# Building Blocks Towards a Proportionate Chemicals Policy With a Focus on the Netherlands

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### Abstract

In this contribution, we propose that 'sound' government policy should be characterised by a proportionate, integral vision with due consideration to tradeoffs between social costs and benefits. This principle also applies to government policy regarding the protection of workers from exposure to chemicals. It should be taken into account that having a job is a huge health benefit. Less educated people are statistically likely to enjoy ten additional healthy years, *if* employed. Although there is no debate about the risks of exposure to high doses of chemicals, there is most certainly debate on the magnitude, nature and possible cumulative effects of low-dose exposure to chemicals. These are established by model-based assumptions. The current advisory structure in which the Health Council of the Netherlands restricts its focus to the immediate health benefits for workers on the basis of risk avoidance models, and the Social and Economic Council of the Netherlands which focuses primarily on policy costs for trade and industry, is hardly a sound basis for well-considered decision making. The challenge for the scientific experts is to provide political administrators with an insightful social cost-benefit analysis, *including* all the concomitant uncertainties.

#### **Keywords**

chemicals policy, human health, employment, dose-response models, social benefit-cost analysis

# Introduction

Generally speaking, the media takes a 'simple' view: the moment workers or people living close to factories are exposed to 'carcinogenics', causal effects are attributed to illnesses in the area and therefore policy measures should be taken. Particularly if 'the norm' has been exceeded. An example is a report in a Dutch national newspaper *De Volkskrant* (12th May 2017)<sup>1</sup> on exposure to perfluorooctanoic acid (PFOA; our translation):

'People living in the vicinity of the DuPont teflon plant in Dordrecht still have dangerously high levels of the toxic perfluorooctanoic acid (PFOA) in their blood. Following blood tests carried out on 382 people, the Dutch Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) found concentrations of up to 147 nanograms of PFOA per millilitre of blood, far exceeding the assumed safety limit of 89 nanograms. [...] years of exposure to the acid may have damaged the health of local residents, is the conclusion of the RIVM ... although ... there is no certainty about the connection with PFOA'.

This example illustrates a well-known scientific dilemma. Scientists would generally not accept from their students the 'conclusion' that although 'there is no certain connection' there is 'possibly' a link between exposure and damage to

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health. As soon as such reports are picked up by the media, politicians feel obliged to respond. The Dutch Minister of the Interior and Kingdom Relations acknowledged this *risk regulation reflex* in the Cabinet paper entitled *Political Balance with Regard to Risk and Responsibility*<sup>2</sup>: 'The risk regulation reflex occurs when a risk brought to the attention of the public causes administrators to adopt risk-reducing measures without deliberate consideration of the costs and benefits of those measures. This can lead to disproportionate measures in the form of new legislation, stricter standards, increased regulation and extra facilities or system changes'.

Three basic principles are set out as part of required government policy:

- Government is to make proportional decisions on coping with risk, that is, that the social costs of safety measures are proportionate to the benefits.
- Citizens are to be involved in decision-making with regards to coping with risk as straightforwardly and as transparently as possible.
- Where possible, safety issues should also be subjected to fewer rules: those who are willing and able must have the opportunity to make their own decisions concerning their own safety.

Below we will argue for the following:

- Decision-making regarding chemicals policy requires the social costs of such a policy to be balanced against the social benefits thereof. This requires adjustment of the existing advisory structure which currently involves the Health Council of the Netherlands and the Social and Economic Council of the Netherlands (*Sociaal Economische Raad, SER*).
- We must be transparent about the limitations of our knowledge regarding exposure to low concentrations of many different chemicals and, of course, we should consider any available data.
- Workers should, therefore, individually and collectively have more say in the developing of chemicals policy of individual organisations, instead of generic standards which have not evolved from an evidence-based social cost-benefit analysis.

This contribution focuses on the future of chemicals policy of the Dutch Ministry of Social Affairs and Employment, which aims to reduce the impact on health due to low-dose exposure to chemicals. There should be no confusion here about the fact that many existing measures, which were and are aimed at protection against high-dose exposure to chemicals, which existed up to 20 years ago, *are evidently proportionate*. Asbestos, solvents and also ordinary stone dust constitute a verifiable and immediate health threat when exposure occurs on substantial levels and over prolonged periods of time. However, it should be kept in mind that past performances of policies do not guarantee future successes.

