Superior Health Council

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Fecundity

Demography and epidemiology of fertility in Belgium and need for assisted human reproduction

3 November 2010

1. INTRODUCTION

A request for advice on human fecundity was submitted to the Superior Health Council by the Federal Agency for Medicines and Health Products (FAMHP) on 15 December 2009. Its primary objective was to enable Minister Laurette Onkelinx to respond to a series of parliamentary questions.
This issue concerns the management of fertility clinics and especially the significance that needs to be given to the use of oocyte donors and foreign sperm banks.
The questions asked were the following:

a) What are the causes of our population's declining fertility?
b) How can the significant demand in oocytes both for assisted human reproduction as well as for stem-cell based research be accounted for?
c) Why are fertility clinics increasingly being resorted to, both in general as well as in the particular case of foreign patients ("fertility tourism")?

In order to be able to provide an answer to these questions, an *ad hoc* working group was set up which included experts in bioethics, embryology, gynaecology, toxicology, demography, epidemiology and reproductive medicine. This advisory report is based on a review of the literature, recorded data and, when none were available, the point of view of the experts.

2. CONCLUSIONS

The SHC issues the following answers to the questions submitted:

The demographic decline in fertility is first of all a consequence of the changed attitude of the population towards parenthood and the desire to have children. As regards biophysiological factors, they have not had any demographically noticeable effect to date on either the overall fertility rate or on the nulliparity rate.

Environmental contaminants are believed to have adverse effects on human reproduction. In a country like Belgium, the semen quality may have deteriorated as a result of the existing internal exposure to pollutants, which include many endocrine disruptors that affect fecundity. In addition, these pollutants could also contribute to the prevalence of endometriosis. It is not clear yet to

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what extent very low doses of endocrine disruptors affect human health in general and fecundity in particular. More research is needed to provide an answer to this question.
Yet it cannot be concluded on the basis of the literature that there is a link between the exposure of the general population to environmental contaminants and lower birth rates. The potentially poorer semen quality does not appear to be a limiting factor as regards the eventual number of births.

Though pollutants may be responsible for individual cases of subfertility or infertility, the current demographic and toxicological data do not provide arguments on the basis of which the SHC could conclude that pollutants are liable to alter the overall reproductive ability of the population significantly.

It is impossible to quantify the precise demand for oocytes in our country.
However, the available data do show that:

- the number of IVF treatments has been increasing steadily in our country since 2004, mainly amongst over 40-year olds.
- the number of oocyte donations increased between 2003 and 2008. The number of Belgian donors and recipients rose significantly, whereas the number of foreign donors and recipients declined.
- the number of oocytes used for embryonic research is fairly small.

Since 2003, the number of IVF treatments has been increasing steadily in our country. Yet this cannot be attributed to a higher number of foreign patients. Possible explanations for this increased number of IVF treatments in our country could be the fact that this treatment has become more easily available and/or its indications have been broadened. The SHC therefore takes the view that it could be appropriate to set evidence-based criteria and guidelines for IVF-treatment.

In order to be able to monitor the way in which the fertility of the population evolves during the next few years as well as to be in a better position to quantify the potential impact of the population's cumulative exposure to the various toxicological factors, the SHC recommends that research be carried out in order to identify and to set up new indicators that are more reliable and more specific than the overall fertility and nulliparity rates among women who were once married.

3. ELABORATION AND ARGUMENTATION

List of abbreviations used:

FAMHP	Federal Agency for Medicines and Health Products
AOA	*Assisted Oocyte Activation*
BELRAP	*Belgian Registry of Artificial Procreation*
BPA	Bisphenol A
IVF	In Vitro Fertilisation
ICSI	*IntraCytoplasmic Sperm Injection*
PCB	Polychlorinated biphenyls
REACH	*Registration, Evaluation and Authorisation of CHemicals*
TFR	Total fertility rate

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3.1 Demographic and clinical definition of fertility and infertility

3.1.1 Demographic definition

In demography, English uses the term *fertility* to denote the actual procreation, whereas *fecundity* is used to refer to the ability to conceive, and *sterility* to the inability to conceive.[1]

3.1.2 Clinical definition

After one year of regular intercourse, 90% of couples achieve the expected pregnancy. As a result, couples which do not achieve pregnancy after one year of regular sexual intercourse are looked upon as subfertile from a clinical point of view (Gnoth et al., 2005 ; De Sutter, 2006).

3.2 What are the reasons for the population's lower fertility?

As regards the first question, the SHC wonders on what grounds the FAMHP claims that the fertility of the population is declining.

There is no doubt that social and behavioural factors play a key role in fertility rates, which have been displaying a downward trend in many industrialised countries (Foster et al., 2008). One of the main factors that affect female fertility is age. Thus, women's fertility begins to decline in their twenties and decreases significantly from the age of 30 (Dunson et al., 2004).

3.2.1 From a demographic point of view

The lower fertility within the population is caused by the historical coinciding of three factors: the economical development that has led parents to prefer to have fewer children (child labour vs. investing in children), the propensity to limit the number of children (for cultural, societal, religious reasons) and, finally, the availability and effectiveness of contraceptives. The long-term decline in fertility, which began in the 19th century, as well as the recent significant drop in the number of births during the seventies of the past century are the outcome of the combined action of these three factors (Andorka 1978; Lesthaeghe & Surkyn 1988).
In the context of fertility treatments and oocyte donations, the question that is put here concerns the extent to which this decline could (also) follow from biological of physiological changes in fecundity.

The evolution of fertility is often measured in terms of the Total Fertility Rate (TFR), which is the sum of the age-specific fertility rates for all women aged 15 to 49 for a given year (figure 1).

[1] Note that, in sharp contrast to what is the case in English, French uses the term *fécondité* to denote the observation of births and *fertilité* the ability to conceive. The term *infertilité* refers to the physiological inability to conceive, whereas in English, *infertility* is used to denote the absence of liveborn children.

