# TNO study on the effects of GSM and UMTS signals on well-being and cognition

Review and recommendations for further research



#### Gezondheidsraad

president

Health Council of the Netherlands

To the Minister of Health, Welfare and Sport



Subject : presentation of report Your reference : VGB/P&L 2444800 Our reference : U-886\EvR\RA\673-A2

Annexes : 1

Date : 28 June 2004

#### Dear Sir,

On 30 September 2003 the Minister of Economic Affairs informed the Lower Chamber of Parliament on the results of a study on possible health effects of exposure to electromagnetic fields generated by mobile telecommunication antennas performed by TNO. This study showed that UMTS signals might have a negative influence on well-being. Also on behalf of the Minister of Economic Affairs, the State Secretary of Housing, Physical Planning and the Environment and the State Secretary of Social Affairs and Employment, you requested the Health Council on 16 March 2004 to inform you on the scientific quality of the TNO study, to indicate what replication and follow up studies might be performed, to indicate whether "perceived well-being" is a sufficiently objective concept for the formulation of scientific conclusions, and to assess whether a reduction in perceived well-being is a sufficiently serious health effect to justify taking mitigating measures. In the present advisory report the Electromagnetic Fields Committee of the Health Council answers these questions. The report has been reviewed by the Standing Committee on Radiation Protection of the Health Council.

I herewith present you with the advisory report *TNO study on the effects of GSM and UMTS signals on well-being and cognition. Review and recommendations for further research.* I have also sent this report today to the Minister of Economic Affairs, the State Secretary of Housing, Physical Planning and the Environment and the State Secretary of Social Affairs and Employment.

In the Netherlands, but even more in other countries, the TNO study has an influence on the perception of the general public concerning possible adverse health effects of mobile telecommunication antennas. In order to be able to adequately address this concern in the population, I think it is important that at short notice more scientific information is gathered to

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answer the question whether exposure to UMTS signals adversely influences health and well-being. I therefore support the pleas for further research given in the present report and the report issued on 4 February 2003.

Yours sincerely,

(signed)

Professor dr JA Knottnerus

# TNO study on the effects of GSM and UMTS signals on well-being and cognition

Review and recommendations for further research

to:

the Minister of Health, Welfare and Sport

the Minister of Economic Affairs

the State Secretary of Housing, Spatial Planning and the Environment

the State Secretary of Social Affairs and Employment

No. 2004/13E, The Hague, June 28, 2004

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues..." (Section 21, Health Act).

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## **Executive summary**

In September 2003, TNO published the results of a study into the effects of controlled human exposure to GSM and UMTS-like electromagnetic fields on well-being and cognitive functions (the COFAM\* -study). Two groups of test subjects were studied. Group A consisted of individuals with health problems that they attributed to exposure to electromagnetic fields, usually from GSM base-station antennas. Group B consisted of individuals who had no such symptoms. Based on the study results, the TNO researchers concluded that the UMTS-like signal had an adverse effect on well-being in both groups.

In the present report, the Electromagnetic Fields Committee of the Health Council of the Netherlands gives its opinion on the scientific quality of the TNO study, at the request of the Minister of Public Health, Welfare and Sport. The Committee also makes proposals for replication and follow-up studies, in addition to answering questions on the definition of 'well-being' and on the consequences of a possible reduction in well-being.

#### **Opinion with comments**

The TNO report has evoked a number of questions from experts within the Committee and elsewhere. Before reviewing the TNO study, the Committee submitted what it felt to be the most important questions to TNO. Details of these questions, and of the responses

\* COgnitive Functions And Mobiles; referred to in this report as 'the TNO study'.

given by the primary investigator of the TNO study, are contained in an annex to this report.

On the basis of the TNO report and of the responses to its questions, the Committee concluded that the TNO study was of good quality, both in terms of design and execution. The Committee had some comments, however, regarding the interpretation of the data.

Exposure to GSM-900 or GSM-1800 electromagnetic fields had no effect on well-being in either experimental group. However, upon exposure to a UMTS-like signal, a small, but statistically significant increase in the well-being score was observed in both groups (a higher score indicates a decrease in well-being). This effect was found after only about half an hour's exposure to what, by everyday standards, was a relatively high environmental field strength. In practice, while individuals in the vicinity of operational UMTS antennas will be subject to continuous exposure, the field strengths in question will be lower. The results of the TNO study cannot be used to assess whether, and to what extent, there will be any effect on well-being in people's day to day environment.

There is some debate concerning the validity of the questionnaire that was used to measure well-being. Accordingly, it cannot be concluded that a change in the score obtained using this questionnaire reflects a real change in well-being. In the course of the TNO study, sufficient data was collected to allow a limited verification of the questionnaire's validity. The Committee recommends that this check be carried out.

Since the two groups of subjects exhibited several differences in terms of their composition, the respective sets of results cannot be compared directly. It is therefore impossible to say whether a given effect observed in both groups is the same or different.

When corrected for multiple exposures, the results of the cognitive function tests show a small but statistically significant difference between control and exposure for only one item: group B completed the memory comparison test faster during UMTS exposure than during sham exposure. It is not clear whether this result has any significance in terms of health.

The TNO researchers did not ask the test subjects whether they were actually able to perceive exposure or whether they believed that they could do so. Nor did they check this possibility.

#### Replication required

The Committee feels that there are good reasons for replicating the TNO study. Most importantly, the widespread exposure to such fields means that the results may well have implications for public health. The TNO study is an initial exploratory study in this area, and it also suffers from the statistical uncertainties inherent to experimental research. Replication studies will serve to further clarify the reliability of the results. These should

be performed by researchers who are independent of TNO, under exposure conditions identical to those used in the TNO study. Some limited technical improvements to the design are acceptable, even desirable. These could include increasing the number of test subjects, and verifying whether they are capable of perceiving the presence of an electromagnetic field.

The Committee recommends that the original TNO questionnaire be used in the replication studies, in order to allow a proper comparison with the original study. At the same time, however, a validated measuring instrument for the determination of well-being should also be used. A degree of similarity between these sets of results would support the validity of the TNO questionnaire. The questionnaire itself should be expanded to include questions on the perception of electromagnetic fields, and on the improvement of well-being.

The Committee feels it important that the groups of test subjects with and without symptoms be as well matched as possible with respect to age, sex, and socio-economic status. This would allow a comparison to be made between the groups. The TNO study provides a basis upon which a detailed research hypothesis for replication studies can be formulated. This hypothesis should then be tested, using statistical procedures already set out in the study protocol.

#### Follow-up studies advisable

Partly on the basis of international consultations, the Committee concludes that there is a need for studies that simulate environmental exposure, as was the case in the TNO study. This has already been indicated in the Committee's report *Health Effects of Exposure to Electromagnetic Fields. Recommendations for Research* issued in February 2003. Of all the ongoing research projects being conducted elsewhere in the world, there is only one dealing with a situation that is comparable to living near a base station. All the other studies deal with exposure to mobile telephones. None of the currently available study descriptions mentions UMTS exposure. It is important that this area be further investigated. Indeed, since the TNO study indicated that UMTS exposure might well produce health effects, the Committee considers it essential that research be carried out into the effects of UMTS signals.

As a result of its present design, the TNO study leaves a number of questions unanswered. It also raises important new issues. The Committee therefore recommends that follow-up studies be carried out to address these matters. The above-mentioned recommendations regarding design improvements for replication studies are, of course, equally applicable to such follow-up research.

The important questions to be addressed in further studies include:

- Can it be objectively determined that some individuals are more sensitive than others to exposure to electromagnetic fields?
- Does the magnitude of any changes in well-being or cognitive functions in individuals who attribute their symptoms to electromagnetic fields differ from that in individuals without such problems?
- How do gender and age influence the effect of exposure?
- Is there a dose-effect relationship between exposure to electromagnetic fields and its effects on well-being and cognitive functions?
- How are these effects influenced by the duration of exposure?
- Do the effects of electromagnetic field exposure on well-being and cognitive functions differ according to the type of base frequency modulation involved? If so, what is the nature and magnitude of this effect?
- Does informing test subjects of the results influence their well-being? For instance, might those who experience such problems be reassured to know that symptoms were not experienced when exposure occurred in the context of the study?

According to the Committee and the expert it consulted, well-being can be scientifically assessed using well-designed questionnaires. The reliability of such measurements is dependent on the degree to which the questionnaires are tailored to the issue at hand. The Committee deems it essential that experts in psychology and psychometrics have an input into such studies.

#### Decreased well-being does not inevitably have repercussions for health

The Committee feels that a decrease in well-being is not necessarily a sufficiently severe health effect to justify mitigating measures. Any such action would depend on the extent of the decrease involved. A great deal naturally hinges on the way in which well-being is defined. The World Health Organization defines health as 'a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity'. On the basis of this definition, any decrease in well-being should be considered an adverse health effect. However, the question is whether a minor decrease in well-being (for instance a degree of discomfort which does not lead to any mental or physical effects) should be considered an adverse health effect. The Committee's position is that only when objective evidence is obtained of the generation or exacerbation of physical or mental symptoms, can it be said that a health effect is involved which requires mitigating measures.

The Committee takes the view that it is not possible, on the basis of the results of the TNO study, to determine the existence of a causal relationship between exposure to electromagnetic fields and decreased well-being or adverse health effects.

Chapter

1

### Introduction

#### 1.1 Background: the TNO study

On 30 September 2003, the results of TNO's so-called COFAM study\* were published <sup>(24)</sup>. This study looked at the effects of exposure to electromagnetic fields produced by GSM and UMTS antennas on human well-being and cognitive functions. The investigators concluded that:

... a statistically significant relationship was found between the presence of radiofrequency fields resembling those produced by a UMTS base station and the perceived well-being of the subjects.

