# D4.3: Satiety Methodology

*Work Package 4*

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[www.satin-satiety.eu](http://www.satin-satiety.eu)

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FP7 – Knowledge based Bio-Economy (KBBE)
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SATIN – SATiety INnovation is a five year (2012 – 2016), €6 Mill. EU funded project which aims to develop new food products using the latest processing innovation techniques. Exploiting better understanding of the biological processes in the stomach and the brain that underpin what makes us feel “full”, the project will evaluate whether this approach is a viable weight management tool.

Work Package 4 (WP4) assesses the effects of food and beverage products on the control of appetite. This involves the identification of key processes controlling food consumption.

Deliverable 4.3 for WP4 is the Satiety Methodology.

The DOW (description of work) states:

**Task 4.2: Development of methodological platform for human dietary trials** *(short term probe days)*

**Task 4.2.1 Satiation/Satiety and food intake** *(UNILDS, UNILIV)* We will identify the changes in satiation, satiety and homeostatic appetite markers (hunger, fullness, desire to eat, prospective consumption) in response to novel dietary components developed and tested in WP 2 and 3. Fixed test meals (proportional to the participants’ RMR) will be piloted to allow the measurement of satiety (reduction of appetite) indicating the strength of the satiety signals generated by food. Ad-libitum test meals will demonstrate an effect on satiation (meal termination signals). Food selection will be assessed by ad-libitum multi-item test meal and snack box consumed under laboratory and free-living conditions. Perceptions of hunger, fullness, desire to eat; prospective consumption and mood will be measured using an electronic data capture device (modified PDA). The instrument (EARS II) is portable, has flexible functionality and will be expanded to collect and store questionnaire and physiological data. Total daily energy intake (under two or more experimental conditions) will be measured and manipulated to assess the within-day effects on satiation and satiety. The nutritional challenges will provide sensitive measures of satiation, satiety, and food selection. In combination with task 4.2.2 (see below) we will evaluate novel food products against objective and highly sensitive behavioural markers of satiation and satiety.
1. Basic principles for conducting high quality research in a food intake laboratory

Conducting valid research in a laboratory environment requires an appropriate experimental design incorporating the control and isolation of variables, together with sufficient power to test the hypotheses under scrutiny. However the outcome of a study can only be as good as the quality of the data collected. It is therefore essential that procedures are put in place to govern the conduct of the experimenters at every stage of the data collection process. This is known as Good Laboratory Practice (GLP). Strictly speaking there is no official code of practice for behavioural studies in contrast to those for pharmaceutical research, for example. However, there are standards which should be met in order to ensure that experimental procedures are enacted in a uniform and consistent manner on every occasion and with every subject. The maintenance of a consistent experimental procedure is best ensured through the use of Standard Operating Procedures (SOPs). These are clearly written statements that carry instructions for every task that an experimenter will undertake during the course of a study. There should be, for example, a SOP for the interaction between an experimenter and the participant that dictates the information and contact that will be delivered. Similar rules apply for the preparation of all test foods, including the accurate weighing of food – to the nearest 0.1g – before and after consumption. Since food intake is often the major parameter of interest – either as a dependent or independent variable – SOPs are essential to control these procedures in the laboratory kitchen. SOPs should also be in place for recording data (adding or subtracting weights of food for example) and for transferring written data to electronic files. Since errors in computation and transcription are a fundamental feature of data collection (i.e. human error), it is essential that every item of data collected and written down (or typed in) should be checked independently by a co-experimenter. It can be assumed, with high certainty, that experimenters make errors in the recording of data, so every effort should be made to minimize these effects. Again this can best be achieved through the use of clearly stated SOPs that incorporate data checking. This can be particularly important, for example, if paper and pencil type scales are used which require the manual measurement of hundreds of responses.

It is the precision and accuracy of every item of data collection (including every item of food) that forms the basis of GLP and which can safeguard the validity of laboratory investigations of food intake. Conversely it is extremely easy to undermine the value of experimental control by a casual and informal approach to the basics of food intake measurement.
A final aspect of GLP for laboratory feeding studies is the security of the data collected. This is paramount in some industry sponsored studies in which the data could subsequently be used in judicial proceedings. Although most of the time researchers will be concerned with their data as evidence in arguments in scientific journals, the same principles of security should apply. Once data have been collected, checked, and entered into files they should be protected from subsequent amendment, except under special cases described in the protocol. The fundamental data comprising the data output of an investigation should be preserved for a minimum number of years (usually 5 to 10). Sometimes the stage of formally securing the data is called the ‘data base lock’. This is a good practice for researchers to adopt.

2. Satiety Methodology

2.1. Preload-Test Meal paradigm

With the exception of observational approaches the most basic form of experimental design used to measure food and energy intake (EI) in the laboratory is the “preload-test meal” paradigm, which has been used to assess the short-term effect of a wide range of manipulations on subjective motivation to eat and often intake at a subsequent test. These experiments are most profitably conducted using a within-subject repeated measures design, in which subjects serve as their own controls. This is important since there is considerable inter-individual variability in food intake behaviour which can reduce the power of between-subjects designs.

A preload is defined as an eating episode that is given at a particular interval before the presentation of a test meal (usually at a usual meal time). The outcome of a preload – test meal design will therefore depend critically on the parameters of the preload, the duration of the preload test meal interval and the nature of the test meal. The key to using this design appropriately is plausibility. The design should provide a fair test of the hypothesis. This means that the manipulated variable should be sufficiently large to be detectable. Second the interval between the preload and the test meal should be realistic and appropriate to the anticipated action of the active variable in the preload. Clearly, if the preload – test meal interval is too small then the effect will not be detected. It follows that a preload test meal interval can be too long (action of the preload has decayed before the test meal is presented) or too short (action of the preload occurs after the test meal is finished). Two common causes of a failure to
detect an effect in this type of design are the minimal size of the preload manipulation (or the active variable) and a test meal presented at an inappropriate time.

