137}Cs). The results of both field (uncontrolled environment) experimentation and campaigns involving children in sanatoria (controlled environment) have indicated that a significant rate of ^{137}Cs decorporation can be obtained with the administration of Vitapect as a daily additive to the normal diet of the child population in the contaminated areas.

Hence, having reviewed the Test project suggested by Profs. Nesterenko and Fernex, the view of the JRC is that a study involving both field measurements (i.e. administration of pectin-based food additives to children in households) and measurements in a controlled environment (i.e. administration of pectin-based food additives in children staying in

[2] It is worth noting that all experiments that have reported good results with regard to the potential of pectin for binding and excreting heavy metals such as lead from contaminated individuals were performed with pure pectin, which was administered at a much higher daily dose than the one foreseen in the protocol of Prof. Fernex.

sanatoria for a period of the order of one to two months annually) could provide important information concerning the efficacy of pectin as a radioactivity-reducing agent. Special care has to be taken in order to ensure that additional measurements such as analysis of urine and/or faeces complement the double-blind clinical trials and the whole body counts of the children involved in the study.

In addition, the project team could consider adding to the study protocol a third group of children. A preparation with higher content of pectin with a lower degree of esterification (i.e. of a higher theoretical potential for binding heavy metals) would be administered to this group. The goal would be the determination of the actual effect that the complexification potential of pectin could have on the decorporation of ^{137}Cs from the body of children in the contaminated areas of Belarus.

The JRC recommends to reduce the total number of children involved by a factor of five, namely from approximately 2,930 in the original proposal to about 540 in order to contain the cost of the project and reduce any potential risk from heavy metal contamination, without significant loss of statistical validity of the results obtained.

The results of this study could have a beneficial impact towards addressing one of the key priorities identified by the UN special mission to Belarus on assessing the status of health in this country, namely, towards reducing the adverse psychosocial effects of the Chernobyl accident on the health of the population in the contaminated areas.

1. Outline of the problem in Belarus - literature review

European surveys undertaken in the context of the EU/CIS co-operation programme to evaluate the consequences of the Chernobyl accident (1991-1995) provided an extensive assessment of the living conditions in the contaminated territories in Ukraine, Belarus and Russia. A key feature of the post-accident situation is the multiplicity and interdependency of the objectives at stake, namely (a) radiological protection of the population, (b) public health care, (c) restoration of acceptable living conditions and (d) long-term economic rehabilitation of the contaminated territories.

15 years after the Chernobyl accident, ^{137}Cs remains the most important radionuclide in the environment and the food chain in Belarus. Radioactive fallout (1 or more Ci/km^2 of ^{137}Cs) still affects 23% of the country.

In 1990 the first cases of childhood thyroid cancer were reported in Ukraine and Belarus[3]. In 1992 the European regional Office of WHO, together with the European Union, convened an expert panel to assess claims from doctors in Belarus. These claims were confirmed and reported by a WHO mission to Belarus[4] but were initially greeted with scepticism. It is now clear that there has been a very marked rise in thyroid cancer in those who were children at the time. The latest report by the United Nations Scientific Committee of the Effects of Atomic Radiation (UNSCEAR) published in 2000 acknowledges 1800 thyroid cancer in children residing in the affected area up to the end of 1998, although others claim that this is an underestimate. An estimate of the total lifetime yield of thyroid cancer is 6 to 8,000 in the three countries. These cancers are associated with exposure to the isotopes of iodine, overwhelmingly most likely ^{131}I, although this is still contested by some.

Studies on the genetic consequences, in terms of micro-satellite instability, in children born after the accident from parents who lived in contaminated zones possibly indicate a genetic effect from paternal irradiation but the results are controversial and the health significance of micro-satellite instability is unclear.

In the fifteen years since the accident many claims of large numbers of casualties, both in terms of morbidity and mortality, of a reduction in fertility and of birth defects have been made by various sources within and outside the affected countries. So far, apart from the thyroid cancer, there has been no internationally accredited evidence for an association with radiation exposure from the accident.

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3 IAEA 1991 The International Chernobyl Project, Technical Report, Para 3.11.2.

4 Kazakov et. al. Nature (1992) **359**, 21-23

A number of surveys and pilot projects have already focused on assessing and improving the quality of the environment and living conditions of the population in the most heavily contaminated areas. These include efforts to educate local people (both children and adults) in radiological protection, to reduce the risk posed by the food chain by improving agricultural practices, and to instil radiological protection practices in households. An evaluation of the results obtained has shown that such multidisciplinary approaches hold good potential for the reduction of the risk posed to public health due to the radiological (mainly ^{137}Cs) contamination of the environment and the food chain.