Where cognitive performance is concerned, we (like other researchers before us) found statistically significant relationships often entailing improvements in such performance. Depending on the cognitive task involved, a statistically significant link was found between task performance and the presence or absence of GSM900, GSM1800 and UMTS fields, both in group A and in group B. However, our results do not support definite conclusions regarding the causes or biological mechanisms involved.

Particular interest has been generated in the Netherlands and various other countries by the findings regarding the implications for well-being of exposure to UMTS signals.

The Minister of Economic Affairs, acting also on behalf of the Minister of Health, Welfare and Sport and the State Secretary for Housing, Spatial Planning and the Envi-

\* COgnitive Functions And Mobiles; referred to in this report as 'the TNO study'.

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ronment, submitted the results of the TNO study to the Lower House of the Dutch parliament. In his covering letter, he wrote:

While we are taking the results of this study seriously, we do not believe that they offer sufficient support for definitive policy conclusions. Studies such as this need to be validated by various means and discussed in international forums. It is very important to consider whether there actually are any (permanent) health implications and, if so, how serious they are.

#### The minister went on to say:

It should be said that the design and findings of this study remain at present unique; repetition by an independent body is necessary in order to establish whether the findings of the research carried out by TNO can be verified.

The minister also made the point that further research was required:

In addition, further scientific research needs to be carried out to establish whether any effect is associated with the field strength, frequency or signal forms used, and whether men and women – or adults and children – differ in terms of their responses.

The Health Council was to be asked to give its advice regarding such further research.

#### 1.2 The request for advice

On 16 March 2004, the Health Council received a request from the Minister of Health, Welfare and Sport, acting also on behalf of the Minister of Economic Affairs, the State Secretary for Housing, Spatial Planning and the Environment and the State Secretary for Social Affairs and Employment, to provide a scientific evaluation of the TNO study and to advise on appropriate follow-up research. The text of the minister's letter is presented in annex A to this report.

#### 1.3 The Committee

The President of the Health Council passed the minister's request on to the Electromagnetic Fields Committee. This committee was established on 1 January 2000 for a period of four years. The Council's President has since extended the Committee's mandate by a further two years, to the end of 2005. The Committee's members are listed in annex B.

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Professor APM Zwamborn, who led the TNO study team, is normally also a member of the Electromagnetic Fields Committee. However, he stood down for the duration of the Committee's deliberations on the matter at hand, acting simply as a consultant.

#### 1.4 Structure of the report

In chapter 2, the report begins by outlining the TNO study, after which the Committee gives its assessment of the study. Annex D lists a number of questions raised by the study, and the responses to these questions provided by TNO. The Committee has taken these responses into account when arriving at its assessment.

Since the minister specifically asked that the Council's recommendations should be placed in the context of international research, chapter 3 contains a brief résumé of what is presently known about the effects on cognition and well-being of exposure to radiof-requency electromagnetic fields; the résumé also outlines those planned and ongoing studies of which the Committee is aware.

On the basis of the information presented in chapters 2 and 3, the Committee addresses the ministers' questions in chapter 4. The Committee's responses include an assessment of the TNO study, and recommendations regarding replication and follow-up studies.

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Chapter

2

## The TNO study

#### 2.1 Purpose

The TNO study was set up to establish whether exposure to electromagnetic fields of the type associated with mobile telephony and of a strength found within the everyday human environment has any influence on well-being or cognitive functions. This possibility was considered an appropriate topic for investigation because some individuals have attributed non-specific health problems to living in the immediate vicinity of mobile telecommunications antennas.

#### 2.2 Study design

The format of the TNO study was experimental and double-blind. In other words, neither the subjects nor the researchers knew whether or not exposure had taken place. The subjects were exposed to electromagnetic fields produced by GSM and UMTS antennas. Exposure occurred in a so-called anechoic chamber designed to exclude electromagnetic fields of external origin. The antenna placed inside the chamber was therefore the only possible source of any electromagnetic fields to which the subjects were exposed in the course of the research.

Exposure involved a 900 MHz GSM signal, an 1800 MHz GSM signal, or a 2100 MHz UMTS signal. The effective strength of the field to which the subjects were exposed was 0.7 V/m where the GSM fields were concerned, and 1 V/m where the UMTS field was concerned.

Each subject was tested over four successive exposure periods. In each case, the first period was simply a 'dry run', during which no exposure actually took place, but subjects had the opportunity to get used to the exposure chamber and the cognitive tests. Two of the three subsequent periods involved actual exposure, while the third involved sham exposure. During sham exposure, all conditions were the same as in the periods of actual exposure, the only difference being that the antenna was not generating electromagnetic fields. Each subject was exposed to two of the three frequency modalities. Each of the possible exposure-sham sequences and combinations was carried out the same number of times in the study. The test schedule is presented in table C-2 in annex C.

According to the researchers, every possible precaution was taken to ensure that there was nothing to indicate whether the antenna was in use or not. There was no noise or indicator lamp, for example, to indicate the presence or absence of an electromagnetic field. However, no steps were taken to ascertain whether the subjects were nevertheless able to tell whether exposure was taking place, e.g. by bringing detectors into the chamber with them.

During the sessions, the subjects were asked to undertake a number of computer-controlled tests designed to measure cognitive functions (reaction time, memory comparison, selective visual attention, multiple tasking). In order to minimise any possible influence of electromagnetic fields generated by the computer monitor, a TFT monitor was used. Immediately after each session, subjects were asked to answer a series of questions relating to their well-being during the session.

In each case, a comparison was made between the data obtained during the sessions in which exposure actually occurred and the sham exposure sessions.

The subjects were divided into two groups. Group A was made up of individuals who had registered with the Monitoring Network Health and Environment as having symptoms that they attributed to living in the immediate vicinity of antennas (in most cases GSM antennas). It was considered potentially instructive to recruit a group of subjects from this subpopulation because such individuals may be more sensitive to electromagnetic fields than most people. The second group of subjects, group B, was made up of volunteers without such symptoms. Demographic details of the two groups are presented in table C-1 in annex C. No information was obtained concerning the socio-economic status of the subjects.

#### 2.3 Results of the TNO study

The results of the cognitive function tests revealed no clear pattern. TNO analysed the data on the basis of a 5 per cent margin of uncertainty and in some cases found statistically significant improvements or deteriorations of the functions under assessment.

However, the distribution of these significant findings across the various combinations of subject category and exposure type appeared to be random (see tables C-3 to C-7 in annex C).

A statistically significant rise was recorded in the well-being questionnaire scores for subjects exposed to UMTS signals (see tables C-8 and C-9 in annex C), indicating a decline in well-being. By contrast, no significant change in the score was associated with exposure to the GSM signals. Diminished well-being was associated with UMTS exposure in both subject groups. In absolute terms, the effect was greater in the group with previously declared symptoms than in the other group (the rise in aggregate score being, respectively, 3.4 and 0.9, out of a maximum of 69). However, comparison of the two groups is not possible, since their composition differed in a number of respects, particularly age and gender profile (see table C-1 in annex C).

#### 2.4 Supplementary data

Following publication of TNO's report on the study, various questions were raised within the scientific community regarding the design and implementation of the experiments, as well as about the analysis of the data. TNO intends to produce a supplementary report addressing these questions, but this report was not available at the time of writing. The Committee referred what it regarded as the most important of the questions raised within the scientific community, as well as certain queries of its own, to TNO. These questions, together with the responses provided by TNO (in the person of Professor APM Zwamborn, TNO study project leader) are set out in annex D.

#### 2.5 Quality of the questionnaires used

The Committee asked an expert in the field of psychometrics, HCM Vorst of the University of Amsterdam, to give an opinion regarding the scientific quality, relevance and validity of the questionnaires used for the TNO study. Mr Vorst was also asked to comment on the validity of the conclusions drawn from the questionnaires by TNO, regarding changes in well-being. Mr Vorst's responses are set out in annex E.

To summarise, Mr Vorst indicated that while the questionnaire used was in principle an appropriate tool for measuring well-being, it had nevertheless been validated in the context of research of a very different kind. Mr Vorst therefore felt that it was not possible to say whether the questionnaire was valid for use in the way TNO had used it, especially in the abbreviated form used by TNO. The data collected in the context of the TNO study did lend itself to some kind of check on the metrological quality of the questionnaires and tests, but no such check was performed.

The systematic nature of the observed diminution of well-being associated with UMTS exposure is such that this effect should be considered consistent. However, it cannot reasonably be concluded from the absence of similar reported effects among individuals exposed to GSM fields that in those cases no such effects occurred. Failure to detect such effects could be due to noise or to unreliable and/or poor measurements, resulting in false negatives.

The Committee endorses these conclusions.

#### 2.6 The Committee's conclusions and comments

The TNO study is one of the first experimental investigations carried out according to the generally accepted principles for such research with the aim of examining the possible effect on human functions of electromagnetic fields produced by base stations. The research was qualitatively sound and the Committee has no reason to dispute the results obtained.

However, the Committee does feel that a number of points should be made regarding TNO's interpretation of the data.