Because of the arbitrary nature of the choice of parameters in the preload test meal design, many experimenters have opted for a meal to meal strategy in which meal 1 is fixed and incorporates the independent variable, and meal 2 is *ad libitum* and is the dependent variable. Of course, some of the same considerations apply about the size and detectability of the independent variable, but the interval is normally based on realistic eating habits and is therefore plausible. Because of the interest attached to snacking, a variation of the preload and meal to meal approach is the manipulated snack. It is important to note that the participant’s eating and drinking behaviour should be controlled and monitored between preload (or snack) and test meal. This is easy if the interval is short but can become more difficult for longer intervals.

It follows that the influence of post-ingestive events will be reflected in the ‘time’ elapsed until the return of the desire to eat (next request for food), or in the amount eaten in a meal presented at a predetermined time. Theoretically the duration of the post-meal interval could be used as a measure of satiety. However it should be borne in mind that the timing of meals is highly conditioned in most humans. The preload-test meal or meal-to-meal strategy is the most commonly used – mainly because of the convenience for the experimenter – but it should not be overlooked that the strength of satiety can be measured along a temporal dimension. Satiety can therefore be quantified by time (till next eating episode) or amount (of food consumed). See figure 4.3.1
Figure 4.3.1 Schematic diagram of the events in a typical preload-test meal design.

In this example, the preload is presented in the form of a breakfast adjusted for the participants energy requirements estimated from equations for resting metabolic rate. The test meal is presented exactly 4 hours after the preload and served in ad libitum quantities. Food intake for the remainder of the day is captured retrospectively using dietary recall. The blue arrows indicate where subjective appetite ratings might be taken.

2.2. Appropriate use of foods (in different EU countries)

In addition to the importance of the preload and the interval till measurement, the nature of the test meal itself can also affect the outcome and the choice of the structure of the meal can be critical. Given that a number of dietary factors can influence food, energy and nutrient intakes in laboratory studies considerable attention should be paid to this aspect of dietary design. The use of familiar, culturally and socially appropriate foods in the laboratory is therefore important. Additionally, a large homogeneous meal in contrast to a buffet meal containing a variety of foods; or use of a high versus a low palatability meal can also affect the measured outcome. Ostensibly it might appear that the use of familiar foods creates a microcosm of the real life feeding situation and overcomes the constraints of using manipulated diets. However, the choice of foods provided in the laboratory is inevitably limited and few reports give scientific explanations of why a certain range or selection of foods was made available to a group of subjects.
2.3. Subjective Appetite Ratings (pen and paper methods)

The visual analogue scale (VAS) technique for measuring subjective appetite sensations is an important and useful contribution to appetite research by providing greater insights into eating than can be ascertained from voluntary food intake data alone. These additional features include revealing information which may not be readily inferred from food intake, improve the interpretation of behaviour, and allow measurement of the motivation to eat without contaminating the main behavioural outcome. VAS is a technique which provides a quantifiable objective measure translated from subjective sensations. As with other areas of psychology (e.g. pain research), VAS has now been accepted as the standard tool for assessing subjective appetite sensations.

VAS use self-report methodology to assess the intensity of a variety of subjective states. The origin of VAS in appetite research dates back to Silverstone and Stunkard (1968). Since then, VAS has been employed as the standard methodology to measure the motivation to eat. Rogers and Blundell (1979) developed the original version of a portfolio of VAS questions which have since been adopted by many researchers. Traditionally, VAS have been administered using the 'paper and pen' (P&P) method. VAS typically take the form of a 100mm horizontal straight line which are unbroken and unmarked, with the two extreme states (minimum and maximum) anchored at either end by a question associated with a particular state (e.g. hunger). Variations in VAS do exist in the form of a 10 point Likert scale, bi-polar and uni-polar scales, a 150mm horizontal line, and a seven-point scale with equally spaced qualitative labels. However, the 100mm horizontal, unmarked line with anchored labels at the extreme is the widely accepted form of VAS.

The original version of the VAS questionnaire (Rogers and Blundell, 1979) included six questions which relate to states of the motivation to eat. However, more recently questions include: How hungry do you feel now?; How full do you feel now?; How strong is your desire to eat now?; and How much food do you think you could eat now? This last question is also known as prospective consumption. An advantage of the VAS technique is that the states (i.e. questions) and anchored labels can be modified to suit the manipulation and experimental design. VAS are completed by the participant at the required time of assessment. This is typically immediately before and after an eating episode, and periodically at intervals between eating episodes. The traditional P&P version requires the participant to complete the VAS by placing a mark on a horizontal line at the intensity of their perceived feeling of that particular
state. It is important to instruct participants that they should use the full range of the scale (100mm line) and to bear in mind that the anchored labels (minimum and maximum) should be considered as extremes. For example, if the participant places the mark at the maximum end of the scale (i.e., very hungry) – this is the hungriest state they have ever experienced. It is recommended to use a standardized operating procedure (SOP) in these instances, in which standard text is read verbatim to the participant. An SOP text for this is:

“Please place a vertical mark on the horizontal line depending on how you feel now. It is important that you rate how you actually feel now, and not how you might think you should feel, or how someone else might expect you to feel. Please consider the extreme labels – ‘not at all’ and ‘extremely’ – as the least hungry and the most hungry you have ever felt. When you complete the first question please proceed to the next and continue through the questions until you have completed them all”

2.4. Subjective Appetite Ratings (electronic methods)

The traditional paper and pencil VAS technique is still used in appetite studies, however it inherently involves some minor problems concerning validity and convenience. With the P&P method it is possible that participants forget to complete question(s) during the test day. The implications of this are that participants either retrospectively complete the questions at the end of the day, which undermines the measurement of ‘state’ sensations, or it inevitably leads to missing data. Equally important, it is possible that error is introduced into the method during the experimenter’s measurement of the location of the mark on the line and on entering the data from the paper version into a spreadsheet. In addition this method of measuring, entering data and quality control checking can be time consuming and tedious. Sometimes these problems can be overcome by using machine-readable VAS, but even this procedure is not perfect and requires visual checking of the accuracy of the translation.