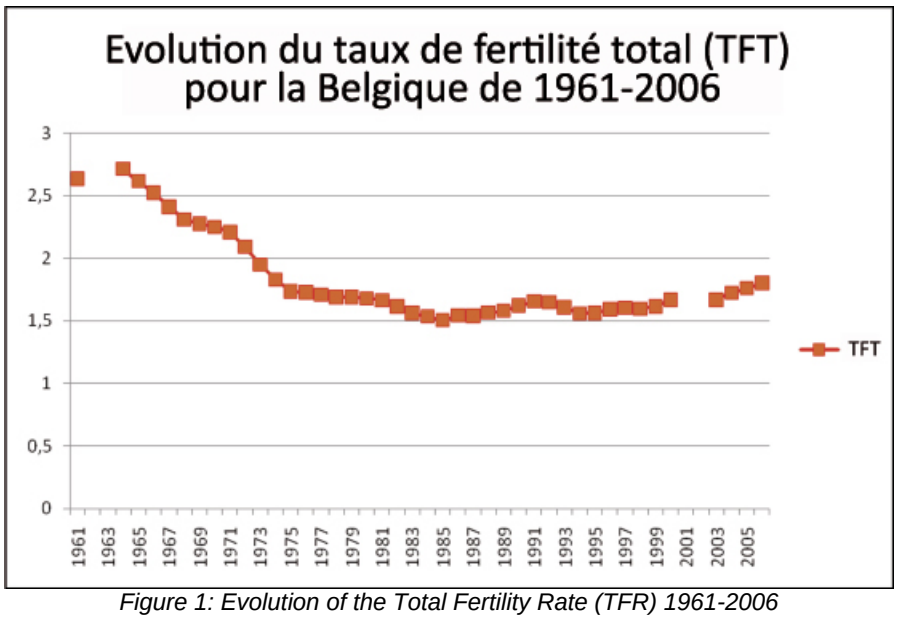

Figure 1: Evolution of the Total Fertility Rate (TFR) 1961-2006
(Source: ADSEI – processing Interface Demography)

The TFR declined until it reached a nadir in 1981 (1,51 children per woman). After a fairly stable period, it recently started to rise again, and reached 1,8 in 2006. However, the evolution of the TFR should be interpreted with great caution. The TFR is a period measure that is sensitive to changes in rhythm. A change in the age of maternity (postponed or earlier) can influence the TFR without affecting the final descent. This highlights once again that there are too many social factors involved to be able to draw any conclusions on the fecundity of the population. Moreover, an additional factor in the recent increase is migration.

Such a synthetic indicator can only be indicative of the overall evolution of the actual fertility. There is little to go on that will allow for measurements to be made of the decline in the physiological fertility of the population, as the actual fertility in Western Europe has been below the physiological limit for centuries now (Newell 1988). There is no doubt that social factors have always played a key role in limiting natural fertility, even in the remote past (Petersen, 1969). In demography, such populations are referred to as Malthusian populations, in which even eventual childlessness does not constitute evidence for sterility (Pressat, 1973). There may have been an evolution in the long-term physiological fertility of the population. Yet the historical and demographic data do not allow to conclude that the physiological fertility is declining. Also in the past, the literature mentioned that around 10% of couples were estimated to be childless as a result of fertility problems (Cox, 1970).

Moreover, it cannot be ruled out that a better diet and/or improved overall sanitary conditions among the population contributed towards increasing fertility. In other words, it is quite possible that, over the years, different factors have had an opposite effect on the physiological fertility potential of the population. This accounts for the fact that quite significant differences can be observed (Espenshade, 1971) among populations with a fertility that is referred to as natural (Henry, 1961).

Eventual childlessness (nulliparity) is an indicator which, from a historical point of view, probably provides a more reliable means to assess the evolution of fertility problems. It can be hypothesized that limiting the number of children has been a deliberate choice for many couples for a very long time, but that, in the past, it was highly exceptional for married couples to decide against having children altogether. As a result, final nulliparity among women who were once married should provide a useful means to assess the impact of physiological problems on fertility. Contraceptives were usually fairly unreliable. In addition, though contraceptives were already actively used to limit the offspring, it is unlikely that it was very common to wish to remain childless and especially to seek a childless marriage. As a rule, we can take the view that, apart

from exceptional cases, the fact that women who were once married did not have any children was due to suboptimal fertility in one of the two partners.

Figure 2 suggests that unintentional childlessness was probably more frequent among women born before 1930 than among more recent birth cohorts. On the basis of the data from the 1991 census, eventual childlessness among married women could reach 20% in the early 20th century. The observations made on the basis of the 2001 census indicate that 10% of married women remained childless at the beginning of the 20th century.[2] The lowest rates are recorded among the 1942 birth cohorts, where 7% of married women remain childless.