- Little or no similar research had been carried out prior to the TNO study. As a result, it was not possible to formulate hypotheses for the TNO study on the basis of existing data. Hence, the research must be regarded as explorative i.e. not purely hypothesis-testing, but also partly hypothesis-generating. This would tend to argue in favour of further replication studies, designed around an experimentally based hypothesis formulated from the TNO study findings.
- In the TNO study, several variables were used, both in connection with the exposure (three different frequency modalities) and in connection with the measured effects (well-being and various cognitive functions). The study therefore addressed several issues. Allowance for this fact should have been made in the statistical analysis of the data, to prevent pure chance yielding statistically significant results. One way of doing this would have been to apply the Bonferroni correction method (see annex D for an explanation). The Committee believes that the TNO report does not indicate sufficiently clearly whether and, if so, to what extent this method was used to correct for the influence of multiple comparisons. The Committee received satisfactory responses to the questions that it subsequently put to TNO on this point, and the Bonferroni correction was retrospectively applied (see annex D).
- The validity of the questionnaire used to measure well-being is unclear. The TNO study yielded sufficient data to allow the questionnaire's validity to be checked to a limited degree, but this was not done. The Committee recommends that appropriate verification should take place. Furthermore, the Committee believes that the measuring quality of the questionnaire used by TNO should be investigated before any

- follow-up research takes place. Alternatively, perhaps use should be made of a different tool, whose qualities are better known and validated.
- The Committee notes that no attempt was made to establish whether subjects had
  any perception of undergoing exposure, and that no checks were made to ascertain
  whether subjects were able to tell in any way whether they were being exposed.
   These matters need to be addressed in any replication study or follow-up research.

In the Committee's view, taking account of the answers to the questions put to TNO, the following conclusions may be drawn from the study:

- A statistically significant rise was recorded in the well-being questionnaire scores for subjects in both groups exposed to electromagnetic fields in the form of UMTS-like signals. In absolute terms, the effect was small: a rise of 3.4 points for group A and 0.9 points for group B, on a scale of zero to 69 (see tables C-8 and C-9). It is not possible to tell from the data which aspects of well-being were affected, or what the health implications of the effects might be.
- Exposure to GSM900 or GSM1800 signals did not appear to affect well-being in either subject group.
- Despite the uncertainty regarding the validity of the measurement instrument used (i.e. the questionnaire), it appears that the measured diminution of well-being associated with UMTS exposure is reliable, particularly in view of the systematic nature of the findings. However, it cannot reasonably be concluded from the absence of similar reported effects among individuals exposed to GSM fields that no such effects occurred in those cases; the procedure used may have produced a false negative. Better understanding of the scientific validity of the questionnaire may help to reduce this uncertainty.
- Because the two groups of subjects differed in composition, no valid cross-comparison of the findings may be made. In fact, the study may be regarded as two separate but simultaneously conducted experiments.
- At the Committee's request, TNO introduced a correction for the effects of multiple comparisons. Following correction, the cognitive function test results produced only one statistically significant finding: subjects in group B performed the memory comparison test more quickly when exposed to the UMTS signal than during simulated exposure (table C-4). The observed effect was small (6.5 milliseconds) and it is not clear what health implications (if any) such an effect might have.

The Committee notes that the observed diminution of well-being in the TNO study occurred upon exposure to what by everyday standards were relatively strong UMTS-like electromagnetic fields lasting only about half an hour. In practice, while exposure in the vicinity of operational UMTS antennas is likely to be continuous, it will involve

weaker fields and a somewhat different signal from to that used in the TNO study. The data yielded by the TNO study does not therefore indicate whether exposure in real-life situations is likely to affect well-being or, if so, to what extent. Furthermore, the Committee cannot exclude the possibility that the significant effects so far observed are attributable merely to chance. It is therefore considered important that the research is replicated, particularly in view of the expected widespread nature of exposure to UMTS fields taking place within the community, the explorative nature of the TNO study, and the possible public health implications of the effects reported by the researchers.

Chapter

3

# Electromagnetic fields, cognition and well-being

When seeking the Health Council's advice, the minister asked that the Council place its recommendations in an international research context. In this section, the Committee accordingly presents a brief overview of what is presently known about the effects on cognition and well-being of exposure to radiofrequency electromagnetic fields. A résumé is also given of the planned and ongoing studies of which the Committee is aware.

#### 3.1 Effects of exposure on cognitive functions

A number of recently published review articles <sup>(6,7,16)</sup> provide a good picture of current scientific knowledge about the relationship between exposure to electromagnetic fields, including fields generated by antennas used in mobile telecommunications, and effects on cognitive functions. All the studies that have so far looked at the influence of exposure to GSM-modulated radiofrequency electromagnetic fields on human cognitive functions have focused on mobile phones as the field source and have been concerned with brief periods of exposure. The conclusions of the studies in question may be summarised as follows:

- Some studies indicated that exposure to radiofrequency electromagnetic fields had an influence on cognitive functions.
- There is little or no consistency between the studies in terms of results.
- Few of the studies were designed on the double-blind principle, which reduces the significance of the results; non-double-blind experiments can yield false positive results or – more occasionally – false negative results.

- Numerous different tests have been used to investigate cognitive functions; it is not clear in all cases whether the tests used had been validated.
- No effects were observed by Haarala, who recently carried out an extensive and well designed study (13).

The Committee regards Haarala's study as the most reliable conducted to date. The purpose of the study was to ascertain whether the findings of an earlier study by Koivisto et al (19) were reproducible. In the Koivisto study, subjects were exposed to 902 MHz mobile phone signals, and various of their cognitive functions were tested to see whether any effect was discernible. Changes were observed in three of the fourteen cognitive functions tested. However, the exposure involved was not clearly defined, and no measurements or calculations were performed to establish the strength of the field to which subjects were exposed. Furthermore, the analysis did not involve correction for the influence of multiple comparisons. Haarala's follow-up research was more extensive and better designed. More subjects were used (sixty-four, as opposed forty-eight) and the tests took place in two laboratories, working independently in Sweden and Finland. In addition, extensive measurements and calculations were made to determine the strength of the field and the subjects' body temperature. Furthermore, the double-blind principle was applied. The subjects performed nine cognitive tests, six of which had been used by Koivisto. Haarala found no evidence to suggest that exposure affected any of the tested cognitive functions.

The Committee concludes that little research has been carried out in this field and that the available data does not provide any convincing evidence that electromagnetic fields can affect human cognitive functions.

#### 3.2 Effects of exposure on well-being

The effects of exposure on well-being have been even less thoroughly studied than the effects on cognitive functions. In this area, too, all published studies focus on mobile phones as the source of exposure. Hence, the fields to which subjects were exposed in the course of these studies were much stronger than those involved in the TNO study.

Reports have been published on two epidemiological studies into the effects of electromagnetic fields on human well-being. In Sweden and Norway, Sandström <sup>(21)</sup> used a questionnaire to look for possible discrepancies between analogue and digital mobile phone users in terms of reported health problems\*. No such difference was found, but a statistically significant association was observed between, on the one hand, the duration

<sup>\*</sup> Subjects were asked about dizziness, discomfort, concentration problems, memory loss, fatigue, headache, sensations of warmth in or behind the ear, burning sensations in the skin, tingling and other problems.

and daily frequency of calls and, on the other, the development of warmth around the ear, headache and fatigue. Santini <sup>(22)</sup> also used questionnaires to inventory the symptoms experienced by mobile phone users. This study found that those with GSM1800 phones were more likely to have difficulty concentrating than users of GSM900 phones. Women who used mobile phones were more likely to suffer insomnia than women who did not. Furthermore, symptoms became more common among digital phone users as usage frequency and duration increased.

Although the Committee believes that properly designed epidemiological research can make a useful contribution to the resolution of specific questions, it is felt that the types of problem addressed by the two studies lend themselves particularly well to experimental research, which is most valuable for indicating whether a cause-effect relationship exists between exposure and effect. In the advisory report on research recommendations published by the Committee in 2003 <sup>(12)</sup>, the importance of experimental research is described as follows:

In view of public concern about possible health problems, the almost total lack of good research data in this field, and the possibility that certain subpopulations might be particularly sensitive to electromagnetic fields, the Committee attaches great importance to human experimental research. It is therefore suggested that research into health problems should be organised, subject to the condition that the effects are open to objectification. Hence, such research should be experimental in character and should take place under controlled conditions in a test environment.

The studies by Sandström and Santini were not of an experimental nature, so exposure did not take place under controlled conditions. The scientific significance of their findings in relation to the problems under consideration is therefore limited. Being non-experimental and concerned with subjective symptoms, there is a possibility that individuals will retrospectively and erroneously attribute symptoms they have experienced to the use of mobile phones ('attribution bias'). Furthermore, it is not possible with research of this kind to establish exactly what level of exposure has taken place. Subjects were asked how often they used a mobile phone and for how long, and their responses were used as exposure indicators. This is not a very accurate way to measure exposure, however. Furthermore, the results of such studies can be distorted to a significant extent if questions are posed in a leading manner. This is another aspect regarding which no data is available. Taking all these considerations into account, the Committee does not believe that the studies by Sandström and Santini support conclusions regarding the possible existence of a causal relationship between exposure to electromagnetic fields generated by mobile phones and changes in human well-being.

The methodological problems outlined above do not affect experimental research, although such research does have the drawback that the test environment can provide

only a limited simulation of a real-life situation. Koivisto <sup>(18)</sup> studied two groups of forty-eight symptom-free volunteers to see whether thirty-minute or sixty-minute periods of exposure to electromagnetic fields generated by a GSM phone led to symptoms such as headache, dizziness and fatigue. The research involved the completion of questionnaires at the start of each session, midway through it and at its conclusion. Each subject underwent a period during which exposure took place and a period during which it did not. Although the subjects were not aware whether exposure was taking place, the researchers were. Certain problems (headache, dizziness, fatigue) increased slightly in the course of the sixty minutes that the experiment lasted. However, no evidence was found to indicate that exposure to GSM electromagnetic fields influenced the three symptoms referred to above, or three others: itching, skin reddening, and a warm sensation in the skin.

