

Midstream Modulation in Biotechnology Industry: Redefining What is ‘Part of the Job’ of Researchers in Industry

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Abstract In response to an increasing amount of policy papers stressing the need for integrating social and ethical aspects in Research and Development (R&D) practices, science studies scholars have conducted integrative research and experiments with science and innovation actors. One widely employed integration method is Midstream Modulation (MM), in which an ‘embedded humanist’ interacts in regular meetings with researchers to engage them with the social and ethical aspects of their work. While the possibility of using MM to enhance critical reflection has been demonstrated in academic settings, few attempts have been made to examine its appropriateness in industry. This paper describes the outcomes of a case study aiming to find out firstly whether MM can effectively be deployed to encourage and facilitate researchers to actively include social and ethical aspects in their daily R&D practice,

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and secondly to what extent the integration activities could form an integral part of the engaged industrial researchers' professional activities. Our data show that after MM, researchers display increased reflexive awareness on the social and ethical aspects of their work and acknowledge the relevance and utility of such aspects on their daily practice. Also, all participants considered actively reflecting on social and ethical aspects to be part of their work. Future research on the role of MM in industrial settings could focus on how to embed social and ethical integration as a regular part of innovation practice. We suggest that one possibility would be through aligning social and ethical aspects with innovation Key Performance Indicators.

Keywords Midstream modulation · Ethics of science & technology · Upstream engagement in industry · Responsible innovation

Introduction

Research Context

Policy makers and social sciences and humanities scholars have advocated for the inclusion of social and ethical aspects in the responsible development and deployment of new and emerging sciences and technologies (NEST) such as nanotechnology and biotechnology (European Group on Ethics 2007; European Commission 2011a; PBL 2012; Webster 2007; Lucivero et al. 2011; Fisher 2011; Jasanoff 2011).¹ Emerging technologies have numerous inherent social and ethical aspects (Van de Poel 2001; Swierstra and Jelsma 2006; Patra 2011), concerning e.g. environmental sustainability, health, public needs, values and opinions, responsible R&D practices, intellectual property rights and funding (see e.g. Funtowicz and Ravetz 1993; Barling et al. 1999; Hessels et al. 2009). Inclusion of social and ethical aspects may help shape NEST (Wynne 2003), especially in the early stages of development (Guston and Sarewitz 2002). Such inclusion has been demonstrated to have positive effects on R&D practices at laboratories, by enabling researchers to work in a more responsible, democratic, conceivably more socially desirable way and by helping them set better research goals and priorities (Van de Poel 2000; Van der Burg 2009; Doorn 2011).

Various methods have been described in the literature to include social and ethical aspects in R&D (see e.g. Delgado et al. 2010), yet few focus on integrating such aspects at the core of R&D: decisions made by researchers working in laboratories (Fisher et al. 2006). One new, potentially transformative (Wynne 2011) method that “*provides evidence of both the possibility and the utility of integrating societal considerations into and during nanoscale engineering research*” (Fisher and Mahajan 2006: 5) is Midstream Modulation (MM). MM was developed in line with other policy instruments that allow for integrating social and ethical aspects in research practices, such as Constructive Technology Assessment (Schot and Rip 1997) and Real-Time Technology Assessment (Guston and Sarewitz 2002). The

¹ While primarily policy makers and social sciences and humanities scholars advocate for this inclusion, also scholars from the natural sciences in the field of biotechnology have done so. See e.g. Wolpert (2007).

‘midstream’ refers to R&D processes that take place between ‘upstream’ funding and ‘downstream’ implementation of R&D (Fisher et al. 2006). ‘Modulation’ refers to the guiding activities that steer R&D processes to include broader social aspects, rather than radically changing such processes (Rip 2006). MM aims to construct collaborative engagement between social and natural scientists in the laboratory, in order to broaden research decisions incrementally (Schuurbiens and Fisher 2009). Such broadening of decisions implies a more systematic consideration of socially relevant aspects (Wilson 2005), such as public morals and values in the process of decision making by researchers on the laboratory floor, but also of internal social aspects such as team communication and cooperation (Fisher and Miller 2009).

MM studies presented in scholarly literature have mostly been deployed in academic settings, often in the field of nanotechnology. Research experience with MM in an industrial setting is limited (see Phelps and Fisher 2011; Thoreau 2010). However, also outside academia R&D activities take place that are worth investigating (Penders et al. 2009) for their capacity to consciously take social and ethical considerations into account as an integral part of their work. In fact, most R&D in Europe and the US—in terms of budget and labour intensity—occurs in industry (European Commission 2011b). Based on the effectiveness of MM in enhancing social and ethical reflection and behaviour in academic laboratories (Fisher 2007; Schuurbiens 2011), the method may prove to be especially beneficial for both R&D practices and societal values if it was found to be effective and appropriate within industrial R&D. Considering that more than half of all innovation projects are estimated to fail (Cozijnsen et al. 2000), possible positive influences on R&D through the integration of social aspects may be welcomed by industry. The active inclusion of social aspects in industrial innovation projects may be encouraged in the light of corporate socially responsible conduct (see e.g. McWilliams and Siegel 2001). However, it is far from clear that what has been shown to work in universities can also be feasible in industry.

The biotechnology industry is characterised by a high degree of NEST-based innovation, for which R&D is essential (DeCarolis and Deeds 1999; Alegre et al. 2009). To our knowledge, industrial biotechnology laboratories have not been included in MM research. Since industrial R&D differs in its research priorities and practices from academic R&D, it is neither evident that MM will work also in industry, nor that MM will be accepted as a logical and integrated part of for-profit, industrial R&D. The question thus arises as to whether MM could be functionally applied to industrial biotechnology settings to enhance the integration of broader considerations during laboratory decision making, or whether corporate practices and institutional boundaries would prevent such integration.

Research Questions

With our study we aim to answer two research questions. First, can Midstream Modulation be effectively deployed in industrial biotechnology R&D to encourage and facilitate researchers to actively include social and ethical aspects in their daily laboratory practice? In contrast to earlier MM studies we will demonstrate whether this is the case within an industrial setting and with multiple participants. Also we wish to ascertain whether researchers in industry find it relevant for their

professional roles to consider the broader social and ethical aspects more explicitly in their decision making processes. Therefore, our second research question is: do industrial researchers appreciate the MM approach, and if so, to what extent? Earlier MM studies have shown that participants appreciate the MM approach (Fisher 2007; Schuurbiens 2011; Conley 2011). But the extent to which social and ethical aspects have become an accepted and regular part of R&D processes has not been assessed.