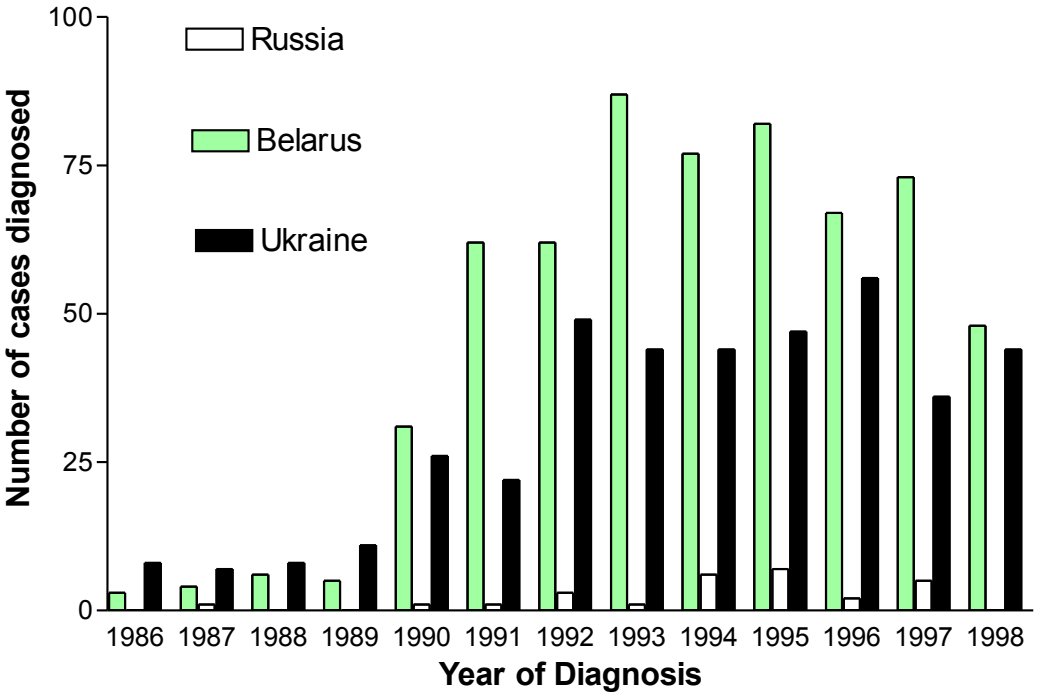

Figure 1: Numbers of cases diagnosed vs. year of diagnosis for thyroid cancer diagnosed in children under the age of 15 years at diagnosis.

The ETHOS project operating in Olmani village near Stollin in the Brest Region of Belarus was a good example of how education of the population into ways of reducing individual risks can be successful both in reducing doses and in giving a degree of personal control over risks incurred.

From a radiological protection point of view, "control" values for maximum contamination levels in foodstuffs for contaminated settlements have been subject to continuous updating over the past 15 years. A primary criterion presently in force is that no one shall receive a dose rate greater than 1 mSv per year. This has led to the setting of control values for caesium and strontium food products at quite low values. Such low values are achieved either through discarding products above such control values or by the use of various agricultural dose reduction techniques referred to above. In addition, there are numerous restrictions on agricultural, forestry and other economic activities on contaminated lands. The overall effect has been to 'ring fence' the risk within the contaminated areas and populations living in them. The loss of productivity from these regions is of no little economic consequence at the national level in Belarus. Thus, a sense of victimisation has been created in the affected populations in relation to neighbouring populations living a freer existence in uncontaminated regions.

While at the present time foodstuffs within the control limits are available through commercial sources it seems to be the case that much of the privately produced food products, particularly milk, is rarely tested and thus, may be being consumed with radioactivity above the control values. In addition, there is an increasing tendency to ignore restrictions on consuming forest products. Thus, in spite of radioactive decay and other processes that have eroded the environmental radioactivity levels, doses may be increasing in a proportion of the

population due to these two factors. It seems to be the case that some of the affected populations, numbering a few tens of thousands, maybe receiving annual doses of the order of 5 mSv a year, while at the present time the majority of the population classified as "affected" receives 1 mSv/year or less. The health of this higher dose rate category should be the primary focus of health related activities directed to the direct effects of radiation.

Environmental rehabilitation and radionuclide removal from the environment is certainly the most effective way for long-term improvement of life quality in the contaminated areas of Belarus. Their results, however, will produce a significant reduction to the level of total effective exposure to radioactivity of the population only in a time frame of ten years. Reducing, therefore, the effective exposure of vulnerable parts of the population in the most contaminated areas (such as the children of the area of Gomel) as soon as possible is a short- to medium-term objective that is expected to alleviate the health burden on children due to post-Chernobyl radiological contamination.

This report is aimed at investigating the possibilities for using food additives as agents for decorporation of artificial radionuclides such as ^{137}Cs in the immediate future, in particular from children living in the most highly contaminated areas of Belarus such as Gomel. About five hundred thousand children in Belarus are exposed daily to radiation from their environment and from contaminated food. Many of these children develop severe illnesses and damage as the result of chronic exposure.

The work of Prof. V. Nesterenko, Director of Institute of Radiation Safety « Belrad » in Minsk, and his colleagues, indicates that a significant decrease in the radiation levels of ^{137}Cs measured in children after treatment with a specific pectin enriched diet. Prof. Nesterenko presented his work and the proposed "Test" project at a meeting at JRC on 21 June 2001. In an experiment reported by Prof. Nesterenko, pectin supplement decreased caesium radiation by 45%, while eating clean (non radiologically contaminated) food, out of Belarus, whereas for children in the control group, eating clean food but no pectin supplement, radiation decreased by 15%. Prof. Yuri Bandazhevski, MD, and his research team have produced a large amount of information on the health effects of chronic exposure to low-level radiation, especially concerning the most vulnerable parts of the population in the contaminated areas, namely infants, children and the elderly.

2. **Assessment of food additives for radiologic protection**

A variety of food additives has been used on an experimental basis for the protection of vulnerable population such as children from radiological hazards caused by chronic exposure. Such substances include selenium, β -carotene, seaweed, spirulin, and pectin.

In this context, it is worth reminding a large-scale food additive field project that was carried out in China, on " Selenium Deficiency and Endemic Cardiomyopathy in China"[5]. Chinese children suffered from Keshan disease, reportedly due to lack of selenium in the soil and in their diet. Giving more than 300,000 children selenium as food additive decreased the disease incidence to 0.27 cases per 1000, as compared with incidence of 1.55 cases per 1000 in more than 1,100,000 children who did not get the selenium. In addition, only one child died in four years among the selenium supplement treated, while 53 died with no selenium supplement.