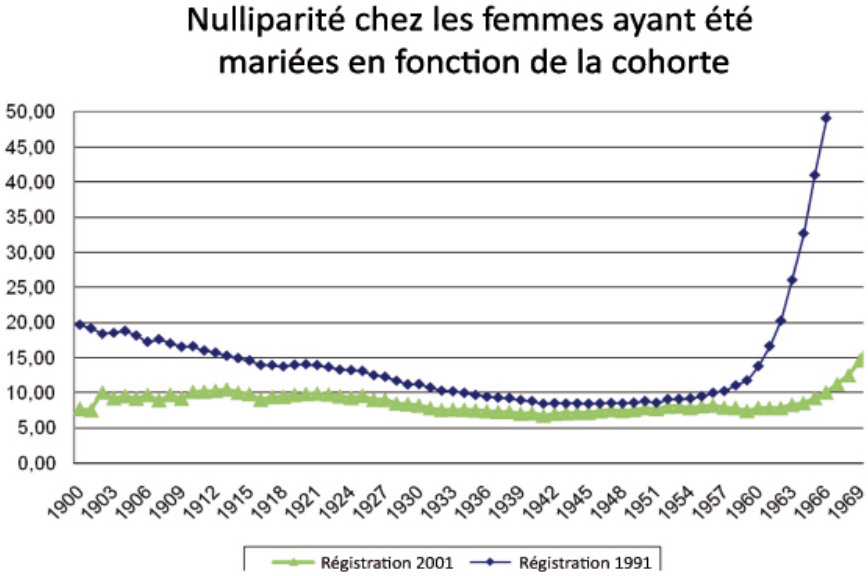

Figure 2: Evolution of nulliparity among Belgian women born between 1900 and 1970 who were once married (Source: ADSEI census data - processing Interface Demography)

This leads the SHC to conclude that in the course of the past century, at least 7 to 10% of couples in the Belgian population could be said to have been subfertile. The declining childlessness among women born between 1900 and 1940 could be partially due to registration problems in the past, but is likely to be connected to the increasingly improved general state of health as well as declining intrauterine and perinatal mortality (Masuy-Stroobant & Humblet, 2004).

As regards the birth cohorts after 1950, it is even more difficult to reach a position on eventual childlessness within marriage on the basis of the 2001 data. In order to do so, more recent data on this subject are required. At any rate, eventual childlessness within marriage remains below the 10% mark until the 1965 birth cohorts. These women belong to the generations whose children were mainly born between 1985 and 2005. Eventual childlessness among these women does not appear to be higher than that among previous cohorts throughout the 20th century.

It has been suggested that the sex ratio at birth (ca. 105 boys for 100 girls) could be a good indicator of hormonal disruptions. Davis et al. (1998) found that there had been a statistically significant decline in the sex ratio at birth in Canada, the Netherlands, the United States and Denmark over a twenty year period. They concluded that "*the reduced male proportion at birth can be viewed as a sentinel health event that may be linked to environmental factors*". However, research on the sex ratio at birth over longer periods of time has shown that the evolution of this

[2] The figures were compiled on the basis of a retrospective survey amongst the entire female population still alive and residing in Belgium in 1991 and 2001, respectively. The series recorded in 1991 and 2001 did not match as a result of the different methods used to collect the data. For 1991, the information was obtained by questioning, which can lead to the number of liveborn children being underestimated. In 2001, administrative data were used, which results in their being overestimated, as no distinction was made between adopted children and stepchildren. Taken together, the two series provide the upper and lower nulliparity limits among women who were once married.

indicator can hardly be accounted for by the sole presence of pollutants in the environment (Møller, 1996; Jongbloet et al., 2001; Davis et al., 2007).

Sweden, which has the longest series of reliable birth statistics, shows that the 1,06 ratio in that country is fairly recent and that it used to be lower (figure 3).

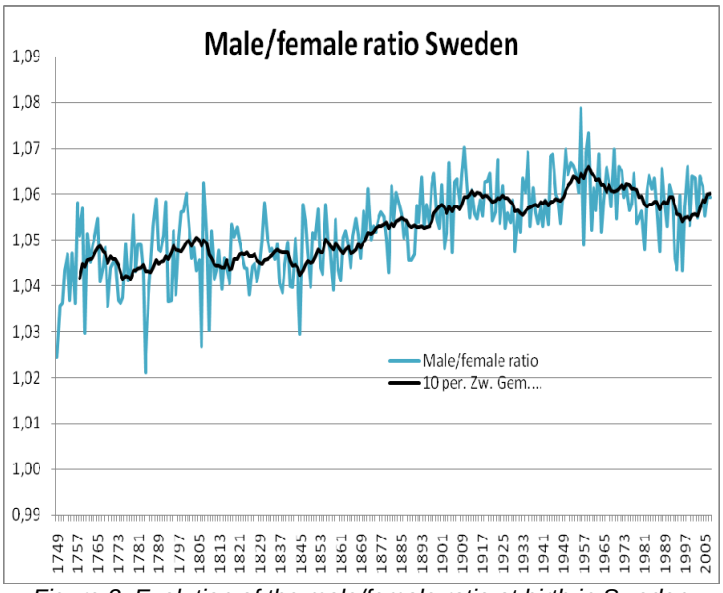

Figure 3: Evolution of the male/female ratio at birth in Sweden 1749-2007 annual data and floating 10-year average (Source: Human Mortality Database -processing Interface Demography)

This ratio could perhaps constitute a "*sentinel health indicator*" (Davis et al., 2007), but not just for the influence of endocrine disruptors from the 20th century industrial production. The downward trend displayed by this ratio in Sweden in the 1950-1995 period, which was also observed in several other industrialised countries, was preceded by a long-lasting increase, with the ratio fluctuating cyclically below 1,05 before 1870.

The calculations for Belgium show that there was a historical decline between 1840 and 1890, an increase due to a series of variations until 1950, a plateau at 1,06 between 1950 and 1985, followed by a recent drop below 1,05 (figure 4).