Background of Midstream Modulation

Decisions and the Decision Protocol

Fisher and Mahajan (2006) proposed in their pioneering MM case study that R&D decision making processes can be rendered more visible with MM, and that researchers may be stimulated to identify and assess opportunities for influencing research decisions in accordance with societal concerns. In their model, an ‘embedded humanist’ (usually a social sciences or humanities scholar, see also Fisher and Miller 2009) engages with participants (natural scientific or engineering researchers) individually in regular meetings for a period of 12 weeks in the researcher’s laboratory. In these meetings, R&D decisions made by the participating researchers are the main topic of conversation. These broader decision making processes, involving social and ethical considerations, serve as the primary unit of analysis in the MM method.²

Modulations of the Midstream

MM theorises that as the interviews progress, researchers themselves, gradually start to consider the social sides of their work. Different ‘modulations’ (Fisher et al. 2006) are posited to appear subsequently, in three stages (see Table 1, but also Fisher and Mahajan 2006, 2010). To start, in *de facto* modulation, decision modulators (opportunities, alternatives, considerations, outcomes) are recognised to shape research projects through a variety of cognitive, social and physical factors. Subsequently, in *reflexive* modulation, participants become aware of and start to recognise the *de facto* modulators’ influence on their research decisions. Hereafter, such awareness of these modulators may (or may not) lead to *deliberate* modulation (whether in a goal-directed, or in a more deliberative manner, *cf.* Fisher and Mahajan 2010) by participants in their research decisions.

Increasing Participants’ Reflexively Awareness

Fisher and Mahajan (2006) used MM to investigate the empirical possibility for integrating social and ethical considerations into research decisions. Such ‘socio-technical integration’ can be demonstrated based on identified changes in ‘reflexive awareness’. Such awareness relates to the attentiveness of participants to “*nested processes, structures, interactions, and interdependencies, both immediate and more removed, within which they [participants] operate,*” (Fisher et al. 2006: 492). Changes

² Their original study serves as the basis for a series of MM studies through Fisher’s NSF funded Socio-Technical Integration Research (STIR) project (NSF #0849101).

Table 1 Midstream modulations with examples of modulators

Modulations	Description	Example of modulation modulators
<i>De facto</i>	<i>De facto</i> modulations are <i>identified</i> which shape research projects	Partners and collaborators who have an effect on research directions are identified
<i>Reflexive</i>	In <i>reflexive</i> modulation, participants become aware of the <i>role</i> of <i>de facto</i> modulations in their research decisions	The various roles of partners and collaborators are assessed and evaluated (in terms of opportunities, considerations, alternatives and outcomes). Teamwork may be recognised as an important criterion for good laboratory practice
<i>Deliberate</i>	In <i>deliberate</i> modulation, participants actively and deliberately integrate the identified <i>de facto</i> modulations in their decision making, since they are aware of the role of such modulations and use them more consciously	Coordinated teamwork activities are deliberately deployed in order to improve research quality

in reflexive awareness can then be assessed using pre- and post-programme interviews (before and after the programme of regular engagements) based on a semi-structured interview guide. Changes in reflexive awareness can be recognised by comparing the answers participants give to questions in the pre-interview to the answers to the same questions in the post-interview. Socio-technical integration can also be demonstrated through narrative accounts of changes in thought, discourse and material practices that unfold over time in conjunction with the regular engagements. We will demonstrate socio-technical integration using a novel way, namely, by analysing the content and outcomes of the regular engagements using the three formal stages of MM (Table 1).

Method

Sample Selection

Similar to earlier MM research, our study is explorative in nature. We designed and conducted a case study research procedure based on MM at Royal DSM N.V, The Netherlands. DSM is a large (>22.000 employees) multi-national science and technology based company active in health, nutrition and materials. Its mission is to “*create brighter lives for people today and generations to come [...] to create solutions that nourish, protect and improve performance*” in the Life Sciences and Materials field (DSM 2012). Its industrial biotechnology R&D facilities are located in Delft, The Netherlands.

Research decisions made by *researchers* are the primary unit of analysis in MM. A group of 5 of DSM’s researchers was assigned to us to participate in this study.³ All five researchers had a background in the field of microbiology, worked on the same project,⁴ but studied different technological aspects of this project. The participants are further introduced in the next chapter.

³ These 5 researchers were asked to participate had the ability to ‘opt out,’ but did not reject.

⁴ The project entails the design of a microbiological production process (based on renewable resources) of a sustainable component that can replace its currently petrochemically produced alternative. The complete project description remains undisclosed in accordance with the confidentiality agreement.

Table 2 Methodological overview of the MM case study

	Week 1	Week 2–11	Week 12
<i>Activity</i>	Semi-structured Pre-interview	10 subsequent weekly interviews	Semi-structured Post-interview
<i>Tool</i>	Interview guide (“Appendix”)	Decision protocol with decision modulators (opportunities, considerations, alternatives, outcomes) (Fig. 1)	Interview guide (“Appendix”)
<i>Purpose</i>	Assess reflexive awareness of participants on social and ethical aspects in research at the beginning of the MM activity	Identify and discuss decision modulators that influence research choices, to investigate if <i>de facto</i> , <i>reflexive</i> and <i>deliberate</i> modulations are observed	Discuss decision modulators one last time; evaluate the use of the MM activity with participants; assess change in reflexive awareness (difference with Pre-interview outcomes)

We realise that industrial research data is sensitive information and give rise to secrecy concerns of firms “*whose competitive advantage is strongly linked to the competence of their R&D efforts*” (Bercovitz and Feldman 2007: 945). A confidentiality agreement was drafted that safeguards sensitive scientific and technological details and the identity of the participants.

MM Activities

The MM activities used to encourage and facilitate researchers to actively include social and ethical aspects in their research practices are summarised in Table 2. The role of the embedded humanist was taken by the first author of this paper. We made three changes to the original MM method to accommodate our industrial R&D environment. First, the original study by Fisher and Mahajan (2006) included 12 interviews using the decision protocol, preceded and followed by a pre- and post-interview. However, we used a compressed timeframe with 10 weekly interviews, conducting the pre- and post-interviews in the weeks before and after,⁵ for a total project duration of 12 weeks. The timeframe was compressed to reduce the demand on time of the participating industrial researchers. All interviews were recorded with consent of the participants. For logistic reasons the 12 interviews could not be planned in 12 subsequent weeks, but all five interview trajectories did run roughly parallel in time, starting early October 2009 and finished early February 2010.⁶

The second change relates to the ‘decision protocol’ used in the MM activity. The embedded humanist and the participant discuss the decisions made in previous research and the decisions that must be made in the future, based on this protocol.