The only other experimental study reported to date was carried out by Hietanen (14). In this study, individuals who believed themselves hypersensitive to the electromagnetic fields associated with mobile phones were exposed to fields generated by analogue phones (NMT) or digital mobile phones (GSM900 and GSM1800). The subjects were not aware whether the phone was switched on or off during the exposure sessions, but the researchers did know. While the sessions of up to thirty minutes were in progress, the subjects' blood pressure and heart rate were monitored every five minutes and subjects were asked to describe how they were feeling. Any sensations experienced were immediately noted in an experimental log. Of the twenty people tested, nineteen described experiencing symptoms. Only the nature of the symptoms in question was recorded, not their degree of severity. In the number of symptoms reported, there proved to be no significant difference between the sham and actual exposure sessions. Women reported more symptoms than men, and in many cases the problems they reported were different. However, proper comparison of the male and female data is not possible because of differences between the age profiles of the male and female subject groups. None of the subjects were able to tell whether exposure was really taking place or not. Both blood pressure and heart rate fell while the experiments were in progress; the highest values for both parameters were always measured during the first of the three or four exposure sessions. This suggests that subjects gradually became used to the general test environment. Exposure was not found to influence either blood pressure or heart rate.

The authors acknowledge that the static position that subjects adopted during the thirty-minute sessions may have influenced the development of symptoms. However, the fact that symptoms were often reported at the start of a session would tend to argue against this possibility. Furthermore, the researchers cannot exclude the possibility that contact between the subjects may have influenced their reporting of symptoms. In view of the latter consideration in particular, the Committee feels that this study is of limited value.

The Committee concludes that the studies by Koivisto and Hietanen provide no evidence that exposure to electromagnetic fields produced by analogue or digital mobile phones has any influence on human well-being.

#### 3.3 Research in progress

According to the information available to the Committee at the time of writing <sup>(2)</sup>, the following studies are in progress or will be started shortly:

- In Australia, a project entitled The Effect of 900 MHz RF Radiation on Human Neuropsychological Responses is looking at the influence of exposure on subjects' attention, concentration and memory.
- In Germany, a project is underway entitled *Microwave Exposure and Effects on Human Orientation*.
- In Finland, subjects are being exposed to 900 and 1800 MHz GSM signals in the context of a project entitled *The Effects of Radiofrequency Electromagnetic Fields on Cognition and Brain Function*.
- In the United Kingdom, the *Link Mobile Telecommunications and Health Research Programme* (MTHR) has been running for some while with funding from the public and private sectors <sup>(1)</sup>. An independent Programme Management Committee decides which projects are to receive support. The projects currently in progress are:
  - *Mobile Cellular Communication and Cognitive Functioning:* healthy subjects are exposed to 900 MHz GSM fields and their cognitive functions and memory tested.
  - Study to Evaluate the Effects of Mobile Telephone Usage on Labyrinthine Function: exposure of subjects with and without headache symptoms to 900 MHz GSM fields produced by a simulated mobile phone; monitoring levels of headache, nausea and spatial disorientation experienced.
  - The Effect of Mobile Phone Use on Symptoms and Neuroendocrine Function in 'Normal' and 'Hypersensitive' Users: exposure of subjects with and without health problems to 900 MHz GSM fields produced by a mobile phone; subjects questioned about particular problems and blood tests carried out.
  - Hypersensitivity Symptoms Associated with Electromagnetic Field Exposure: this project is divided into two parts; first, a questionnaire will be developed as a means of determining the extent to which a potential subject exhibits symptoms of electromagnetic hypersensitivity (the EHS Symptoms Scale); thereafter, people who register particularly high or low scores on the scale will be studied while undergoing either sham or actual exposure to an electromagnetic field like that generated by a mobile telephony base station. The design of this study resembles the TNO study in certain important respects. A series of psychological, physiological and general health indicators are to be studied.

- A project is currently running in Italy entitled *Human Cognitive Performance and Tympanic Temperature with Exposure to a 902.4 MHz GSM Signal During and Prior to Four Performance Tasks*: subjects are exposed to 900 MHz GSM signals, then their cognitive functions are measured, as is the temperature at the tympanic membrane.
- In Sweden, two studies are underway, looking into the effects of exposure to 900 and 1800 MHz GSM fields; the first study is looking at headache problems, while the second is focusing on hypersensitivity of the skin.

The Committee believes there is a need for research that seeks to simulate exposure in the normal day-to-day environment. However, only one of the studies mentioned above attempts to recreate a situation comparable to living in the vicinity of a base station. All the others involve exposure to signals from mobile phones. Furthermore, none of the studies is looking at exposure to UMTS signals. It is, however, important that this area be further investigated. Indeed, since the TNO study indicated that UMTS exposure might well produce health effects, the Committee considers it essential that research be carried out into the possible effects of UMTS signals. Replication of the TNO study would be a first step.

Chapter

4

### Recommendations

In this chapter, the Committee addresses the four questions raised by the ministers when they wrote asking the Health Council for its advice.

#### 4.1 Assessment of the TNO study

The minister's first question was as follows:

What is the Health Council's assessment of the quality of the COFAM study and what does the Council see as the best approach to replication of the study?

The TNO report has evoked a number of questions from experts within the Committee and elsewhere. Before making a formal assessment of the study, the Committee put what it regarded as the most important of these questions to TNO. Details of these questions, and of the responses given by the primary investigator of the TNO study, are contained in an annex to this report.

On the basis of the TNO report and of the responses to its questions, the Committee concludes that the TNO study is of good quality, both in terms of design and execution. With regard to the research results, the Committee makes the following observations:

• A statistically significant rise was recorded in the well-being questionnaire scores (indicating reduced well-being) for both groups of subjects exposed to electromagnetic fields in the form of UMTS-like signals. In absolute terms, the effect was small: a rise of 3.4 points for group A and 0.9 points for group B, on a scale of zero

- to 69. It is not possible to tell from the data which aspects of well-being were affected.
- Exposure to GSM 900 or GSM 1800 signals did not appear to affect well-being in either subject group.
- The validity of the questionnaire used to measure well-being is unclear. Therefore it
  cannot be concluded that a change in the score obtained using this questionnaire
  reflects a real change in well-being. In the course of the TNO study, sufficient data
  was collected to allow a limited verification of the questionnaire's validity. Accordingly, the Committee recommends that appropriate verification should take place.
- Since the two groups of subjects exhibited several differences in terms of their composition, the respective sets of results cannot be compared directly. In fact, the study may be regarded as two separate but simultaneously conducted experiments. It is therefore impossible to say whether a given effect observed in both groups is the same or different.
- After correction for the influence of multiple comparisons, the cognitive function test results showed up only one statistically significant difference between sham and actual exposure: subjects in group B performed the memory comparison test more quickly when exposed to the UMTS signal than during sham exposure. In absolute terms, the observed effect was small (6.5 milliseconds) and it is not clear what the significance of this finding is in relation to human health.
- No attempt was made by the researchers to establish whether subjects believed they
  were being exposed to an electromagnetic field or whether there were any physical
  indications allowing them to observe whether this was the case.
- The change in the subjects' well-being scores was associated with exposure to what by everyday standards were relatively strong fields lasting only about half an hour. In practice, while individuals in the vicinity of operational UMTS antennas will be subject to continuous exposure, the field strengths in question will be lower. The results of the TNO study cannot be used to assess whether, and to what extent, there will be any effect on well-being in people's day-to-day environment.

The Committee feels that there are good reasons for replicating the TNO study. Most importantly, the widespread exposure to such fields means that the results may well have implications for public health. The TNO study is an initial exploratory study in this area and also suffers from the statistical uncertainties inherent to experimental research (working with a random sample leaves scope for false positive or negative results). Replication of the study would further clarify the reliability of the results. This should be performed by researchers who are independent of TNO, under exposure conditions identical to those used in the TNO study. Nevertheless, some technical improvements to the study design would be acceptable, or even desirable. A larger number of subjects would

be advantageous, for example, as would checks to ascertain whether subjects are able to tell when a field is being generated, e.g. using cues such as light, sound, or mechanical vibrations.

The Committee recommends that, in the interests of comparability, the questionnaire used by TNO should be used for the replication study as well. However, use should also be made of an additional, previously validated tool for measuring well-being. A degree of similarity between these sets of results would support the validity of the TNO questionnaire. The questionnaire itself should be expanded to include questions on the perception of electromagnetic fields, and on the improvement of well-being.

The Committee feels it important that the groups of test subjects with and without symptoms be as well matched as possible with respect to age, gender, and socio-economic status. This would allow a comparison to be made between the groups. The TNO study provides a basis upon which a detailed research hypothesis for replication studies can be formulated. This hypothesis should then be tested, using statistical procedures already set out in the study protocol.

#### 4.2 Desirability of additional research

The minister's second question was as follows:

Is it desirable that additional research is carried out and, if so, what particular points should that research address, bearing in mind the nature of research activities in progress elsewhere?

The Committee believes that there is a need for research that, like the TNO study, seeks to simulate the kind of exposure that occurs in the day-to-day human environment. This has already been indicated in the Committee's report *Health Effects of Exposure to Electromagnetic Fields. Recommendations for research*, published in February 2003 <sup>(12)</sup>. Of all the ongoing research projects being conducted elsewhere in the world, there is only one dealing with a situation that is comparable to living in the vicinity of a base station. All the other studies deal with exposure to mobile telephones. None of the currently available study descriptions mentions UMTS exposure. It is, however, important that this area be further investigated. Given that the TNO study has indicated that UMTS exposure may have implications for human health, the Committee considers it important that further research into this possibility is conducted.

As a result of its present design, the TNO study leaves a number of questions unanswered. It also raises important new issues. The Committee therefore recommends that follow-up studies be carried out to address these matters. The above-mentioned recommendations regarding design improvements for replication studies are, of course, equally applicable to such follow-up research.