# The Necessity of Proportionate Chemicals Policy: To Have a Job Is Equal to Being Healthy

Indubitably, it sounds sympathetic to improve the protection of workers as to reduce risk of exposure to chemicals, yet incurred costs of such policy can be high. The loss of a job, for instance, is not just an 'economic fact' but is also a factor impacting human health. According to Statistics Netherlands (Centraal Bureau voor de Statistiek, CBS), the difference between high- and low-income levels translates to about 7 years average life expectation, and even 14 years in terms of healthy life years. According to the CBS in 2014 life expectancy without physical limitations for a 25-year-old from their 25th year stands at 40 years for the lowest income level, and at 53.4 years for the highest income level. These facts underline what has been long acknowledged that in order to gain insight into the costs and benefits of health policies, number of people who die as a result of disease, if that can be established unambiguously, is a less important indicator than establishing the number of healthy life years which may be gained or lost.

For this purpose, the World Health Organization developed the DALY (Disability-Adjusted Life Years), a measure used to provide an indication of the overall burden of disease.<sup>3</sup> The DALY measures not only the number of people who die prematurely from disease but also the number of years which people live with a disability caused by disease. Each type of disability is shown to correspond to a particular percentage of a healthy year of life.

If we want to have a broad-spectrum idea of costs and benefits of health policies, the value of statistical life (VSL) is a useful tool as well. VSL is now shaped by an extensive literature base that can be used to test the effectiveness and efficiency of regulation. This risk–risk approach monetises human life as to make regulatory comparisons possible.<sup>4</sup>

Considering safety at work: working at height, which is mostly done by young personnel cause per victim a higher loss of DALY than occupational risks which cause primarily death and disability at a higher age, such as assumed nearness to chemicals that might be carcinogenic. The benefits of preventing falling accidents, which, again, are primarily focussed on younger employees, *grosso modo* is greater than diseases like cancer resulting from low-dose exposure to chemicals such as carcinogens.

Suppose we calculate what a structural loss of 10,000 jobs, say, because of a ban of chromium-6 in the metal industries,<sup>5</sup> amounts to in terms of DALY. According to Statistics Netherlands (Table: Healthy Life Years; income level), in 2014 life expectancy without physical limitations for a 25-year-old from their 25th year stands at 40 years for the lowest income level, and at 53.4 years for the highest income level.

Let us assume that the loss of a job means that a young person is forced into the lowest income level. In this case, the young person thus loses some 13 healthy life years in contrast to a situation in which the same person was in a well-paid job (provided of course he would stay in that income class for the rest of his life). This assumption would mean that a structural loss of 10,000 jobs i  $\times$  13 DALY per job = 130,000 DALY. Clearly not every employed person is young, so assuming an average age the loss of DALY would amount to 65,000 over the 40 years of a working life. That is, 1650 DALY per year.

The possible benefits of a tighter chromium-6 policy are probably much smaller than the costs of 1650 DALY per year. According to Baars et al.,<sup>6</sup> historical exposure to all inhalable chemicals leads to a loss of 9,200 DALY per year to lung cancer. Chromium-6 is one these chemicals. No partition of every single chemical has ever been tried in the Netherlands. These historical figures are misleading, however. According to recent research,' when using modern workplace ventilation, no exposure to chromium-6 can be measured so the loss of DALY most likely is close to nil. Nowhere in the media or in scholarly or advisory council standpoints have we found the abovementioned simple calculation. This leaves measurement bias undiscussed. The reason for 'concern' is often because people are going on the hunt for 'dangers'. Once found, demand is put out as to remove said found danger. However, nobody would have ever cared, or even noticed, if the 'hazardhunt' never took place.

The computations done here are in line with classical research that has shown that greater spending on safety measures results in lower prosperity, particularly among lower-income groups. In other words, every Euro spent on safety measures leads to less income growth among lower income groups, than a Euro which is invested to boost prosperity. Growth, by contrast, precipitates greater expenditure on healthpromoting products such as medicines and healthy foods.<sup>8</sup> This effect can be quantified. If we were to apply the data from the United States directly to the Netherlands, roughly each 13 million Euros spent on safety policy would cost one statistic human life (equal here to 75 DALY). Conversely, 15 million Euros of additional economic growth and wealth, that is, rise in GNP, result 'automatically' in one extra statistic human life.<sup>9</sup>

As a guideline for political decision making, the Dutch Council for Health and Society sets an amount of 680,000 per DALY.<sup>10</sup> The idea is that this amount, which is based on a life expectancy of 75 years, calculates the value of a statistical human life at 66 million. For clarity's sake, these numbers do not claim to attribute monetary value to human life, highly educated or otherwise. These are simply statistical facts quite separate from any ethical debate about the value of human life.