⁵ The interview guide is given in “Appendix”. It is based on the one used by Schuurbiens (2011), who kindly provided us with his protocol.

⁶ In addition to the interviews, the embedded humanist also visited the researchers in their laboratories and offices on numerous occasions, and was present at weekly research meetings. While these observations do help the embedded humanist to interpret the interview results, the additionally obtained data is not used in this paper, similar to earlier MM research.

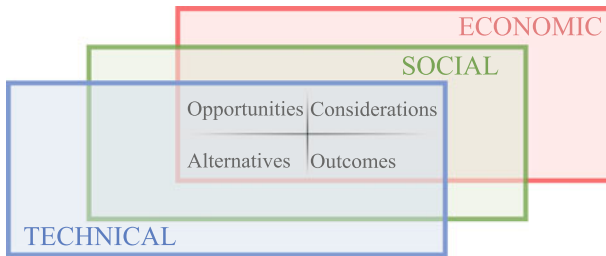


Fig. 1 Decision protocol based on Schuurbiers and Fisher (2009: 426, Fig. 2), showing decision modulators (Opportunities, Considerations, Alternatives, Outcomes), with a third economic perspective added to the social and technical perspectives

Using this protocol, decisions are subdivided into different ‘modulators’ that make up a decision, being the research *opportunities*, the different *considerations* that play a role in the decision, the possible *alternative* options and the projected *outcomes* of the decision. Fisher (2007) provided narratives using this decision protocol in practice. The power of MM lies in enabling participants to look at technical decisions and broadening those with a social perspective. Namely, the different modulators that make up a decision can be viewed from a technical perspective, but also from a social perspective (see also Schuurbiers and Fisher 2009). However, we determined that the decision protocol used by Schuurbiers and Fisher (2009: 426, Fig. 2) is insufficient for modulating decisions in industrial settings. These two perspectives (social and technical) may be sufficient for academic research environments in which the protocol was used, but in industry a corporate, economic perspective must be added. We expanded the protocol accordingly with an economic perspective (see Fig. 1). Therefore, decisions made by researchers were modulated into opportunities, considerations, alternatives and possible outcomes of the choices, and looked at from economic, social and technological perspectives.

Third, we added several specific questions to the MM pre- and post-interviews, in order to find out to what extent participants appreciate the MM approach. Participants were asked to reflect on their perceived use of the method in the post-interview. Also, in contrast to earlier MM research, in the pre-interviews participants were asked whether they considered this as something extra, on top of their work, or considered it to be part of their work. This question was repeated in the post-interview, to observe a possible change in their perceived use of the MM method and the integration of social and ethical aspects as a regular part of their daily R&D work.⁷

⁷ Additionally, in interview 6 the method was evaluated to allow participants to give advice on how to improve the method, to see if expectations were met and to investigate whether participants were still willing to continue to participate in the study. Participants did not make critical comments at that time and wanted to continue in this study, so we do not further elaborate on the outcome of this evaluation moment in this paper.

Data Analysis and Presentation

The limited number of case studies using MM presented in scientific literature (cited above) all use different data interpretation and presentation methods. In contrast to earlier MM research, we present our results per participant. This allows insight in the actual MM practice to see what happens during the interviews.

Fisher and Mahajan (2006) propose that the differences in answers the participants give to similar questions in the pre- and post-interviews—i.e. before and after the interviews using the decision protocol—are indicative of changes in reflexive awareness on the social and ethical dimensions of their work. Fisher (2007) provides an ethnographic account of actual engagements and the increasingly reflexive decision outcomes that took place over time with one participant in this study. Building on both Fisher and Mahajan's (2006) focus on reflexive awareness as well as Fisher's (2007) detailed account of changes in practice, we sought to more systematically demonstrate the effects of the protocol in practice. Our research aim made us look not only for indications of researchers actively integrating social and ethical aspects into their decisions, but we asked whether such integration followed the three formal stages of MM theory. We therefore take the concept of reflexive awareness as a starting point of our analysis to demonstrate if researchers have become more aware on the social and ethical aspects of their work, and then we turn to the interview transcripts in order to more systematically analyse the actual engagements.

As also posited by Fisher and Mahajan (2006: 3), *reflexive* modulation is necessary and instrumental condition for *deliberate* modulation and “*its presence (or absence) can be taken as one indicator of the possibility (or lack thereof) of socio-technical integration and of the normative influencing of engineering research.*” In addition to a change in reflexive awareness, we therefore look for of *de facto*, *reflexive* and *deliberate* modulations in the interviews. The *deliberate* modulations form indications of participants using reflexive insights actively and deliberately in their decision making.

The twelve interviews with five participants resulted in roughly 60 h of recorded interviews which were subsequently analysed and partly⁸ transcribed *ad verbatim*. We used quotations that illustrate the presence of *de facto*, *reflexive* and *deliberate* modulations based on the guidelines in Table 1. Quotations used in this article were translated to English and checked by the research participants for accuracy and possible misinterpretation by the authors.

To summarise, in finding active inclusion of social aspects in R&D work, we focus in our interview analysis firstly on a change in reflexive awareness based on the pre- and post-interviews with the participants. Hereafter we show an example of how such awareness is typically generated during the interviews based *on de facto*, *reflexive* and *deliberate* modulations.

⁸ We analysed interviews on recorded audio and transcribed segments about decision making and social and ethical aspects. Of the 60 h of interviews 20 h were transcribed, resulting in roughly 78,000 words of *ad verbatim* transcripts.

Outcomes

Interviews were analysed for indicators of reflexive awareness and *de facto*, *reflexive* and *deliberate* decision modulations. The interviews revealed numerous examples of perceived research opportunities, considerations, alternatives and anticipated outcomes that influence research choices which were modulated, on technological, social and economic levels. We restrict ourselves to a limited number of examples that illustrate the course of events in the MM activity and exemplify modulations. We present first a narrative with one participant where we identify changes in reflexive awareness and various decision modulations, to illustrate what happens during the MM interviews. Second, a summary of modulations and changes in reflexive awareness per participant is given. Last we present results of our investigation of the appreciation of the MM activity by our participants.