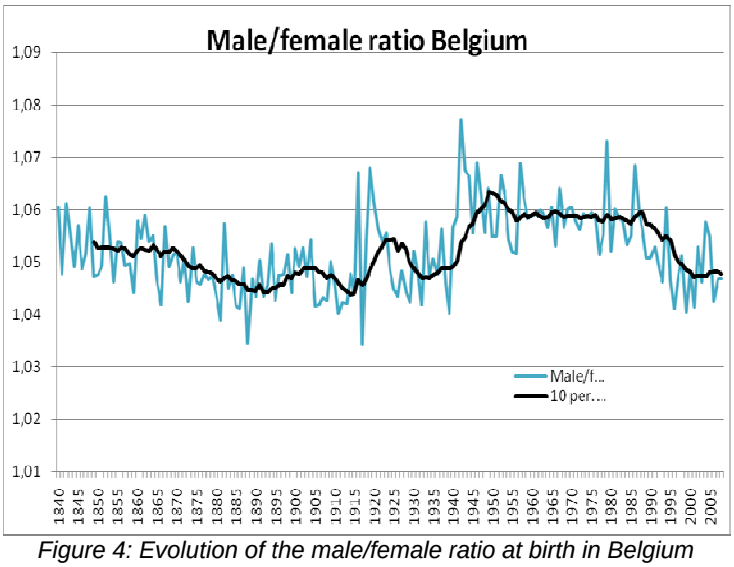

Figure 4: Evolution of the male/female ratio at birth in Belgium 1840-2008 annual data and floating 10-year average (Source: Human Mortality Database -processing Interface Demography)

This evolution does not appear to be easy to account for. First of all, it must be assumed that there have been no systematic errors in recording the data, which cannot be excluded, especially as regards the remote past. The downward trend observed in the course of the 19th century could be linked to industrialisation (to be examined on the basis of more detailed figures), but this does not account for the subsequent rise during a period of increasing industrialisation. Recent figures from after World War II are not in line with the evolutions observed in certain other countries such as the United States and the Netherlands. It follows that the sex ratio at birth probably results from several factors that do not necessarily all have the same effect. At any rate, there is little ground to draw a connection between the Belgian figures and a decline in physiological fertility on the basis of the Davis et al. (2007) hypothesis.

The demographic data cannot account for the potential emergence of suboptimal fecundity in men and/or women at the population level, especially as regards suboptimal fecundity due to the presence of endocrine disruptors in the environment or the food chain. After more extensive research, it turned out that the decline that was observed in the actual fertility of Hutterites (North-American population whose religious convictions make them strive for maximal fertility), which was also attributed to environmental factors, could largely be accounted for by the increasing use of contraceptives (Curtis, 2002).

Even if fecundity were to be sub-optimal in Belgium, at present, this cannot be shown to affect birth rates. It is possible that this is compensated by medical assistance. However, it is very difficult to deduce this from the demographic data that are available and it is likely that this will be even more so in the future. Indeed, it is increasingly less the case that marriage is the only environment in which the desire for children is fulfilled, and, conversely, deliberate childlessness has become significantly more frequent within partner relationships. Demographic indicators such as the male/female ratio at birth cannot provide evidence in support of the impact of endocrine disruptors either.

3.2.2 From a toxicological point of view

There is a broad range of agents that could affect reproduction and/or development. They include dioxins, polychlorinated biphenyls, phyto-oestrogens such as isoflavones, heavy metals, phthalates, organic solvents, polyaromatic hydrocarbons, etc.

The adverse health effects of exposure to environmental contaminants at the levels reported in current studies remain uncertain and controversial.
Since environmental contaminants were found to have the ability to bind with gonadal steroid receptors, mimic the activity of steroid hormones, alter steroid hormone production and turnover, there has been increasing concern that exposure to these chemical agents (endocrine disruptors) could have serious adverse effects on development and reproduction (Foster et al., 2008; Diamanti-Kandarakis et al., 2009). Contaminant residues were found in human serum, follicular fluid and seminal plasma (Gerhard et al., 1999; Jarell et al., 1993; Younglai et al., 2002). This finding, as well as the reportedly poorer semen quality (Abell et al., 2000; Auger et al., 1995; Carlsen et al., 1992; Irvine et al., 1996), have raised concern that exposure to these environmental contaminants is affecting fertility. In addition, subfertility has been linked to occupational exposure to pesticides (De Cock et al., 1994; Fuortes et al., 1997), which provides further support to the view that exposure to environmental contaminants is hazardous to human fertility. Moreover, evidence from animal studies has led to the hypothesis that exposure to environmental contaminants could increase the risk of infertility.

It has been abundantly shown that semen quality has declined during the last decades, at least in some regions (Flanders, Denmark, France, United Kingdom, United States, etc.) (Bay et al., 2006; Auger et al., 1995; Irvine et al., 1996; Swan et al., 2000), whereas this decline is not reflected in a lower fertility of couples. According to some recent studies, the downward trend in semen quality appears to have turned (Hamilton et al., 2006).

However, changed fertility rates do not by themselves constitute evidence in support of the fact that there may or may not be environmental factors involved in infertility (failure to conceive within one year of unprotected intercourse).

Animal experiments and wildlife observations clearly show that exposure to endocrine disruptors can result in lower fertility (Joffe, 2003). Many of the examples for the adverse effects which chemical agents in the environment have on wildlife involve aquatic animals (Carson, 1962; Jobling & Sumpter, 1993; Guillette, 1994). Indeed, the latter are constantly exposed to chemical agents dissolved in the water.

The evidence in support of a decline in human fertility is scarce.
Though there are several well-documented cases of infertility in certain occupational environments, there is less certitude concerning the exposure of the general population to environmental toxicants (Sharpe & Irvine, 2004; Foster et al., 2008). In this case, the levels of exposure are usually unknown.
Several studies examined the connection between both infertility and differences in time to pregnancy (TTP) on the one hand, and exposure due to living in heavily contaminated areas and occupational exposure, on the other (Foster et al., 2008). No clear causal relationship has been shown to exist to date.