The nature of the advisory structure in the Netherlands in the area of chemicals policy is not conducive to providing decision makers, that is, the Minister of Social Affairs and Employment, with broad-based recommendations. At the present moment, the Health Council advises the Ministry of Social Affairs and Employment as well as the Sub-committee for Threshold Limit Values in the Work Place of the Social and Economic Council of the Netherlands (Sociaal Economische Raad, SER). The SER subsequently also advises the Minister of Social Affairs and Employment. None of these advisory bodies currently exercises an integral view on chemicals policy:

- The Health Council of the Netherlands takes into account only the health of exposed workers and therefore recommends 'simply' keeping exposure as limited as possible.
- For the Threshold Limit Values in the Workplace Sub-Committee of the SER, two of the three independent/ advisory members are also members of Health Council committees, and the third member is an expert in the field of employer liability. There is therefore no expertise or incentive in this sub-committee to draw up a broad-based social cost-benefit analysis.
- The SER itself is made up of representatives of employers and employees (supplemented with a number of independent experts). It seeks a compromise between what the members see as company interests and employee interests; thus, should take a broader view than its Sub-Committee. However, the SER does not have expertise to question the advice of its Sub-Committee or the incentive to take into account the broader social costs and benefits.<sup>11</sup>

# A crucial caveat: We often just do not know (but are embarrassed to tell)

The Dutch Institute for Public Health and the Environment (RIVM) provides input for the Overview of Dutch Working Conditions (Arbobalans) on, for example, the impact of exposure to chemicals.<sup>12</sup> The Overview subsequently states 'the RIVM has calculated', but this expression suggests a level of accuracy that does not exist in connection with exposure to many different chemicals.

In an ideal scientific world things would be simple: clinical research would show that exposure to a particular concentration of a certain chemical damages health. As a scientific hardliner could contend: 'You really need sound insight into pathophysiological processes and interventions under standardised conditions whereby one observes that this process is different or no longer pathophysiological in order to show causality.' This is, in part, the reality in, for example, mechanistic studies into new drugs, and this is still an idealised description rarely matched in real life.

Abovementioned reality, however, does not exist with regards to chemicals policy; we can in general observe only very indirectly that a chemical is harmful in a certain concentration over a certain period of time. *After all, Paracelsus' axiom rules supreme.* The effects of lower concentrations on health depend on so many aspects of the individual and the environment that it becomes a question of probability distribution: we look at the chance of a person's health being affected as a result of exposure to a certain concentration of a certain chemical over a certain period of time. This type of research known as epidemiological studies is usually carried out among large groups of exposed people (such as workers), subsequently compared to that of a (non or marginally

exposed) control group. The epidemiological conundrums are well known and need not be rehashed here in full.<sup>13</sup> Fundamentally, causality can never be shown via this route.<sup>14</sup>

A major *existential* problem is that even with large-scale experimental setups, risks which are smaller than 'one in a thousand' cannot realistically be determined with any certainty. Additionally, the so-called supporting (or confounding) factors - genetics, diet, lifestyle, sex, and etc., - determine to an undefined extent the outcome of any epidemiological study.<sup>15</sup> The second existential dilemma is that in the light of the above, harmful effects on health resulting from low dose exposure to chemicals have to be constructed using modelbased assumptions. The required input for these models is the proven harmful impact on health of high concentrations of chemicals. Dose-response curves are thus only validated for higher doses of chemicals; doses to which today's workers will never be exposed. Here, the issue of linearity, such as the linear non-threshold model (LNT) for genotoxic carcinogens, vs other dose-response models such as hormesis prominently surfaces.<sup>16</sup>

There is, unsurprisingly, considerable resistance among toxicologists to the use of hormesis-type models as it is believed that a margin of uncertainty in the calculations is preferable. In, for example, Beausoleil et al.,<sup>17</sup> we find the archetypal reasoning that hormesis-type (Non-Monotonic) modelling can be used *only* if it can be proven that small doses do not cause negative effects, which is exactly at stake in the LNT-model. Damage is assumed at the single molecular level in the LNT-model as empirical proof is simply impossible.<sup>18</sup> Tellingly therefore, precondition is not applied to the preferred model in that study.

It must surely be clear by now that if hormesis, instead of the LNT-model, *is* selected as the preferred risk assessment model in order to study harmful effects of chemicals, this would have a quite the impact on investments in risk policy. The threshold limit values at which a chemical is deemed hazardous 'appear' 'suddenly' to be higher, resulting in a lower demand for protective measures, *which nevertheless would be much more cost-effective with respect to actual overall workers health*.