Example of MM Narrative

Participant 1 (P1) is the lead genetics researcher within the project. Together with his team of researchers he develops the micro-organism that will produce the product. Working in the field of genetics implies working with various ethical and social aspects regarding genetic engineering. But also working within a team, an organisation and a scientific community has ethical and social sides. During the pre-interview the following was discussed in light of ethical and social issues:

Embedded Humanist (EH): Have you been confronted in any way with ethical issues during the last 12 months?

P1: No.

EH: What about social issues?

P1: Yes, well, you mean... [thinks for a while] No, not really, also not from any of my family or acquaintances. [Pre-interview, P1, 9 October 2009]

P1 is unable to tell which ethical and social aspects are connected to his work. During the 10 interviews between the pre- and post-interview many of such aspects were identified and subsequently discussed. During the post-interview, 3 months later, a similar question was asked:

EH: Can you just think of some ethical, social and legal aspects of your work?

P1: Yes.

EH: Can you give examples?

P1: Well, ethical, that we are working with GMOs. So we give genes to an organism that it did not have by itself. There may be some ethical objections against that. Also socially, there may be quite some discussion. We discussed that extensively together. [Post-interview, P1, 22 January 2010].

After 3 months, P1 can easily refer to the ethical and social sides of his work. P1 refers in this post-interview to the discussions he had with EH about the social aspects of his work. These included among others, the role of sustainability in the design of the organism. He continues to speak about these social aspects:

P1: Yes, well, when you're working on a process that should be greener than the chemical process, than you are certainly working on social aspects [Post-interview, P1, 22 January 2010].

During the discussions P1 more consciously considered some ethical and social aspects of his work. He recognises that making the product 'greener' (i.e. more sustainable) than the petrochemical alternative is an important social aspect. He appears to have gained some reflexive awareness on the social sides of his work. To illustrate how such awareness may be generated, we looked into the *de facto*, *reflexive* and *deliberate* modulations of P1. Below we give an example of one of these discussions regarding the role of external communication of research design and method.

EH: So, at some point, you intended to present a poster about this research at a congress or event. And that was cancelled at the last moment. Why?

P1: Because business [department, EH] thought it was too early. Well, not even too early, but business thought that we shouldn't have to reveal our technology. [Interview 4 P1, 30 October 2009]

P1 was not allowed by the business department to show his research results to the outside scientific community. We see a *de facto* research modulation: the role of business in P1's decision making process on what to communicate externally. In the following conversation, several social and moral dimensions to his response were further explored. First, presenting research results to the scientific community is a way for researchers to gain recognition and reputation personally (see e.g. Hessels et al. 2009), but possibly also for the company. Second, he felt that for the advancement of science, it might be (morally) good for the scientific community to also know about his team's discoveries. Third, scientific peers may be able to give valuable research input at conferences, possibly beneficial also for the company. But business prevented him from doing that, which he did not fully understand. The discussion continued:

EH: Not reveal it yet, or not at all?

P1: Well, at that time it was 'not yet'. [...] I wrote an abstract in which we stated that we had made a yeast for [product] production. That was actually the only information in it. And that we introduced some heterologous genes, but not even how we did that. But anyway, the information the market could get from it, was that we were working next to [other organism] also with yeast. [Interview 4 P1, 30 October 2009]

In this quotation, some reflection emerges, as P1 not only relates his arguments to the science, but also to corporate stakes in the market. During the further discussion, this business perspective was further elaborated on. EH figured this business perspective might also be valid, and could be more actively considered as an internal social political argument for the company, which researchers like P1 might not be immediately familiar with.

EH: So, this was all seen as 'too much information'?

P1: Yes, well, it's just very 'double': on one side, DSM proclaims to be a company using open innovation strategies and sharing things with one another. [...] Maybe we can publish this when the process is further developed, if we may, but at some point it was just decided during a meeting by a number of executives that we were not going to do this. [Interview 4 P1, 30 October 2009]

Again, we observe some reflection, but this time not about DSM, but regarding the company's policy in relation to innovation, and the possible vision of DSM in the eyes of others. We see reflection on how the company should act in society. Nevertheless, the question is what P1 can do himself about this situation, since he wanted to present his results for he believes it is both in his own and the company's interest. He concludes:

P1: In any case, at the business level it was decided that we were not going to do this [present results at conferences]. So, now I have to lobby for next year. [Interview 4 P1, 30 October 2009]

It appears that a *deliberate* modulation moment emerged: a choice has been made. At the end of the discussion, P1 acknowledges the difficulty of the situation, and sets some targets for himself: he will lobby for the next conference and remains confident. Somewhat later, EH also discussed the matter with the earlier mentioned executives and the team leader. In the last interview P1 reports he was allowed to speak at a conference:

P1: Now I do have permission to tell something at the conference. That's very nice. But until now we have not contributed anything to the scientific community, since everything we do here isn't communicated to the outside world. [...]

EH: Why do you think you have permission now to tell something at a conference?

P1: Because we need to convince the market that we have a unique concept for the production of [product]. [...] So, that our process [...] from the perspective of the Life Cycle Assessment is much greener than the [other organism] process. [Post-interview P1, 22 January 2010].

P1 chose, *deliberate*, a different perspective to speak about communicating his research results. In building up his argument, instead of using only scientific arguments, he now, 2 months later, uses a sustainability related argument, connected to a business argument. Instead of framing reasons from a moral research perspective, he chose a socio-economical perspective.

Reflexive Awareness and Typical Modulations Per Participant

All participants show similar narratives to the one provided above, namely they move from a *de facto* to a *reflexive* to a *deliberative* mode with respect to the interplay of social, technical and economic considerations in their decision making processes. For practical purposes we refrain from providing the narratives for all five participants in this paper.⁹ To demonstrate changes in reflexive awareness, we

⁹ The four additional narratives are available upon request for interested readers.

summarised the answers the remaining four participants give to pre-and post-interview questions pertaining to relevant social or ethical aspects of their work in Table 3. The most prominent modulation moments for all participants are given in Table 4. The data show that all participants demonstrate an increased reflexive awareness on a particular social or ethical aspect of their work.