Lifestyle and dietary habits may have an effect on fertility. The latter can be affected by a high consumption of fish containing PCBs and mercury (impact on spermatogenesis and semen quality) (Foster et al., 2008; Joffe, 2003; Buck et al., 1999; Buck et al., 2000; Courval et al., 1999). However, such consumption is not necessarily linked to an increased TTP and therefore to an effect on fertility.
Certain populations show a considerable dietary intake of phytoestrogens. This is by far the most significant route of exposure to exogenous endocrine disruptors. The most important are isoflavones such as genistein, which soybeans and soy-based foodstuffs are particularly rich in. Exposure to isoflavones and other phytoestrogens has been shown to alter a number of functions of the female reproductive system in rodents, resulting in e.g. early puberty, subfertility and irregular oestrus cycles (Joffe, 2003). Perinatal, neonatal or prepubertal exposure appears to produce the most marked effects. There is no certainty over whether these findings apply to humans (Joffe, 2003).

There is abundant evidence that direct exposure to tobacco smoke has an adverse effect on human fertility and there is concern that this is also true for passive smoking (Foster et al., 2008).
Ethanol consumed in the form of alcoholic beverages affects male fertility (Chopra et al., 1973; Pajarinen & Karhunen, 1994). This is the conclusion drawn from effects such as testicular atrophy, low libido and testosterone levels, as well as increased oestrogen levels. In addition, menstrual cycle disturbances lead to the conclusion that human female fertility too is affected. These effects, which were observed in humans, were also reported in experimental animals that had received high oral doses.
Two epidemiological studies showed an effect on female fertility at relatively low doses, viz.
a decline in the fertility of women with a low alcohol intake (5 drinks/week) and a connection between the consumption of alcohol (between 1-12g alcohol/week) and a reduced rate of conception per menstrual cycle (Jensen et al, 1998; Hakim et al., 1998).
Occupational exposure to pesticides was found to be linked to low semen quality and a higher incidence of female infertility and spontaneous abortions (Foster et al., 2008; Sanborn et al., 2004). However, conflicting results are reported in the epidemiological literature: some studies show that exposure to pesticides affects fertility, whereas others cannot establish such a link. Whilst numerous animal studies have shown that exposure to pesticides has an adverse effect on fertility, these studies are often conducted at concentrations that exceed the levels to which human are exposed (levels many thousand times lower). According to recent data, these chemical agents increase or reduce aromatase activity in cell cultures, which suggests that exposure to these chemicals could alter target tissue levels of gonadal steroids *in vivo*. However,

this hypothesis has not been tested yet. On the whole, the data show that many pesticides pose a threat for reproduction, yet the risk for human fertility remains unknown.
Human exposure to bisphenol A (BPA) has been clearly demonstrated (BPA has been found in blood, urine, breast milk and other human tissues), but there is no evidence in the literature that links exposure to BPA to a decline in human fertility (Foster et al., 2008). Some studies on rodents have shown that BPA is toxic for reproduction/fertility and development (study reports INERIS, 2010 and INSERM, 2010). It has also been shown that the time of exposure (fœtal or perinatal exposure) plays a significant part in the effects in adulthood. Yet there are diverging views and conclusions in the literature as regards the relevance of the effects at low doses as well as that of those observed in certain (sensitive) rodent strains in assessing the risk in humans. The studies carried out *in-vivo* on several strains of the same species show that the response to BPA varies within the same species (and from one individual to another) (genetic polymorphism, previous exposures, ...). It should be pointed out that there are too few epidemiological studies available to be able to determine whether the effects observed in animal experiments also apply to humans (study reports INERIS, 2010 and INSERM, 2010). Moreover, these studies show numerous methodological flaws (retrospective approach, imprecise sampling scheme, failure to take into account the potential effects of the pathologies themselves on BPA).
Toxicological studies provide sufficient evidence that some phthalate esters and their metabolites are reproductive and developmental toxicants in rats (Hauser & Calafat, 2010). However, the human studies currently available with which the exposure to phthalates can be linked to health effects are either too scarce or inadequate (Sharpe & Irvine, 2004).

Some animal studies have shown that high exposure during pregnancy and/or early postnatal life plays a key role in the development of reproductive disorders. Measuring the exposure of the human fœtus to chemical agents and linking this to disorders that may not appear until decades later entails major logistical problems (Shakkebaek et al., 2006; Diamanti-Kandarakis et al., 2009).

There is substantial evidence indicating that endocrine disruptors contribute to the risk of cancer, developmental disorders, diabetes, possibly also obesity and metabolic syndrome as well as to subfertility. That is why the Endocrine Society as well as the American Chemical Society recently issued scientific statements on endocrine disruption. In these statements, these scientific societies recommend that increased efforts should be made towards identifying and studying endocrine disruptors, that the education on this subject should be broadened throughout the formal education structures (in universities and schools) and that the general public and especially healthcare professionals and chemists should be better informed. The Endocrine Society stresses the importance of the precautionary principle, considering the scarcity of direct information on causes and effects. It takes the view that the precautionary principle is of critical importance in protecting reproductive and hormonal health.

The presence of endocrine disruptor compounds in the environment is also raising increasing concern in Europe, where the focus is on improving the identification and assessment of environmental and health hazards posed by these compounds. Most legislations (such as REACH, EU Regulation 1907/2006) and the Regulation concerning the placing of plant protection products on the market (Regulation 1107/2009) include regulatory procedures that determine the specific way in which the hazard posed by compounds with endocrine disrupting properties is to be identified and assessed.

3.2.3. Conclusions

The demographic decline in fertility is first of all a consequence of the changed attitude of the population towards parenthood and the desire to have children. As regards the biophysiological factors, the effect they have had to date on either the overall fertility rate or on the nulliparity rate is at most very marginal. It is not noticeable at the demographic level.

Environmental contaminants are believed to have adverse effects on human reproduction when the levels of exposure exceed a given threshold. In a country like Belgium, the semen quality may have deteriorated as a result of the existing internal exposure to pollutants, which include many endocrine disruptors that affect fecundity. In addition, these pollutants could also play a part in the prevalence of endometriosis. It is not clear yet to what extent very low doses of endocrine disruptors affect human health in general and fecundity in particular. More research is needed to provide an answer to this question.
Yet it cannot be concluded on the basis of the literature that there is a link between the exposure of the general population to environmental contaminants and lower birth rates. The potentially poorer semen quality does not appear to be a limiting factor in terms of the final number of births.