Recently, electronic versions of VAS known as the Electronic Appetite Rating System (EARS) and EARS II have been developed which circumvent these (figure 4.3.2). The most recent system employs the HP iPAQ Personal Digital Assistant to mimic the traditional P&P method of administering VAS. In essence, EARS is a technologically updated method of the P&P VAS method which facilitates and enhances the quality of time-verified subjective appetite sensation data.
EARS II is easy to use, portable, light-weight and involves a stylus that simulates the use of pen and paper. This system automatically records and time-stamps the participants’ responses and is then downloaded. Like traditional pen and paper VAS, the scale is anchored on both ends with the most negative (e.g. ‘not at all...’) and the most positive (e.g. ‘extremely...’) aspect of a given sensation. The use of this method has been validated (Gibbons et al. 2011).

EARS II can be programmed to alert volunteers as to when to complete the scales allowing collection at precise points throughout the day both within the laboratory setting and in a free-living environment.

**Figure 4.3.2** The electronic appetite ratings system for VAS methodology

The features of EARS II include automatic verification of the date and time of completion of the VAS, identification of incomplete and/or incorrect entries, and preventing participants from retrospectively completing ‘missed’ questions. It also provides an automatic measure of the intensity of the subjective rating. All these data are stored in the device and automatically downloaded to a spreadsheet. The data are downloaded to a desktop or laptop via a cable and are transferred in a few seconds. Once the data are downloaded they can be opened and viewed using Excel. Data are labelled by subject name, condition, date, time, question number (e.g., hunger, desire to eat) and the intensity of the subjective appetite sensation in mm.
2.5. Validity of VAS methodology for subjective appetite ratings

A series of experimental studies have demonstrated that the VAS method of assessing subjective appetite sensations is sensitive to manipulations – for a review see Stubbs et al, (2000). In terms of reproducibility when individuals are fed a diet to maintain energy balance via fixed meal and energy intake patterns, a consistent fluctuation in diurnal profile of appetite sensations occurs. Other studies demonstrate the high reproducibility of VAS (Delargy et al, 1996; Stubbs et al, 1997; Stratton et al, 1998; Whybrow et al, 2006). A series of reviews and discussions have been dedicated to interrogating the validity and reliability of VAS (de Graaf, 1993; Flint et al, 2000; Raben et al, 1995; Reid et al, 1998). In addition, their ability to predict subsequent food intake has also been examined (Doucet et al, 2003; Drapeau et al; 2005; 2007). The findings are mixed; some studies demonstrating that subjective appetite sensations are strong predictors of energy intake, and others not. The reader is referred to the review by Stubbs et al, (2000) for a more detailed discussion of the predictive power of subjective appetite sensations. VAS is a reproducible method of assessing subjective appetite sensations – which is strengthened using within subjects designs.

2.6. Functional quantification of VAS: what can be measured?

2.6.1. Inter-meal changes

By comparing the pattern of VAS scores taken at fixed time points, inter-meal differences in satiety between and within participants can be examined.

2.6.2. Area Under the Curve

The area under the curve (AUC) provides an aggregate for each subjective appetite sensation. In essence, the AUC represents the area bounded by the hunger profile and is computed by the trapezoid measure (Figure 4.3.3) or more readily as the mean of all the data points. The AUC can be calculated for the whole of the measurement period, or parts of the measurement period. It is usual to exclude baseline or fasting values when calculating the AUC. The rationale for doing this is to remove any bias or differences at baseline which might artificially alter the mean AUC, and introduce more random variation into the measured response.
2.6.3. **Recovery (return to baseline)**

The rate of return of hunger is an indication of the power of a food/meal to influence satiety. That is, the slower the return of hunger after a meal, the more powerful effect exerted on satiety. This is typically attained by calculating the difference between the post-meal value and the pre-meal value of the next eating episode. An alternative approach is to calculate the time taken for subjective motivation to eat to return to 50% of its original (fasting or pre-meal) value.

2.6.4. **Satiety Quotient**

One definition of the satiating efficiency of a food is “the effectiveness of a pre-load at suppressing test meal intake per unit of energy delivered”. This concept was modified to include VAS ratings and was termed the Satiety Quotient (SQ - Green et al, 1997) and reflects a change in the rating score (mm) per unit (kcal) of energy consumed. The advantage of the SQ is that it provides a temporal measure of the satiating power of a meal or food. The SQ is an indicator of the power of a food, food component or drug to suppress motivation to eat. The SQ provides an indication of the capacity of an individual’s signalling system, and is an interaction between the individual and the food. The SQ can therefore reveal features of the individual (who has eaten) or the food (that has been eaten). In essence the SQ is an expression of the change in motivation to eat as a function of energy consumed (Figure 4.3.4). The SQ can be analysed across time points in the inter-meal interval or an aggregate variable can be derived from AUC or mean post-meal values. However, it should be noted that because of the non-linear relationship between energy consumed and the consequent suppression of hunger, the SQ works optimally when used with a meal of fixed size.

\[
AUC_{1-n} = \sum \left\{ \frac{Cp_1 + Cp_2}{2} \cdot (t_2 - t_1) \right\} + \left\{ \frac{Cp_2 + Cp_3}{2} \cdot (t_3 - t_2) \right\} + \ldots
\]

**Figure 4.3.3** Formula for calculating Area Under the Curve by Trapezoid method
3. Satiation Methodology

Satiation is the process that brings a meal to an end. Verbal reports on the processes that bring a meal to an end indicate that “fullness” and “boredom with taste” are two major reasons to stop eating (Hetherington, 1995). Satiation is important because it determines meal size. Within the perspective of energy balance and obesity, it is instructive to note that there is no strong relationship between eating frequency and body weight (e.g. Whybrow et al, 2007). Before focusing on the methodology of measuring satiation it should be realized that in real life most meals/snacks/eating occasions are terminated through environmental factors/cues such as portion size. In most cases people consume most (or all) of the food on the plate.