Participant 2 (P2) is the researcher Information Technology within the project. Based on his analysis of computer-modelled metabolic pathways, he proposes to the geneticist (P1) a strategy to modify the used micro-organism on a genetic level, for example gene insertions or deletions. P2 also investigates if his strategies are or can be patented. Considering his role in the project, working on the earliest design stages of the production process that must be designed for the company, discussions with P2 revolved very much on the role of giving direction to research, and how decisions are made that affect the entire team. For P2 modulations pertained to

Table 3 Answers participants 2–5 (P2–P5) give to similar questions in the pre- and post-interview, relating to the social and ethical aspects of their work

	Pre-interview	Post-interview
P2	<p>EH: Who decides on the direction of your research, your proposals?</p> <p>P2: Hmm, well... [thinks] [...] Eventually the project leader [Name], has to approve of course. I come up with a proposal, and I can like it, the team may like it, but if [project leader] says: "Well, I don't like it", then well, ha-ha, yes...</p>	<p>EH: Who would you say, determines the direction of the research?</p> <p>P2: The direction of the research? [...] Difficult question. I think the team does. The team consists of a group of scientists. [...] I think it's a joint effort. [Post-interview P2, 12 March 2010]</p>
P3	<p>EH: Are there specific societal goals linked to your research?</p> <p>P3: I'm not sure if sustainability is one of them. [thinks] I think so, yes</p>	<p>EH: What are the societal goals linked to your research?</p> <p>P3: That we're making a sustainable product. More sustainable than the chemical [product]</p>
P4	<p>EH: Looking at the possible social or societal goals in this project, can you name a few examples?</p> <p>P4: An example is showing that the product we make, is 'green'. By coincidence I am involved in that part of the project. In this project we are doing a Life Cycle Analysis [LCA], comparing various process options, with the goal to calculate and work towards a process as green as possible</p>	<p>EH: What are the societal goals of the project?</p> <p>P4: Making a product that, according to me, is green. So, a reduction in the problems of waste disposal, but also a reduction in CO2 emissions. So, an improved LCA when compared to existing product</p>
P5	<p>EH: Could you, regarding your work in the [...] project, name certain ethical, societal or legal aspects?</p> <p>P5: Pfff. Eh... [thinks] I understand your question, but I can't think of anything in that direction. Eh. Can you, eh, rephrase that so I, eh...</p>	<p>EH: What were, to you, during the past 12 months the most obvious ethical, legal or social aspects of your work?</p> <p>P5: Ethical, legal... I didn't really encounter many ethical things. But definitely ecological, regarding the LCA, that was obvious. Do we have a better process? Did we calculate correctly?</p>

Table 4 Summary of observed modulations for participants 1–5 (P1–P5)

	Modulation	Example
P1	<i>De facto</i>	Business departments influence P1's choice to present scientific research results at a conference
	<i>Reflexive</i>	P1 realises that there are strategic business considerations related to what P1 wants to say at a conference
	<i>Deliberate</i>	Different arguments are needed to convince management to speak at conferences. Not scientific or moral arguments, but socio-economic arguments that relate to business strategy
P2	<i>De facto</i>	Not only the project leader influences what research is to be carried out. There are more influencing factors
	<i>Reflexive</i>	Not only technological reasons influence research decisions. It's also about who discusses the options, and how arguments are presented
	<i>Deliberate</i>	P2 looked for more convincing arguments to convince the team to use a certain research method in the future
P3	<i>De facto</i>	Sustainability is recognised to influence research decisions
	<i>Reflexive</i>	Not only research is influenced, sustainability also plays an important role in corporate business strategies. It is important for customers to be able to compare different products based on how sustainable these product are
	<i>Deliberate</i>	P3 organised a symposium on the communication of scientific results (including sustainability, LCAs) for his fellow researchers, to make also them see the importance of sustainability externally
P4	<i>De facto</i>	Sustainability influences research choices but also relates to corporate reputation management. The choices researchers make, influence how sustainable the company is perceived to be
	<i>Reflexive</i>	P4 recognises his own role in corporate reputation management: he is a researcher, and his research decisions influence how the business operates and thereby how it is perceived by society
	<i>Deliberate</i>	P4 realises that he needs information to convince business of using a certain machine. Not scientific information, but information about production scenarios, including societal considerations like sustainability. P4 therefore is going to obtain that information
P5	<i>De facto</i>	Sustainability is recognised to influence research decisions
	<i>Reflexive</i>	Sustainability relates also to perceived corporate image by customers. For customers to trust you, it is important to make the calculations on sustainability (LCAs) credible
	<i>Deliberate</i>	To make calculations credible, these should be vetted by an independent, external organisation. This is also done at DSM

research decision authorisation (Table 4), and he demonstrates an increased reflexive awareness on the decision making process (Table 3).

Participant 3 (P3) is the lead researcher in fermentation within the project. He and his team of researchers use the micro-organisms designed and developed by P1 and P2 to investigate under which circumstances (temperature, pH, oxygen demand) the micro-organism produces most product and at which rate, in biological reaction vessels. Working with genetically engineered micro-organisms in factories implies working with various ethical, legal and social aspects regarding contained use

(limiting micro-organisms leaving the factory), but also related to the product that is being produced and sold. These aspects of his work were discussed extensively during the interviews with P3. He demonstrates an increased reflexive awareness on the social aspect of sustainability (Table 3) and discussions with P3 revolved much around the topic of sustainability in relation to corporate reputation management (Table 4).

Participant 4 (P4) is the researcher responsible for designing and developing the downstream processing of the production process. He works with the outcome of the fermentation process developed by P3. The fermentation process delivers a liquid broth containing micro-organisms and many other biological components that need to be separated from the products. Coming from a fermentation broth to purified products in crystal form requires much electricity and heat, in fact a major part of the energy consumption in the over-all production process. Therefore, modulators in the form of social aspects relating to sustainability are prominently present and recognised in interviews with P4 (Table 4). P4 is able to more concisely and accurately describe the social aspects of his work after the 10 weekly meetings, indicating increased reflexive awareness on the social dimensions of his work (Table 3).

Participant 5 (P5) is the researcher analytics and quality control for the project. He is responsible for assessing product quality related specifications of the end product, especially in terms of product purity. Further, leads a team of analysts who conduct all chemical analyses in the project. In his job as a quality controller he links customer demand for specifications of the end-product to the possible specifications of the product that is purified by P4. Similar to other participants P5 displays an increased reflexive awareness on the social and ethical aspects of his work (Table 3) pertaining mostly to sustainability and the role of sustainability on corporate reputation (Table 4).

Appreciation of the MM Method

We enquired about participants' appreciation of the MM method, first by asking them why it was useful for them to participate in this study (Table 5). P1 acknowledged that EH made him aware of several aspects of his work that he himself had never considered, especially regarding the relevance of this research to society. P5 also considered this a useful contribution to his work. P2 and P4 stated that they appreciated EH's input in making them consider more alternatives in choices for research, enabling more thoroughly thought through decisions. P3 related his positive experiences with the MM method to science communication and the role of science in society, as well as internal communication and cooperation.