To return to the function of the Health Council which provides recommendations to the Minister of Social Affairs and Employment (with or without inclusion of the SER), recommendations based on the models generally include an additional uncertainty factor of at least 10. On the surface, this sounds scientifically prudent but this is not necessarily the case. Beyond the realm of political decision making, the benefits of the chemicals policy are suddenly 'increased' by a factor of 10 without explicit scientific foundation. An honest balance between costs and benefits of the policy is therefore rendered impossible a priori.

# Can Today's Chemicals Policies be based on Voluntarism

It should now be clear that decision making regarding chemicals policy must be made on the basis of a social costs and benefits analysis, but that such analyses are generally extremely complex and perhaps even impossible when it comes to low-dose exposure to chemicals. Central government risk policy such as described recently in 2015 in the Cabinet paper Equilibrating Risk and Responsibility in regulation provides a possible solution through the application of the premise that 'those able and willing should have the opportunity of deciding about their own safety'.<sup>19</sup> We shall now examine briefly this solution. We shall first discuss the aspect of voluntarism.

Determining precisely when a person is 'voluntarily at risk' is complicated. Government policy speaks of such preconditions as 'willing and able'. This suggests that the risktaker should understand the risk and that he has a genuine choice at his disposal whether to take the risk or not. Those who undertake mountain sports fall into the category of voluntary risktakers whom most people judge intuitively as meeting both preconditions. Residents of high-priced country residences located in flood plains of rivers fall intuitively into this category as well.

In contrast, voluntarism among workers appears intuitively more complicated. It seems to be the case that employees with union links stand stronger in relation to the individual employer, particularly in the case of small- and medium-sized organisations, because trade unions and work councils in large organisations have the final say in the compilation of Overviews of Dutch Working Conditions. The Inspectorate of the Ministry of Social Affairs and Employment enforces therefore what is set out in the Overview unless a business functions according to alternative evidence-based data. No small- or medium-sized business has the resources for such research.

Coffee consumption could intuitively also be regarded as voluntary in the light of its stimulant properties, its taste and habit-forming properties. But according to classic monotonic modelling, this habit results in carcinogenic risks via small amounts of PAHs (polycyclic aromatic hydrocarbons) found in coffee, which are well-known carcinogens. As Aaron Wildavsky once remarked:<sup>20</sup>

"... There are nearly a thousand chemicals in a cup of coffee, of which fewer than thirty have been tested for cancer in rodents. Are coffee drinkers involuntary subject to the remaining hundreds. Or is human life full of unrecognized goods and bads? ...'

Would we wish to permit a similar voluntary exposure in a work environment? A common argument against voluntary risk taking is that people are not good at dealing consciously with risk. In the 1990s, Willem A. Wagenaar pioneered research into conscious risk taking. He found that:<sup>21</sup> '…*people engage in most of their everyday behaviour without a conscious consideration of the associated risks*'. Scientists such as Wagenaar find it therefore unreasonable to expect a worker to make a conscious choice regarding workplace risk, in which case there is no question of true voluntarism.

In line with the Cabinet paper, our recommendation nevertheless is that employees, individually and collectively, should have a greater say in chemicals policies of individual organisations instead of abiding by a generic standards regime, if and only if there is a lack of scientific evidence on which to base an adequately reliable social cost-benefit analysis. Let us be clear on this point: such a scientific basis is currently grosso modo lacking with regard to low-dose exposure to chemicals. We opt, therefore, for the basic principle of adequately informed (organised) employees who are capable of acting. The role of government remains in the first instance limited to helping tackle the problem of collective action by letting employees organise themselves through unions and work councils. In addition, government should ensure the provision of adequately clear information on the risks for which voluntary decision making is required. The fact that employees cannot possess expert knowledge does not detract from the reasonable assumption that based on daily experience, these risks may be considered 'familiar' when compared to everyday risks such as road traffic or smoking. To reiterate, a complex aspect is that organised employees are in a much stronger position to reach agreements on additional policy measures with employers than the self-employed and other flexworkers who are not usually collectively organised. The issue remains, however, that additional policy measures cannot be made mandatory if there is no scientific basis which can be translated into a positive costbenefit analysis.

Voluntarism, as a solution to chemicals policy, can also be analysed from the perspective of the so called 'greedy governance'. Governments seem to struggle to accept that a risk taken voluntarily can result in serious damage to health. Trommel speaks of 'greedy governance' specifically if a government purposely takes full responsibility for safety and security, even when it cannot fulfil that role.<sup>22</sup> In his analysis, Trommel gives as argument that since the 1980s, the Dutch government has been forced to dismantle the welfare state because public funding became unmanageable. The government subsequently adopted a sort of compensatory attitude through its safety policy. At the end of the day, the costs of safety measures *prescribed* by the government are carried by society itself. For example, employers (indirectly the employees) foot the bill for health and safety policy and each Dutch citizen pays for the costs of, in some cases, disproportionate safety policies.