The Chernobyl Chronic Syndrome (CCS) as lipoperoxic stress coupled with deficits for essential antioxidants for contingents exposed to low (children) and low-middle (adults) radiological burdens and rates has been evaluated by a team of the Institute of Biochemical Physiscs in Moscow[6]. A new radiogenic mechanism for human hypovitaminoses E and A, widespread in the developed countries affected by the accident, has been found. Peroral therapy by multivitamin bioantioxidants prevented, ameliorated or cured all studied

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[5] Selenium Deficiency and Endemic Cardiomyopathy in China, Keyou Ge, Institute of Nutrition and Food Hygiene, Chinese Academy of preventive Medicine, Beijing, in: Nutrition, Lipids, Health, and Disease;.S.H, Ong, E. Niki, and L. Packer, Editors, AOCS Press, Champaign, Illinois

[6] Bioantioxidants for the Health of the People in Chernobyl, Eugene A. Neyfakh, Institute of Biochemical Physics RAS, Moscow, Russia, ISRH 2001 Satellite Symposium

radiogenic interrelated pathologies, increasing human radioresistence significantly. Further attempts were made to evaluate a significant number of children (about 700) who had been exposed for a long time to different doses of radiation during and after the Chernobyl accident[7]. The level of oxidation of in vivo blood lipids in children from the contaminated areas was increased; higher in the case of girls than for boys.

The above are two examples of studies carried out on children and adults, using food supplements to remedy radiation damage. These two studies take different approaches from the one used and suggested by Prof. Nesterenko. It may be possible to use an extract of the algae *Dunalliela bardawil* in capsulated powder form (β-carotene) as a replacement to pectin. However, it was not claimed that this substance is removing caesium from the body of the patients. It could be used as a control and comparison system to the pectin under study.

Other work presented in the Radioprotectors for Human Health meeting of July 2001 in Kyoto[8] reports mainly on experiments with animals or laboratory experiments that were carried out on tissues and cells, and not on humans.

Pectin can be useful for its absorbent properties in cases of intoxication by heavy metals to reduce radionuclides in the organisms. The first reports that pectin was a good antidote for heavy metal poisoning were published in 1951[9]. Since then, it has been discovered that the absorption of strontium into the bone structure of rats can be suppressed by pectin [10,11,12]. The gastrointestinal tissue of rats fed a diet containing pectin was found to contain only 0.1% of ^{90}Sr in the diet. The binding of strontium *in vivo* is less effective of acidic than at alkaline pH. Waldron-Edward et al (1965)[13] did not detect any strontium in the blood, 24 hr after their subjects ingested pectin; strontium concentration in the skeleton was significantly lower, when compared to that from a pectin-free diet.

The affinity of pectin for metals is, as follows: Mg < Mn < Cr < Hg < Fe < Ni < Co < Cu < Zn < Sr < Cd < Ba < Pb[14]. Pectin has been evaluated as a prophylactic agent against lead toxicosis. Pectic substances form insoluble pectinates *in vivo* that are excreted in the stool and urine. Typical symptoms of lead poisoning disappeared when some factory workers ate 8-9 g of pectin per day[15].

Following the Chernobyl nuclear disaster, Ukrainians were fed pectin-enriched foodstuffs, in order to take advantage of the complexing ability of pectin with radioactive nuclides[16]. For prophylactic purposes, one should take 15 gr. of pectin with food each day. The advantage is that the suggested Vitapect is a food product and not a medicine. A potassium supplement could be justified to correct the potassium loss due to an increased faecal volume[17].

Finally, with regard to the metabolic effects of dietary pectins the following conclusions can be drawn from clinical research thus far[18]:

1. The feeding of pectin to healthy and especially to hypercholesterolemic subjects significantly reduces cholesterol levels considered a risk factor in heart disease.

2. The inclusion of pectin in carbohydrate-containing meals or drinks significantly reduces the glucose and insulin responses of both normal and diabetic subjects.

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7 Ben-Amotz, A., Yatziv, S., Sela, M., Greenberg, S., Rachmilevich, B., Shwarzman, M., Weshler, Z. (1998) Effect of natural β-carotene supplementation in children exposed to radiation from the Chernobyl accident, *Radiat. Environ. Biophys.*, **37**, 187-193.

8 *Radioprotectors for Human Health*, ISRH 2001 Satellite Symposium, July 16, 2001, Kyoto, Japan.

9 Kertesz, Z.I. (1951), *The Pectic Substances*, Interscience publishers, New York.

10 McDonald, N.S., Nusbaum, R.E., Ezmirlian, F., Barbera, R.C., Alexander, G.V., Spain, P., Rounds, D.E. (1952), Gastrointestinal absorption of ions I. – Agents diminishing absorption of strontium, *J. Pharmacol. Exp. Ther.*, **104**, 348-353.

11 Rubanovskaya, A.A. (1960), The influence of pectin on the radio strontium absorption from the gastrointestinal tract under experimental conditions, *Postupila v redakciju 16/XI*, 43-47 (in Russian).

3. The feeding of pectin does not decrease the bioavailability of minerals such as calcium, magnesium, zinc, and copper. However, the bioavailability of iron has been shown to decrease by pectin in some, but not all, human studies.

4. Additional human research is needed to determine the effect of pectin on the bioavailability of vitamins.

Based on these findings, the inclusion of moderate levels of pectin in the diet appears to be advantageous.