Additionally, in the pre- and post-interviews participants were asked whether they considered the weekly interviews as something extra, on top of their work, or as part of their work. The answers the participants gave indicate that four of the five participants considered the engagement activity up front as something extra, on top of their work (Table 6). In contrast, *after* the interviews, all considered it part of their work. P1 commented that it was fun, P3 commented that it gradually became part of his work. P4 was surprised to see it becoming more and more part of his work, and

Table 5 Answers of Participants 1–5 (P1–P5) to the usefulness of the engagement activity (Midstream Modulation) from the participants' points of view

Post-interview questions and answers pertaining to the usefulness of Midstream Modulation	
<i>P1</i>	EH: Retrospectively, what struck you as most unforgettable? P1: A great many things. Mostly the discussions we had on the role this project has to society and what we could achieve with it in society. That's something one's very busy with. What's the use of this? Does society think something different? What do they think of genetic engineering? Those kinds of things, that sticks and I learned to think about it. Something else I liked: your enthusiasm, you making a research overview, and also some things you noticed that I didn't even see
<i>P2</i>	EH: Why was it useful to you? P1: Well, useful in a sense that I usually don't consider the things you ask about. Not that I actively think about those things now, but that I'm more aware of those aspects. These things may become interesting later. Secondly, the research process: you look at the process critically. I think it's good that someone observes the entire process, and then comes with particular feedback and questions that make me reconsider. What can we do differently? Are there alternatives? Usually we work under a lot of time pressure, you just have to reach a certain objective. You cannot consider too many alternatives, you follow intuition for the best possible solution. It might be better to think a little bit more broadly, starting from alternatives and working towards a concrete objective, rationally. In that sense this has been quite useful
<i>P3</i>	EH: What did you think of it? P3: The importance of communicating results to the outside world, to society, I became much more aware of that. We talked a lot about that. All the rest [technology] may be details to you, not relevant, but what I took from it regards also communication and cooperation, especially within the team. That you asked lots of questions about our meetings, and asked how I thought they went. You gave examples, tips and tricks to improve them. For example about sensitivity: you need to be careful what you say. That was an eye-opener to me, which I will take along
<i>P4</i>	EH: What did you appreciate? P4: The way you do it and the way you dive into the process and the team. Trying new things, discussing new options, that's a very nice way [of engagement]. I don't think you could have done it when you were a complete outsider. You have to really dive into the company, otherwise you couldn't contribute in this way
<i>P5</i>	EH: Where there things you maybe have missed? P5: No. [...] No, but we did put a lot of things in a more philosophical context. That there are multiple aspects regarding this project, a continuous process that is not one-dimensional. I always think that in many scientific publications, things are addressed very one-dimensionally [technologically]. But if you put that [research] in a larger context... If you don't, the research would lose relevance. [...] Placing it in a larger context is important

even stated that it allowed him to do his other tasks more efficiently. P5 even goes a step further and stated that increased attention to the social and ethical dimensions of technological work should be an obligatory part of all technical studies.

Discussion

Result Interpretation

Our data show that the MM method can be deployed in industry to enable researchers to actively consider social and ethical aspects in their daily R&D work. In earlier

Table 6 Answers of participants 1–5 (P1–P5) to the question whether they considered the midstream modulation activity as something extra, on top of their work, or as part of it

Pre-interview	Post-interview
P1 I see it as extra, but not a burden. I don't think it's part of my work, 'cause if it would be, then every employee of DSM should do this	It became part of my work. Yeah, at first I figured it was extra, but at some point... Well, just talking to you for an hour every week, it was a lot of fun!
P2 Yes, extra	It's part of it now. First it was on top of my work, but now it's part of it
P3 Tough question. Most importantly, I'm open to it, enthusiastic about it. [...] But it is something that I have to do next to my work. My agenda remains full, doesn't take [EH] into account who has to do an interview. But as I said, I'm willing to contribute some free hours for this	At first I think I would say: I'll take it as something extra. But I gradually saw it more and more as part of my agenda, belonging to my work. I think that's a plus for you
P4 In terms of time, it's on top of my work, because the other work also needs to happen. But in terms of content it's part of it, maybe now more consciously than before	Part of [my work]. I didn't expect that to happen. First I thought: again one hour you have to miss. But looking back on it: it did take time, but you also win time back in other parts of the project through this. [...] More focus on what you are doing and on what you should be doing
P5 Well, I just think it is my work	I think it could be part of my work, but I don't think it will be for everybody. Especially in larger projects it is advisable that people get educated in this area, and become more aware of it. All technical studies should incorporate it. I know that's happening now, but more as electives instead of as obligatory courses

explorations of MM results were not presented per participant, preventing a discussion of the effect per participant. We applied the same MM approach to five participants in industry. All five participants fulfil a different technological function within the research group we studied, and all are confronted with different relevant ethical and social aspects based on the context of their particular scientific and technological field of interest. Our explorative case study data show that all five participants displayed an increased reflexive awareness on the social aspects of their work.

Participants upfront seemed to be to some extent aware of several social and ethical aspects (*cf.* Patra 2011), but did mostly not consider actively the further ramifications of these aspects, especially on their own work (*cf.* Fisher and Miller 2009). Our participants became more communicative and reflexive on both external social aspects such as sustainability and science communication, and internal social aspects such as team communication and management aspects.

In line with the findings of Fisher and Mahajan (2006), *de facto* modulations in the form of social aspects could be identified in the interviews for all five participants. Also various *reflexive* modulation moments were identified for all five participants. In addition to *de facto* and *reflexive* modulations, also for every participant a limited

number of *deliberate* modulations was identified and actively used by participants. While only a small number of *reflexive* modulations were found to be actively deployed by the participants in their research decisions in the form of *deliberate* modulations, these *deliberate* modulations do indicate an active inclusion of social and ethical aspects in R&D decision making. The data show that modulations are viewed by participants from a technical, social and economic viewpoint. Especially the combination of socio-economic considerations in technological decisions appears to be of relevance for participants, e.g. through aligning technical considerations with sustainability and corporate image. This justifies our choice for adding the economic perspective to the decision protocol in this industrial case study.