This reluctance to accept the consequences of voluntarism is also evident, for example, in the position taken by the Dutch Supreme Court. During the landmark, 'cellar trap door case' in 1965,<sup>23</sup> the Supreme Court defined 3 criteria with which to assess unlawfulness. These were the relationship between the likelihood of an accident, the possible seriousness of the consequences of an accident and the degree of difficulty of putting in place precautionary measures: so chance, effect and cost of safety measures. In the event of the possibility of serious harm to health, the Supreme Court tends to hold the 'endangering agent' (i.e. employer vis-a-vis chemicals policy) accountable for the consequences. Relatively recently, in 2004, the Dutch Supreme Court added a fourth element relevant to the assessment of the extent of voluntarism in regard to risk taking: 'the likelihood that the potential victim will neglect the care and attention to his personal safety'. This criterion inherently places greater responsibility with the endangering agent than with the potential victim. For this reason, we had earlier called for an essential and explicit change to the law or at least a new Cabinet paper.<sup>24</sup> Such a Cabinet paper did indeed come about and constitutes a core element of the present writing.

# In Summary

We realise that this contribution presents a complex three-part message:

- (1) We call for a proportionate chemicals policy based on a scientifically sound, social cost-benefit analysis.
- (2) We are of the opinion, however, that the above is not (yet) possible with respect to low-dose exposure to most chemicals given the limitations of the toxicological models used. We contend, therefore, that the risks involved are, for the most part, inherently relatively small.
- (3) For this reason we believe it prudent and in line with central government policy to allow the well-informed worker, on the basis of voluntarism, to take responsibility for the small risks involved in exposure to small amounts of chemicals. We are aware of the fact that organised employees are in a better position to negotiate additional protection policy than the growing ranks of self-employed and other flexible workers who are often less well organised.

Proportionality in chemicals policy we propose to be based on DALY and VSL. Again, this has nothing to do with monetising human health and life. It tries to capture efficiency of public and private expenditures particularly focussed on effective protective measures. As that should be the focus, the downsides to health as a result of excessive protective measures must be part of the equation as well.

Toxicologically understanding low-dose exposures, as one of the themes of this Journal, is still limited. This is not a shortcoming on the part of science per se, other than a lack of focus and interest, but nevertheless is inherent to scientific knowledge growth about which we should be transparent. The philosopher Thomas Nagel had the following to say on matters of understanding reality:<sup>25</sup>

"... for objectivity is both underrated and overrated, sometimes by the same persons. It is underrated by those who don't regard it as a method of understanding the world as it is in itself. It is overrated by those who believe it can provide a complete view of the world on its own, replacing the subjective views from which it has developed. These errors are connected: they both stem from an insufficiently robust sense of reality and of its independence of any particular form of human understanding'. Fear of exposure to chemicals among workers cannot, in our view, be a formative reason for recommendations for stringent policy despite the absence of an evidence-based costbenefit analysis. In a democracy, the House of Parliament, of course, makes the final decision and can do so according to its perception of public opinion, but in the words of Sunstein:<sup>26</sup>

'A deliberative democracy does not simply respond to people's fears, whether or not those fears are well-founded. Indeed, participants in a deliberative democracy are alert to the fact that people might be frightened of risks that are actually quite small and indifferent to risks that are extremely serious. In these circumstances, a quantitative analysis of risks, to the extent that it is possible, is indispensable to a genuinely deliberative democracy. ... We need far less in the way of intuitions and interest groups, and not a great deal of populism, but far more in the way of science, peer review, and informed public deliberation'. There are, of course, known reservations about the degree of actual voluntarism in the relationship between employer and employee, and the well-known fact that knowledge alone does not determine workers' safe behaviour. This does not, however, negate the fundamental problems of the current chemicals policy.<sup>27-32</sup> To reiterate, we believe that as long as there is no proof, safety policy should not be imposed on society. Even if the extent of freedom of choice of workers is, in practice, limited, there is no reason to introduce safety measures of which the cost-benefit ratio is negative or unknown. It is our conviction that the Dutch Ministry of Social Affairs and Employment should take up the challenge of developing a proportionate chemicals policy framework which is transparent, especially regarding uncertainties, and provides genuine choices for workers. The present advisory structure in which the Health Council and the SER provide too narrow recommendations does not facilitate the Ministry of Social Affairs and Employment in its complex task. The Ministry should ask the Health Council for comprehensive recommendations which should include the social costs and benefits of new chemicals policies.

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