3. **Review of alternatives to food additives for radiological protection**

To date, three different products or substances have been used as chelators or binders of Cs in order to reduce the body burden. These are bentonite (a clay mineral), natural or artificial zeolites, and ammonium-ferric-hexacyanoferrate (AFCF, $NH_4Fe[Fe(CN)_6]$); AFCF is also called Prussian blue or "Berliner Blau". It is the active ingredient in Giese salt (65 % AFCF the rest is ammonium chloride). AFCF has proven to be about 10 times more effective than bentonite and zeolites. The experience of the international radioprotection scientific community comes mainly from trials with farm animals like cows, sheep and goats and from reindeer. In addition, a few trials with AFCF have been made on humans. Zeolites and AFCF has been used therapeutically in larger scale in Scandinavia on sheep (Norway) and reindeer (Sweden) in areas that received Chernobyl fall-out.

All substances are insoluble in water and gastro-intestinal juices. They are given to the animals through the mouth in a granulated form. They stay in the gastro-intestinal tract and they are excreted with the faeces. They are not absorbed into the blood and transported to other organs. They all have a high selectivity for Cs in comparison with essential ions like Na^+, K^+, Ca^{2+}. Therefore, the electrolyte balance of the body is not compromised by the administration of these substances. AFCF is also binding thallium and is used as an antidote for thallium poisoning.

Bentonite, zeolites and AFCF reduce the Cs-137 content in the body by two mechanisms:

1) By reducing the uptake of Cs-137 from ingested food items.

2) By binding Cs-137 in the fluids secreted to facilitate food digestion (like saliva, gastric juice, bile,). The total production of digestive fluids in a 70-kg person is 7-9 liters/24h. Most of this fluid is reabsorbed in the large intestine together with the water ingested (10-12 liters/24h). Hence, the recirculation of body fluids through the gastro-intestinal system provides an efficient mechanism to bring body fluids in contact with insoluble material in the intestinal lumen.

As already mentioned, AFCF is the most efficient of the compounds discussed above. Scientists working in the field consider AFCF as the first choice in Cs reduction therapy. Pure AFCF is non-toxic although the commercial product Giese salt may show some toxicity because of its content of ammonium chloride. About 7% of the hexacyanoferrate in AFCF is absorbed but it is rapidly excreted through the kidneys. Long-term treatment (more than 3 months) may lead to some accumulation of hexacyanoferrtate in tissues. Some of the hexacyanoferrate is degraded to Fe-ions and CN^- but they are metabolised before reaching toxic concentrations.

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[12] Patrick, G. (1967), Inhibition of strontium and calcium uptake by rat duodenal slices: Comparison of polyuronides and related substances, *Nature*, **216**, 815-816.

[13] Waldron-Edward, D., Paul, T.M., Skoryna, S.C. (1965), Suppression of intestinal absorption of radioactive strontium by naturally occurring non-absorbable polyelectrolytes, *Nature*, **205**, 1117-1118.

[14] Paskins-Hurlburt, A.J., Tanaka, Y., Skoryna, S.C., Moore, W., Stara, J.F., Stara, J.R. (1977), The binding of lead by a pectic polyelectrolyte, *Environ. Res.*, **14**, 128-140.

[15] Stantschev, S., Kratschanov, C., Popova, M., Kirtschev, N., Marteschev, M. (1979) Anwendung von granuliertem Pektin bei Bleiexponierten, *Z. ges. Hyg.*, **25**, 585-587.

[16] H.-U. Endress (1991) Nonfood uses of pectin, in: R.H. Walter (ed.) *The chemistry and technology of pectin*, Academic Press, 251-268.

[17] Depiesse, D. (2001) personal communication.

[18] Reiser, S. (1987) Metabolic effects of dietary pectins related to human health, *Food Technology*, 91-99.

Comparing the use of non-food additives such as the substances discussed above and pectin the following observations are in order. Pectin has some capacity to bind Cs as well as other mono-, di-, and trivalent cations but not at all with the same selectivity as for example AFCF. The fact that pectin works as a lead (Pb) antidote does not per se mean that it will work with Cs. The behaviour of pectin in the gastro-intestinal system is not known, but since it is a polysaccaride it can be assumed to be digested - at least partly - while bentonite, the zeolites and AFCF are by almost inert. In addition, pectin products can be contaminated by heavy metals like Pb and Cd (depending on the level of heavy metal contamination in the primary material, e.g. apple). This potential risk warrants additional precautions when given to vulnerable receptors such as children in particular. Referring to the problem with Cs-137 contamination of the children in the Chernobyl- and other Cs-137 contaminated areas, the emphasis must be put on reducing the intake of Cs-137 in the first instance, either by providing non-contaminated food or by the introduction of simple procedures to reduce the Cs-137 in food items. By adapting certain cooking procedures the Cs-137 content in vegetables, meat and fish can be reduced with up to 75%. Milk can be purified by introducing zeolite or AFCF traps in diary factories or at home level on the farm. Some Cs accumulating food items, like mushrooms, should be avoided. In special “bad cases” the possibility of AFCF therapy can be considered but the toxicological impact on humans of prolonged use is not known and care must therefore be taken particularly when given to children. A better understanding of the therapeutic use of AFCF could be another promising avenue with respect to research priorities, possibly even more so than the use of pectin.

4. Technical analysis of Vitapect

4.1Analysis of radiological contamination of Vitapect

Gamma spectrometric analysis was carried out on a sample of Vitapect in order to determine the possible degree of radiological contamination in the pectin-based preparation. The sample has been analysed by gamma spectrometry at the JRC laboratories for radioactivity measurements. It was poured in an appropriate plastic container (90.4 grams of the original 150 grams), for which the detector calibrations in energy and efficiency had been previously calculated.