Satiation is measured through the measurement of ad libitum food consumption of particular experimental foods under standardized conditions. The ad libitum consumption of foods varies to a large extent. The proper methodology of the measurement of satiation takes into consideration the properties of food and the environmental/contextual factors that may be involved in meal termination. In view of the processes of the satiety cascade it is clear that sensory factors play a major role in satiation. Many studies showed that palatability has a strong effect on ad libitum food intake, both from controlled experimental studies (e.g. de Graaf et al, 1999) as well as from more real life studies (e.g. de Graaf et al, 2005). So, when studying the effect of particular food properties on satiation, it is important that the experimental foods are similarly liked.

The satiety cascade also shows that cognitive factors may play an important role in meal termination. On the basis of the consumption of thousands and thousands of foods through our lifetime we gradually learn to estimate the satiating effects of many foods. These learning mechanisms determine our expectations about the satiating properties of foods, and probably also determine how much we put on

\[
\text{SQ} = \frac{\Delta \text{pre-meal VAS score}}{\text{Energy Intake (kcal or kJ)}}
\]

Figure 4.3.4 Formula for calculating Satiety Quotient
our plate (e.g. Brunstrom, 2007). This also affects how much we eat ad libitum from particular food in experimental situations.

A crucial role in this learned response (expectations) about satiation is the energy density of the product. At first sight, it seems that regular portion sizes of low energy density foods (e.g. many liquids) are much higher than regular portion size of energy density foods (e.g. chocolate, cheese, peanuts, etc). However, there are no systematic data in scientific papers comparing portions sizes of low energy density foods to portion sizes of high energy density foods. Nevertheless, this observation implies that it is crucial to match foods for energy density, when investigating the effect of food properties on satiation.

The texture of foods is also important in satiation. People consume more ad libitum from more liquid foods than they consume of more solid foods. The higher eating rate may be caused by the bite/swallow size which is probably higher in liquids compared to (semi-)solids. These observations imply that controlling for texture may be an important prerequisite when investigating the effects of food properties on meal termination.

In summary, the amount that we eat from a particular product is influenced by a variety of factors, related to the properties of food and the context in which the food is consumed. In general ad libitum consumption of foods is a learned response based on associations between the sensory properties of foods and its metabolic consequences after ingestion. When studying satiation we need to take into consideration the palatability, energy density, and texture of foods, the motivational state (hungry vs., satiated) of subjects, potential important environmental cues (e.g. visual cues, plate size, effort to eat) and cognitive factors. All of these factors can influence the effects of similar caloric loads on satiation. A further important issue is the inter-individual variation in the rate of satiation for comparable caloric loads.

3.1. Ad libitum food intake

Ad-libitum test meals can be used to demonstrate an effect on satiation (meal termination signals). At an appropriate time-point a multi- or single-food ad libitum meal will be provided in order to measure satiation (i.e. self-determined meal size). All participants should be provided with an excess of each food and allowed to consume until they are comfortably full (figure 4.3.5). Acceptability and pleasantness of
test foods will have already been assessed during screening. Volunteers will not be allowed to consume food or drink (other than water and study food provided) during the test day.

Figure 4.3.5 Typical ad libitum test meal presentation (with EARS II)

3.2. Within Meal Satiation Automated Monitoring (Liverpool only)

Whilst, the macro-structural measures of eating behaviour, such as total intake and intake of individual food items, potentially require little automation to record data, the measuring of minute by minute changes in human feeding behaviour is far more methodologically challenging. It requires the constant monitoring of the research participant through either direct observation, full automation or a combination of both. In the case of micro-structural analysis, eating rate and changes in its trajectory (cumulative intake curves), both directly measured in micro-structural analysis, have been shown to be useful in detecting both the effects of experimental manipulations and individual differences in eating behaviour. These changes in eating rate would be difficult, if not impossible, to identify using the macro-structural approach.

It is important to assess satiation while food is actually consumed and this can be achieved through use of the Universal Eating Monitor (UEM) (figure 4.3.6). The UEM detects moment to moment changes and is extremely sensitive to the sensory/textural and oral processing properties of foods. Within SATIN, to measure the effects of modified foods on the microstructure of eating behaviour, a UEM (The Sussex
Meal Patterning System) is available and may be deemed appropriate depending on the anticipated mechanism of action for the Satin WP4 foods. Test meal intake will be continuously monitored using the UEM equipment, which consists of a digital balance positioned beneath, but protruding above, the table surface. The balance is obscured from participants' view by a plastic place mat and is connected to a PC computer. The UEM software is custom-programmed to interrupt the participant after each 150 g of test meal consumed, to ask the participant to complete on-screen VAS ratings of hunger and fullness, providing a measurement of within-meal satiety processes, and can also measure changes in palatability (Yeomans 1996). The UEM software measures intake every 1 min of the test meal and generates cumulative intake (in grams) curves by treatment group. Eating rate is calculated as total amount eaten (grams) divided by time taken (seconds). Both intake (gram and kilocalorie) and within-meal VAS parameters (hunger and fullness) can be extrapolated to provide data on five incremental stages of the test meal (0%, 25%, 50%, 75% and 100% intake) for all participants using a simple interpolation rule (at 150g intervals). The SQ and the UEM have never been used conjointly but WP4 will provide an opportunity to markedly upgrade the sensitivity of appetite monitoring by joint use of these procedures. Palatability measures will also assess the hedonic components of intake both in relation to satiety (Blundell & Finlayson, 2008) providing a link to liking and wanting procedure conducted at Leeds but also in the wider consumer benefits context.
3.2.1. Validity of automated within-meal satiation measurement