Though pollutants may be responsible for individual cases of subfertility or infertility, the demographic and toxicological data do not provide arguments on the basis of which the SHC could conclude that pollutants have a significant effect on the overall reproductive ability of the population.

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3.3 How can the significant demand in oocytes both for assisted human reproduction as well as for stem-cell research be accounted for?

This question can be divided into several subquestions, i.e.

- Is there a significant demand for oocytes?
- How many IVF treatments are administered in our country and is this figure rising?
- How many oocyte donation treatments are administered and is this figure rising in proportion?
- How many oocytes are used for assisted human reproduction and how many for scientific research?
- Where do these oocytes come from?

Oocytes can be obtained from patients who are receiving IVF treatment and undergo stimulation in order to satisfy their own desire to have children. They can also be donated on a voluntary basis to meet other couples' desire for children if the latter do not have normal oocytes themselves. Additional information on these types of oocyte donations can be found in the SHC advisory report No. 8639 (2010).
The oocytes can also be donated to scientific research both by the patients themselves as well as by voluntary donors. Nevertheless, these are usually surplus oocytes that have no other purpose.
For greater clarity, a systematic distinction will be made between the patient's "own" oocytes and donor oocytes.

It is impossible to quantify the precise demand for oocytes in our country. Clinical practice has shown that the demand for donor oocytes is significant. As there is no real record of this demand, the SHC can only provide data about the number of oocyte donations that are carried out in our country.

In order to provide an answer to the subquestions above, data were requested from the Belgian College of Specialists in Reproductive Medicine, which is in charge of the Belgian register for assisted human reproduction (Belrap). In addition, data were consulted on the www.belrap.be website. The issue of the number of oocytes or embryos created and/or used for research on embryos and embryonic stem cells was also submitted to the Federal Commission for medical and scientific research on embryos in vitro.

Table 1 contains the results from the Belrap data on the evolution of the number of IVF cycles carried out in Belgium and the number of oocyte donation cycles.
The number of initiated treatment cycles is equivalent to the number of stimulations initiated and the number of pick-ups to the actual number of oocyte punctures. The percentage of oocyte donations therefore amounts to

$$\frac{\text{Number of oocyte donations} \times 100}{\text{Number of oocyte punctures (pick-up)}}$$

Table 1: Number of IVF treatments per year (2004 – 2008)

	2004		2005		2006		2007		2008	
National Institute of Health and Disability Insurance (INAMI) %		84.1%		80.7%		81.9%		85.0%		85.3%
Number of treatment cycles initiated	15,555		17,268		17,504		18,025		19,401	
Number cancelled	1,012		1,270		1,409		1,438		1,742	
Number of oocyte punctures (pick-up)	**14,543**		**15,998**		**16,095**		**16,587**		**17,659**	
Number of donation cycles initiated (2)					507		506		578	
Number of egg-sharing cycles [3](3)					11		51		82	
Total number of donation cycles (2 + 3)	**404**	**2.60%**	**396**	**2.29%**	**518**	**2.96%**	**557**	**3.09%**	**660**	**3.40%**

This table shows that the number of oocyte punctures (pick-ups) has increased significantly since 2004 (this number went from 14,543 to 17,659, which amounts to a ± 20% increase). The proportion of oocyte donation cycles went from 2.6% in 2004 to 3.4% in 2008. The percentage of patients entitled to reimbursement by the INAMI hasn't changed notably between 2004 and 2008, which means that the percentage of foreign patients has remained proportionally constant and hasn't risen more rapidly than the percentage of Belgian patients.

Table 2: Median patient age

Median age at treatment	**2004**	**2005**	**2006**	**2007**	**2008**
Age of patients treated with their own oocytes	33.5	33.7	34	34	34
Donor age	31.9	32.5	31	31	31
Recipient age	39.4	38.5	37	38	38

The median age of patients treated in Belgium has remained constant between 2004 and 2008.

Table 3: Evolution of the number of cycles per age category of the women treated with their own oocytes (donations excluded)

Age category of the patients	**2004**	**2005**		**2006**		**2007**		**2008**	
			Variation % / 2004		Variation % / 2005		Variation % / 2006		Variation % / 2007
≤ 36 years	8,149	9,837	20.7	10,249	4.2	10,304	0.5	10,565	2.5
36 to 39 years	2,559	2,800	9.4	3,410	21.8	3,367	-1.3	3,625	7.7
40 to 42 years	1,214	1,510	24.4	1,782	18.0	1,842	3.4	2,128	15.5
≥ 43 years	178	216	21.3	239	10.6	218	-8.8	264	21.1

[3] Egg-sharing: This concerns oocyte donors who are patients themselves and are undergoing treatment. They give up some of their oocytes (if there are enough available when the puncture is carried out) in the context of their own IVF treatment.

Especially as regards the age categories over 40, the number of cycles is found to increase steadily from 2004.

The Belgian College of Specialists in Reproductive Medicine has provided the SHC with the following data on oocyte donation cycles.