Important questions to be addressed in further studies include:

- Can it be objectively determined that some individuals are more sensitive than others to exposure to electromagnetic fields? (This question might be addressed by organising follow-up research using various groups of subjects, some consisting of individuals with symptoms that they attribute to exposure to electromagnetic fields, others being free of such symptoms. Similarity between the groups in terms of their age, gender and socio-economic status profiles is important in order that valid cross-comparisons can be made between the findings.)
- If the existence of 'hypersensitive groups' can be demonstrated, do individuals in such groups differ from symptomless individuals in terms of the degree to which their well-being or cognitive functions are affected by exposure to electromagnetic fields?
- How do gender and age influence the effect of exposure?
- Is there a dose-effect relationship between exposure to electromagnetic fields and its effects on well-being and cognitive functions?
- How are the effects of exposure to electromagnetic fields on well-being and cognitive functions influenced by the duration of the exposure?
- Do the effects of electromagnetic field exposure on well-being and cognitive functions differ according to the type of base frequency modulation involved? If so, what is the nature and magnitude of this effect? (The UMTS signals currently in use differ from the signal used for the TNO study.)
- Does informing test subjects of the results influence their well-being? (Since, at the conclusion of an experimental research project, subjects are sometimes informed about their own results, it is pertinent to ask to what extent such information may influence the subjects' perception of their health. This question is of particular importance in relation to individuals who attribute their health problems to electromagnetic fields. Might such individuals be reassured, for example, to know that symptoms were not experienced when exposure occurred in the context of the study?)

The Committee would also emphasise that the research recommendations contained in the report it published in February 2003 remain valid <sup>(12)</sup>.

#### 4.3 The measurability of well-being

The minister's third question was as follows:

Is 'perceived well-being' a sufficiently objective concept for the formulation of scientific conclusions?

According to the Committee and the expert it consulted, well-being can be scientifically assessed using well-designed questionnaires. However, the Committee believes that the reliability of well-being measurements made in this way is directly related to the extent to which the questionnaire used is tailored to the issue at hand. The Committee deems it essential that experts in psychology and psychometrics have an input into such studies.

#### 4.4 Well-being and health

The minister's fourth and final question was as follows:

Does the diminution of 'perceived well-being' amount to a sufficiently serious effect on health to justify countermeasures?

The Committee believes that this is not necessarily the case; justification for mitigating measures depends on the degree of diminution involved. A great deal naturally hinges on the way in which well-being is defined. The World Health Organisation defines health as 'a state or complete physical, mental and social well-being, and not merely the absence of disease or infirmity'. On the basis of this definition, any decrease in well-being should be considered an adverse health effect. However, the question is whether a minor decrease in well-being (for instance a certain degree of discomfort which does not lead to any mental or physical effects) should be considered an adverse health effect. The Committee's position is that only when objective evidence is obtained of the generation or exacerbation of physical or mental symptoms, can it be said that a health effect is involved which requires mitigating measures

The Committee takes the view that it is not possible, on the basis of the results of the TNO study, to determine the existence of a causal relationship between exposure to electromagnetic fields and decreased well-being or adverse health effects.

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## **Annexes**

#### Annex

### А

## The request for advice

On 16 March 2004, the President of the Health Council received the following request.

On behalf of the Minister of Economic Affairs, the State Secretary for Housing, Spatial Planning and Environmental Management, the State Secretary for Social Affairs and Employment and myself, I ask that you give your attention to the following matters.

On 30 September 2003, the report was published on TNO's study into the relationship between, on the one hand, exposure to electromagnetic fields generated by GSM and UMTS antennas and, on the other hand, cognitive functions and well-being. The outcome of the study was as follows:

- TNO found a statistically significant association between the presence of radiofrequency fields resembling those produced by a UMTS base station and the perceived well-being of the subjects. No such link had previously been observed. Subjects perceived their well-being to deteriorate in the presence of such fields.
- Certain statistically relevant associations were found between the presence of fields generated by UMTS and GSM base stations and the performance of various cognitive functions. In many cases, cognitive performance actually improved. Similar findings have been reported by other authors.

The study findings are being taken seriously by the relevant government departments concerned, and are considered by us to warrant follow-up research into the relationship between EM fields and well-being and cognitive functions. In connection with these matters, we wish to draw upon the expertise of your Council.

Against this background, we wish you to provide us with a brief report addressing the following questions:

- 1. What is the Health Council's assessment of the quality of the COFAM study and what does the Council see as the best approach to replication of the study?
- 2. Is it desirable that additional research is carried out and, if so, what particular points should that research address, bearing in mind the nature of research activities in progress elsewhere?
- 3. Is 'perceived well-being' a sufficiently objective concept for the formulation of scientific conclusions?
- 4. Does the diminution of 'perceived well-being' amount to a sufficiently serious effect on health to justify mitigating measures?

I look forward to receiving your recommendations.

Yours sincerely,

Minister of Health, Welfare and Sport (signed) H Hoogervorst

Annex **B** 

### The Committee

- Prof. EW Roubos, *Chairman* Professor of Zoology, neurobiologist; Nijmegen University
- Dr LM van Aernsbergen, consultant physicist; Ministry of Housing, Spatial Planning and the Environment, The Hague
- Prof. G Brussaard
   Emeritus Professor of Radio Communication; Eindhoven University of Technology
- Dr J Havenaar psychiatrist; 'Altrecht' Mental Health Care Foundation, Utrecht
- FBJ Koops biologist; Arnhem
- Prof. FE van Leeuwen
   Professor of Cancer Epidemiology; Vrije Universiteit Amsterdam epidemiologist; The Netherlands Cancer Institute, Amsterdam
- Dr HK Leonhard, consultant physicist; Ministry of Economic Affairs, Groningen
- Dr GC van Rhoon physicist; Erasmus University Medical Center Rotterdam
- Dr MM Sitskoorn psychologist; University Medical Centre, Utrecht
- Dr GMH Swaen epidemiologist; University of Maastricht

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- DHJ van de Weerdt, physician
   Specialist in Environmental Medicine; Zwolle Municipal Medical and Health
   Service
- Prof. APM Zwamborn, consultant
   Professor of Electromagnetic Effects; Eindhoven University of Technology physicist; TNO, The Hague
- Dr E van Rongen, *secretary* radiobiologist; Health Council, The Hague

With regard to the research into well-being carried out by TNO using a questionnaire, the Committee sought the advice of HCM Vorst, a psychologist at the Psychology Department, Faculty of Social and Behavioural Sciences, University of Amsterdam.

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Annex

## **TNO study data**

Table C-1 summarises the demographic details of the two groups of subjects. Group A was made up of individuals with previously declared symptoms; group B consisted of those without such symptoms.

Table C-1 Subjects' demographic details.

		Group A	Group B
Gender	Male (n)	11	22
	Female (n)	25	14
	Total (n)	36	36
Age	Mean ± standard deviation (years)	55.7 12.0	$46.6 \pm 16.4$
	Range (min - max) (year)	(31 - 74)	(18 - 72)

The subjects were placed in blocks by means of balanced random division, so that each group was divided into eighteen blocks of two subjects, taking account of all sequences. Table C-2 summarises all the exposure sequences used.

Table C-2 Summary of exposure sequences used.

Group	Block	N	Session 1	Session 2	Session 3	Session 4
	1	2	Training	Sham	2100 MHz	900 MHz
	2	2	Training	Sham	2100 MHz	1800 MHz
	3	2	Training	Sham	900 MHz	2100 MHz
	4	2	Training	Sham	1800 MHz	2100 MHz
	5	2	Training	Sham	900 MHz	1800 MHz
	6	2	Training	Sham	1800 MHz	900 MHz
	7	2	Training	900 MHz	Sham	2100 MHz
	8	2	Training	1800 MHz	Sham	2100 MHz
A/B	9	2	Training	2100 MHz	Sham	900 MHz
	10	2	Training	2100 MHz	Sham	1800 MHz
	11	2	Training	900 MHz	Sham	1800 MHz
	12	2	Training	1800 MHz	Sham	900 MHz
	13	2	Training	900 MHz	2100 MHz	Sham
	14	2	Training	1800 MHz	2100 MHz	Sham
	15	2	Training	2100 MHz	900 MHz	Sham
	16	2	Training	2100 MHz	1800 MHz	Sham
	17	2	Training	900 MHz	1800 MHz	Sham
	18	2	Training	1800 MHz	900 MHz	Sham

Tables C-3 to C-7 contain the results of the analyses of the cognitive function tests. These tables differ from those presented in the TNO report in that the present analyses are based on individual comparison of actual and sham exposure. Hence, the exposure group and the sham exposure group each contain twenty-four subjects. For comparison, the averages of all the sham values (N=36) stated in the TNO report are also given.

Table C-3 Response time (msec).

Exposure	Group A				Group B	p-value Group			
	Mean	SEM	N	p-value <sup>a</sup> vs. sham	Mean	SEM	N	p-value <sup>a</sup> vs. sham	A vs. Group B
Sham	1153	22.3	36		1139	23.2	36		0.6579
Sham <sup>a</sup>	1136	22.9	24		1149	30.3	24		
900 MHz	1196	34.6	24	0.0137	1161	32.3	24	0.4858	
Sham <sup>a</sup>	1172	30.9	24		1149	20.4	24		
1800 MHz	1161	25.5	24	0.5457	1121	24.7	24	0.4207	
Sham <sup>a</sup>	1152	27.7	24		1120	32.5	24		
2100 MHz	1172	27.2	24	0.4416	1179	38.8	24	0.3635	

<sup>&</sup>lt;sup>a</sup> Sham only for those subjects exposed to the frequency concerned.

Table C-4 Memory comparison test (msec).