Various datasets show that UEM curves are influenced by gender and food deprivation, as well as by the composition and palatability of test meals, demonstrating that they are valid representations of the changes in appetite that occur within meals. With regard to manipulations in hunger, satiety and palatability, measuring changes in within meal appetite ratings may be particularly useful (Yeomans et al., 2000; Gray et al., 2002; Robinson et al., 2005). UEM measurements such as cumulative intake curves have not always been able to discriminate the effects of administration of endogenous satiety factors such as Glucagon-Like-Peptide (GLP-1) (Naslund et al., 1998; 1999). Similarly, with the ‘satiety’ enhancing drug sibutramine, some researchers have failed to find any effect of drug on parameters of within meal satiation such as eating rate or cumulative intake curves (Barkeling et al., 2003). Others have found significant effects on eating rate, reductions in within meal hunger and increases in within meal fullness, and a trend towards a great frequency of normal decelerating intake curves in the drug condition (Halford et al., 2007) thus indicating within meal satiation is produced by the drug. Therefore, measuring
changes in appetite ratings during the meal may be particularly important in assessing the effects of hormones and drugs. With regard to the reliability of this methodology, modern UEM systems possess good test-retest reliability for within individual UEM curves (Barkeling, 1995; Westerterp, 2000; Hubel et al., 2006).

4. Consumer Benefits Methodology

Many of the potential consumer benefits of satiety enhancing foods result from their long-term effects on appetite and their potential in weight management (key EFSA health claims). However, with so few satiating products on the market it remains largely only an assumption that short-term suppression of appetite can over time produce clinically meaningful health outcomes mediated through tangible benefits to the consumer in terms of their daily experience of appetite and perceived ability to control it.

Phase 2 of SATIN consists of two clinical components, one (WP4) focuses on specific single site studies to substantial health claims for individual products around appetite and weight loss and the second (WP5) to examine the benefits of a satiety based approach to weight management in a large scale multi-centre weight regain prevention study. As laid out in the original proposal, methodologies for testing consumer benefits will be developed and trialled within WP4 (objectives 5 and 6) for use in WP5 (objective 7). Prior to the project and during Phase 1 of SATIN an International Institute for Life Science (ILSI) task force, containing a number of SATIN partners (Coca-Cola, Copenhagen, Leeds and Liverpool) reviewed the literature base to determine the potential benefits of satiety to the consumer (Hetherington et al, 2013). The exercise took three years and the outcomes of this activity were summarised in a published review in 2013. This activity informs our approach to consumer benefits within the SATIN project. Potential consumer benefits identified by Hetherington et al are listed in table 4.3.1.

Evidence on potential consumer benefits of satiety is lacking. Overall, Hetherington et al., (2013) found that while there was convincing evidence for a number of short-term benefits of satiety, there was only probable evidence for longer-term benefits in hunger management. Specifically, it was possible that satiety enhancing foods could produce benefits to mood and cognition but there was inadequate evidence to demonstrate they promoted weight loss (although the pharmacological approaches to
Satiety enhancement clearly suggest potential). Also it was unclear which consumers would benefit most from satiety enhancing products. Nonetheless, Hetherington et al proposed a number of potential benefits of satiety directly relevant to weight control including 1) providing appetite control strategies for consumers generally and for those who are highly responsive to food cues; 2) offering pleasure and satisfaction associated with low-energy/healthier versions of foods without feeling ‘deprived’; 3) reducing dysphoric mood associated with hunger especially during energy restriction; and 4) improved compliance with healthy eating or weight-management efforts.

**Table 4.3.1 - Possible benefits to the consumer of foods that enhance satiety**

<table>
<thead>
<tr>
<th>Possible benefits to the consumer of foods that enhance satiety include:</th>
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<td>(a) Providing appetite control strategies for consumers who are highly responsive to the food environment and eat opportunistically;</td>
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<tr>
<td>(b) Offering pleasure and satisfaction associated with low-energy/healthier versions of food products without feeling ‘deprived’;</td>
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<tr>
<td>(c) Reducing dysphoric mood states associated with feeling hungry especially during periods of energy restriction;</td>
</tr>
<tr>
<td>(d) Increasing feelings of subjective wellbeing, maintaining or preventing a decline in cognitive function associated with skipping meals or lowered energy intakes;</td>
</tr>
<tr>
<td>(e) Improving the ability to cope with fluctuations in hunger over the day;</td>
</tr>
<tr>
<td>(f) Improving compliance with healthy eating targets and weight-management efforts;</td>
</tr>
<tr>
<td>(g) Increasing self-efficacy through adherence to diet goals;</td>
</tr>
<tr>
<td>(h) Achieving weight loss and preventing weight (re)gain, maintaining a healthy body weight and reducing risk of weight regain.</td>
</tr>
</tbody>
</table>
4.1. What can be achieved in SATIN on Consumer Benefits?