Our results show social and ethical aspects being recognised and reflected on by the participants. More interestingly and importantly, they came to *deliberately* include these aspects in their daily practices. In addition all participants were enthusiastic about the MM approach and highlighted why they found MM to be of value. They much appreciated their increased awareness on social and ethical aspects, but next to that some participants indicate the MM activity enabled them to do their job better. Remarkably, no negative comments were made about the used method. Also participants indicate, after the 10 weekly discussions, and contrary to the majority of expressed views at the beginning of the study, that they see the considerations of social and ethical aspects as part of their work. They more and more considered integration of such aspects to be an accepted and normal part of their daily practice.

Midstream Modulation in Industry: Opportunities and Challenges

Our study shows that MM can indeed be used to facilitate and enhance the active inclusion of social and ethical aspects in DSM researchers' decision making processes. We asked to what extent participants considered the activity to be extra or part of their work. Their answers indicated that MM can become a functional, integral and appreciated part of R&D practice. Wynne (2011) asked in a recent commentary on MM whether MM-like approaches can become a permanent, institutionalised part of innovation cultures. Our results suggest that this may in fact be the case, which is possibly a valuable contribution to the MM research and engagement enterprise. Importantly, corporate institutional boundaries do not prevent the active integration of social and ethical aspects in industrial R&D. Moreover, our results show that the compressed 12 week engagement, with only 10 weekly decision protocol based discussions instead of 12 in the original MM work, is sufficient to integrate social and ethical aspects in industrial practice.

Wynne (2011) also suggested MM activities to take place higher up in the hierarchy of institutions. Industrial researchers have a different task compared to PhD-students in academia. They set up the research and analyse the results, but mostly do not carry out the laboratory work. However, since they do shape the research and interpret the results for designing subsequent research steps, they were considered adequate for this study: their decisions directly influence what happens in industrial laboratory practice. Next to that they are closer to management than the laboratory, indicating that we positively showed the utility of MM one step above the lab bench.

Nevertheless, various aspects of the MM process need some further deliberation, related first to the setup of this case study, second to the participants, and third to the embedded humanist. First, this case study is explorative in nature. Only five researchers all working on one project of a single project participated. The results cannot be generalised for all researchers at all companies, or in research contexts other than industrial biotechnology, although we did use nearly identical methods and generated consistent results as compared to MM studies carried out in other laboratory research contexts.

Second, it remains unclear to what extent participants will *deliberately* include identified *de facto* modulators in future decision making, since our observations are restricted to twelve weekly meetings. Researchers might fall back in their previous, non-engaged behaviour since they might lack intrinsic motivation to continue to consider social and ethical aspects (*cf.* Ryan and Deci 2000). By making MM an integral part of industrial R&D work, it could be further investigated to what extent *deliberate* modulation reoccurs. Our results show that standardisation of MM may be possible, since all participants considered the activity to be part of their work after. Were MM to be standardised, we do recommend that it preserves the open-ended qualities of the MM process, which stresses experimental, critical and collaborative inquiry.

It is possible that participants only learn to give socially desirable answers (or those they assume are desirable for the embedded humanist), or that the attention and interest of the embedded humanist are solely enough to spark enthusiasm by the participants about the method. Furthermore, participants' actual decision making process may remain unchanged after the conclusion of the laboratory engagement study. However, the fact that decision making was observed to change over time in correlation to the reflections that increasingly took place during the MM engagements (see the narrative with P1 and Table 4), suggests that these explanations do not fully account for the results. For, regardless of the participants' answers to direct questions and future intentions, participants actively considered and reflected upon the social and ethical aspects of their projects during the MM engagements: e.g. P1 changed his communication towards management and P3 organised a meeting on communication. In addition, the interpretation of the results was vetted by the participants and the MM activity was ultimately perceived by the participants to be both a useful and an integral part of their work.

Third, embedded humanists always remains guests in a research group and depend on the acceptance and endorsement of the researchers (see also Schuurbiens 2011; Doorn and Fahlquist 2010). Participants were selected on their willingness to participate. However, in industry also acceptance and endorsement of management is indispensable, especially in stimulating industry to participate in MM studies. Critical views of the humanist are allowed as long as they are 'research tolerable' (Fisher et al. 2006) but beyond that, they could threaten to break good relations, not only with researchers but also with corporate management. A stable and robust relationship that allows for criticism therefore needs to be established first, which takes time. Our experience shows that 12 weekly meetings provide enough time for such a relationship to be established.

Also, MM relies on the 'interactional expertise' (Collins and Evans 2002) of a single embedded humanist, with his/her own moral values and beliefs. We stress

that these values and beliefs are not necessarily ‘better’ than the one the researcher may bring into the engagement. The power of MM is in the collaboration between the humanist and the participants, who bring complementary expertise, values and beliefs. The challenge is to balance these in a constructive way (Stegmaier 2009).

In addition, the role changes during the MM activity (see also Stegmaier 2009). During the first weeks the humanist needs to become acquainted with the research, as well as establish a relationship that allows for critical views. Simultaneously, the participants need time to understand the different way—of the humanist—of looking at scientific aspects. Understanding one another’s language is imperative for mutual understanding and reflexivity to take place. In our case, the embedded humanist did have some basic knowledge on biotechnology R&D, but only learned about the technological details of this specific R&D process through interaction with the participants. The challenge for the embedded humanist is to purposefully refrain from passing judgement about social and ethical aspects (Patra 2011), and instead engage researchers with these aspects in a Socratic way (Calleja-Lopez and Fisher 2009), not ‘feeding’ any suggestions to the participants. Our data indicate that 12 weeks is enough time for the interlocutors to learn one another’s language and engage in meaningful and valuable discussions on how to integrate social and ethical aspects in R&D work.

Value of Midstream Modulation in Industry

Our data show that all participants mention in their post-interview that the weekly interviews had become part of their work rather than something extra. This further paves the road for the institutionalisation of integrating social and ethical aspects in corporate R&D practice, ideally making such integrations a normal practice in industrial R&D. But while critical reflections on the social and ethical aspects of industrial research may be desirable from the perspectives of policy makers, members of the public and science studies scholars, what, precisely, is the ‘added value’ that MM brings to the private sector?