The gamma spectrometry analysis has been carried out using a Germanium detector, shielded with lead (10 cm isotropic thickness), with the following nominal characteristics:

- type GX-p
- resolution at 1.33 MeV: 1.78 keV
- resolution at 122 keV: 0.87 keV
- peak/Compton ratio for Co-60: 69.1
- relative efficiency at 1.33 MeV: 43.5 %.

The measurement lifetime was 60000 seconds, with a dead time of about 2 %. The laboratory background has been subtracted. The minimum detectable activity is about $4 \cdot 10^{-2}$ Bq total for Cs-137 (662 keV) and about $8 \cdot 10^{-1}$ Bq total for K-40 (1460 keV).

The gamma spectrometry analysis has shown only the presence of K-40. No artificial radionuclide has been detected. The attached picture shows the full gamma spectrum. The regions identified as peaks are in red colour. The concentrations of natural radionuclides are comparable to those present in the laboratory background, but the K-40, calculated as 0.7 Bq per gram of sample, with an uncertainty of 3.7% at 1 σ.

4.2 Analysis of selected potential contaminants

A total of 5 pectin samples of one batch were analysed for patulin (a toxic fungal metobolite that is known to occur in apple products of low quality) and the heavy metals lead and cadmium.

4.2.1 Methods of analysis used

Analysis of patulin: The sample material was extracted with ethyl-acetate and analysed according to an official method[19].

Analysis of heavy metals: The sample material was mineralised with nitric acid and analysed by AAS (atomic absorption spectroscopy) according to an official method[20].

4.2.2 Analytical results - discussion

The results of the analytical tests are summarised in the table below:

Table 1: Concentration of selected contaminants in Vitapect

Contaminant	Concentration (mean values)
Patulin	< 10 µ g/kg
Cadmium	0.017 mg/kg
Lead:	2.033 mg/kg

The level of patulin contamination did not exceed the commonly proposed maximum limit for apple juice[21].

The level of cadmium found in the samples is below the regulatory limit of 0.05 mg/kg given for vegetables and fruit[22].

The value of lead exceeds the regulatory limit of 0.1 mg/kg for vegetables and fruit. Furthermore, the regulatory limit of the US EPA for lead in water is 0.15 ppm. According to the indications provided by Prof. Nesterenko's team Vitapect powder is administered to children diluted in a glass of water. Hence, the lead concentration limit found in the powder with lead in drinking water or fruit juice was deemed as a reasonable benchmark for Vitapect.

At the request of the JRC, Prof. Nesterenko's team had additional analyses made on the current Vitapect production by the State Laboratory of Belarus. These analyses showed a lead concentration on the order of 0.035 ppm. According to Prof. Nesterenko these samples contained Vitapect that was produced from apples coming from a non-contaminated area of Belarus. The samples originally analysed by the JRC were produced from apples coming from Ukraine.

Moreover, the analyses done by the JRC showed great variability with regard to the content of the sampled material in lead. Hence, the JRC sent an additional two samples to an external laboratory under strict confidentiality conditions and without disclosing the nature, name or origin of the samples. The results have an average value of lead of 1.75 ppm.

The conclusion of the JRC team is that lead contamination may be an issue of concern when administering Vitapect to vulnerable individuals such as children. The variability in the lead content indicated that significant effort has to be made to ensure that the manufacturing process results in a consistently high quality product. At the same time, analytical quality controls have to be put in place upstream the manufacturing process in order to be certain that the raw material used (apples in this case) is not contaminated. Finally, quality control at the end of the manufacturing process needs to be continuously operational, especially if large-scale production is required to meet the needs of the contaminated territory.

4.3 Analysis of the chemical composition of Vitapect

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19 Journal of the AOAC, vol.83, pp.1387-1394.

20 Sammlung offizieller Analysenverfahren nach 35 LMBG.

21 The national regulatory limit for patulin in several EU member states is currently 50 µ g/kg.

22 EC Regulation 466 2001 (08.03.2001).

Samples of Vitapect were analysed at an external (to the JRC) laboratory, which is specialised in analysis of pectin and pectin-containing preparations. The results are as follows:

Table 2. Chemical composition of Vitapect samples

30 % Sugar (reducing sugars after inversion)
15 % Fructose (enzym.)
6 % Glucose (enzym.)
4 % Sucrose (enzym.)
5 % other sugars (calculated)
28 % insoluble dietary fibres (AOAC total dietary fibre method)
12 % Pectin with a degree of esterification (DE) = 77.4 % (titrated according to Deuel)
3 % Starch (enzym.)
8 % Water (2h, 105°C)
6 % Ash (2h, 550°C)
6 % Citric Acid (enzym.)
5 % Protein (N x 6,25)
_____
98 % in total

This composition looks like a milled apple pomace fortified with some other substances. A pectin content of 12 % is very low. A DE of 77 % is typical for the native pectin in apples and apple pomace. Also a pectin content between 10 and 15 % is usual for dried apple pomace. The smell of the Vitapect-2 is also typical for dried apple pomace.

It was concluded that Vitapect-2 is not produced from isolated pectin. Vitapect-2 probably is milled apple pomace (with some apple powder) fortified with different substances but not with pectins. The DE is very high. A low degree of esterification is required so that pectin can effectively bind and excrete heavy metals. This should also be necessary for caesium. In the colon, bacteria producing pectin-degrading enzymes could de-esterify this pectin; consequently, also highly esterified pectin could be transformed into the more effective pectin with low degree of esterification. However, the latter would only act in the colon and thereafter and not in the small intestine where resorption should take place.