Within the existing SATIN proposal WP4 provides an experimental framework in which we can start to examine consumer benefits. In addition to reducing hunger and / or energy in short-term chronic paradigms, we can investigate i) the pleasure (enjoyment and gratification) provided by palatable, energy dilute, satiety enhancing foods (and in longer protocols whether this combats feelings of deprivation), ii) whether these foods reduce the dysphoric moods states associated with feeling chronically hungry, and iii) whether this in turn prevents the associated decline in cognitive function associated with hunger, low mood and trying to maintain caloric restraint. Within longer term studies (12 weeks) we can then determine how foods help individuals i) cope with daily hunger, ii) control eating behaviour, and how this in turn improves iii) weight management success, iv) compliance, and perhaps as part of a larger trial (WP5) examine the roles of v) self-efficacy and vi) subjective well-being. A number of experimental and self-report techniques will be employed for specific site based studies.

4.2. Operationalisation of Consumer Benefits Methodology

4.2.1. Greater overall summed satiety effect for total diet

Consuming products designed to increase within meal-satiation and strengthen post-meal satiety should lead consumers to i) feel fuller when maintaining their normal energy intake and / or ii) experience no discernible increase in post meal hunger in modest energy deficit. Such effects can be captured when specific foods are administered and their effect on appetite (measured by visual analogue scales) and subsequent energy intake are measured across the day in a controlled laboratory environment (and are necessary evidence in substantiating appetite based health claims). Outside the laboratory a variety of approaches can be employed. Retrospective assessment of appetite experience over that day can be captured through direct question (e.g. ‘how hungry have you today?’, ‘how filling have the foods you have eaten been today?’; ‘how well did these foods satisfy your appetite today?’) or validated tools such that directly assess their appetite experiences over the preceding 7 days (e.g. Control of Eating Questionnaire). However, daily fluctuations in appetite between meals really cannot be interpreted in the absence of contextual information about the number and timing of eating occasions and their nutritional consequences, and this can limit the potential usefulness of the resulting data.
4.2.2. Greater liking of foods and greater food reward

For an act of consumption to be enjoyed two components are important – sensory pleasure combined with a gratifying level of repletion (satisfaction of hunger). The sensory experience of food can readily be ascertained within experimental designs as can the pleasant feelings they potentiate as they are consumed. Taste and hedonic response (explicit liking and wanting) will be measured during and after the test meal in all WP4 designs (using standard ratings). Salience of these effects is critical to reward effects so memories of pleasantness and satisfaction can be tested at the end of the day in all WP4 studies.

4.2.3. Improved acceptance of lower energy foods

Preference for either i) individual foods in their regular and reduced calorie forms, or ii) between differing foods that can be characterised as clearly low or high energy, provide an objective test of acceptance. To assess change in acceptance this must be measured at baseline, at start of exposure and after prolonged experience of testing. WP4 provides the opportunity to test whether acceptance increases for the specific study food, and whether that generalises to a discreet number of similar low energy foods. Here, during the 4 and 12-week studies standard choice paradigms and rating of individual products can be employed. Explicit liking will be measured through subjecting ratings of pleasantness at all sites. The stimuli chosen will depend upon the specific product in the specific trial.

4.2.4. Reduced hunger dysphoria

A number of tools with known psychometric properties capture individuals’ experience of appetite and changes in trait appetite under active weight management. These include measures of trait hunger in general (TFEQ hunger scale also termed the perceived hunger scale of the Eating Inventory) and specifically measures of cravings (Food craving inventory and Control of Eating Questionnaire). Similarly, these tools could also assess the impact of satiety enhancing products, and whether any reductions in hunger and cravings improve mood (which could include Mental Well Being Scale, POMS, PANAS and / or Center for Epidemiologic Studies Depression Scale CES-D). Cognitive tests of i) affect and ii) alertness / performance could be incorporated within some designs and relevant cognitive methodological approaches will be developed.
4.2.5. Reduced stimuli for opportunistic eating

A number of tools or sub-scales within them assess the external stimuli for eating and/or the susceptibility to over consume in a permissive food environment. These include but are not limited to the DEBQ External Eating Scale which focuses on individual responsiveness and the Power of Food Scale that focuses upon the psychological impact of living in food abundant environments. The Mindful eating scale captures key environment stimuli associated with reduced control of eating. Dieter’s Inventory of Eating Temptations (DIET) may also pick up on this factor. In addition, laboratory based measures of cognitive/attentional bias will be developed.

4.2.6. Better control over food intake

A number of tools or sub-scales within them assess feelings of control or lack of control over eating behaviour. These include the emotional eating scale of the DEBQ and the disinhibition scale of TFEQ. The Power of Food Scale potentially captures feelings of being controlled by hunger. Flexible restraint would indicate a more adaptive response to weight control. In addition to the measures of hunger, cue responsiveness and control discussed above, indices of self-efficacy and eating self-efficacy should demonstrate whether consumption of satiety enhancing products makes it easier for participants to adhere to and successful comply with weight management programmes.
5. References


Annex A

Suggested methodology for Consumer Benefits platform:

**Experimental Paradigms**

**Reactivity to external stimuli**

In order to evaluate reactivity to external appetitive stimuli we will utilise two related, but separable, measures of cognitive bias—specifically attentional bias and automatic approach responses. Attentional bias refers to the ability of environmental stimuli to grab and hold the attention of an individual with highly salient stimuli being more likely to hold attention. An automatic approach response refers to the ability of appetitive stimuli to elicit acquisitive conditioned motivational responses. Both of these measures are consistently associated with weight status and current motivational state (e.g., Castellanos et al. 2009; Braet & Crombez 2003; Mogg et al. 1998; Nijs et al. 2010a; Nijs et al. 2010b; Veenstra & de Jong 2010; Brignell et al., 2009), but as yet, have yet to be employed to investigate changes in cognitive processes during dietary interventions.