Table 4: Number of oocyte donation cycles initiated (2003 -2008) in function of the donor's place of residence

		Donor residence				*Total*
		Belgium	***Europe***	***Other***	***Unknown***	
Year	***Type***					
2003	*Fresh donation cycle*	172	253	6	35	**466**
	Fresh "egg-sharing" cycle	38	1	0	0	**39**
	Total	210	254	6	35	**505**
2004	*Fresh donation cycle*	209	169	11	65	**454**
	Fresh "egg-sharing" cycle	12	3	0	0	**15**
	Total	221	172	11	65	**469**
2005	*Fresh donation cycle*	232	154	4	62	**452**
	Fresh "egg-sharing" cycle	11	2	0	1	**14**
	Total	243	156	4	63	**466**
2006	*Fresh donation cycle*	305	145	9	48	**507**
	Fresh "egg-sharing" cycle	9	2	0	0	**11**
	Total	314	147	9	48	**518**
2007	*Fresh donation cycle*	306	144	11	45	**506**
	Fresh "egg-sharing" cycle	18	32	0	1	**51**
	Total	324	176	11	46	**557**
2008	*Fresh donation cycle*	393	140	3	42	**578**
	Fresh "egg-sharing" cycle	32	43	0	7	**82**
	Total	425	183	3	49	**660**

This table shows that the number of oocyte donation cycles increased by 23% during the period under examination (2003-2008).
For foreign donors, the number of cycles was found to decline by 40% between 2003 and 2008.

Table 5. **Number of oocyte donation cycles initiated (2003 -2008) in function of the recipient's place of residence**

		Recipient residence				
		Belgium	***Europe***	***Other***	***Unknown***	***Total***
Year	***Type***					
2003	*Fresh cycle recipient*	259	353	32	29	**673**
2004	*Fresh cycle recipient*	250	313	10	34	**607**
2005	*Fresh cycle recipient*	326	266	18	53	**663**
2006	*Fresh cycle recipient*	383	264	7	43	**697**
2007	*Fresh cycle recipient*	409	276	10	56	**751**
2008	*Fresh cycle recipient*	414	348	10	48	**820**

As regards the number of recipients, the number of Belgian patients was found to increase between 2003 and 2008, whereas the number of foreign patients remained virtually the same.

The Federal Commission for medical and scientific research on embryos *in vitro* has informed the SHC of the following:

"A l'heure actuelle, la Commission ne possède pas de données chiffrées précises antérieures à 2008. Les données présentées tiendront donc comptent uniquement des 14 dernières demandes d'avis soumises à la Commission depuis 2008. Le tableau ci-dessous récapitule les projets ayant nécessité la création d'embryons pour la recherche de manière générale et des projets de recherche spécifiquement liés aux cellules souches. Les projets relatifs aux cellules souches à partir d'embryons congelés surnuméraires ne sont pas mentionnés. Au cours de la période 2008-2013, 1.842 ovocytes ont été ou seront intégrés aux différents projets nécessitant la création d'embryons pour la recherche. Parmi ceux-ci, trois projets (006-015-025), pour un total de 806 embryons, sont directement ou indirectement liés à l'étude des cellules souches" (i.e. At present, the Commission does not have any precise figures prior to 2008. The data presented therefore only take into account the 14 most recent requests for advice submitted to the Commission since 2008. The table below summarises the projects that require the creation of embryos for research purposes in general and research projects specifically related to stem cells. The projects that concern stem cells obtained from surplus frozen embryos are not mentioned. Between 2008 and 2013, 1,842 oocytes have been or will be used for the different projects that require the creation of embryos for research purposes. Among them, three projects (006-015-025), which involve a total of 806 embryos, are directly or indirectly linked to the study of stem cells.

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Table 6: Projects using embryos created for research purposes

No.	Project title	Type	Year of project Number of embryos/oocytes planned for use			
026	*Effect van geassisteerde eicel activatie (AOA) op de bevruchting bij patiënten met een gefaalde fertilisatie na ICSI.*	Oocytes and AOA	2010 9	2011 9	2012 9	2013 9
025	*Totipotency and cell commitment during the human preimplantation development (FWO project)*	Embryos and totipotency	2010 120	2011 120	2012 120	2013 120
024	*Optimalisatie van de cultuuromgeving tijdens de embryonale ontwikkeling van in vitro gematureerde eicellen afkomstig uit kleine ovariële follikels*	Oocytes and small follicles	2010 100	2011 100	/ /	/ /
020	*Analyse van calcium patroon in humane eicellen en toepassing van diverse activatiestimuli*	Oocytes and Ca++	2010 150	2011 250	2012 250	2013 150
015	*Genexpressie in humane pre-implantatie embryo's en embryonale stamcellen: karakterisatie van de humane totipotente cel*	Embryos and totipotency	2008 129	2009 113	2010 cf. 025	2011 cf. 025
006	*Isolatie en kweek van embryonale stamcellijnen uit menselijke blastocysten*	Embryos and stem cells	2004 2005 73	2006 0	2007 11	2008 0

This table shows that the number of oocytes used for embryonic research or stem cell research is limited.
It should also be stressed that most of the oocytes mentioned are not obtained with the intent to carry out research. Rather, this concerns surplus oocytes from fertility treatments which are then donated to research. The figures are very low compared to those of the IVF treatments carried out in our country (18,000 in 2007, which amounts to the retrieval of some 160,000 oocytes).

Conclusions

The data above show that:
- the number of IVF treatments has been increasing steadily in our country since 2004, mainly amongst over 40-year olds.
- The number of oocyte donations increased between 2003 and 2008. The number of Belgian donors and recipients rose significantly, whereas the number of foreign donors and recipients declined.
- The number of oocytes used for embryonic research is fairly small.

3.4 Why is the use of fertility clinics on the increase, both in general as well as in the particular case of foreign patients ("fertility tourism")

3.4.1 Cross-border reproductive care

The Belrap register only contains data on IVF, not on inseminations. The following paragraph therefore only deals with data on IVF.
The number of cycles that are not reimbursed (table 1) remains fairly constant. It follows that it cannot be concluded that there has been any change in the cycles that are not reimbursed and, indirectly, in the number of foreign patients.