5. Technical evaluation of the TEST project

The project TEST is a thoroughly prepared scheme aiming at evaluating the efficacy of using Vitapect for radiological decontamination of children in the area of Gomel in Belarus. A series of double-blind tests will be carried out using the preparations Vitapect and placebo. The authors of the project recommend carrying out TEST in zones with different contamination levels, with different internal and external radiation doses, with different levels of foodstuff contamination and different levels of radionuclide accumulation in the children body. In order to measure the efficacy of introducing Vitapect in the normal diet of the children as a strategy for their immediate protection from radiation in the food chain and the environment the project proposal foresees that the research would be carried out at their place of residence. The project would be combined with three public seminars, in the beginning, the middle and the end of the project in order to explain to the inhabitants of the villages involved its scope and findings. TEST is expected to involve approximately 2930 children from schools in 12 villages of the area of Gomel.

If the results are not proven and Vitapect-2 has no positive effect on the caesium level of the volunteers we will have no information on the effect of a pectin or a pectin based product like Medetopekt (which can not be compared with Vitapect-2). To get this information a further study or eventually parallel to the Vitapect-2 study a Medetopect or pure pectin study should be done. The dosage probably has to be higher than suggested by Prof. Nesterenko. We suggest 3 g pure pectin a day or 3 times a day 5 tablets of Medetopect.

A number of modifications are proposed by the JRC to the structure of the project TEST as prepared by Prof. Fernex. They can be summarised as follows:

1) Reduce the number of children involved in the study by a factor of three. The original project would involve about 2,930 children living in several villages spread across the region of Gomel. However, the requirements for statistical significance of the results could be met by working at approximately six of the most contaminated villages, involving about 90 children in each village. This would amount to 540 children in total. The groups of 90 children could be divided in three sub-groups of 30 as follows:

- A group taking Vitapect for the period of the trial
- A group taking purer pectin with a low degree of esterification
- A group taking placebo

2) Special care should be taken to ensure that the children involved are chosen amongst the most contaminated ones. This would offset all possible (even if unlikely) burdening of their body with heavy metals such as lead, which might be present in the Vitapect preparations. Lead contamination of the preparation is possible due to the inhomogeneity observed in the Vitapect composition.

3) Accompany the implementation of the TEST protocol with ancillary measurements beyond the total body count. These measurements should include analysis of urine (and to the extent that it is possible, faeces) and blood testing. The scope of these additional analyses would be twofold: to allow a better understanding of the mechanism and excretion rate of caesium from the children body; and to ensure that the children participating in the study do not run the risk of contamination from heavy metals such as lead, traces of which might be found in the Vitapect preparation.

4) The study should be made in two parts:

(a) a measurement campaign done in a controlled environment like a sanatorium, where children would be eating decontaminated or uncontaminated food and, in addition, the food additive (be that Vitapect, high-quality pectin or placebo); and

(b) a field measurement campaign done at the schools of the six villages; the children here, would undergo their normal diet (consisting of uncontrolled food).

The reason for integrating the studies in controlled and uncontrolled environment is to make sure that the effect of the food additive on ^{137}Cs decorporation is isolated and unambiguously verified. At the same time, the uncontrolled environment study would provide evidence on the efficacy of using Vitapect for radiological protection in real-life situations in Gomel.

The cost of the modified project TEST as per the JRC suggestions would be almost €120,000 in contrast to the €147,000 of the originally proposed test (EC contribution). It would have the same duration as the originally planned project.

6. Conclusions

The direct effects on health of sensitive parts of the population in areas affected by chronic exposure to radioactive fall-out of the Chernobyl accident is still a matter of scientific debate and further epidemiological research. The overall condition of the health in contaminated areas of Belarus like Gomel has markedly deteriorated over the last five years. This can be attributed partly to long-term exposure to contaminated food (including local agricultural produce and husbandry products) and economic impoverishment. Although remedial actions targeting the improvement and rationalisation of local agricultural and farming practices will bring definite long-term benefits, action to reduce the chronic contamination loading of vulnerable subjects such as children would have a doubtlessly positive impact on local health.

The use of food and non-food additives for the decorporation of ^{137}Cs (the main radionuclide of concern in this context) has been experimentally investigated since the 1970s. Recent results of the team of Prof. Nesterenko in Belarus have given encouraging results.

These results, however, would need validation from the international scientific community. The JRC has performed an extensive review of the related literature; it has analysed chemically and radiologically the pectin-based preparation used by Prof. Nesterenko (Vitapect); and it has reviewed the technical and financial requirements of the project TEST (a double-blind study aiming at investigating the effectiveness of Vitapect as an agent inducing the reduction of radioactive contamination of Belarus children). Indications of lead contamination of Vitapect were found from chemical analyses both by the JRC and by an external laboratory. Furthermore, analysis of the chemical composition of the product showed low content of pectin; moreover, the heavy metal binding capacity of this pectin would be expected to be relatively low.

Thus, the JRC has put forward a series of recommendations aiming at improving the relevance of project TEST to the thorough investigation of the effectiveness of pectin in radiological decontamination. In addition, the JRC recommendations aim to reduce the number of subjects involved to the bare minimum in order to limit potential hazards from heavy metal contamination.

The overall conclusion is that project TEST has the potential to provide a definitive answer to the questions raised with regard to the effectiveness of pectin in the fight against radiological contamination, validated through an international ethical committee. The JRC suggests that the ethical committee includes internationally renowned scientists in order to safeguard the validity of the results. The following experts are suggested for consideration as members of the committee:

- Dr. K.F. Baverstock, Regional Advisor on environmental radiation and public health at the WHO Regional Office for Europe, Helsinki, Finland.
- Dr. A. Enflo, Swedish Radiation Protection Institute, Stockholm, Sweden.