Exposure	Group A				Group B	p-value Group A			
	Mean	SEM	N	p-value <sup>a</sup> vs. sham	Mean	SEM	N	p-value <sup>a</sup> vs. sham	vs. Group B
Sham	27.8	2.9	36		26.4	2.8	36		0.6456
Sham <sup>a</sup>	26.2	3.6	24		27.2	3.6	24		
900 MHz	25.8	3.6	24	0.9025	23.3	2.6	24	0.0612	
Sham <sup>a</sup>	26.1	3.1	24		24.4	2.6	24		
1800 MHz	29.4	4.6	24	0.5218	20.2	4.2	24	0.2607	
Sham <sup>a</sup>	31.5	3.5	24		27.5	3.9	24		
2100 MHz	32.6	4.2	24	0.7915	20.7	3.8	24	0.0034	

<sup>&</sup>lt;sup>a</sup> Sham only for those subjects exposed to the frequency concerned.

*Table C-5* Visual selective attention test (m).

Exposure	Group A				Group B	p-value Group A			
	Mean	SEM	N	p-value <sup>a</sup> vs. sham	Mean	SEM	N	p-value <sup>a</sup> vs. sham	vs. Group B
Sham	10.57	0.91	36		7.19	0.26	36	J. J	< 0.007
Sham <sup>a</sup>	10.80	1.24	24		7.11	0.35	24		
900MHz	11.25	1.55	24	0.5456	7.01	0.35	24	0.0810	
Sham <sup>a</sup>	10.71	1.04	24		7.26	0.33	24		
1800MHz	11.08	1.13	24	0.6873	7.29	0.34	24	0.8368	
Sham <sup>a</sup>	10.20	1.07	24		7.21	0.26	24		
2100MHz	9.15	0.77	24	0.0461	6.79	0.26	24	0.0498	

<sup>&</sup>lt;sup>a</sup> Sham only for those subjects exposed to the frequency concerned.

*Table C-6* Response parameter test (msec).

Exposure	Group A				Group B				p-value Group A
	Mean	Mean SEM		N p-value <sup>a</sup> vs. sham		SEM	N	p-value <sup>a</sup> vs. sham	vs. Group B
Sham	1304	37	36		1261	35	36		0.2822
Sham <sup>a</sup>	1300	48	24		1682	46	24		
900MHz	1317	43	24	0.6033	1273	46	24	0.7982	
Sham <sup>a</sup>	1317	49	24		1251	32	24		
1800MHz	1324	42	24	0.8200	1202	28	24	0.0408	
Sham <sup>a</sup>	1321	39	24		1250	47	24		
2100MHz	1336	41	24	0.5568	1247	35	24	0.2666	

<sup>&</sup>lt;sup>a</sup> Sham only for those subjects exposed to the frequency concerned.

Table C-7 Indicator for filtering of irrelevant information (msec).

Exposure	Group A				Group B		p-value Group A		
	Mean	SEM	N	p-value <sup>a</sup> vs. sham	Mean	SEM	N	p-value <sup>a</sup> vs. sham	vs. Group B
Sham	192.0	37.5	36		124.7	30.5	36		0.0934
Sham <sup>a</sup>	206.4	42.7	24		146.7	35.9	24		
900MHz	150.5	31.6	24	0.0368	128.5	22.4	24	0.5269	
Sham <sup>a</sup>	195.4	43.7	24		100.8	14.6	24		
1800MHz	220.5	37.6	24	0.4619	94.9	13.7	24	0.7453	
Sham <sup>a</sup>	173.6	30.0	24		126.5	35.9	24		
2100MHz	168.9	20.9	24	0.6813	104.0	15.7	24	0.4356	

<sup>&</sup>lt;sup>a</sup> Sham only for those subjects exposed to the frequency concerned.

Tables C-8 and C-9 contain the results of the analyses of the data on well-being. Again, the data presented in these tables differs from the data in the TNO report in that the present analyses are based on individual comparison of actual and sham exposure. Hence, the exposure group and the sham exposed group each contain twenty-four subjects. For comparison, the means of all the sham values (N=36) stated in the TNO report are also given.

Table C-8 Well-being: outcome of various statistical tests for Group A (individuals with reported symptoms).

Session	Parameters	5				p-value exposure vs sham				
	Mean	Median	Std	N	SEM	Anova, all co-variables	Anova, subject as covariable	Rank-sign test	Median test	
Training	5.722	4.0	7.53	36	1.25					
Sham	7.472	5.5	8.21	36	1.37					
Difference <sup>a</sup>	+1.750	+1.0	4.87	36	0.81					
Sham	7.833	5.0	9.85	24	2.01					
900MHz	8.708	4.5	10.84	24	2.21					
Difference	+0.875	-0.5	9.51	24	1.94	0.6581	0.6563	0.9249	0.8318	
Sham	7.208	6.0	5.52	24	1.13					
1800MHz	7.333	6.0	5.82	24	1.19					
Difference	+0.125	+0.5	6.22	24	1.27	0.9651	0.9224	0.8664	0.6636	
Sham	7.375	6.0	8.80	24	1.80					
2100MHz	10.750	8.0	10.07	24	2.06					
Difference	+3.375	+2.0	4.87	24	0.99	0.0032	0.0025	0.0019	0.0414	

<sup>&</sup>lt;sup>a</sup> Comparison between training and sham not meaningful because of differences in conditions.

Table C-9 We	ll-being: outco	me of various	statistical	tests for G	roup B (indiv	viduals without sy	iduals without symptoms).						
Session	Parameters	3			p-value expo	p-value exposure vs sham							
	Mean	Median	Std	N	SEM	Anova, all co-variables	Anova, subject as covariable	Rank-sign test	Median test				
Training	1.833	4.0	2.55	36	0.42								
Sham	2.444	2.0	2.26	36	0.38								
Difference <sup>a</sup>	+0.611	0.0	2.30	36	0.38								
Sham	2.625	2.0	2.20	24	0.45								
900MHz	2.250	2.0	2.19	24	0.45								
Difference	-0.375	0.0	2.30	24	0.47	0.4323	0.4325	0.2146	0.4807				
Sham	2.500	2.0	2.36	24	0.48								
1800MHz	1.958	1.5	2.51	24	0.51								
Difference	-0.542	0.0	2.02	24	0.41	0.2220	0.2022	0.1993	0.3323				
Sham	2.208	1.5	2.25	24	0.45								
2100MHz	3.083	2.0	3.43	24	0.70								
Difference	+0.875	+1.0	1.60	24	0.33	0.0088	0.0132	0.0096	0.0213				

<sup>&</sup>lt;sup>a</sup> Comparison between training and sham not meaningful because of differences in conditions.

Annex

D

# Questions regarding the study and TNO's responses

Set out in this annex are what the Committee regards as the most important questions regarding the analysis of the TNO study. The answers were provided by Professor APM Zwamborn, who led the TNO study team.

Question: Each of the two groups contained thirty-six subjects. However, the design of the study was such that only twenty-four subjects per exposure modality were actually exposed to an EM field. Yet, in the analysis, the scores for all thirty-six sham exposed subjects were compared with the scores for each group of twenty-four actually exposed subjects. Would it not have been better to perform the analysis on the basis of the sham exposures of each individual subject, so that the number of shams involved in each case was also twenty-four?

*TNO's response*: This suggestion is correct. The statistical analyses were indeed performed by comparing each subject's score for the sham exposure with their scores for the actual exposure sessions. The outcome of these analyses differs from the originally reported outcome in that there is one fewer statistically significant result for the cognitive tests. The differences between the well-being scores remain significant.

All the additional analyses referred to below are based on subject-specific comparison, i.e. twenty-four sham sessions per group.

*Question*: The standard deviations (calculated from the stated standard errors of the mean, SEM, in tables 11.5-11.10 in the TNO report) are equal to or in some cases greater than the corresponding means: a clear

indication that the distributions were skewed. An Anova\* is ordinarily based on a normal distribution of values. Was anything done to take account of the serious skewness in the score distributions? Before performing the Anova, was anything done to check whether the data was normally distributed and whether the differences between the variances were non-significant?

TNO's response: In essence, what we have here is two questions. First: are the values normally distributed? Second: is data on well-being subject to 'floor and ceiling' effects – these data cannot be normally distributed because the well-being score can never be less than 0 or more than 69. To get around these problems, the data on well-being was not only subjected to an Anova, but was also analysed using the non-parametric (distribution-free) rank-sign test and the median test. Application of these analysis techniques did not influence the number of significant results, although it did produce different absolute p-values (see tables C-8 and C-9 in annex C). It should be noted that the p-values for well-being were calculated for the differences per subject between actual and sham exposure, which are not subject to floor and ceiling effects. The p-values for the cognitive functions were calculated using the means for each category, which were tested for normality and were not found to deviate. The variances did not differ significantly.

*Question*: The TNO report does not indicate that the statistical analysis involved any correction for the influence of multiple comparisons (Bonferroni correction)\*\*. Hence, several of the significant differences observed may have been the result of making multiple comparisons and may therefore be chance occurrences.

*TNO's response*: It is indeed the case that the statistical analysis of the data did not involve a Bonferroni correction for the influence of multiple comparisons. Given the design of the study, such a correction should have been made. The hypothesis tested by the study was: exposure to GSM or UMTS fields does not influence well-being or cog-

\* Analysis of variance, one of the statistical analyses presented in the TNO study report.