**Attentional bias:** Attentional bias will be measured using the visual probe task (figure 4.3.7). During the trials on the visual probe, two task pictures are presented simultaneously (one appetitive and a matched control picture) before both pictures disappear and a probe appears in the location of one of these pictures. Faster reaction times to congruent probes (behind the appetitive picture) are indicative of attentional bias. However, we will also use eye tracking technology (ASL Eye Trac6) to take direct measures of attentional bias, as this has superior reliability compared to reaction time measures (see Field & Christiansen 2012 for a discussion). Furthermore, using eye tracking procedures will also allow attentional processes to be broken down. Specifically, we can investigate maintenance of attention (total time the gaze dwells on a given picture) compared to initial orientation of attention (where the individual is looking for the first 200 ms of the trial; see Cisker & Koster 2010). The distinction between initial orientation of attention and maintenance may be a particularly important contrast. Werthman et al. (2011) demonstrated that overweight female adults display an approach-avoidance reaction to food stimuli, whereby attentional bias is observed during initial orientation to food, but not in the maintenance of attention on such stimuli. This initial orientation of attention to food stimuli is also related to food craving and is not evident in healthy-weight individuals. These findings imply that differences in motivational value assigned to food stimuli may influence involuntary attention allocation to such stimuli.
Figure 4.3.7 Schematic of visual probe task (congruent trial depicted)

Automatic approach responses: Automatic approach responses will be measured using a stimulus response compatibility task (SRC; figure 4.3.8). During a trial on this task a single picture (appetitive or matched control) is presented in the centre of the screen with a manikin above or below it. Participants are instructed to make the manikin approach one group of pictures and avoid the other according to block instructions. For example in the “approach food block” the participant would be required to press down if the manikin was above a food-related picture and up if it was below the picture; if the picture was a control picture they would be required to move the manikin away (e.g. press “up” if it was above the picture). The “avoid food block” is identical but with the instructions reversed (avoid food, approach neutral). Faster responses in the approach food compared to the avoid food block are indicative of an automatic food-approach processing bias.
**Behavioural control**

Obesogenic behaviours and current motivational state are also correlated with impairments in the ability to suppress reward driven behaviour (inhibitory control). Indeed, cognitive tasks such as the Stop-Signal and Go/No-Go which measure ability to withhold prepotent responses have revealed poor inhibitory control is associated with consumption of highly palatable unhealthy foods in taste tests (Guerrieri et al., 2007), self-reported hunger (Loeber et al., 2013) and obesity in adults, adolescents, and children (Nederkoorn et al., 2006; Batterink Yokum & Stice 2010; Verdejo-Garcia et al., 2010). Furthermore, there is evidence of a causal relationship between inhibitory control and the ability to control the intake of high fat foods, with inhibitory training showing short term reductions in calorific food intake (Houben & Jansen 2010).

**Behavioural control:** The Go/No-Go task will be used to assess the ability to withhold prepotent responses in the presence of appetitive cues (see Loeber et al., 2013; figure 4.3.9). During the Go/No-Go participants will first be instructed to respond as rapidly as possible to appetitive cues and withhold responses to neutral cues. In the next block the instructions will be reversed; withhold responses to appetitive, respond as rapidly as possible to neutral cues. This pattern is repeated for 10 blocks (the first two of which will be practice blocks). Commission errors (failures to inhibit responding to appetitive stimuli) are indicative of failures in inhibitory control.
In order to investigate the effect of satiating products on cognitive biases for food and self-control a food cue exposure paradigm could be employed to evoke a “hot state” in participants before exposing them to appetitive foods that are available for consumption. A food cue exposure paradigm similar to that used by Fett et al (2009), whereby a participant engages with the sight, smell and feel of foods without consuming it, is likely to evoke desire to eat and appetitive motivations. Evoking food cue reactivity prior to assessment of cognitive biases such as those mentioned above would allow for the investigation of how a state of heightened motivation for appetitive food (deliberately generated by food cue exposure) is manifested in cognitive bias for food stimuli and subsequent consumption in an ad-libitum taste test. Comparison of these effects in participants who are consuming satiating products and those who are not would allow for the assessment of how enhancements in satiety affect appetitive reactivity at both a cognitive and behavioural level. Enhancing physiological satiety may make participants better equipped to reduce or withhold responses to food cues.
Psychometric Tools

End of Day Appetite Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>How hungry have you been today?</td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Very hungry</td>
<td></td>
</tr>
<tr>
<td>How filling have the foods you have eaten been today?</td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Very filling</td>
<td></td>
</tr>
<tr>
<td>How well did the study foods satisfy your appetite today?</td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Very</td>
<td></td>
</tr>
<tr>
<td>Did the product reduce your feeling of hunger before meals?</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
<tr>
<td>Almost never</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td></td>
</tr>
<tr>
<td>Fairly often</td>
<td></td>
</tr>
<tr>
<td>Often</td>
<td></td>
</tr>
<tr>
<td>Very often</td>
<td></td>
</tr>
<tr>
<td>All the time</td>
<td></td>
</tr>
<tr>
<td>Did the product reduce the need/desire to snack between meals?</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
<tr>
<td>Almost never</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td></td>
</tr>
<tr>
<td>Fairly often</td>
<td></td>
</tr>
<tr>
<td>Often</td>
<td></td>
</tr>
<tr>
<td>Very often</td>
<td></td>
</tr>
<tr>
<td>All the time</td>
<td></td>
</tr>
<tr>
<td>Did the product reduce the need/desire to eat sugary foods between meals</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
<tr>
<td>Almost never</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td></td>
</tr>
<tr>
<td>Fairly often</td>
<td></td>
</tr>
<tr>
<td>Often</td>
<td></td>
</tr>
<tr>
<td>Very often</td>
<td></td>
</tr>
<tr>
<td>All the time</td>
<td></td>
</tr>
<tr>
<td>Have you found it easy to resist temptation?</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
<tr>
<td>Almost never</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td></td>
</tr>
<tr>
<td>Fairly often</td>
<td></td>
</tr>
<tr>
<td>Often</td>
<td></td>
</tr>
<tr>
<td>Very often</td>
<td></td>
</tr>
<tr>
<td>All the time</td>
<td></td>
</tr>
</tbody>
</table>
Did hunger distract you today?