Since 2003, these interventions are only being reimbursed to those entitled to social security. Patients may not be over 43 in order to qualify for reimbursement, which is limited to 6 cycles. Any patient in this category who is not entitled to reimbursement is therefore assumed to be foreign.
If these conditions (less than 43 but over 6 cycles or over 43) are not met, the patients (including Belgian patients) do not qualify for reimbursement.

Table 7 contains the data for different patient categories with or without social security.

Table 7: Number of cycles with fertilisation in the laboratory (patient and donor oocytes) for patients with and without social security

Nombre de cycles	2004			2005			2006			2007			2008		
avec mise en fécondation en laboratoire	Sec soc	Pas sec soc	% *	Sec soc	Pas sec soc	% *	Sec soc	Pas sec soc	% *	Sec soc	Pas sec soc	% *	Sec soc	Pas sec soc	% *
Toutes catégories	12.344 (84,2%)	2.308 (15,8%)		13.078 (81,0%)	3.076 (19,0%)		13.151 (84,2%)	2.459 (15,8%)		14.382 (87,8%)	1.998 (12,2%)		15.124 (87,4)	2.184 (12,6%)	
< 43 ans et < 7 cycles	10.559 (98,4%)	177 (1,6%)		12.278 (95,2%)	613 (4,8%)		12.330 (95,2%)	623 (4,8%)		13.578 (99,2%)	112 (0,8%)		14.096 (94,5%)	818 (5,5%)	
< 43 ans et ≥ 7 cycles	422 (28,1%)	1.081 (71,9%)		469 (28,7%)	1.165 (71,3%)		683 (29,3%)	1.647 (70,7%)		655 (28%)	1.688 (72,0%)		854 (42,5%)	1.157 (57,5%)	
≥ 43 ans	195 (45,6%)	233 (54,4%)	**2,9%**	173 (38,9%)	272 (61,1%)	**2,7%**	138 (42,2%)	189 (57,8%)	**2,1%**	149 (42,9%)	198 (57,1%)	**2,1%**	174 (45,4%)	209 (54,6%)	**2,2%**

Soc sec = patients with social security. No soc sec = patients without social security; %* Ratio total number of patients aged ≥ 43 and total number of cycles with fertilisation in the laboratory (for patients with and without social security).

On the whole, it is not possible to show that there has been a significant change in the number of patients with or without social security. It can therefore be hypothesised that, in the period under examination, the number of patients without social security, most of whom are foreign, has remained constant. The number of patients over 43 also remains stable if the total number of cycles is taken into account (donated oocytes and the patient's own oocytes).

A study was recently carried out in Europe (Shenfield et al., 2010), which 9 of the 18 Belgian B-Centres (50%) participated in. During one calendar month, all foreign women who arrived in Belgium for treatment received an inquiry form. In this period, 23 women came to Belgium for oocyte donation. On an annual basis, this would amount to 23 x 12 months = 276 patients. The distribution was as follows: France 12, Netherlands 8, Italy 2 and United Kingdom 1. The French and Dutch women responded that their main incentive was their hope of finding better quality treatment in Belgium. The second was that it was legally impossible to receive this treatment in their own country. The woman's age plays a role in this context. However, according to this study (Shenfield et al., 2010), most of the patients who needed an oocyte donation went to Spain or the Czech Republic. A Belgian study (Pennings et al., 2009) shows that 185 patients came to Belgium in 2003, 152 in 2004, 153 in 2005,136 in 2006 and 120 in 2007. The number of patients for this treatment is found to decrease fairly steadily. Moreover, 5 of the 16 centres that took part in the latter study mentioned that foreign patients were only taken into consideration if they were accompanied by their own oocyte donor.

The conclusion that can be drawn from the Pennings et al. (2009) study is that the number of foreign patients treated in Belgium hasn't increased these past few years. In actual fact, it is slightly declining.

3.4.2 Rise in the number of IVF treatments in Belgium between 2003 and 2008.

As was shown above, the growing frequency of IVF treatments (+ 20% in five years) cannot be accounted for by rising numbers of foreign patients or oocyte donation treatments or by an increased need for oocytes for embryonic research. In addition, there are insufficient demographic and toxicological arguments in support of attributing the number of IVF treatments to a reduced physiological fertility. If the intrinsic fertility does not decline but the number of treatments is on the increase, other explanations must be sought. In Belgium, IVF treatment has been reimbursed since 2003 (six cycles until the patient's 43rd birthday). That the number of treatment cycles would increase in 2004 was predictable, but not that this trend would continue year after year. At present, IVF can be carried out if the gynaecologist who treats the patient delivers a certificate that confirms that this treatment is indicated. In this case, the medical officer will authorise the reimbursement without applying any additional criteria. The availability of IVF treatment is of course a good thing for subfertile couples, but it could result in its being resorted to too readily without justification. If IVF were to be available without verification of the treatment criteria, the outcome could be an increase in the number of IVF treatments that are not (yet) necessary. As a result, the SHC takes the view that it might be judicious to suggest treatment criteria. In order to do so, it proposes that a new working group be set up which would draw upon the evidence available in the literature (EBM) to work out a treatment algorithm.

3.4.3 Conclusions

Since 2003, the number of IVF treatments has constantly been on the increase in our country. Yet this cannot be attributed to a rising number of foreign patients. Possible explanations could be the fact that this treatment has become more easily available and/or its indications have been broadened. The SHC therefore takes the view that it might be appropriate to set evidence-based criteria and guidelines for IVF-treatment.

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5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group in a **private capacity**. The names of the members and experts of the Superior Health Council are indicated with an asterisk*.

The following experts took part in drawing up the advisory report:

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The working group was chaired by par Petra DE SUTTER, the scientific secretary was Muriel BALTES

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, a referring committee) and 4) the final endorsement of the advisory reports by the Board (ultimate decision-making body). This coherent set of procedures aims at allowing the SHC to issue advisory reports based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

The advisory reports drawn up by the working groups are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

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