It is common for a study to look at the effect of exposure in terms of a number of possible outcomes. When this is done, there is always the possibility that pure chance will produce statistically significant results. The more possible outcomes are investigated, the greater the likelihood of such false positive findings. It is consequently necessary to correct for the influence of multiple comparisons, by application of the Bonferroni correction, for example. The correction is made to the  $\alpha$ , the figure that represents the acceptable risk of a false positive result. Ordinarily,  $\alpha$  is 0.05, corresponding to a one-intwenty chance of a false positive result. As the number of comparisons made increases, a smaller  $\alpha$  value has to be used, so that the risk of an false positive result is reduced for any one outcome, but remains the same (0.05) for all outcomes together. However, it is sometimes the case that the parameters under study are not entirely independent of one another, due to the existence of certain correlations. Under such circumstances, the correlations need to be identified and allowance made in the multiple comparisons correction factor. This is then reduced, resulting in a smaller reduction in the  $\alpha$  value than where no allowance has been made for correlations.

nitive functions. It follows that separate corrections should be made for well-being and for cognitive functions. Where well-being is concerned, the correction should allow for three comparisons (three frequencies). The  $\alpha$  upon which testing should be based therefore works out at 0.017. When the appropriate correction is made to the well-being data on the two groups for exposure to the UMTS signal, the results of the Anova and the rank-sign test remain significant (see table C-8). The median test, which is the least sensitive, does not produce significant results. The conclusion that exposure to a UMTS signal results in diminished well-being therefore remains valid.

The analysis of the data on cognitive functions should also involve a correction for the influence of multiple comparisons. Since it is likely that there is some degree of correlation between the various cognitive parameters referred to in the TNO report, the size of the correction factor depends on the degree of correlation. For example, a correlation of 0.88 has been calculated between the results of the response parameter test and the indicator for the filtering of irrelevant information. The Bonferroni correction needs to be made for three frequencies times five cognitive functions, i.e. a total of fifteen comparisons. Without correlation, this would have resulted in  $\alpha$ =0.0034. If correlation is conservatively put at 0.4, then  $\alpha$ =0.01. When this figure is applied, only the results of the memory comparison test performed by group B at 2100 MHz remain significant.

*Question*: Neither the tests used to assess cognitive functions nor the questionnaire used to assess well-being have been validated. This raises doubts regarding the validity of the results.

*TNO's response*: It is indeed the case that the Taskomat test battery used to measure certain cognitive functions has not been validated for experiments involving exposure to electromagnetic fields. However, the test battery has been used in various pharmacological studies and is regarded as a good tool for measuring changes in cognition <sup>(8,9,11)</sup>. There is no reason to assume that the tests are unable to measure any changes in cognition that might be brought about by exposure to electromagnetic fields. Furthermore, if no changes in cognition are induced, validation is impossible.

The subset of questions taken from the questionnaire developed by Bulpitt has not been validated in its own right. Furthermore, the Bulpitt questionnaire as a whole has been validated only in the context of certain cardiovascular studies <sup>(3)</sup>. The reason that the TNO study used only a subset of questions, is that the full questionnaire contains various non-relevant questions, whose inclusion was felt by the ethical review committee to represent an unnecessary potential burden for the subjects. The fact that the subset has not been validated is in any case not consequential, since only internal comparisons of well-being are made (sham exposure versus actual exposure for each individual subject).

*Question*: How was it determined that a two-point overall movement on the scale used to measure well-being represented a clinically relevant change in well-being?

*TNO's response*: The two-point criterion is based on a cardiovascular study <sup>(23)</sup>. The primary investigator of that study, a clinical pharmacologist and recognised expert in the assessment of quality of life within cardiology, came to the conclusion that a movement of two points was clinically relevant in consultation with the questionnaire's developer, Bulpitt. The cardiovascular study in question made use of the full questionnaire.

However, a change that is clinically relevant in cardiology is not necessarily also clinically relevant in the context of a study such as that conducted by TNO. The number of questions in the TNO study was twenty-three, compared with thirty-seven in the cardiovascular study referred to, which means that the maximum overall score attainable was lower than Bulpitt envisaged. Hence, a movement of two points in the TNO study represents a greater shift in relative terms. It is therefore reasonable to assume that a two-point change is definitely clinically relevant in the TNO context.

Question: Which co-variables\* were considered relevant, and what was done to take account of them?

TNO's response: The analysis took account of the following co-variables:

- Session (2, 3 or 4; training session 1 was not considered see table C-2) the sequential position of a session within the study may be relevant, because learning effects may occur
- Sequence of exposure (eighteen different possibilities ('blocks') see table C-2) it is possible that a given exposure modality could affect the results of the following session ('carry-over' effect)
- Subject naturally a particular session sequence was assigned to each subject, so
  when testing 'sequence' as a co-variable, 'subject' should be regarded as a subordination of sequence, since some of the differences between subjects could in fact be
  attributable to the effects of the sequence.

The primary variable is exposure modality (GSM 900 MHz, GSM 1800 MHz or UMTS 2100 MHz).

A co-variable is a parameter that may induce a difference in an effect, either in addition to or instead of the parameter in which the researcher is primarily interested. In the TNO study, exposure is the primary parameter being studied, i.e. the primary variable. The hypothesis under investigation may be summed up as 'exposure has no effect'. If an effect is nevertheless observed, it is always possible that this effect is not caused – or not caused solely – by the primary parameter (in this case, exposure), but at least partly by one or more other, possibly unrelated, parameters. Any relationships between the primary variable and the co-variables or between different co-variables can also be investigated.

The effects of the co-variable 'session' were not statistically significant in the analysis of the data on well-being. For a number of cognitive tests, 'session' did prove significant, suggesting that in the relevant cases there was very probably a learning effect. It is not practical to discuss the results for each test and group in the context of this response, however.

As one would expect, testing of 'sequence' against 'subject' did not reveal any statistical significance, since each subject underwent the sessions in a particular order, so that the sequences and the subjects are linked. The co-variable 'sequence' was accordingly regarded as less relevant and the analysis was repeated using only the co-variables 'exposure' and 'subject'. The linkage between 'sequence' and 'subject' means that any variance in the former is included in the variance in the latter.

*Question*: When the co-variables are taken into account, is the residual variance\* different from what it would otherwise have been?

*TNO's response*: When the only significant co-variable (subject) is taken into account, naturally the residual variance is smaller and the discriminative power is greater. The role of the other (non-significant) co-variables (session, sequence) is marginal.

*Question*: There appears to be a systematic difference between the female subjects' scores and those of the male subjects. Unfortunately, this was not directly tested, but merely alluded to indirectly in female A-B and male A-B comparisons. Could the effect observed in group A have been influenced by the overrepresentation of women?

TNO's response: Without further research, it is not possible to answer this question.

The Hague, April 2004, Professor APM Zwamborn, COFAM Project Leader

<sup>\*</sup> The residual variance is the distribution in the study results remaining after one has corrected for the distribution of all known co-factors. The residual variance may be attributable to unidentified co-factors, or to chance.

Annex

E

# Observations regarding the method used to measure well-being in the TNO study

Generally speaking, the research was well designed and carefully reported, and produced clear results. Nevertheless, I have criticisms in two areas:

- 1 The design of the study
- 2 The metrological quality of the tests and questionnaires used.

These criticisms are explained below.

#### Design of the study

A feature of the study design is the non-equivalent two-group approach, intended to allow the evaluation of effects both on individuals who had previously reported symptoms that they attributed to exposure to GSM signals (group A) and volunteers who had not reported such symptoms (group B). The two groups appear to have exhibited unintended prior differences in terms of gender and extroversion. These variables are interrelated; women tend to be more extrovert than men. These differences make cross-comparison of the results difficult. The extent to which these two variables have been included as covariates in the analyses is not clear to me (see p.47 of the TNO report).

Furthermore, the tables include analyses of the questionnaire data and cognitive test data across conditions and across subject groups (A and B). This creates the impression that personality characteristics and cognitive skills depend on the conditions – probably a difficult contention to defend (except where quality of life is concerned). It would

seem more appropriate to make a correlation analysis or a variance analysis using personality characteristics, with cognitive skills as a covariate.

The conclusion drawn by the TNO team – that it is not possible to make meaningful comparisons between the two groups because of compositional differences – is supported by the considerations outlined above. However, it would therefore have been better if no comparisons had been made in the tables.

#### Metrological quality of the tests and questionnaires used

I came across three (or perhaps four) questionnaires in the description of the study.

- Questionnaire A: Symptomatic Enquiry (Bulpitt QOL questionnaire.pdf and Artikel Bulpitt.pdf; Appendix A, B; respectively 35 and 11 items; Appendix C is not used in the TNO study).
- Questionnaire B: 'Big Five' personality test (Protocol, pp. 36-40, 41-44; 60 items).
- Questionnaire C: 'Quality Of Life' (Protocol, pp. 45-47; 23 items).

In addition, five cognitive tests were used (pp. 35-36 and pp. 53-58 of TNO study report).

In the following paragraphs, I present a number of critical comments concerning the use of the tests and questionnaires. Since certain psychometric observations apply equally to the cognitive tests, these are put forward where appropriate (even if not directly requested).

#### E.2 Introduction

In psychometrics (the measurement of psychological characteristics), it is normal to establish whether an instrument is a reliable means of measuring a characteristic under examination, preferably (1) under the study conditions and (2) for the study population. An instrument is not automatically invariant. In other words, it will not necessarily give comparable results when used under different conditions or for different individuals. The requirement stipulated above applies even if an instrument is known to have good metrological qualities (as with questionnaire B). However, it is particularly important that the requirement is met if one is planning to use a questionnaire whose metrological qualities are dubious or uncertain, as is the case with questionnaire C. The conditions in the laboratory used may differ from the conditions under which the quality checks were performed on the questionnaire (as described in a paper or guidelines). Furthermore, the composition of the test population may differ from that of the groups involved in assessing the metrological quality of the questionnaire (frequently students in lecture rooms).