Never 1
Almost never 2
Occasionally 3
Fairly often 4
Often 5
Very often 6
All the time 7

Have you over-eaten today?

Never 1
Almost 2
Occasionally 3
Fairly 4
Often 5
Very 6
All the time 7

How long did you feel satisfied for after eating the meals today?

A very long time 1
A long time 2
A fairly long time 3
Neither a long time nor a short time 4
A fairly short time 5
A short time 6
A very short time 7

How often did you have cravings for sweet foods during the day?

Never 1
Almost never 2
Occasionally 3
Fairly often 4
Often 5
Very often 6
All the time 7

How often did you have cravings for fatty foods today?

Never 1
Almost never 2
Occasionally 3
Fairly often 4
Often 5
Very often 6
All the time 7

How difficult has it been to go between meals without eating unhealthy snacks today?

Very difficult 1
Difficult 2
Fairly difficult 3
Neither difficult nor easy 4
Fairly easy 5
Easy 6
Very easy 7
Control of Eating Questionnaire

Please read each question carefully and put a mark through the line at the point that best represents your experience. Answer all questions according to your experience over the last 7 days.

1. How hungry have you felt?
   - Not at all ________________________________ hungry
   - Extremely hungry

2. How full have you felt?
   - Not at all ________________________________ full
   - Extremely full

3. How strong was your desire to eat sweet foods?
   - Not at all ________________________________ strong
   - Extremely strong

4. How strong was your desire to eat savoury foods?
   - Not at all ________________________________ strong
   - Extremely strong

5. How happy have you felt?
   - Not at all ________________________________ happy
   - Extremely happy

6. How anxious have you felt?
   - Not at all ________________________________ anxious
   - Extremely anxious
7. How alert have you felt?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Extremely alert</th>
</tr>
</thead>
</table>

8. How contented have you felt?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Extremely contented</th>
</tr>
</thead>
</table>

A food craving is a strong urge to eat a particular food or drink

9. During the last 7 days how often have you had food cravings?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Very often</th>
</tr>
</thead>
</table>

10. How strong have any food cravings been?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Extremely strong</th>
</tr>
</thead>
</table>

11. How difficult has it been to resist any food cravings?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

12. How often have you eaten in response to food cravings?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>After every one</th>
</tr>
</thead>
</table>

How often have you had food cravings for the following types of food/drink?

13. Chocolate or chocolate flavoured foods

<table>
<thead>
<tr>
<th>Not at all</th>
<th>____________________________</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

14. Other sweet foods (cakes, pastries, biscuits, etc)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>often</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

15. Fruit or fruit juice

<table>
<thead>
<tr>
<th>Not at all</th>
<th>often</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

16. Dairy foods (cheese, yoghurts, milk, etc)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>often</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

17. Starchy foods (bread, rice, pasta, etc)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>often</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

18. Savoury foods (french fries, crisps, burgers, pizza, etc)

<table>
<thead>
<tr>
<th>Not at all</th>
<th>often</th>
<th>Extremely often</th>
</tr>
</thead>
</table>

19. Generally, how difficult has it been to control your eating?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

20. Which one food makes it most difficult for you to control eating?

..................................................................................................................

21. How difficult has it been to resist eating this food during the last 7 days?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>
Additional Question from Broader conception of self-control

How much effort did you put into controlling urges to eat?

1. All my effort
2. a great deal of effort
3. Significant effort
4. no more effort than usual
5. modest effort
6. little effort
7. no effort at all

How difficult did you find it controlling your urges to eat?

1. Very difficult
2. Difficult
3. Fairly difficult
4. Neither difficult nor easy
5. Fairly easy
6. Easy
7. Very easy

Broader conception of self-control

Investigating a broader conception of behavioural control may also give us some interesting comparisons. The strength model of self-control argues that self-control is a limited resource; if self-control is used over prolonged period of time then subsequent lapses of self-control are more likely (see Hagger et al., 2010, 2009 for a review and meta-analysis). Ecological momentary assessment studies in the alcohol field have indicated that self-report use of self-control is associated with incidents of drinking over self-imposed limits (Muraven et al., 2005). If satiating products reduce physiological hunger signals that promote the urge to consume appetitive foods these individuals will have used less self-control to resist eating in response to physiological hunger urges and therefore be better equipped to resist temptation (hedonic urges) later. By simply asking participants how much self-control they have used to stick with their low calorie diet throughout the day we can investigate whether the impact of the satiating foods on improved dietary outcomes is at least partially mediated by perceived use of self-control. Indeed, it may be useful to get a measure of self-control use before ad-lib consumption sessions in particular.
Liking and Pleasantness

Prospective

How tasty is this food?
Not at all  ____________________________  Very tasty

How pleasant is this food?
Not at all  ____________________________  Very pleasant

How much do you like this food?
Not at all  ____________________________  Very much

How satisfying do you think this food will be?
Not at all  ____________________________  Very satisfying

Retrospective

Thinking back today how tasty was (insert name of study food) you ate for (insert details of meal and / or time of day)?
Not at all  ____________________________  Very tasty

Thinking back today how pleasant was (insert name of study food) you ate for (insert details of meal and / or time of day)?
Not at all  ____________________________  Very pleasant

Thinking back today how much did you like (insert name of study food) you ate for (insert details of meal and / or time of day)?
Not at all  ____________________________  Very much

Thinking back today how satisfying was (insert name of study food) you ate for (insert details of meal and / or time of day)?
Not at all  ____________________________  Very satisfying