One participant indicated that the activity helped him do his work more efficiently for it enabled more focus. Another participant afterwards considered more research options more thoroughly, allowing for a more creative and robust scientific investigation. These examples indicate an improved R&D practice on the technical level, even though it is difficult to express the claimed increased efficiency and more extensive investigation in business-relevant (monetary) terms. We had suggested to DSM before the case study that MM could be useful for individual researchers in enhancing their responsive capacity pertaining to the social relevance of their work and in stimulating creative out-of-the-box thinking by these researchers, based on previous experience with MM in literature. This suggestion may have been perceived as a promise by DSM that allowed for top-down, management support for carrying out this case study. In our experience, industrial actors will participate if they perceive ‘added value’ in the engagement method for their employees or the entire company. In reviewing the MM case study with project management, managers did acknowledge the value of this pilot case study for individuals. But they had hoped also for a more general and prominent advantage to the entire company.

In setting up this case study we did not consider larger institutional effects. However, our data do give rise to some further considerations in light of the use of MM for a company. We initially hypothesised that institutional boundaries may limit researchers in actively considering social and ethical aspects. But in fact our results show an alignment of social and ethical aspects with corporate communication and reputation management strategies. This indicates a further use for MM to allow researchers to influence corporate reputation management or to include reciprocally corporate reputation considerations actively in R&D. That may form the basis for a cultural R&D change towards more socially responsible innovation practices, in which social and ethical aspects play a more prominent role (European Commission 2011a).

Generally, largely because of their training, scientific and engineering researchers are only to a limited extent aware of the broader social and ethical context of their work (Fisher and Miller 2009). This possibly also holds for researchers at DSM. We therefore suggested that the participants may become ‘internal ambassadors’ in demonstrating the use of reflecting on social aspects in R&D projects. In fact, one participant organised after the 12 week activity a workshop on external communication and the role of sustainability.

Even though the MM approach focuses on individual researchers, there are possible larger institutional effects e.g. in the integration of marketing and communication with R&D practices, or in stimulating corporate socially responsible innovation strategies. Forward looking, active responsibility (Bovens 1998) pertaining to ecological, social and economic sustainability may be considered important for industry in light of corporate social responsibility (*cf.* McWilliams and Siegel 2001; Carolan 2007). Previously, it has been theorised that MM may stimulate aspects relevant for responsible innovation practices to be more actively considered in industrial R&D (Fisher and Miller 2009). Our data systematically confirm that this is in fact the case. Normative reasons for corporate social responsibility and ‘socially responsible’ innovation may develop into instrumental value in industry e.g. in marketing and communication. Again, we stress the need to preserve the MM engagement process so as to allow critical inquiry and reflection, if it is to remain more than a public relations tool.

Further alignment of industrial project performance indicators or success factors with the activity of MM may further enhance the usefulness of MM to industry, and result in a larger institutional effect. Future MM activities could focus on the possibility of such integration of social and ethical aspects with business considerations, e.g. in the form of innovation Key Performance Indicators. Nevertheless, we surmise that DSM takes the social dynamics of its R&D practices seriously, as it recently employed two ethnographers to further study and improve their corporate R&D environment.

Conclusion

Since its conception in 2006 (Fisher 2006), MM has been established, re-established, tested, retested and tweaked. In this research we explored the possibility

of functionally integrating social and ethical aspects in industrial R&D. The data presented in this paper positively answers the first research question: whether or not Midstream Modulation be usefully deployed in industrial biotechnology R&D to facilitate and enhance researchers' active inclusion of social and ethical aspects in their daily laboratory practice. During 12 weekly interviews, an embedded humanist reflected with five researchers at Royal DSM N.V. on the social and ethical dimensions of their R&D work. After MM, all participants showed an increased reflexive awareness on the social and ethical dimensions of their own work, in their own specific contexts, and actively integrated the newly recognised social and ethical aspects in their routine decision making processes.

In our second research question, we asked to what extent industrial researchers appreciate the MM approach. All participants stressed that they found it useful to participate in this study. They indicated various aspects they particularly valued, pertaining to the broader dimensions of their work, more efficient R&D conduct and team communication and cooperation. Furthermore, a methodological contribution to MM was found by asking participants if they considered the MM activity to be part of their work. Their positive answers further pave the road for MM type engagements in industry in a more institutionalised way, allowing a more prominent role for considerations of social and ethical aspects.

MM could be made more interesting to industry if it would include also an institutional advantage besides individual learning, e.g. in the form of more socially responsible conduct or improved project performance. In future research we aim to align the social and ethical dimensions of corporate R&D to its Key Performance Indicators in order to explore another dimension of the utility of MM in an industrial setting. Research on MM could thereby enhance its focus on the social and ethical relevance of MM results, the validity and reliability of MM methods, and the role of the embedded humanist, with a fuller understanding of the ways in which critical reflection on social and ethical aspects can be further and more functionally embedded in innovation practice.

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Appendix

See Table 7.

Table 7 Interview guide used during pre- and post-interviews

Semi-structured questionnaire interview guide

- 1 Please tell me more about your research. What are the research goals?
- 2 Could you tell me about the origin of this project/What is the motivation for starting?
- 3 How is the study funded? Is there cooperation with other industry, academia?
- 4 What are currently the most important scientific challenges?
- 5 What does the project contribute to research progress in your field of science?
- 6 What opportunities does your research provide for industrial application?
- 7 What would you say the driving force behind your research is? Application vs. Scientific value vs. Economic potential?
- 8 When (in time) do you expect your research to offer a concrete industrial application?
- 9 Regarding decisions on research progress: who decides the direction of research? Subsequent steps? What is your role in this process?
- 10 What kinds of considerations play a role in these progress decisions?
- 11 What are the criteria for determining the success of your specific research?
- 12 How is the research reviewed during the research process? Who is involved?
- 13 Are there any Economical goals specifically linked to your research? Examples?
- 14 Are there any Societal goals specifically linked to your research? Examples?
- 15 Could you please name some Ethical, Legal or Social aspects of your work?
- 16 How have you been confronted with ELS aspects the past 12 months?
- 17 Could you elaborate on the role of these ELS aspects in your daily work? If so: how?
- 18 What role does your own personal opinion on ELS issues play in determining the future direction of research?
- 19 Do you consider any specific social or economic challenge for your research?
- 20 Do you think society benefits from scientific research in industry?
- 21 Do you think society should benefit from industry research?
- 22 Do you think that society benefits from your research?
- 23 Would it be “good” for the quality of industry research to increase attention on social, ethical, legal implications? How?
- 24 Do you think it would be beneficial for society if industrial science would take into account ethical, legal and social issues? How?
- 25 What are your expectations for the next 12 weeks, if any?
- 26 Do you consider this method as something extra, over and above work? Or rather as something that is part of your work?
- 27 Do you have any further questions, or are there issues that have not been addressed?

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