Invariance has regularly been refuted in published literature, particularly where instruments are translated into other languages. It often proves that differences between the conditions, subjects and languages impact upon the quality of the instrument.

The strategies adopted in relation to this metrological invariance problem come under three headings:

- Thorough testing of the instrument's invariance, requiring a large number of subjects.
- Comparative assessment of the instrument's invariance where possible (not involving thorough testing).
- Assumption of the instrument's invariance (usually where insight into the invariance problem is lacking or where the researchers are not as thorough as they might be).

Some of the criticisms that may be levelled at the psychometric aspects of the TNO study will already be apparent from the foregoing. In particular, there is no empirical evidence to indicate the metrological qualities of the subscales and tests when used with the particular subject groups and under the conditions that prevailed for the study. The number of subjects was sufficient to enable the reporting of such indices. Broadly speaking, the relevant issues were as follows (see E.3):

- The consistency reliability of the scales (and subscales) of the questionnaires and the cognitive tests (and subtests).
- The repeatability of scales (and subscales) and tests (and subtests).
- The indications of the validity of the instruments (do they actually measure the characteristics under study; are they mutually independent, and are they related to the induced effects?).

#### E.2 General remarks regarding the questionnaires and cognitive tests

The argumentation for the choice of the three questionnaires used is weak. The validity of the first questionnaire appears incontrovertible. Biographical data is required. The reasons for using a questionnaire to measure personality characteristics are not explained. It remains unclear why personality is relevant in this context; furthermore, the reasons for selecting the Big Five are not given in the protocol or in the results. Inclusion of the psychological Quality Of Life test (Symptom Rating Scale by Kellner & Sheffield <sup>(17)</sup>) is justifiable, but there are other and better alternatives (e.g. Profile Of Mood States <sup>(20)</sup>). It should also have been possible to develop a customised questionnaire for the study on the basis of the symptoms reported to the Monitoring Network Health and Environment by individuals in subject group A.

#### Questionnaire A:

This questionnaire is discussed in the paper by Bulpitt & Fletcher <sup>(3)</sup> under 'symptomatic enquiry' and appended to that paper in Appendices A and B. The questionnaire has been used to screen subjects and facilitate the application of inclusion and exclusion criteria.

I can say little about this questionnaire, other than it has been used in several studies and appears to work well. It is not based upon any particular psychometric model, so it can be assessed only by looking at the way the questions and possible answers are formulated. Since I do not have access to a Dutch translation of the questionnaire, I am not able to make a proper assessment in this way.

No comparison is made between the data obtained using the questionnaire from the seventy-two subjects involved in the TNO study and the data given by Bulpitt & Fletcher <sup>(3)</sup> in Table 1 (section B) and Table 3 (section A). This rules out another possible assessment approach. Hence, the quality of the questionnaire cannot be assessed. However, since the questionnaire does not form part of the results section, that is not a serious drawback.

#### Questionnaire B: Big Five personality test

The Neo-PI-R/Neo-FFI <sup>(15)</sup> is a standard questionnaire published by Harcourt (previously Swets); it is an authorised translation of the original questionnaire developed by Costa & McCrae <sup>(4,5)</sup>. The questionnaire is generally regarded as good (see Evers, van Vliet and Groot <sup>(10)</sup>, p.43, par. 24-28, p.444-445). In the TNO study, this questionnaire was used to investigate the differences between group A (individuals with previously reported symptoms) and group B (reference group of volunteers). Group A subjects proved to be more extrovert.

Notably, the reliability of the personality test has not been established. The reliability (including Cronbach's Alpha) depends on the random sample studied and cannot be deduced from the data in the manual. It is not currently possible to assess the usefulness of the questionnaire under the conditions that pertained during the TNO study. In addition, it seems likely that checks should have been carried out to establish whether differences in personality are related to sensitivity to the experimental variables (radiofrequencies). No such checks were made, however.

#### Questionnaire C: Quality Of Life

The Quality Of Life questionnaire is discussed in the Bulpitt & Fletcher <sup>(3)</sup> paper under psychological well-being (p.354). The Symptom Rating Test (SRT) produced by Kellner & Sheffield <sup>(17)</sup> involves thirty-seven items on four subscales: depression, anxiety, somatic problems and inadequacy. The subscales are discussed in the TNO report on pp. 35-36, p.45 and the results on pp. 49-53. In the TNO study, five subscales are

defined, covering twenty-three items: anxiety symptoms (4 items), somatic symptoms (8), inadequacy symptoms (5), depression symptoms (2) and hostility symptoms (4).

No reasons are given for organising the items on five subscales instead of four. No data is made available concerning the quality of the metrological model with its five subscales, or therefore concerning the reliability of the subscales. The most serious concerns relate to the limited number of items on the subscales. The four subscales of the original SRT do appear to possess criterion validity (see Bulpitt & Fletcher <sup>(3)</sup> and Kellner & Sheffield <sup>(17)</sup>).

The formulation of items on the Dutch SRT is generally in order. However, the following items contain double expressions (i.e. make use of 'or' or 'and'): 2, 4, 5, 7, 8, 14 and 16. This practice is generally discouraged by authoritative sources. This criticism could have been countered in the study if there had been indications for an adequate metrological quality.

#### Five cognitive tests

These tests were used in previous TNO studies. However, there is no information about the metrological quality of the tests (consistency reliability, inter-correlations between the five tests). The extent to which the measurements involve independent cognitive aspects is therefore unclear to the reader.

### E.3 Analyses of questionnaire scores and cognitive test scores absent from the TNO study

So what is the situation with the TNO study under consideration? I feel that the technical elements of the study are of very high quality (particularly the design of the study and the SAR measurements, except the non-equivalent two-group approach). As a result, one expects the psychometric quality of the research to be of a similar standard, but unfortunately this is not the case.

In my opinion, the test conditions used for the TNO study may differ considerably from the quality control conditions used for the cited questionnaires and tests. In addition, it seems likely that the subjects are quite unlike those who took part in the quality research (as described in papers and guidelines). In view of these observations and the high quality of the technical research, it might have been expected that the metrological quality of the TNO study would be subject to certain checks. The size of the subject groups and the number of variables involved in the research do provide some scope for metrological quality checks of the questionnaires and tests, but unfortunately no such checks were performed.

With 72 observations, it would have been easy to determine a number of the metro-logical qualities of the subscales/subtests:

- a The internal consistency of the (sub)scales/subtests.
- b The repeat reliability of the subscales/subtests (five/four repeated SRT measurements and cognitive tests under various conditions and with intervals).
- c The one-dimensionality of the subscales/subtests (for determination of this quality, more subjects are really required, but a provisional test could have been performed).
- d The inter-correlations of the subscales (five personality characteristics/five aspects of psychological quality of life/five cognitive skills).
- e The correlations between various measurements (personality and psychological quality of life, personality and cognitive skills, personality and SAR measurements, psychological quality of life and cognitive skills, psychological quality of life and SAR measurements, cognitive skills and SAR measurements).
- f Regression analysis of the qualities of the tests and questionnaires on the basis of the effects/conditions.

Points a and b would have provided some reassuring feedback concerning the reliability of the tests, particularly if the findings had been broadly in line with the findings of earlier research (papers and guidelines).

Point c would have provided pointers as to whether and to what extent clearly defined aspects were being measured; in particular the overall score for questionnaire C could by definition measure only a combination of characteristics (twenty-three items and five characteristics cannot measure a single dimension). This is apparent from the findings: none of the five are equally sensitive to the conditions (tables 11.6 - 11.10 in the TNO report).

Points d and e would have provided information about the independence of (certain aspects of) the measurements. Very strong correlations would have indicated that the measured characteristics were not independent and that one or more should have been eliminated from the research.

Point f would have provided information about which questionnaire characteristics made an independent contribution to the conditions. It would also have served to support economy in the design of the follow-up research.

#### E.4 Summary

I acknowledge that the performance of all these analyses would have led to the results being open to the influence of chance. Hence, chance would have a major influence on the correlation analysis results because of the unfavourable ratio between the number of variables (fifteen to twenty) and the number of observations (seventy-two). But the TNO study did not involve the performance or reporting of any of these analyses. The consequence is uncertainty for the reader. To reiterate: the metrological quality of the sub-

scales of questionnaire C and the five cognitive subtests is open to question, pending the availability of further information. Being so systematic, the observed effects appear highly credible. The same cannot be said for the 'no effect' findings. These could be attributable to noise, or to unreliable and/or less than entirely valid measurements. The significant differences found between groups A and B (in four of the five tests) and the experimental conditions on the one hand and the sham condition on the other (six of the thirty tests) nevertheless give the impression that the subscales performed well. The absence of significant differences within the depression subscale (a stable trait) also tends to suggest that the subscales worked well. Nevertheless, the possibility remains that further differences might have been revealed if the subscales had been more reliable and of a higher metrological quality.

The reporting of effects in terms of overall SRT scores entails a degree of risk. The reason being that one is dealing with a composite instrument based on four characteristics that do not appear to have entirely consistent effects under the various conditions, and one characteristic that shows no variation across the conditions. The overall score is not a measure of a single characteristic, but of several characteristics that are not homogeneously dependent on the conditions. The overall score also displays different effect patterns in association with different conditions than separate scores would have done (comparable only with 'inadequacy symptoms'). It is therefore highly desirable that the individual characteristics should be reported separately. Nevertheless, reporting of the overall score may be defended as an omnibus test. Such a defence is not particularly persuasive, however, since no allowance is made for reporting of the specific aspects of the SRT.

In preparation for a follow-up study, the modified SRT should first be thoroughly assessed to determine its metrological quality. Alternatively, use might be made of a different tool, whose metrological qualities are better known.

Amsterdam, April 2004 HCM Vorst