The detailed information on the two experts and their contact details are available upon request.

A l'attention du Professeur Michel Fernex et de Wladimir Tchertkoff

Commentaires sur le rapport de D.Sarigiannis, Y Sidere er E,Anklam:

"Appréciation technique de la pectine en tant qu'additif alimentaire destiné à l'élimination des éléments radioactifs et toxique de l'organisme des habitants de la Bielarus"

Page 4

Pour la fabrication de Vitapect on n'utilise pas de la pectine pure mais du tourteau de pomme (la pulpe après qu'elle ait été pressée pour en extraire le jus) qui est composé de pectine (environ à 12%) et de cellulose. Il nous est arrivé de produire du Vitapect à base de pectine pure (fabriquée en Autriche) comme à base de tourteau de pomme contenant de la pectine. En 2000 lorsque nous nous trouvions en Autriche (Tyrol) avec deux groupes d'enfants, nous avons fait prendre à 20 enfants pendant 21 jours du jus fait à base de pure pectine autrichienne et à 20 autres enfants – le Vitapect biélorusse contenant un mélange de pectine et de cellulose. L'examen de contrôle au moyen du SRH de ces enfants avant le voyage et après le séjour en Autriche a montré que le taux de césium 137 avait diminué de 30% chez les enfants qui avaient pris le jus à base de pectine pure et de 45% chez ceux qui avaient reçu le Vitapect avec pectine et cellulose.

Tout le stock de tourteau de pomme que nous désirons acheter est soumis avant l'achat à un contrôle sur la présence de césium 137 et de plomb. En outre une fois par mois, à mesures qu'elles sont produites, les boîtes de Vitapect sont soumises à un contrôle du Centre de certification et de sécurité des produits alimentaires du ministère de la Santé de Belarus concernant tous les éléments qu'elles contiennent.

Nous sommes d'accord d'ajouter au programme des examens à effectuer au sanatorium, des analyses supplémentaires du sang, des urines et des selles de ceux des enfants qui prendront des additifs alimentaires.

Nous sommes d'accord d'inclure au protocole des examens un troisième (peut-être même un quatrième) groupe d'enfants qui prendraient des produits à plus forte teneur de pectine à faible niveau d'estérification.

On a fait l'expérience en Bielorus au sanatorium clinique d'Aksakovchtchina (près de Minsk) de donner pendant 5 jours à des enfants à forte accumulation de cesium 137 dans l'organisme du charbon activé. La purification de l'organisme pour ce qui est du cesium 137 s'est révélée efficace cependant le charbon avait parallèlement éliminé de l'organisme de ces enfants jusqu'à 50% du cuivre et du zinc, métaux absolument vitaux. Il a donc fallu compenser le manque de ces éléments en faisant prendre aux enfants un ensemble de vitamines contenant des éléments mineurs (Unicap, Belgique). Cette méthode pour purifier l'organisme du césium 137 a été reconnue dangereuse et fut interrompue.

A propos de la diminution de 2930 à 540 du nombre d'enfants inclus dans l'étude.

Le fait est que le nombre de villages a été choisi en tenant compte des diverses conditions de vie dans chacun:

- villages situés sur des sols différents aux coefficients différents du transfert des radionucléides des sols dans les plantes, villages situés en terrain découvert (steppe) ou au milieu de forêts, dans les zones à divers taux de contamination des sols par le césium 137 : 37 à 185 kBq/m², 185 à 555 kBq/m², 555 à 1480 kBq/m²;
- dans les jardins d'enfant les enfants reçoivent 4 repas par jour, ils consomment donc assez peu d'aliments chez eux;
- dans les écoles, ils n'ont que deux repas par jour, par conséquent ce qu'ils mangent chez eux, par tradition familiale ou suite au niveau de vie de la famille, agit fortement sur les niveaux de césium 137 qu'ils accumulent dans l'organisme;
- les enfants de ces régions tombent très souvent malades. Nous incluons 45 personnes dans chaque groupe pour pouvoir au bout des 21 jours de traitement au Vitapect choisir 20 à 25 enfants qui auraient pris régulièrement du Vitapect tous les jours, sans interruption pour cause de maladie;
- on ne peut jamais être sûr que les enfants dans les familles prennent régulièrement l'additif alimentaire, c'est pourquoi nous accordons incontestablement notre préférence aux enfants des jardins d'enfant et des écoles où ils prennent le produit sous contrôle de l'infirmière, de l'institutrice ou des professeurs.

Page 5

Aucun doute qu'il serait excellent de procéder dans le courant d'une année à un examen médical parallèle des enfants qui prennent un additif alimentaire à la pectine (ECG, état des yeux, analyse du sang,

tests immunitaires etc…) pour mettre en évidence la diminution des effets nocifs des conséquences de la catastrophe de Tchernobyl au niveau physiologique.

Le nombre déclaré des cancers de la thyroïde des enfants et des adultes déjà diagnostiqués en Bélarus est bien en dessous de la réalité.

Les organisations internationales reconnaissent pour l Belarus qu'il y a un lien de cause à effet entre les cancers de la thyroïde chez l'enfant et la radioactivité. Il serait vraiment d'actualité de réaliser des projets communs avec les médecins d'Italie, de France, d'Allemagne, de Belgique et d'autres pays sur l'étude de l'action radiologique et toxique du césium 137 sur l'ECG des enfants, sur leur vue (cataractes) etc…

Page 6

Le projet ETHOS (et d'autres semblables) nous incite aux observations suivantes. Trop peu d'attention est accordée dans le projet ETHOS au travail avec la population locale pour lui apprendre à utiliser activement les divers moyens de radioprotection, pour lui montrer les divers procédés permettant de diminuer leur charge radioactive annuelle.

- chercher et trouver des financements spécialisés destinés aux habitants des régions contaminées afin qu'ils puissent fertiliser avec des engrais minéraux leurs lopins de terre pour diminuer le transfert des radionucléides des sols dans la chaîne alimentaire;
- assurer la fertilisation par engrais minéraux (potassium, phosphore, calcium) des prés et pâturages pour obtenir du lait et de la viande "propres";
- introduire des engrais minéraux (potassium, lignite) dans les sols des forêts dans un rayon de 8 à 10 km autour des localités pour y obtenir des champignons et des baies "propres";
- travailler avec les habitants pour faire entrer dans leurs habitudes de procéder régulièrement au contrôle radiologique des fruits et légumes de leur potager et des produits de la forêt qu'ils consomment;
- procéder régulièrement au moyen du SRH à la mesure des valeurs de césium 137 incorporé dans l'organisme des gens et leur faire prendre régulièrement des additifs alimentaires à la pectine pour diminuer le niveau de radiation accumulé et la charge radioactive annuelle;
- former les enseignants, les parents, les écoliers aux méthodes de traitement des aliments visant à diminuer leur teneur en radionucléides (séparation du lait, macération des champignons, de la viande etc).

Page 7

Nous avons procédé dans notre Institut à un petit test sur l'utilisation de la spiruline (l'additif alimentaire russe Fito-splat à base de spiruline) qui a montré qu'elle était moins efficace au niveau de l'élimination du césium 137 que les produits à la pectine (le produit ukrainien Iablopect et le produit biélorusse Vitapect). Mais nous sommes prêts à sélectionner un groupe d'enfants de plus qui prendraient la spiruline parallèlement au groupe qui prend Vitapect.

Page 8

Nous aurons bientôt un appareil permettant de déterminer instantanément le taux de plomb dans le sang (appareil américain) et nous pourrons ainsi déterminer l'efficacité de l'élimination du plomb de l'organisme parallèlement à celle du césium 137 (grâce aux mesures à l'aide du SRH) chez les sujets traités aux additifs alimentaires.

Page 11

Je confirme une fois de plus que depuis l'été 2001 l'Institut utilise pour la fabrication de Vitapect du tourteau de pomme en provenance de l'usine de conserve de Borissov (à 80 km de Minsk). Le Centre de certification et de sécurité des produits alimentaires du ministère de la Santé de la Belarus a établi dans ce tourteau une présence de plomb de l'ordre de 0,035 ppm/kg. Le 19 février 2002 ce même Centre du ministère de la Santé a de nouveau procédé à l'analyse de Vitapect et a établi qu'il contenait une quantité de plomb inférieure à 0,04 ppm/kg, et de cadmium – inférieure à 0,01 ppm/kg.

L'additif alimentaire Vitapect se prend sous forme de solution (5 g de Vitapect sur 100 g d'eau) trois fois par jour. La concentration totale de plomb dans le liquide ainsi absorbé ne dépasse pas les normes de sécurité établies pour la Belarus et la Russie.

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Un contrôle permanent (une fois par mois) de la qualité (en particulier au niveau du plomb) du tourteau initial comme du produit final (l'additif alimentaire) est assuré par le Centre de certification et de sécurité des produits alimentaires du ministère de la Santé de la Belarus.

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Nous sommes d'accord de procéder dans les mêmes conditions à un test parallèle de l'efficacité du Medetopect.

Les tests du produit à pectine ukrainien Iablopect ont permis d'établir les doses suivantes : pour les enfants âgés de moins de 6 ans il est recommandé de prendre 10 g de produit par jour, pour ceux qui ont plus de 6 ans – 15 g par jour . C'est pourquoi nous acceptons la proposition des experts d'augmenter le nombre de prises à 3 fois par jour.

On peut accepter les propositions des experts concernant le nombre de villages mais il faut tenir compte du fait qu'il est nécessaire de sélectionner dans chaque village des groupes d'enfants du jardin d'enfant et de l'école qui devront prendre chacun un des produits suivants:

Vitapect
Medetopect
Spirulina
Placebo.

Compte tenu du fait que l'échantillonnage doit être fiable, que certains enfants peuvent être exclus pour cause de maladie, il faut qu'il y ait dans chaque groupe 32 enfants du jardin d'enfant et 32 enfants de l'école :

6 villages x 64 enfants x 4 groupes = 1536 enfants

Les lieux où nous achetons le tourteau de pomme excluent entièrement le risque d'accumulation importante de plomb dans l'organisme des enfants par absorption de l'additif alimentaire.

En sanatorium on pourra organiser des analyses des urines et du sang.

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Les études de terrain dans les villages se feront sur la base des écoles de village.

Les propositions de ONC (?) améliorent indiscutablement le projet de l'étude complète de l'efficacité de l'utilisation de la pectine pour la purification de l'organisme des enfants des régions contaminées de Belarus, et nous les acceptons.

Je suis d'accord avec la proposition d'inclure au sein du comité d'éthique le professeur Baverstock et le docteur Enflo. En août 2001 j'ai rencontré le professeur Baverstock à Minsk: nous avons eu un entretien de 3 heures à notre Institut.

Je serais reconnaissant d'obtenir des renseignements sur le docteur Enflo de l'Institut suédois de radioprotection.